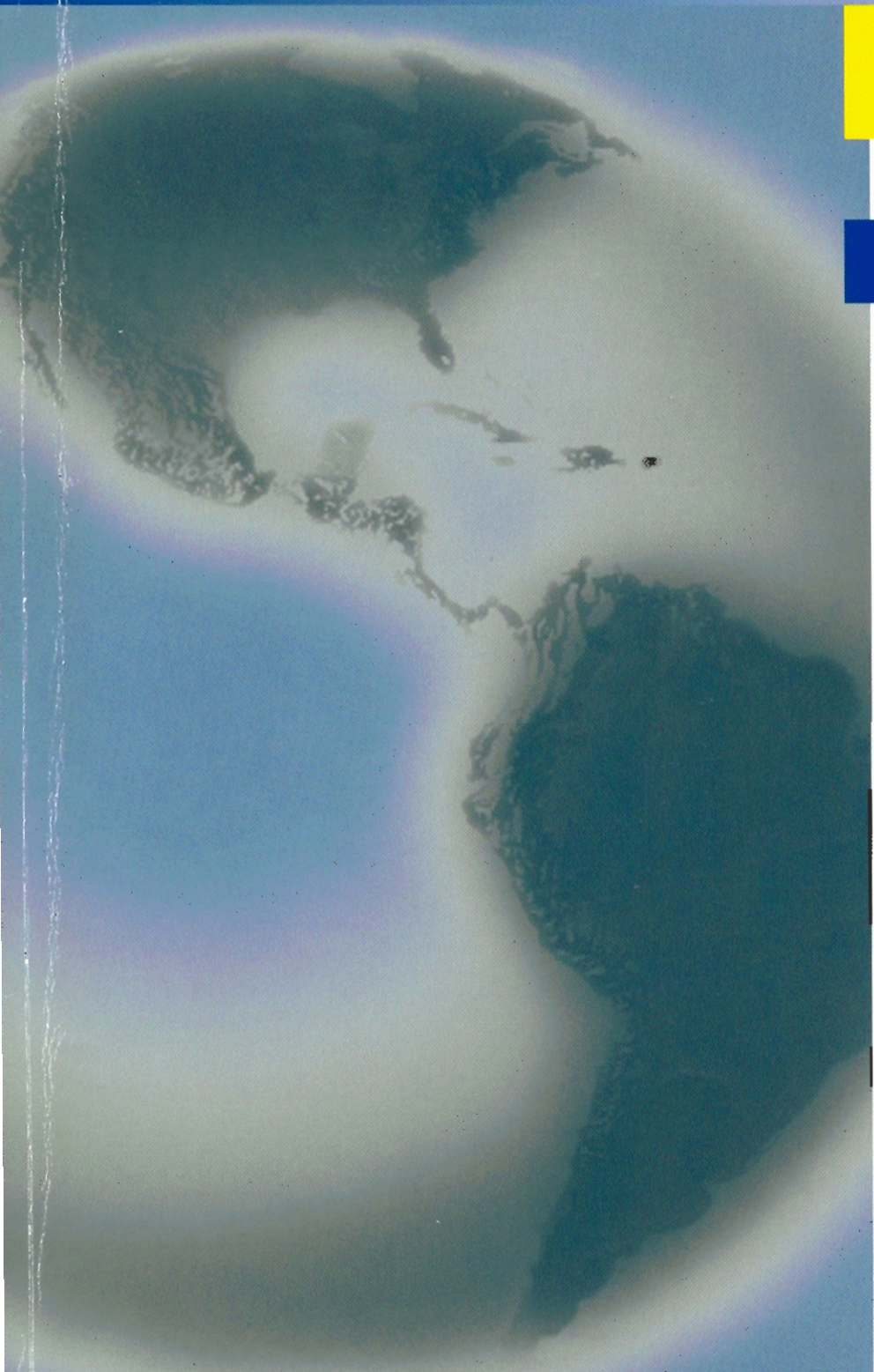
REVISTA PANAMERICANA DE SALUD PÚBLICA

PAN AMERICAN JOURNAL OF PUBLIC HEALTH

NÚMERO ESPECIAL SOBRE IMAGINOLOGÍA MÉDICA, RADIOTERAPIA Y RADIOPROTECCIÓN

SPECIAL ISSUE ON MEDICAL IMAGING, RADIATION THERAPY, AND RADIOLOGICAL PROTECTION



Artículos e informes especiales / Articles and special reports

Organización Panamericana de la Salud
Oficina Regional de la Organización Mundial de la Salud

Pan American Health Organization
Regional Office of the World Health Organization

Vol. 20, Nos. 2/3
Agosto-septiembre / August-September 2006

Nota especial de agradecimiento a la Dra. Cari Borrás

El equipo de redacción de la Revista Panamericana de Salud Pública/Pan American Journal of Public Health *quisiera expresar su sincero agradecimiento a la Dra. Cari Borrás, quien fungió como coordinadora del número especial sobre imaginología médica, radioterapia y radioprotección. Sus aportes y dedicación fueron extraordinarios y contribuyeron a crear un número especial más interesante, más riguroso y más útil para nuestros lectores y para todos quienes trabajan en el mejoramiento de la salud de los pueblos de las Américas.*

Special note of thanks to Dr. Cari Borrás

The members of the staff of the Revista Panamericana de Salud Pública/Pan American Journal of Public Health *would like to offer a very sincere, heartfelt expression of thanks to Dr. Cari Borrás, who served as the coordinator for this special issue on medical imaging, radiation therapy, and radiological protection. Her contributions and dedication to the special issue were extraordinary, and they have helped make the special issue more interesting, more accurate, and more useful to our readers and all others who work to improve the health of the peoples of the Americas.*

REVISTA PANAMERICANA DE SALUD PÚBLICA/PAN AMERICAN JOURNAL OF PUBLIC HEALTH

Revista mensual sometida a arbitraje publicada por la Organización Panamericana de la Salud

ISSN 1020-4989

La Organización Panamericana de la Salud (OPS) es un organismo internacional especializado en la salud pública e integrado por 35 Estados Miembros, tres Participantes, un Miembro Asociado y dos Observadores. Su órgano ejecutivo, la Oficina Sanitaria Panamericana (OSP), cumple al mismo tiempo las funciones de Oficina Regional de la Organización Mundial de la Salud para las Américas.

Información general. La *REVISTA PANAMERICANA DE SALUD PÚBLICA/PAN AMERICAN JOURNAL OF PUBLIC HEALTH (RPSP/PAJPH)* es la principal revista técnica y científica de la OPS y un vehículo importante para dar a conocer las políticas de salud de los países de la Región; los problemas de salud que aquejan a las poblaciones de estos países y las estrategias adoptadas para combatirlos; los factores sociales, demográficos y económicos que determinan la prevalencia, incidencia y distribución geográfica y poblacional de dichos problemas; las características estructurales y funcionales de los sistemas y servicios de salud de los países americanos; y, sobre todo, los resultados de las investigaciones que se llevan a cabo en ellos en el campo de la salud pública. Las investigaciones originales y revisiones bibliográficas se someten a un proceso de arbitraje por pares y todos los materiales publicados se eligen a la luz de los propósitos fundamentales de la OPS: promover las acciones y coordinar los esfuerzos de los países de la Región por proteger la salud, combatir las enfermedades, prolongar la vida y fomentar el bienestar físico, mental y social de sus habitantes.

Indización. La *RPSP/PAJPH* está indizada en Current Contents/Social & Behavioral Sciences, Social Sciences Citation Index, Index Medicus/MEDLINE/PubMed, DIALOG, EMBASE/Excerpta Medica, Biological Abstracts y muchas otras bases de datos bibliográficas biomédicas con su título abreviado en español únicamente (Rev Panam Salud Publica). Se distribuye una tirada mensual de 7 000 ejemplares entre profesionales y técnicos de todas las especialidades de la salud pública, tanto en la Región de las Américas como en muchas otras partes del mundo. La *RPSP/PAJPH* también se encuentra en las principales bibliotecas biomédicas de diversos países y se publica electrónicamente por medio de su propia página web (http:// journal.paho.org/), donde hay acceso gratuito a todo el contenido en texto completo y una función de búsqueda por tema, título, autor o fecha de publicación. El sitio es interactivo y ofrece, además, la posibilidad de entrar en diálogo con expertos y con los autores de los materiales publicados. También hay acceso electrónico a la revista por medio de SciELO Salud Pública (www.scielosp.org) y de Ingenta (www.ingentaselect.com).

La "Guía para autores", donde se detallan las normas de formato y contenido establecidas por la redacción, se encuentra en inglés y español en el sitio de la revista en la web (http://journal.paho.org/) y en cada número de enero. En todos los números aparecen, además, versiones resumidas de esta guía.

Las opiniones expresadas por los autores son de su exclusiva responsabilidad y no reflejan necesariamente los criterios ni la política de la OPS ni de los Estados Miembros. La mención de determinadas sociedades mercantiles o del nombre comercial de ciertos productos no implica que la OPS los apruebe o recomiende o los prefiera a otros similares que no se mencionan.

Suscripciones. La *RPSP/PAJPH* se publica mensualmente en formato impreso y electrónico y el precio de la suscripción varía según el formato y el país donde vive el suscriptor. La suscripción a la versión electrónica puede hacerse por medio de la página web de la revista (http://journal.paho.org/), donde también se puede solicitar el envío mensual automático del índice de materias de cada número nuevo. Si desea recibir la versión impresa, puede suscribirse a ella por medio de la librería en línea: http://publications.paho.org

Para comunicarse. Dirección postal: Organización Panamericana de la Salud, Publicaciones (PUB), 525 Twenty-third Street, N.W., Washington, D.C. 20037, EUA; teléfono: (202) 974-3055; fax: (202) 338-0869.

REVISTA PANAMERICANA DE SALUD PÚBLICA/PAN AMERICAN JOURNAL OF PUBLIC HEALTH

A peer-reviewed monthly journal published by the Pan American Health Organization

ISSN 1020-4989

The Pan American Health Organization (PAHO) is an international agency specializing in public health and consisting of 35 Member States, 3 Participating Governments, 1 Associate Member, and 2 Observers. Its executive branch, the Pan American Sanitary Bureau (PASB), is also the Regional Office of the World Health Organization for the Americas.

General information. The *REVISTA PANAMERICANA DE SALUD PÚBLICA/PAN AMERICAN JOURNAL OF PUBLIC HEALTH* (*RPSP/PAJPH*) is the main scientific and technical periodical published by PAHO. It is an important vehicle for discussing public health policy throughout the Region; the most important health problems that afflict the countries and the measures undertaken to alleviate them; the social, demographic, and economic factors that determine their prevalence, incidence and geographical distribution; the structural and functional characteristics of the countries' health systems and services, and, most particularly, the public health research that is being conducted in Latin America and the Caribbean. All original research papers go through a peer review process, and materials are selected for publication in light of PAHO's fundamental mission: to support and coordinate all efforts on the part of Member States to preserve health, fight disease, prolong life, and foster the physical, mental, and social well-being of their inhabitants.

Indexing. The *RPSP/PAJPH* is included, under its abbreviated Spanish title only (Rev Panam Salud Publica), in Current Contents/Social & Behavioral Sciences, Social Sciences Citation Index, Index Medicus/MEDLINE/PubMed, DIALOG, EMBASE/Excerpta Medica, Biological Abstracts, and many other bibliographic biomedical databases. The monthly pressrun is 7 000 copies which are distributed among all types of public health professionals and technical personnel, both in the Americas and in other parts of the world. The *RPSP/PAJPH* is also housed in major biomedical libraries throughout many countries and is published electronically through its own website (http:// journal.paho.org/), where its full contents are available free of cost and searches can be conducted by topic, title, author, or date of publication. In addition, the site is interactive and offers users the ability to engage in scholarly debate and to communicate with the authors of published materials. Electronic access to the journal is also available through SciELO Salud Pública (www.scielosp.org) and Ingenta (www.ingentaselect.com).

The "Guidelines for Authors", which describe journal standards for format and content as established by the journal editor, can be viewed in Spanish and English on the PAHO website and in all January issues of the journal. Abbreviated versions of these instructions appear in every issue.

Any views expressed are the sole responsibility of the authors and do not necessarily reflect the opinions or policies of PAHO or its Member States. The mention of specific companies or brand names does not imply that they are endorsed or recommended by PAHO or that the Organization prefers them to others that are not mentioned.

Copyright. The *RPSP/PAJPH* reserves all legal rights over the reproduction of its content. Manuscripts are accepted for publication with the understanding that they have not been published elsewhere, in part or in full, and that they will not be published elsewhere in the future in print or electronic format (Internet) without the express authorization of PAHO. Publications of the Pan American Health Organization are protected under Protocol 2 of the Universal Copyright Convention. However, PAHO grants permission to reprint and translate its published materials for didactic purposes as long as the source is cited and copies of the reprinted texts are sent to Publications (see address below). PAHO also grants permission to photocopy texts for internal institutional use, educational use in schools, or clients' personal use within its Member States. In all these cases, institutions, universities, or other entities wishing to reproduce materials published by PAHO must pay the required fee to the Copyright Clearance Center. Before photocopying items, please contact the Copyright Clearance Center, telephone: (978) 750-8400; fax: (978) 750-4470; e-mail: info@copyright.com; web: www.copyright.com

Subscriptions. The *RPSP/PAJPH* is published monthly in printed and electronic format, and the price of the subscription depends on the format and on the country where the subscriber lives. You can subscribe to the electronic version of the journal via the journal's website (http:// journal.paho.org/), where you can also register for monthly automatic E-mail table of contents alerts. If you are interested in subscribing to the print version you can do it through the online bookstore: http://publications.paho.org

Contact information. Mailing address: Publications (PUB), Pan American Health Organization, 525 Twenty-third Street, N.W., Washington, D.C. 20037, EUA; telephone: (202) 974-3055; fax: (202) 338-0869.

REVISTA PANAMERICANA DE SALUD PÚBLICA

PAN AMERICAN JOURNAL OF PUBLIC HEALTH

Contenido
Año 85, Vol. 20, Nos. 2/3
Agosto/septiembre 2006

Contents
Year 85, Vol. 20, Nos. 2/3
August/September 2006

ISSN 1020 4989

Fundada en 1922 con el nombre de *Boletín Panamericano de Sanidad*
Established in 1922 as *Boletín Panamericano de Sanidad*

NÚMERO ESPECIAL SOBRE IMAGINOLOGÍA MÉDICA, RADIOTERAPIA Y RADIOPROTECCIÓN / SPECIAL ISSUE ON MEDICAL IMAGING, RADIATION THERAPY, AND RADIOLOGICAL PROTECTION

LA PERSPECTIVA DE LA OPS / PAHO'S PERSPECTIVE

REFLEXIONES DE LA DIRECTORA / FROM THE DIRECTOR

INTRODUCCIÓN SINÓPTICA / INTRODUCTORY OVERVIEW

ANTECEDENTES HISTÓRICOS / HISTORICAL BACKGROUND

ARTÍCULOS E INFORMES ESPECIALES / ARTICLES AND SPECIAL REPORTS

LA PERSPECTIVA DE LA OPS

PAHO'S PERSPECTIVE

La física radiológica dentro del marco de la cooperación técnica de la OPS

Mirta Roses Periago[1]

A finales del siglo XIX la medicina se transformó gracias a varios descubrimientos en el campo de la física. En 1895 Roentgen descubrió los rayos X, que permitieron visualizar las estructuras internas del cuerpo humano; al año siguiente, Becquerel descubrió la radiactividad, y en 1898 el matrimonio Curie anunció el descubrimiento de dos elementos radiactivos: el polonio y el radio. Este último se empezó a utilizar inmediatamente para obliterar o reducir tumores, tanto cutáneos como internos (1). Sin embargo, estas nuevas tecnologías no estaban exentas de peligros: el primer informe acerca de los efectos adversos de los rayos X para la salud humana, tras la sobreexposición de un paciente sometido a una radiografía en Chicago, Illinois, Estados Unidos de América, se publicó en 1896 (2). Desde el primer momento, la imaginología (uso de técnicas de diagnóstico por imágenes), la radioterapia y la protección radiológica han evolucionado de forma paralela.

Durante la Segunda Guerra Mundial, los avances de la Física en el campo de las radiaciones se aplicaron al desarrollo de las armas nucleares, lo que dio paso a una carrera entre las potencias mundiales por crear y fabricar este tipo de armamento. En la década de 1950, los Estados Unidos —conscientes de las posibles aplicaciones de las nuevas tecnologías a la agricultura, la industria y la medicina y en un afán por fortalecer el uso de la energía nuclear para fines pacíficos— promovieron la iniciativa Átomos para la Paz, que incentivó el desarrollo de las técnicas nucleares y radiológicas en todo el mundo. Dicha iniciativa abarcó también a los países en desarrollo, muchos de ellos en América Latina y el Caribe.

Durante esa misma década apareció en algunos países europeos, como el Reino Unido y Suecia, la nueva disciplina de la física médica. Los físicos médicos son científicos que aplican sus conocimientos de la física a la medicina, como lo hicieron en su momento Roentgen, Becquerel y los Curie, especialmente en el campo de la radiología diagnóstica y terapéutica. En 2006, el número de físicos médicos en el mundo sobrepasa los 16 000 (3) y continúa aumentando a medida que avanza el desarrollo tecnológico.

En la década de 1970, con la invención del primer tomógrafo computarizado, la física radiológica cambió nuevamente (1). Hoy en día, gran parte del equipo que se usa en este campo está computarizado y hasta se ha logrado aplicar algunas técnicas de imaginología en el nivel celular, pudiéndose así identificar las moléculas que participan de manera crítica en el desarrollo de ciertas enfermedades mucho antes de que aparezcan las manifestaciones clínicas.

[1] Directora, Oficina Sanitaria Panamericana, Washington, D.C., Estados Unidos de América.

El efecto benéfico de estos adelantos tecnológicos sobre la salud pública es muy grande. Gracias a estas innovaciones, actualmente podemos diagnosticar en etapa temprana diversas enfermedades, entre ellas muchas afecciones cardiovasculares y neoplasias, y curarlas con más facilidad. En gran número de casos, las técnicas radioterapéuticas han permitido tratar el cáncer con menos morbilidad y resultados cosméticos más satisfactorios que la cirugía.

Debido a la trascendencia de estas técnicas —no solo para las especialidades clínicas, sino también para la salud pública en general—, la Organización Panamericana de la Salud ha venido asesorando a los gobiernos y entrenando a los profesionales de la salud de los países de América Latina y el Caribe mediante su programa de radiología y radioprotección. Este proceso de colaboración, que comenzó en la década de 1960, y los antecedentes históricos de los resultados del programa en la Región se exponen en un artículo de este número especial escrito por los tres últimos asesores regionales a cargo del programa (4).

El trabajo que falta realizar es inmenso y exige la formación de alianzas estratégicas. Mantenemos una estrecha relación con los Centros Colaboradores de la Organización Panamericana de la Salud/Organización Mundial de la Salud que están en países de las Américas (5) y contamos con la cooperación de las sociedades profesionales de radiología (Colegio Interamericano de Radiología, CIR) (6), de radioterapia (Asociación Latinoamericana de Terapia Radiante Oncológica, ALATRO) (7), de física médica (Asociación Latinoamericana de Física Médica, ALFIM) (8) y de técnicos radiológicos (Asociación Latinoamericana de Técnicos de Radiología, ALATRA) (9). Además, junto a otros organismos intergubernamentales formamos parte de dos comités mundiales, uno sobre la seguridad radiológica (*Inter-Agency Committee on Radiation Safety*, IACRS) (10) y otro sobre las emergencias radiológicas y nucleares (*Inter-Agency Committee on Response to Nuclear Accidents*, IACRNA) (11). En estos momentos nos encontramos en la etapa de revisión de las *Normas básicas internacionales de protección contra la radiación ionizante y para la seguridad de las fuentes de radiación* (12), cuya versión anterior fue endosada por nuestros Cuerpos Directivos (13) y cuya nueva edición esperamos complemente —más que reemplace— las normas establecidas.

La *Revista Panamericana de Salud Pública/Pan American Journal of Public Health* (RPSP/PAJPH) ha reunido algunos artículos e informes sobre radiodiagnóstico, radioterapia y radioprotección escritos por profesionales de diversas especialidades, entre ellos radiólogos, radiobiólogos, físicos médicos y especialistas en radioprotección. Con este número especial de la RPSP/PAJPH se busca elevar el nivel de conciencia de las autoridades y profesionales de la salud pública acerca de las necesidades y los retos que impone la aplicación de estas tecnologías. Esperamos que su lectura motive a dichos profesionales y a los funcionarios de los ministerios de salud de los países de las Américas a extender a estas áreas los campos tradicionales de la salud pública y contribuya a acelerar los cambios que urge realizar para mejorar la salud de nuestros pueblos.

REFERENCIAS

1. Mould RF. A century of X-rays and radioactivity in medicine. Bristol, PA: Institute of Physics Publishing; 1993.
2. Johnston R. List of radiation accidents and other events causing radiation casualties [página en Internet]; 2006. Hallado en: http://www.johnstonsarchive.net/nuclear/radevents/radaccidents.html. Acceso el 3 de agosto de 2006.
3. International Organization for Medical Physics. Welcome [sitio en Internet]. IOMP. Hallado en http://www.iomp.org. Acceso el 8 de agosto de 2006.
4. Hanson GP, Borrás C, Jiménez P. History of the radiological health program of the Pan American Health Organization. Rev Panam Salud Publica. 2006;20(2/3):87–98.
5. Centros Colaboradores de la Organización Panamericana de la Salud/Organización Mundial de la Salud en la Región de las Américas [sitio en Internet]. BIREME. Disponible en http://www.bireme.br/whocc. Acceso el 8 de agosto de 2006.
6. Colegio Interamericano de Radiología [sitio en Internet]. CIR. Hallado en http://www.cir-radiologia.org. Acceso el 3 de agosto 2006.
7. Asociación Latinoamericana de Terapia Radiante Oncológica [sitio en Internet]. ALATRO. Hallado en http://www.alatro.org. Acceso el 8 de agosto de 2006.
8. Asociación Latinoamericana de Física Médica [sitio en Internet]. ALFIM. Hallado en http://www.alfim.org. Acceso el 8 de agosto de 2006.
9. Asociación Latinoamericana de Técnicos de Radiología [sitio en Internet]. ALATRA. Hallado en http://www.computechpro.net/clients/alatra/spanish/index.asp. Acceso el 8 de agosto de 2006.
10. Inter-Agency Committee on Radiation Safety [sitio en Internet]. IACRS. Hallado en http://www. iacrs-rp.org. Acceso el 8 de agosto de 2006.
11. Inter-Agency Committee on Response to Nuclear Accidents [sitio en Internet]. IACRNA. Hallado en http://www-ns.iaea.org/tech-areas/emergency/iacrna/login.asp. Acceso el 8 de agosto de 2006.
12. Organización de las Naciones Unidas para la Agricultura y la Alimentación, Organismo Internacional de Energía Atómica, Organización de Cooperación y de Desarrollo Económicos, Organización Internacional del Trabajo, Organización Mundial de la Salud, Organización Panamericana de la Salud. Normas básicas internacionales de seguridad para la protección contra la radiación ionizante y para la seguridad de las fuentes de radiación. Viena: Organismo Internacional de Energía Atómica; 1997. (Serie Seguridad no. 115).
13. Organización Panamericana de la Salud. Resolución CSP24.R9. 24.ª Conferencia Sanitaria Panamericana, Washington, D.C., Estados Unidos de América, septiembre de 1994. Washington, D.C.: OPS; 1994. Hallado en http://www.paho.org/Spanish/GOV/CSP/ftcsp_24.htm. Acceso el 8 de agosto de 2006.

Radiological physics within the framework of PAHO technical cooperation programs

Mirta Roses Periago[1]

Medicine was revolutionized at the end of the 19th century thanks to a number of discoveries in the field of physics. In 1895, Roentgen discovered X-rays, which made it possible to visualize internal structures in the human body. The following year Becquerel discovered radioactivity, and in 1898 the Curies (husband and wife) announced the discovery of two radioactive elements: polonium and radium. The latter was immediately put to use to obliterate skin cancers and deep-seated tumors or reduce their size (1). However, these new technologies were not without dangers: the first report of adverse effects of X-rays on human health, after overexposure in a patient who underwent radiography in Chicago, Illinois, United States of America, was published in 1896 (2). Since their inception, image-based diagnostic techniques, radiotherapy (also known as radiation therapy), and radiation protection have evolved in parallel.

Regrettably, advances in physics in the field of radiation during World War II also led to the invention of nuclear weapons, which in turn gave rise to an era of competition between world powers to develop and produce arms of this type. During the 1950s, the United States—aware of the potential applications of these new technologies to agriculture, industry, and medicine, and in an effort to further the use of nuclear energy for peaceful ends—promoted the Atoms for Peace initiative, which fomented the development of nuclear and radiological techniques throughout the world. This initiative also involved developing countries, many of them in Latin America and the Caribbean.

It was also during the 1950s when a new discipline, known as medical physics, made its appearance in certain European countries such as Sweden and the United Kingdom. Medical physicists are science professionals who, just as Roentgen, Becquerel, and the Curies did in their day, apply their knowledge of physics to medicine, particularly in the area of diagnostic and therapeutic radiology. As of 2006, medical physicists number more than 16 000 throughout the world (3), and this number continues to rise with continuing technological advances.

In the 1970s, the invention of the first computed tomography scanner changed the world of radiological physics once again (1). Currently, most of the equipment used in this field is computerized, and imaging techniques are now being applied at the cellular level, with the result that molecules that play a critical role in the development of certain diseases can be identified long before the clinical symptoms appear.

The beneficial effects of these technological advances for public health are substantial. Thanks to these innovations we are able to diagnose a number of diseases, such as cardiovascular

[1] Director, Pan American Sanitary Bureau, Washington, D.C., United States of America.

disorders and neoplasms, in the early stages, and to cure them more easily. In many cases, radiotherapeutic techniques have made it possible to control cancer with less morbidity and more satisfactory cosmetic results than surgery.

Owing to the importance of these techniques—not only in clinical specialties but also in public health—the Pan American Health Organization has been advising governments and training health professionals in countries in Latin America and the Caribbean through its radiology and radiation protection program. In an article in this special issue the three most recent regional advisors to the program (4) describe this collaborative process and offer a historical perspective on the results of the PAHO radiological health program, since its inception in the 1960s.

The work remaining to be done is enormous, and strategic alliances are of key importance. We maintain close contact with the Collaborating Centers of the Pan American Health Organization/World Health Organization that are in countries of the Americas (5), and have the support of professional societies of radiologists (*Colegio Interamericano de Radiología*, CIR) (6), radiation oncologists (*Asociación Latinoamericana de Terapia Radiante Oncológica*, ALATRO) (7), medical physicists (*Asociación Latinoamericana de Física Médica*, ALFIM) (8) and radiological technologists (*Asociación Latinoamericana de Técnicos de Radiología*, ALATRA) (9). In addition, together with other intergovernmental organizations, we belong to two international committees, one devoted to radiation safety (*Inter-Agency Committee on Radiation Safety*, IACRS) (10) and one concerned with radiological and nuclear emergencies (*Inter-Agency Committee on Response to Nuclear Accidents*, IACRNA) (11). At this time we are in the process of reviewing the *International basic safety standards for protection against ionizing radiation and for the safety of radiation sources* (12), whose previous version was endorsed by our Governing Bodies (13) and whose new edition we hope will complement—rather than simply replace—the established standards.

Revista Panamericana de Salud Pública/Pan American Journal of Public Health (RPSP/PAJPH) has put together this collection of articles and reports on diagnostic radiology, radiotherapy, and radiation protection written by professionals from different backgrounds, including radiologists, radiobiologists, medical physicists, and specialists in radiation protection. This special issue of the RPSP/PAJPH aims to raise awareness on the part of health officials and public health professionals regarding the needs and challenges we face in applying these technologies. We hope that reading this issue will motivate our professional colleagues and health ministry workers in the Americas to broaden the traditional scope of public health to include these disciplines, and will help accelerate changes that are so urgently needed and that will go a long way toward improving the health of the peoples of the Americas.

REFERENCES

1. Mould RF. A century of X-rays and radioactivity in medicine. Bristol, PA: Institute of Physics Publishing; 1993.
2. Johnston R. List of radiation accidents and other events causing radiation casualties [Internet site]; 2006. Available from: http://www.johnstonsarchive.net/nuclear/radevents/radaccidents.html. Accessed 3 August 2006.
3. International Organization for Medical Physics. Welcome [Internet site]. IOMP. Available from: http://www.iomp.org. Accessed 8 August 2006.
4. Hanson G, Borrás C, Jiménez P. History of the radiological health program of the Pan American Health Organization. Rev Panam Salud Publica. 2006;20(2/3):87–98.
5. Centros Colaboradores de la Organización Panamericana de la Salud/Organización Mundial de la Salud en la Región de las Américas [Internet site]. BIREME. Available from: http://www.bireme.br/whocc. Accessed 8 August 2006.
6. Colegio Interamericano de Radiología [Internet site]. CIR. Available from: http://www.cir-radiologia.org. Accessed 3 August 2006.
7. Asociación Latinoamericana de Terapia Radiante Oncológica [Internet site]. ALATRO. Available from: http://www.alatro.org. Accessed 8 August 2006.
8. Asociación Latinoamericana de Física Médica [Internet site]. ALFIM. Available from: http://www.alfim.org. Accessed 8 August 2006.
9. Asociación Latinoamericana de Técnicos de Radiología [Internet site]. ALATRA. Available from: http://www.computechpro.net/clients/alatra/spanish/index.asp. Accessed 8 August 2006.
10. Inter-Agency Committee on Radiation Safety [Internet site]. IACRS. Available from: http://www.iacrs-rp.org. Accessed 8 August 2006.
11. Inter-Agency Committee on Response to Nuclear Accidents [Internet site]. IACRNA. Available from: http://www-ns.iaea.org/tech-areas/emergency/iacrna/login.asp. Accessed 8 August 2006.
12. Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Organisation, Nuclear Agency of the Organisation for Economic Co-operation and Development, Pan American Health Organization, World Health Organization. International basic safety standards for protection against ionizing radiation and for the safety of radiation sources. Vienna: IAEA; 1996. (Safety series 115).
13. Organización Panamericana de la Salud. Resolución CSP24.R9. 24.ª Conferencia Sanitaria Panamericana, Washington, D.C., Estados Unidos de América, septiembre de 1994. Washington, D.C.: OPS; 1994. Available from: http://www.paho.org/Spanish/GOV/CSP/ftcsp_24.htm. Accessed 8 August 2006.

El papel de la radiología diagnóstica y terapéutica en el campo de la salud pública

Cari Borrás,[1] coordinadora del número especial

La publicación periódica de la Organización Panamericana de la Salud (OPS) *La salud en las Américas*, en su edición de 2002, contiene reflexiones sobre los cambios demográficos, socioeconómicos y epidemiológicos que han tenido lugar en la Región de las Américas en los últimos años y documenta el aumento de la esperanza de vida en todos los países hasta su promedio actual (con la exclusión de Haití) de más de 70 años (1). Según la edición de 2006 de la publicación electrónica de la OPS *Estadísticas de salud de las Américas* (2), que presenta los datos de 37 países, la esperanza de vida al nacer para el quinquenio de 2005–2010 en ambos sexos variará entre 65,4 (en Guyana) y 80,7 años (en Canadá) y será de 73,3 años en promedio, con una desviación estándar de 5,17 años (excepto en Haití, donde se prevé que esta cifra será de 53,5 años). El envejecimiento progresivo de la población representa un gran reto para los ministerios de salud, ya que la prevalencia de las enfermedades crónicas, que afectan a la población a edades más avanzadas, va en aumento.

Según las estadísticas de 2006, las 10 principales causas de muerte en 31 países de la Región explican entre 43,1% y 59,8% de las defunciones registradas en esos países (2). Las enfermedades cerebrovasculares se encuentran entre las 10 principales causas de muerte en ambos sexos en los 31 países y la cardiopatía isquémica, en todos menos en Dominica, Haití y Honduras. En hombres, el cáncer de próstata es una de las 10 principales causas de muerte en 17 países. Asimismo, las enfermedades crónicas de las vías respiratorias inferiores, la insuficiencia cardíaca y sus complicaciones, y las cardiopatías mal definidas se encuentran entre las principales causas de muerte en 14 de los países analizados. En las mujeres, la influenza y la neumonía están entre las 10 principales causas de muerte en 30 países; la cardiopatía isquémica, en 28; y la insuficiencia cardíaca, en 25. Los cánceres de mama y útero continúan figurando entre las 10 principales causas de muerte en 16 países, seguidos del cáncer de colon en seis países y del cáncer de tráquea, bronquios y pulmón en cinco (2).

En este contexto, las aplicaciones radiológicas cobran una enorme importancia. El diagnóstico de las enfermedades cerebrovasculares, cardiopatías y neoplasias se facilita gracias a la radiología diagnóstica, mientras que algunos de los tratamientos de elección para estas afecciones se basan en la radiología intervencionista. Muchas de las radiaciones empleadas, tanto en la radiología convencional como en la tomografía computarizada, son de tipo ionizante; otras, como las empleadas para la ecografía y la resonancia magnética, no lo son. Mientras que algunas técnicas dependen del uso de radiaciones producidas por equipos de rayos X, otras se basan en la visualización de sustancias radiactivas que se le administran al paciente y que el organismo absorbe. Para la radioterapia se pueden usar equipos de radiación electromagnética externa, como los aceleradores lineales, o fuentes radiactivas, como las unidades de cobaltoterapia y las fuentes selladas de cesio-137 utilizadas en las aplicaciones ginecológicas.

El objetivo fundamental de todas estas técnicas radiológicas es prolongar la vida de los pacientes y disminuir la morbilidad. A medida que se extiende su uso, esta tecnología adquiere mayor complejidad. La realización eficiente y segura de los procedimientos de diagnóstico y

[1] Dirección postal: 1501 Forty-fourth Street, NW, Washington, D.C. 20007, Estados Unidos de América. Correo electrónico: cariborras@starpower.net

tratamiento con fuentes de radiación exige que el personal que los lleva a cabo esté adecuadamente formado y entrenado. El médico clínico, el especialista en radiología, el radiooncólogo, el especialista en medicina nuclear, el físico médico, los tecnólogos y el personal de enfermería son miembros de ese gran elenco interdisciplinario que conforma el personal de salud de los servicios de radiología. Southon (3) analiza los beneficios de contar con redes de profesionales que puedan respaldar las políticas nacionales relacionadas con los servicios de salud —que abarcan los de radiología— y mejorar la calidad de las prestaciones.

En su función rectora y normativa, los ministerios de salud son los responsables de velar por y garantizar la calidad de los servicios de radiología. Una manera de llevar a cabo esta tarea es mediante programas de acreditación. En el artículo de Jiménez et al. (4) se examinan las características potenciales de tales programas en países en desarrollo, en particular en el contexto de los servicios de imaginología básicos, como los de radiografía, fluoroscopia, mamografía y ecografía, mediante la fusión de los aspectos físicos y clínicos.

Es un hecho reconocido que los procedimientos de radiología deben estar sujetos a programas de control de la calidad con un fuerte componente de seguridad radiológica. Indudablemente, tales programas mejoran la calidad de la imagen radiológica y disminuyen la dosis de radiación que reciben el paciente y los operarios. Pero ¿aumentan los diagnósticos certeros? Esta cuestión fue estudiada por un grupo de investigadores que, con el apoyo de la OPS, evaluaron la calidad de los servicios de radiodiagnóstico en cinco países de la Región de características sociales y avances tecnológicos muy diferentes: Argentina, Bolivia, Colombia, Cuba y México. Fleitas et al. (5) presentan los resultados de esa investigación, que demuestra la gran importancia de la formación y experiencia de los radiólogos y de los técnicos de radiología para lograr más diagnósticos certeros. Esta investigación abarcó, entre otros, servicios de mamografía, tanto de tamizaje como de diagnóstico.

Someter a una mamografía a todas las mujeres a partir de cierta edad, aunque estén asintomáticas, es una estrategia de salud pública para la detección temprana del cáncer de mama que ha suscitado grandes polémicas. En este número especial, Feig (6) demuestra que los beneficios de dicha estrategia superan a las limitaciones propias de la poca sensibilidad de la técnica y a los riesgos relacionados con las dosis de radiación recibidas. La mamografía sigue siendo hoy en día la única técnica reconocida para el tamizaje del cáncer de mama.

La imaginología puede ser diagnóstica o intervencionista. Las técnicas de diagnóstico permiten obtener información morfológica (estática) o información fisiológica (dinámica). Para todo ello se dispone de los recursos de la radiología convencional, la ecografía, la resonancia magnética y la medicina nuclear, siendo esta última la única que permite realizar estudios fisiológicos además de morfológicos, para lo cual depende de la introducción de radiofármacos en el organismo del paciente. Una de las nuevas tecnologías, la tomografía por emisión de positrones (PET), ha revolucionado no solo el conocimiento que se tiene acerca de las funciones cerebrales humanas, sino que además se está convirtiendo en una herramienta imprescindible para la localización y delimitación de neoplasias. No existen muchos equipos de PET en América Latina y el Caribe; el Brasil es uno de los países más avanzados en este campo, como nos explica Robilotta (7).

Se debe destacar que los avances tecnológicos no han ocurrido solamente en el campo del diagnóstico. A medida que la incidencia de cáncer aumenta en el mundo, se buscan nuevas formas de tratamiento. Junto con la cirugía y la quimioterapia, la radioterapia ofrece posibilidades de curación y paliación que prolongan la supervivencia y disminuyen la morbilidad. Castellanos (8) nos informa acerca de las necesidades y retos en el campo de la radioterapia en la actualidad.

Para curar un tumor con radiaciones hay que aplicar dosis muy grandes de radiación. Las nuevas técnicas de imaginología permiten visualizar el volumen del área que debe tratarse y circunscribir la radiación a los tejidos afectados por el tumor. Sin embargo, a pesar de los avances descritos por Castellanos, es imposible impedir que los tejidos sanos alrededor del tumor se vean expuestos a alguna radiación, aunque sea a dosis más bajas. Los efectos de la radiación en estos tejidos son analizados por Hendry et al. (9), quienes cuantifican los riesgos en función de la dosis.

En radioterapia es esencial que la dosis prescrita coincida con la dosis que recibe el paciente. El Organismo Internacional de Energía Atómica y la Organización Mundial de la Salud establecieron en 1969 un programa de dosimetría postal que permite verificar si las unidades de radioterapia de alta energía están calibradas adecuadamente. En la Región de las Américas, la OPS administra este programa. Iżewska et al. (10) presentan y examinan los resultados de las evaluaciones realizadas de 1969 a 2003 en los países de América Latina y el Caribe y muestran los grandes adelantos que se han logrado.

Lamentablemente, los errores en las dosis que reciben los pacientes sometidos a radioterapia no se deben solamente a la mala calibración de las unidades de tratamiento. Borrás (11) describe un error de sobreexposición de 28 pacientes en Panamá debido a la utilización inapropiada del sistema computarizado de planificación de tratamientos. Asimismo, describe las medidas tomadas por la institución y la OPS para prevenir errores semejantes en el futuro.

¿Cuándo se considera que una irradiación es excesiva? Las dosis usadas para la radioterapia son 1 000 veces mayores que las que se utilizan para el diagnóstico. ¿Son todas peligrosas? ¿Cómo se aseguran los ministerios de salud de que la población no reciba dosis dañinas? ¿Quién controla las fuentes de radiación? ¿Quién permite su entrada o fabricación en el país? Arias (12) nos informa acerca del desarrollo de los programas de protección radiológica y define el papel de las autoridades reguladoras en ese sentido.

Según Arias, entre los tejidos y órganos más sensibles a la radiación se encuentran los del embrión y el feto. El miedo irracional a las radiaciones lleva a muchas mujeres embarazadas que han pasado por un examen o tratamiento radiológico a preocuparse por los efectos de la radiación en la criatura en gestación y se plantean la necesidad de interrumpir el embarazo. Brent (13) comparte con nosotros algunos de estos casos y los resultados del asesoramiento proporcionado a las mujeres en situaciones semejantes.

La población no solo les teme a las radiaciones ionizantes, sino también a las que no son ionizantes y emanan de campos electromagnéticos, como los de los teléfonos celulares. Toda radiación, sea ionizante o no, se tiene que regir por normas y estándares. Skvarca et al. (14) explican los límites de exposición y los protocolos de medición para las radiaciones no ionizantes, tomando como base su utilización en la Argentina.

Para ilustrar los diferentes aspectos de la radiología diagnóstica y terapéutica, se podrían haber solicitado contribuciones sobre muchos otros temas. Este campo es cada vez más amplio. El objetivo de los artículos seleccionados para este número especial es dirigir la atención de los lectores de la *Revista Panamericana de Salud Pública/Pan American Journal of Public Health* hacia un campo —quizá desconocido, pero fascinante— que abre enormes posibilidades, impensables muy pocos años atrás. Gracias a las tecnologías propias de este campo, los pacientes ya no tienen que someterse a largas hospitalizaciones y pueden gozar de una vida más larga y de mejor calidad.

La radiología genera esperanzas, permite tener ilusiones. La intención de los artículos e informes presentados en este número especial es llevar al lector a profundizar en este novedoso campo. Quiero agradecerles inmensamente a todos los autores a quienes les solicité contribuciones originales para este número su desprendimiento y generosidad. Me gustaría pensar que gracias a estas contribuciones y al esfuerzo de los editores, en algún lugar de las Américas alguna persona se salvará o tendrá una vida de mejor calidad.

REFERENCIAS

1. Organización Panamericana de la Salud. Salud en las Américas, 2002. Washington, D.C.: OPS; 2002. (Documento Oficial no. 587).
2. Organización Panamericana de la Salud. Estadísticas de salud en las Américas, 2006. Washington, D.C.: OPS; 2006. hallado en: http://www.paho.org/Spanish/DD/AIS/hsa2006. htm. Acceso el 9 de agosto de 2006.
3. Southon G. The role of professional networks in radiology services. Rev Panam Salud Publica. 2006;20(2/3): 99–103.
4. Jiménez P, Borrás C, Fleitas I. Accreditation of diagnostic imaging services in developing countries. Rev Panam Salud Publica. 2006; 20(2/3):104–12.
5. Fleitas I, Caspani CC, Borrás C, Plazas MC, Miranda AA, Brandan ME, et al. La calidad de los servicios de radiología en cinco países latinoamericanos. Rev Panam Salud Publica. 2006;20(2/3):113–24.
6. Feig SA. Screening mammography: a successful public health initiative. Rev Panam Salud Publica. 2006; 20(2/3):125–33.
7. Robilotta CC. A tomografia por emissão de pósitrons: uma nova modalidade na medicina nuclear brasileira. Rev Panam Salud Publica. 2006; 20(2/3):134–42.
8. Castellanos ME. Las nuevas tecnologías: necesidades y retos en radioterapia en América Latina. Rev Panam Salud Publica. 2006;20(2/3): 143–50.
9. Hendry JH, Jeremić B, Zubizarreta EH. Normal tissue complications after radiation therapy. Rev Panam Salud Publica. 2006;20(2/3):151–60.
10. Iżewska J, Vatnitsky S, Shortt KR. Postal dose audits for radiotherapy centers in Latin America and the Caribbean: trends in 1969-2003. Rev Panam Salud Publica. 2006;20(2/3): 161–72.
11. Borrás C. Overexposure of radiation therapy patients in Panama: problem recognition and follow-up measures. Rev Panam Salud Publica. 2006;20(2/3):173–87.
12. Arias CF. La regulación de la protección radiológica y la función de las autoridades de salud. Rev Panam Salud Publica. 2006;20(2/3):188–97.
13. Brent RL. Counseling patients exposed to ionizing radiation during pregnancy. Rev Panam Salud Publica. 2006;20(2/3):198–204.
14. Skvarca J, Aguirre A. Normas y estándares aplicables a los campos electromagnéticos de radiofrecuencias en América Latina: guía para los límites de exposición y los protocolos de medición. Rev Panam Salud Publica. 2006;20(2/3):205–12.

Introductory overview

The role of diagnostic and therapeutic radiology in the field of public health

Cari Borrás,[1] coordinator of this special issue

The 2002 edition of *Health in the Americas* (1), serially published by the Pan American Health Organization (PAHO), contains reflections on the demographic, socioeconomic, and epidemiologic changes that have taken place in the Americas in recent years, and documents the increase in life expectancy to the current average of more than 70 years in all countries of the Region (excluding Haiti) (1). According to the 2006 on-line edition of *Health Statistics from the Americas* (2), another PAHO publication that presents data for 37 countries, life expectancy at birth for the five-year period from 2005 to 2010 in both sexes is expected to range from 65.4 years (in Guyana) to 80.7 years (in Canada), with a mean of 73.3 years and a standard deviation of 5.17 years (except in Haiti, where the estimated life expectancy is 53.5 years). Steady aging of the population represents a considerable challenge for health ministries in the Americas as the prevalence of chronic illnesses, which affect older people in the population, is on the rise.

According to statistics for 2006, the 10 leading causes of death in 31 countries in the Region account for between 43.1% and 59.8% of all deaths recorded in these countries (2). Cerebrovascular diseases are among the 10 leading causes of death in both sexes in all 31 countries, and ischemic heart disease is among such causes in all countries except Dominica, Haiti, and Honduras. Among men, prostate cancer is one of the 10 leading causes of death in 17 countries. In addition, chronic diseases of the lower respiratory tract, heart failure and its complications, and ill-defined heart conditions are among the main causes of death in 14 of the countries. In women, influenza and pneumonia are among the 10 leading causes of death in 30 countries; ischemic heart disease, in 28; and heart failure, in 25. Breast and uterine cancers continue to rank among the 10 leading causes of death in 16 countries, followed by colon cancer in 6 countries, and cancer of the trachea, bronchus, and lung in 5 countries (2).

Within this context, the application of radiological technologies takes on enormous importance. The diagnosis of cerebrovascular diseases, cardiac anomalies, and neoplasms is made easier thanks to diagnostic radiology; moreover, certain treatments of choice for these illnesses are based on interventional radiology. Many types of radiation used in both conventional radiology and computed tomography are ionizing in nature; others, such as those used in ultrasound and magnetic resonance imaging, are non-ionizing. Some technologies depend on the use of radiation produced by X-ray equipment, whereas others are based on the visualization of radioactive substances administered to the patient and absorbed by the body. Radiotherapy can involve the use of radiation-generating equipment, such as linear accelerators, or radioactive sources in cobalt teletherapy units and sealed cesium-137 sources used in gynecological applications.

The main objective of these radiological techniques is to prolong the patient's life and to decrease morbidity. As its use increases, the technology becomes more complex. The efficient and safe use of diagnostic and therapeutic procedures involving radiation sources requires that the staff performing the procedures be appropriately educated and trained. Clinicians, radiologists, radiation oncologists and nuclear medicine specialists,

[1] Send correspondence to: Cari Borrás, 1501 Forty-fourth Street, N.W., Washington, D.C. 20007, United States of America; e-mail: cariborras@starpower.net

medical physicists, technologists, and nursing staff all form part of this large, interdisciplinary team of radiology service health workers. Southon (3) analyzes the benefits of having access to professional networks that can support the national policies surrounding health services—which include radiology services—and improve the quality of healthcare delivery.

In their normative and regulatory role, health ministries are responsible for overseeing and ensuring the quality of radiology services. One way to accomplish this task is through accreditation programs. The article by Jiménez et al. (4) examines the potential characteristics of such programs in developing countries, particularly in the context of basic imaging services such as radiography, fluoroscopy, mammography, and ultrasound, through a combination of physical and clinical features.

It is a recognized fact that radiological procedures should be subject to quality control programs that include a robust radiation safety component. These programs unquestionably improve the quality of radiological images and decrease the dose of radiation received by patients and operators. But do such programs increase diagnostic accuracy? This question was investigated by a research group that, with support from PAHO, assessed the quality of diagnostic radiology services in five countries in the Region that differ widely in their social and technological characteristics: Argentina, Bolivia, Colombia, Cuba, and Mexico. Fleitas et al. (5) present the results of this research, which shows that the training and experience of radiologists and radiology technicians are very important in improving diagnostic accuracy. This research involved screening and diagnostic mammography, among other types of radiology services.

Performing mammography on all women beyond a certain age, including asymptomatic women, is a public health strategy for the early detection of breast cancer that has given rise to substantial controversy. In this special issue, Feig (6) shows that the benefits of this strategy outweigh the limitations of the technique's low sensitivity and the risks related to the doses of radiation received. Currently, mammography remains the only recognized screening technique for detecting breast cancer.

Imaging techniques may be diagnostic or interventional. Diagnostic techniques make it possible to obtain morphological (static) or physiological (dynamic) information. Among the resources now available for this purpose are conventional radiology, ultrasound, magnetic resonance and nuclear medicine. This last technology, based on the visualization of radioactive substances inside the patient's body, makes physiological as well as morphological studies possible. Positron emission tomography (PET), one of the newer technologies, has not only revolutionized our knowledge of the functioning of the human brain but is also becoming an indispensable tool for localizing and delimiting neoplasms. Few PET units are in operation in Latin America and the Caribbean. As explained by Robilotta (7), Brazil is one of the most advanced countries in this field.

It should be emphasized that technological advances have occurred not only in the field of diagnostic imaging. As the incidence of cancer throughout the world increases, new forms of treatment are being sought. Together with surgery and chemotherapy, radiotherapy offers the possibility of curative or palliative treatment that can prolong survival and diminish morbidity. Castellanos (8) reports on current needs and challenges in the field of radiotherapy.

To cure a tumor with radiation, very large doses of radiation are needed. New imaging techniques make it possible to visualize the volume of the site requiring treatment so that radiation can be applied only to the tissues affected by the tumor. However, despite the advances described by Castellanos, it is impossible to prevent the healthy tissues surrounding the tumor from being irradiated, albeit at lower doses. The effects of radiation on these tissues are addressed by Hendry et al. (9), who quantify the risks associated with different doses.

In radiotherapy it is essential that the dose delivered to the patient match the prescribed dose. In 1969 the International Atomic Energy Agency and the World Health Organization established a postal dose audit program that made it possible to verify whether high-energy radiotherapy units were properly calibrated. In the Region of the Americas this program is run by PAHO. Iżewska et al. (10) report the results of audits performed between 1969 and 2003 in countries of Latin America and the Caribbean and conclude that great strides have been made.

Unfortunately, miscalibration of treatment units is not the only source of dosimetry errors in patients who undergo radiotherapy. Borrás (11) describes an overexposure error in 28 patients in Panama that resulted from the inappropriate use of a computerized treatment planning system. She also describes the measures that were taken by the treatment facility in Panama and by PAHO in order to prevent similar errors from happening in the future.

When is irradiation considered excessive? The doses used for radiotherapy are 1 000-fold higher than those used for diagnostic purposes. Are they all dangerous? How can health ministries ensure that patients do not receive harmful doses? Who controls the sources of radiation? Who allows radiology units to be imported to or built in a given country? Arias (12) reports on the development of radiological protection programs and outlines the role of regulatory entities in this area.

According to Arias, the tissues and organs belonging to the embryo and fetus are among the most sensitive to radiation. Irrational fear of radiation leads many pregnant women who have undergone radiological tests or treatment to worry about the effects of radiation on their developing baby and to consider terminating their pregnancy. Brent (13) describes some of these cases and the outcome of counseling provided for women in such situations.

People fear not only ionizing radiation, but also non-ionizing radiation produced by electromagnetic fields, such as those coming from cell phones. Any radiation, whether it be ionizing or non-ionizing, must be subject to rules and standards. Skvarca et al. (14) explain the exposure limits and the measurement protocols for non-ionizing radiation, based upon current practice in Argentina.

Since radiological technology is an expanding area, many more contributions on additional topics could have been solicited for this special issue in order to illustrate different aspects of diagnostic and therapeutic radiology. The aim of the articles selected for the issue is to direct the attention of readers of the *Revista Panamericana de Salud Pública/Pan American Journal of Public Health* toward a fascinating field that is perhaps little known but offers enormous potential that was unthinkable only a few years ago. Thanks to the technologies applied in this field, patients no longer need to undergo prolonged hospital stays and can enjoy a longer, better life.

Radiology offers hope and better prospects for the future. The articles and reports in this special issue are intended to encourage readers to delve more deeply into this innovative field. I am extremely grateful to all the authors who, at my request, submitted original contributions on specific topics for this issue. Thanks to their generosity and to the efforts of editors involved, perhaps somewhere in the Americas someone's life will be saved or improved.

REFERENCES

1. Pan American Health Organization. Health in the Americas, 2002 edition. Washington, D.C.: PAHO; 2002. (Scientific and Technical Publication No. 587).
2. Pan American Health Organization. Health statistics from the Americas, 2006 edition. Washington, D.C.: PAHO; 2006. Available from: http://www.paho.org/English/dd/ais/hsa2006.htm. Accessed 9 August 2006.
3. Southon G. The role of professional networks in radiology services. Rev Panam Salud Publica. 2006;20(2/3): 99–103.
4. Jiménez P, Borrás C, Fleitas I. Accreditation of diagnostic imaging services in developing countries. Rev Panam Salud Publica. 2006; 20(2/3):104–12.
5. Fleitas I, Caspani CC, Borrás C, Plazas MC, Miranda AA, Brandan ME, et al. La calidad de los servicios de radiología en cinco países latinoamericanos. Rev Panam Salud Publica. 2006;20(2/3):113–24.
6. Feig SA. Screening mammography: a successful public health initiative. Rev Panam Salud Publica. 2006; 20(2/3):125–33.
7. Robilotta CC. A tomografia por emissão de pósitrons: uma nova modalidade na medicina nuclear brasileira. Rev Panam Salud Publica. 2006; 20(2/3):134–42.
8. Castellanos ME. Las nuevas tecnologías: necesidades y retos en radioterapia en América Latina. Rev Panam Salud Publica. 2006;20(2/3): 143–50.
9. Hendry JH, Jeremić B, Zubizarreta EH. Normal tissue complications after radiation therapy. Rev Panam Salud Publica. 2006;20(2/3):151–60.
10. Izewska J, Vatnitsky S, Shortt KR. Postal dose audits for radiotherapy centers in Latin America and the Caribbean: trends in 1969–2003. Rev Panam Salud Publica. 2006;20(2/3): 161–72.
11. Borrás C. Overexposure of radiation therapy patients in Panama: problem recognition and follow-up measures. Rev Panam Salud Publica. 2006;20(2/3):173–87.
12. Arias CF. La regulación de la protección radiológica y la función de las autoridades de salud. Rev Panam Salud Publica. 2006;20(2/3):188–97.
13. Brent RL. Counseling patients exposed to ionizing radiation during pregnancy. Rev Panam Salud Publica. 2006;20(2/3):198–204.
14. Skvarca J, Aguirre A. Normas y estándares aplicables a los campos electromagnéticos de radiofrecuencias en América Latina: guía para los límites de exposición y los protocolos de medición. Rev Panam Salud Publica. 2006;20(2/3):205–12.

History of the radiological health program of the Pan American Health Organization[1]

Gerald P. Hanson,[2] Cari Borrás,[3] and Pablo Jiménez[4]

Key words: delivery of health care, radiologic health, radiology, radiation protection, radiotherapy, Pan American Health Organization, Americas.

[1] A more extensive version of this article will be available on the PAHO website (www.paho.org).

[2] Former Regional Advisor in Radiological Health for the Pan American Health Organization, Washington, D.C., United States of America. Send correspondence to: Dr. Gerald P. Hanson, 2 Winterberry Court, Bethesda, Maryland 20817, United States of America.

[3] Former Regional Advisor in Radiological Health for the Pan American Health Organization, Washington, D.C., United States of America.

[4] Current Regional Advisor in Radiological Health for the Pan American Health Organization, Washington, D.C., United States of America.

The radiological health program of the Pan American Health Organization (PAHO) was established in 1960. Although the program has undergone various organizational changes, it continues to operate to this date. It has been operational through the administrations of five of the Directors of the Pan American Sanitary Bureau (PASB), which is PAHO's Secretariat, and has been located in various PAHO divisions or areas of work. Its program emphasis has evolved with the requirements of the Member States of PAHO. However, the program has essentially remained a unit with activities in research, training, radiation protection, and services in the areas of public health and clinical medicine.

1959–1975, PASB DIRECTOR ABRAHAM HORWITZ

In the 1950s the world superpowers were actively engaged in a nuclear arms race and were testing weapons in the atmosphere. Governments and people throughout the world were deeply concerned about the effects of worldwide radioactive fallout. Civil defense shelters were being constructed to protect against such fallout and against nuclear blasts, and schoolchildren were being taught to deal with a nuclear attack. Also, the peaceful uses of atomic energy were being promoted, and radioisotopes were being developed for diagnosis, research, and therapy.

In 1960, PAHO established the Radiological Health Unit, with two professionals and a secretary, to promote the role of public health authorities in the field of applied nuclear energy. The head of the Unit was Regional Radiological Health Advisor Irvin Lourie, a physician who was supported by Specialized Technical Advisor Thomas Shea, a health physicist.

The 1960 *Annual report of the Director* of the PASB (1) stated that the program of the Radiological Health Unit would be directed along four main lines: (1) stimulating national health services to develop procedures for regulations governing the use of X-rays and radioisotopes and the disposal of radioactive wastes, based on the recommendations of the International Commission on Radiological Protection; (2) promoting the teaching of basic health physics and radiological protection in schools of medicine, dentistry, public health, veterinary medicine, etc.; (3) fostering the use of radioiso-

topes for medical diagnosis, therapy, and research, and (4) encouraging research on applications of radiation that might be of importance to medicine, public health, or veterinary medicine.

In 1962 the XVI Pan American Sanitary Conference approved a research policy for PAHO and requested that the Director of the PASB "take all possible steps to expand the research activities of the Organization, including specific projects and their financing, for the mutual benefit of the countries of the Region [of the Americas]" (2). In 1962, PAHO established the Advisory Committee on Medical Research (ACMR). This had a stimulating effect on the research aspects of PAHO's technical programs, including radiological health.

In collaboration with physicist Merrill Eisenbud of New York University (NYU), preliminary studies were performed of food, water, and human teeth from the areas of Brazil with a high natural radiation background. Later, a conference was held to elucidate the public health significance of background radiation, and financial support for the Biophysics Institute of the University of Brazil and the Catholic University of Rio de Janeiro to conduct biological and physical studies was obtained from the Atomic Energy Commission of the United States of America. During the course of the project, numerous Brazilian scientists received training in Brazil and at New York University, and valuable information concerning chronic exposure in areas of high natural radiation background was obtained. PAHO continued to support this project until the end of 1975. By then, development, such as paved roads and building construction, had changed the character of the area.

In Chile a coordinated research project on manganese poisoning in miners was initiated, with collaboration between the Brookhaven National Laboratory, for biochemical analysis, and the School of Medicine of the Catholic University of Chile, for clinical evaluation. Initiated in 1962, the project continued through 1974. It resulted in an understanding of the biochemical basis of action of various amino acids in chronic manganese poisoning and in Parkinson's disease.

In 1962 and 1963, plans were made to study the effects of irradiation at high altitudes on large animals (*burros* and *llamas*). In November 1964, a meeting was held in Lima, Peru, to develop a research project. The *altiplano* (highland plateau) of Peru was selected as a natural laboratory environment to determine if hypoxia exerts a protective influence by reducing the number of cases of aplastic anemia following high doses of gamma radiation, as well as to study the central nervous system syndrome. It was envisaged that this information might contribute to a better understanding of the development of leukemia in humans.

Over the 1960–1964 period, the Radiological Health Unit also directed efforts toward such other areas as: (1) providing fellowships for training PAHO staff and national professionals, (2) preparing Spanish-language translations of training materials (manuals, pamphlets, slides, movies) and disseminating these materials, (3) promoting radiation control legislation and regulations and establishing national programs, (4) providing advice to governments concerning radiation exposure and control, (5) assisting governments in obtaining international support and arranging scientific collaboration, and (6) representing PAHO at international conferences and meetings.

A program for the radiological surveillance of air and milk in Latin America and the Caribbean was in operation from 1962 to 1981. At the end of 1976 this program was reevaluated. Subsequently, in collaboration with the School of Public Health of the University of Texas, a program to measure environmental radiation exposure using thermoluminescent dosimeters was organized. By 1981, interest in environmental surveillance had waned. A final report was prepared, and all activities were terminated.

By 1963, PAHO Regional Radiological Health Advisor Lourie was disappointed that it had not been possible to establish a single national radiation protection program within the health ministries. He felt it was imperative to assign a staff member to the field. Specialized Technical Advisor Shea did not wish to leave the Washington, D.C., area and resigned from PAHO.

In December 1964, PAHO recruited Gerald Hanson, a 28-year-old engineer, to be Regional Advisor in Radiation Protection. Hanson had master's degrees in sanitary engineering and in radiological health from the University of Michigan, as well as practical experience as a radiation control program director for the state of Kansas and as a radiation safety officer for a federal government laboratory in the United States.

Stationed in Lima, Peru, Hanson was responsible for providing advice and establishing radiation protection programs within the health ministries of the countries of Latin America and the Caribbean. During the 1965–1968 period, Hanson made numerous visits to countries that had requested technical advice. The topics covered included identification of sources of radiation; radiation protection surveys in hospitals, medical centers, and industries; drafting of legislation and regulations; organizing radiation protection services, including film dosimetry laboratories; training of national staff, including the identification of potential leaders for fellowship support; setting up and operating fallout monitoring programs; pro-

moting and coordinating research; and coordinating activities with national and international radiation protection agencies.

A training team was formed by appointing two consultants: Jorge Roman, an occupational health engineer from Peru, and Robert Bostrom, a training specialist from the U.S. Public Health Service (USPHS). Using excellent training materials (the *Basic science review* and the *Basic manual on radiation protection*) that had been prepared in collaboration with the USPHS, short courses were presented in various countries.

In mid-1967, PAHO Regional Radiological Health Advisor Lourie felt he had no alternative but to resign. He had made the strongest case possible for increasing the resources available to the PAHO radiological health program, but was informed by the Director that no additional funds or staff would be assigned. From that point onward, until Jorge Litvak, a Chilean endocrinologist with training in nuclear medicine, joined PAHO in 1969, the program was implemented by the unit's secretary, (Rida Luellsdorf), in Washington, D.C., and Regional Advisor Hanson, now stationed in Santiago, Chile.

By the end of 1968, 10 countries had signed formal agreements with PAHO for assistance in establishing a radiation protection program within their health ministries. These countries were Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Guyana, Jamaica, Uruguay, and Venezuela. In the radiological fallout surveillance program, 12 stations in 10 countries were in operation, with all 12 forwarding daily air samples and 6 sending weekly to monthly composite milk samples. Also, with cooperation from the U.S. Atomic Energy Commission, six radiological health scientific libraries, with several hundred volumes each, were established. They were located in Argentina, Bolivia, Brazil, Chile, Colombia, and Venezuela.

In 1968 a seminal meeting on dosimetric requirements in radiotherapy centers, took place in Caracas, Venezuela, with participation from the International Atomic Energy Agency (IAEA), PAHO, and the World Health Organization (WHO). The recommendations of the meeting included three key items: (1) preparation of a basic manual on dosimetry adapted to Latin American needs, (2) organization of Regional training courses in radiotherapy physics, and (3) creation of Regional dosimetry laboratories. On several occasions in 1969 and 1970, PAHO invited a physicist, John Massey of the Christie Hospital in Manchester, United Kingdom, and a radiation oncologist, Mayer Zaharia of the National Cancer Institute in Lima, Peru, to PAHO Headquarters in Washington, D.C. Those two experts worked with Litvak on the manual on dosimetry. When finished, the manuscript, including its Spanish translation, was handed over to the IAEA, and the world-renowned *Manual of dosimetry in radiotherapy* (the "Massey Manual") was published in 1970, bearing the logos of the IAEA, PAHO, and WHO (3).

In 1970 a Regional course for physicists specializing in radiotherapy was presented at the Puerto Rico Nuclear Center, jointly sponsored by PAHO and the IAEA. Similar courses were held in 1973 in Mexico and in 1975 in Brazil and Chile.

Following PAHO's recommendation, in 1969 WHO established the first Regional Reference Center for Secondary Standard Dosimetry (SSD) within the laboratories of the Atomic Energy Commission of Argentina. For many years this laboratory, and others throughout the world (including ones established within the Nuclear Energy Commission of Brazil and the Health Ministry of Mexico), received funding from WHO. The periodic newsletter of the Secondary Standard Dosimetry Laboratories (SSDLs) was published by WHO from 1970 until 1986, at which time the IAEA took over the responsibility. By the end of 2005 there were 81 SSDLs in 64 countries, and 13 of these laboratories were located in 13 different countries of the Americas.

Also arising out of the 1968 meeting in Caracas was the postal IAEA/WHO program for the intercomparison of radiation therapy doses, using thermoluminescent dosimeters (TLDs). Two physicists serving with the IAEA, Paul Pfalzner of Canada and Robert Loevinger of the United States, had devised a simple method for measuring the radiation dose from cobalt-60 teletherapy units by using capsules containing thermoluminescent powder that could easily be transported through the mail. PAHO and WHO immediately grasped the impact that such a system could have on improving the practice of radiation therapy, and they joined with IAEA to organize this service on a worldwide basis. From its inception in 1969 through the end of 2005, approximately 2 200 measurements (radiation-beam checks) in 330 hospitals or radiation therapy centers in 24 countries in the Americas were made. Since 1991, this has included measurements on linear accelerators. The results of the TLD program—now known as postal dose audits—are described in an article by Iżewska et al. in the current issue of this journal (4).

Participation in the 1968 Caracas meeting cemented Hanson's resolve to obtain training in medical physics. While conducting radiation protection surveys in hospitals and training national staff for this purpose, he was shocked by the lack of support for radiological physics. The hospital physicist was practically nonexistent, with probably no more than a dozen medical radiation physicists working

in hospitals in all of Latin America and the Caribbean (2 in Argentina, 5 in Brazil, 1 in Colombia, 1 in Jamaica, and 3 in Mexico). In contrast, in 2006 the International Organization for Medical Physics had around 600 members from 11 countries of Latin America and the Caribbean.

The PASB Director allowed Hanson a two-year leave of absence to obtain his doctoral degree at the University of California in Los Angeles (UCLA). Subsequently, Jorge Litvak was invited to take the vacant post of Regional Advisor in Radiological Health in Washington, D.C. Jorge Roman was appointed to the post of Regional Advisor in Radiation Protection in Santiago, Chile. During 1969 and 1970, Litvak and Roman worked as a team, PAHO's program continued, and a general model for radiation protection legislation was prepared. In these two years a record number of 18 fellowships was awarded for radiological health studies to officials from Argentina, Barbados, Bolivia, Brazil, British Honduras, Chile, Colombia, Costa Rica, Ecuador, Jamaica, Peru, Trinidad and Tobago, and Venezuela.

The team of Litvak and Roman did not continue beyond the first months of 1971. Roman's contract was not renewed, and soon afterward Litvak returned to Chile. By April 1971, Hanson had completed his doctoral studies at UCLA and was assigned to PAHO Headquarters.

The Radiological Health Unit entered into an era of close cooperation with the PAHO Cancer Unit and, in collaboration with the national cancer authorities of Brazil, a study group meeting on the training of personnel in Physics Applied to Radiotherapy was held in Rio de Janeiro in 1972. Radiation oncologists, physicists, and cancer specialists from the Region met with PAHO staff and consultants to develop a plan to satisfy the need for radiotherapy physics services. PAHO invited Carlos Eduardo de Almeida, a young Brazilian student who was pursuing a degree in medical physics at the University of Texas' M. D. Anderson Hospital in Houston, Texas, to attend the meeting as a consultant. Subsequently, de Almeida made a significant contribution to the development of medical physics and radiation protection in the Region of the Americas.

In 1973, PAHO provided to the Government of Haiti a special type of cobalt-60 teletherapy unit called JANUS that had been designed by Ulrich Henschke, a radiation oncologist. With PAHO's support, Henschke and his colleagues provided operational assistance and training in radiation therapy.

The PAHO Radiological Health Unit also began working closely with the Pan American Development Foundation (PADF), and donations of used equipment were offered to countries in the Americas. PADF relied on PAHO's technical advice in deciding whether to accept the offers. During this period PAHO also learned about a revolutionary new diagnostic X-ray machine. Richard Chamberlain, a diagnostic radiologist at the University of Pennsylvania, who had developed the machine, named it the "Technamatic."

In the latter part of 1973 the vacant post of Regional Advisor in Radiological Health was filled. The Radiological Health Unit had a new chief, Godofredo Gomez Crespo, a physician from Spain, who had been the regional advisor in the WHO Regional Office for the Eastern Mediterranean. From 1974 to 1979, both the regional advisor in radiological health and the regional advisor in radiation physics were stationed in Washington, D.C. Gomez Crespo devoted his efforts mainly to diagnostic radiology, nuclear medicine, and radiation therapy. Hanson worked in radiation protection, environmental surveillance, and support for radiation therapy, including the Postal TLD Intercomparison Program.

Soon after becoming the chief of the PAHO Radiological Health Unit, Gomez Crespo was introduced to Chamberlain and immediately recognized the utility of the Technamatic X-ray machine that Chamberlain had developed. The Unit's two regional advisors organized a pivotal working group meeting, held in March 1975 at PAHO Headquarters in Washington, D.C., on planning and developing radiological facilities. Chamberlain, who was terminally ill, participated vigorously, along with experts from Europe, Latin America, and the United States, including Thure Holm, a diagnostic radiologist from Sweden who was an expert on X-ray equipment. The working group developed a diagnostic radiology system for primary care centers, including the specifications for a simple X-ray machine that could operate under adverse conditions. The working group also developed designs for appropriate X-ray rooms and plans for the training of radiology personnel. A year later, Philip Palmer, a diagnostic radiologist from the University of California in Davis who had also attended the March 1975 meeting, wrote a manual that provided the information needed to establish an X-ray department in a small hospital. PAHO published the text (5) in both English- and Spanish-language editions in 1978.

1975–1983, PASB DIRECTOR HECTOR ACUÑA

Hector Acuña became the Director of the PASB in 1975. One of his first priorities was reorganizing the institution. The Radiological Health Unit became part of the Environmental Health Division,

where it remained until 1979. Within the Environmental Health Division, the country-level projects dealing with air pollution, industrial hygiene, and radiation protection were consolidated within the Division's core program of water supply and waste water disposal. Within a few years, in most countries the country-level budget assigned for the entire environmental engineering program was less than the previous budgets for either industrial hygiene or radiation protection activities alone. During the 1970s, PAHO had made bilateral agreements with several Latin American and Caribbean governments to establish radiological protection programs. When the agreements reached the end of their timeframe, they were not renewed, and by 1977, none of the country radiation protection projects remained.

During his years in the Environmental Health Division, the Regional Advisor in Radiological Health continued to promote the primary care radiology system (PCRS) and the training of technologists. A prototype machine loaned by the University of Pennsylvania was tested for three months in El Salvador in 1975, and a report on that was presented at the Second International Symposium on the Planning of Radiological Departments, held in Philadelphia, Pennsylvania, United States, in 1976. Information concerning curricula in technologist training programs was obtained through visits to various countries, and in 1976 a meeting of directors of schools and programs in X-ray technology training was held in Caracas, Venezuela.

In the radiation protection area, continuing support was provided to the national programs through visits by the Regional Advisor in Radiation Physics and the Regional project's resources, because country projects had declined. The concept of incorporating the emerging activity of quality assurance into national programs was promoted, as were the radiation protection aspects of facility planning; quality assurance in diagnostic radiology, nuclear medicine, and radiation therapy; and the maintenance of radiological equipment. Contact was maintained with international organizations, such as the International Commission on Radiological Protection (ICRP) and the International Commission on Radiation Units and Measurements (ICRU), to assure uniformity in PAHO's efforts to promote international standards.

The Radiological Health Unit was transferred from the Environmental Health Division to the Disease Prevention and Control Division in mid-1979, and soon after, Gomez Crespo left PAHO. The responsibilities of both the Regional Advisor in Radiological Health and the Regional Advisor in Radiation Physics were entrusted to Hanson. The Radiological Health Unit was now dealing with radiation medicine (diagnostic radiology, radiation therapy, and nuclear medicine) as well as protection from radiation hazards from any source.

In the area of diagnostic radiology, efforts focused on developing the simplified X-ray system. In 1980 a commitment was obtained from the General Electric Company to provide four prototypes of their new "Technamatic" machine for a field trial in Latin America. This was an updated version of Chamberlain's invention. The new machines incorporated an improved tube stand and an advanced inverter type of "multipulse" X-ray generator. Since Chamberlain had purposely left the name "Technamatic" in the public domain (without trademark protection), General Electric used the name because it sounded innovative. PAHO selected Colombia to receive the four machines since that country had an active primary care program. The machines were delivered in 1983, and the successful field trial was concluded in 1984.

In 1980, in collaboration with the Inter-American Social Security Research Center (*Centro Interamericano de Estudios de Seguridad Social*, CIESS), a seminar was held in Mexico City to assess the status of diagnostic radiology in the Region of the Americas. Also in 1980 the results of a survey of Spanish-language teaching materials for X-ray technologists that had been initiated the year before were published by PAHO. In 1981, in collaboration with Member States and the Inter-American College of Radiology, a rapid assessment of the radiological health situation was conducted by the Radiological Health Unit, using questionnaires covering diagnostic radiology, radiotherapy, nuclear medicine, and radiation protection. The production of training materials for technologists was promoted by the Radiological Health Unit through cooperation with other PAHO technical units in an international workshop on the training of middle-level technicians held at PAHO Headquarters in Washington, D.C., in 1981.

In the radiotherapy area, the IAEA/WHO Postal Dose Intercomparison Program for cobalt-60 teletherapy machines was gradually expanded, with an average of 60 radiotherapy centers per year being included over the 1979–1986 period. In 1980, PAHO provided follow-up technical cooperation, through visits by a radiation physicist to identify and correct errors in those radiotherapy centers where a deviation of greater that 5% between their reported measurements and the actual values measured in the IAEA laboratory had been found. This was the first time that such on-site follow-up was provided, a practice that both PAHO and the IAEA have continued to this date.

In the area of nuclear medicine, in collaboration with the USPHS Bureau of Radiological Health and the Federated Council of Nuclear Medicine

Organizations, the Radiological Health Unit organized an international symposium on quality assurance, which was held in April 1981 at PAHO Headquarters, with 200 participants. The purpose was to review the status of nuclear medicine and to develop minimum standards for quality assurance programs. PAHO also collaborated in organizing a workshop on quality assurance for in vivo procedures in Santa Fe de Bogotá, Colombia (May 1981), and helped the IAEA and the Brazilian Association of Medical Physicists (*Associação Brasileira de Física Médica*, ABFM) organize a workshop on quality assurance in São Paulo, Brazil (September 1981). Again in collaboration with the USPHS Bureau of Radiological Health and the Federated Council of Nuclear Medicine Organizations, in 1982 PAHO hosted the International Symposium on the Developing Role of Short-Lived Radionuclides in Nuclear Medical Practice. With the same partners, PAHO also hosted the following symposia: Single Photon Ultrashort-Lived Radionuclides in Medical Practice (1983), Clinical Applications of Radionuclide Studies of the Brain (1984), and The Role of Non-Invasive Imaging Modalities in Clinical Decision-Making: Coronary Artery Disease (1985).

In radiation protection, the collaborative efforts of PAHO and the national radiation protection services of Argentina, Colombia, and Mexico resulted in the publication of Volume I of the revised *Manual básico de protección radiológica* [Basic Manual on Radiation Protection] by the Ministry of Health of Colombia. In collaboration with the Brazilian Institute of Radiation Protection and Dosimetry (*Instituto de Radioproteção e Dosimetria*, IRD) and with support from the U.S. Department of Energy, PAHO organized the Regional Seminar on Radiation Accidents and Procedures for Managing Irradiated Persons, which was held in Itaipava, Brazil, in December 1981. Seven years later, when a cesium-137 contamination accident occurred in Goiânia, Brazil, the Brazilian authorities were firmly in control of the situation and, using both national and local experts, skillfully handled the aftermath.

1983–1994, PASB DIRECTOR CARLYLE GUERRA DE MACEDO

Soon after Carlyle Guerra de Macedo became the Director of the PASB in 1983, PAHO Headquarters staff members were assembled into groups for an introspective analysis that covered a period of several months. Shortly after, the function of program coordinator was created in the various PAHO technical divisions and continued until 2003.

From 1983 until 1987, the PAHO radiological health program continued on its main course, with radiation medicine (diagnostic radiology, radiation therapy, and nuclear medicine) and radiation protection being its major components.

A survey conducted by the Radiological Health Unit in 1983–1984 in cooperation with the health authorities of Argentina, Brazil, Colombia, Costa Rica, the Dominican Republic, Ecuador, Mexico, and Nicaragua showed that the use of X-ray equipment for diagnosis was low in small hospitals (ranging from 1% to 5% of patients) as compared to referral hospitals, where 20% to 30% of patients underwent an X-ray examination. This reinforced the priority given by PAHO and WHO to basic radiology at the Regional and global levels.

Four basic X-ray machines manufactured by the Siemens Corporation were delivered to Nicaragua in 1984 and, with the collaboration of WHO Headquarters staff (radiologist Eero Lehtinen), a field trial was conducted. In 1985, two machines manufactured by the Phillips Corporation were installed for a field trial in Chile. Results again demonstrated that with a short training period and proper supervision, excellent radiographs could be produced by local hospital staff.

In the radiotherapy area, efforts were made by the Radiological Health Unit to extend and improve the IAEA/WHO Postal Dose Intercomparison Program, following the recommendations of a working group meeting of the SSDL directors hosted by the M. D. Anderson Hospital in Houston in 1982. However, the results remained essentially the same, with only 60% of participating centers meeting the standard criteria of a deviation of 5% or less. In 1983 a key meeting, the First International Symposium on Quality Assurance in Radiation Therapy: Clinical and Physical Aspects, was held at PAHO Headquarters in Washington, D.C., with the collaboration of radiological societies from Europe, Latin America, and the United States and government institutions. The participants reviewed experiences in radiation therapy from around the world, and a consensus was reached concerning minimal as well as optimal standards for both clinical and physical aspects of quality assurance. The proceedings were published by Pergamon Press in 1984 on behalf of the co-organizers of the meeting (6).

During 1984 and 1985, assistance was provided to Argentina in a successful effort that resulted in the production of a cobalt-60 teletherapy machine within the country. With PAHO's collaboration, Neutron Products, a United States company that refurbished used cobalt-60 units, provided valuable technical assistance to Argentine institutions. These included the Ministry of Health, the

Atomic Energy Commission, and the Institute of Applied Research in Bariloche, which subsequently collaborated in designing and manufacturing the Argentine machine.

In the area of nuclear medicine, PAHO, in collaboration with the WHO Collaborating Center in Nuclear Medicine in Danbury, Connecticut, United States, launched a new program for evaluating the quality of nuclear imaging procedures in 1983, using specially designed "phantoms" that could be mailed. Designed by the American College of Pathologists, the phantoms simulated various human organs as required for the relevant nuclear imaging procedure.

In radiation protection, assistance was provided to 20 countries from 1983 to 1986, through visits by the PAHO regional advisor and consultants, on legislation, organization of services, radiation measurements, radiation accidents, shielding calculations, and training.

In April 1987, Hanson was invited to become the Chief of Radiation Medicine at WHO Headquarters in Geneva, Switzerland, and resigned from PAHO. In March 1988, Cari Borrás took over the position of Regional Advisor in Radiological Health at PAHO Headquarters in Washington, D.C. A native of Spain, Borrás had a doctor of science degree from the University of Barcelona. She had prepared her thesis at Thomas Jefferson University in Philadelphia, Pennsylvania, as a Fulbright scholar. By the time she joined PAHO she had considerable international experience.

From 1988 to 1994, under Director Macedo's administration, Borrás continued PAHO's technical cooperation. She worked at both the Regional and country levels. Her tasks included data collection and situation analysis; revision and development of standards and guidelines; preparation and distribution of publications; consultations in radiation medicine and in radiation protection; assessment of policies and resources for radiology services coverage and for radiation protection programs; training activities, such as courses, seminars, and congresses; organization of and participation in scientific meetings; promotion and development of quality assurance programs; support to and collaboration with WHO and IAEA programs; initiation of a network of radiological physics centers, equipment donations, and loans; the removal of spent radioactive sources, and assistance in case of radiological emergencies (7, 8). The radiological health information collected from the countries was mainly published in PAHO's quadrennial *Health in the Americas* report (9, 10).

Efforts centered mainly on education. The PAHO Regional Advisor lectured in 40 country and/or Regional training events that were organized and/or cosponsored by PAHO. The most significant one was a hands-on course on physical dosimetry in radiation therapy held in San Antonio, Texas, in August 1988, which was attended by 45 Latin American medical physicists. The event was cosponsored by the International Organization for Medical Physics (IOMP) and the medical physics societies of the United States (AAPM), Latin America (ALFIM), and Spain (SEFM), in collaboration with PAHO and the IAEA.

A different training approach was taken in developing and establishing the radiological physics centers, which were institutions that could provide in situ practical training in radiological physics to physicians, medical physicists, engineers, and technologists involved in diagnostic and therapeutic radiology services. The first center was established in Caracas, Venezuela, in 1993, and the second one was set up in Tegucigalpa, Honduras, in 1995.

Through the IAEA/WHO postal dose audits, which verified the accuracy of the calibration of high-energy radiotherapy units with TLDs, and through the quality assurance workshops on radiation therapy held during that period (7, 8), it was ascertained that the source strength of most cobalt-60 units in Latin American and Caribbean countries was too low for effective radiotherapy treatments. In 1993, PAHO, in collaboration with WHO, the IAEA, and the United Nations Industrial Development Organization, convened an advisory group meeting in Washington, D.C., to assess the situation and make recommendations concerning the problems of existing teletherapy units, including both cobalt-60 units and current linear accelerators. The proceedings of the meeting, which were published by Los Alamos National Laboratory in December 1995 (11), also presented new alternative designs for teletherapy units.

Consultations with the countries of the Americas concerned radiation medicine and also radiation safety, including prevention, preparedness, and response in case of a nuclear accident or a radiological emergency. The most significant radiological accident during that period involved three workers in San Salvador, El Salvador, in February 1989, with a cobalt-60 industrial irradiator used for sterilizing medical products. Due to the high radiation doses that the workers received, one of them died and another had his legs amputated (12).

Other minor accidents or incidents involved discarded brachytherapy sources in several Caribbean countries in the early 1990s. Concerned about potential exposures, PAHO contracted a United States company, NSSI/Sources and Services, to de-

contaminate the premises where needed, to condition the sources, and to transport the sources to the United States for safe storage.

To prevent radiological accidents and to improve the radiation safety infrastructure in its Member States, PAHO joined the Inter-Agency Committee on Radiation Safety (IACRS) in 1991 and strengthened its cooperation with WHO and the IAEA. In 1993, it cosponsored a workshop on radiation safety for Central America and the Caribbean. In 1994 the XXIV Sanitary Conference endorsed the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) (13), which had been jointly prepared through the IACRS.

1995–2003, PASB DIRECTOR SIR GEORGE A.O. ALLEYNE

In the year 2000, PAHO's radiological health activities became part of the Essential Drugs and Technology Program within the Division of Health Systems and Services. Borrás became the program's coordinator, while also continuing to be responsible for radiological health activities. PAHO presented guidelines on radiology services in a 1997 publication, *Organization, Development, Quality Assurance and Radiation Protection in Radiology Services: Imaging and Radiation Therapy* (14). The text, which described the organizational and technical aspects of radiology services, was aimed at political leaders, administrators, planners, and health professionals, as well as ministries of health, and was intended to help them allocate resources and determine technological configurations for the provision of decentralized radiology services under health sector reform.

Guidelines for patient radiation protection were given at the International Conference on the Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy, which was held in Málaga, Spain, in 2001 and cosponsored by the IAEA, the European Commission (EC), PAHO, and WHO (15). It was attended by 800 people, 17 of them partially subsidized by PAHO. In 2002 the IAEA Board of Governors approved an International Action Plan on the Radiological Protection of Patients, to be carried out in cosponsorship with the EC, PAHO, and WHO. PAHO, along with several other international organizations, also cosponsored the IAEA's new requirements on preparedness and response for a nuclear or radiological emergency (16). PAHO also participated in an international conference on the management of radioactive waste from non-power applications, which was organized by the IAEA (17); joined the Inter-Agency Committee on Response to Nuclear Accidents (IACRNA); and became part of the Joint Radiation Emergency Management Plan of the International Organizations (18). PAHO also increased its radiation protection technical cooperation in the area of nonionizing radiation, providing advice on the health effects of electromagnetic fields (especially those of cellular telephones), lasers, microwaves, ultrasound, magnetic resonance, and ultraviolet light.

The educational activities continued. During that period the Regional Advisor lectured in 98 country and/or Regional training events that were organized and/or cosponsored by PAHO (19–21). Most of the courses were aimed at Member States of PAHO or WHO and dealt with the implementation of the BSS in medical practice. A training manual, consisting of 1 200 slides, was developed by PAHO for the IAEA.

The radiological physics center in Tegucigalpa, Honduras, was coordinated by the Autonomous University of Honduras (*Universidad Autónoma de Honduras*), which signed an agreement with the Ministry of Health to carry out activities of joint interest, including a special degree program for radiation technologists. In 1997–1999, this center was partially subsidized, through PAHO, by the Ministry of Health of Spain.

PAHO continued to provide support during this period to the World Health Imaging System for Radiography (WHIS-RAD). In the mid-1990s, it purchased 11 of these units and installed them in Haiti. In spite of the inherent reliability of the equipment, the services had serious problems because of lack of maintenance, poor X-ray technician training, and inadequate radiation protection measures. Other efforts to upgrade radiology services involved Belize, Chile, Dominica, Haiti, St. Kitts and Nevis, and Trinidad and Tobago.

Efforts to upgrade radiotherapy services were carried out in various countries of the Americas. In Colombia, a countrywide evaluation was conducted; in Honduras, remote-control low-dose rate brachytherapy was introduced; in Trinidad and Tobago, a completely new cancer treatment facility was planned; and in Panama, cobalt therapy was replaced by linear accelerators. Quality assurance programs in radiation therapy services continued to be promoted, mainly through the TLD IAEA/WHO Regional postal dose audit. A meeting on this program for TLD program coordinators from the Region of the Americas was held in Santo Domingo, Dominican Republic, in July 1999.

If one of the participating Costa Rican facilities had acknowledged a significant deviation that had appeared for several years, it could have prevented the overexposure of 114 patients—many

of them children—that occurred as a consequence of a miscalibration of a cobalt-60 unit. PAHO was asked to provide technical assistance, and a year later the IAEA carried out its own investigation. PAHO was also asked to investigate a radiotherapy overexposure incident that occurred in Panama, caused by the improper use of treatment planning software. The details of the Panama exposure are published in this issue of this journal, in a report by Borrás (22).

In November 2001 and April 2002, Costa Rica again asked PAHO to assess potential radiation overexposures, this time caused by one or two medical linear accelerators. No evidence of overexposures was found.

Recognizing the need for standards in medical radiation dosimetry, PAHO cosponsored an international symposium in 2002 on standards and codes of practice in medical radiation dosimetry (23). PAHO also promoted an accreditation program for radiotherapy services to be implemented in the countries of Latin America and the Caribbean.

In 1999 the radiological health program won the research competition convened by PAHO's Director, with the theme of "quality assessment of radiology services," and prepared the terms of reference for the submission of projects. Seven countries applied, and five of them (Argentina, Bolivia, Colombia, Cuba, and Mexico) were awarded a research contract, which involved medical physicists and radiologists in these countries. The results of this health services delivery research project are presented in this issue of this journal, in an article by Fleitas et al. (24).

In 2001 a Regional diagnostic radiology research program to evaluate the image quality and the average glandular dose in mammography units in countries of the Americas was undertaken by PAHO and the Inter-American College of Radiology, in collaboration with the IRD in Brazil, and the Center for Devices and Radiological Health (CDRH) in the United States. Data from 61 units in 11 Latin American and Caribbean countries were collected and analyzed. Eighty-eight percent of the units evaluated complied with the image quality requirement, and only 8.5% of all the units exceeded the dose limit for the average glandular dose.[5]

[5] Borrás C, Mota H, Skvarca JJ. Measurements of image quality and dose in 61 mammography units in 11 countries [conference presentation]. 89th Radiological Society of North America Scientific Assembly and Annual Meeting, 28 November–3 December 2004, Chicago, Illinois, United States. Abstract available at: http://rsna2003.rsna.org/rsna2003/VBK/conference/event_display.cfm?id=66601&em_id=3107772. Accessed on 19 February 2006.

2003 TO THE PRESENT, PASB DIRECTOR MIRTA ROSAS PERIAGO

In January 2003, Mirta Roses Periago, who had previously served for eight years as the Assistant Director of the PASB, was the first woman to become the Director of the PASB. Organizational changes were made, and the radiological health program was located in the Area of Technology and Health Services Delivery (THS), first within the Health Services Organization Unit and finally within the Unit of Essential Medicines, Vaccines, and Health Technologies. Regardless of its location, the radiological health program carries out its activities by interacting with numerous areas within PAHO, following the new management model implemented by Director Roses.

Pablo Jiménez joined PAHO in July 2002 as an associate professional expert and became the regional advisor of the radiological health program in January 2004. A physicist, Jiménez received the Spanish equivalent of a master of science degree in physics from the University of Madrid (*Universidad Complutense de Madrid*) in 1988, and a degree (equivalent to a medical specialty) in medical physics and radiation protection from Spain's Ministry of Health and Ministry of Education in 1996. The other professional who was working in the radiological health program at PAHO Headquarters during this period, as an associate professional officer, was Ileana Fleitas. A nuclear engineer from Cuba, she joined PAHO in February 2003 and returned to Cuba in February 2006, where she is now working as a PAHO staff member in the radiological health program.

The main activities since 2003 have included strengthening diagnostic imaging and radiotherapy services, promoting regulations to protect against both ionizing and non–ionizing radiation, and improving the countries' capacity to respond to radiological or nuclear emergencies. Emphasis has been placed on advising on technology management.

Concerning diagnostic imaging and radiation oncology services, currently around 150 high-energy radiotherapy units are checked annually in Latin America and the Caribbean through the IAEA/WHO TLD postal dose audit. The evaluation of radiation therapy and diagnostic imaging services has been continued in the Bahamas, Costa Rica, Guyana, Nicaragua, and Panama.

Technical advice and assessment in technology management were provided for the incorporation of new technology in Argentina, Costa Rica, Cuba, El Salvador, Guatemala, Trinidad and Tobago, Uruguay, and Venezuela.

The radiological health program has also been very active in organizing, cosponsoring, and supporting educational activities at the national,

Regional, and global levels. The program organized a workshop on clinical quality in radiation therapy in Montevideo, Uruguay, and two subregional training workshops on quality assurance in radiology services for radiographers and radiological technologists, one in San Salvador, El Salvador for radiological technologists from Central America, and the other in Guyana for radiographers and radiological technologists from the Caribbean. Within a project called Teaching the Teachers Initiative for Ultrasound Training in Latin America and the Caribbean, a total of 12 radiologists from 12 countries was selected to attend an intensive 12-week training program during 2005 and 2006 at the Jefferson Ultrasound Research and Education Institute, which is located in Philadelphia and is one of the PAHO/WHO Collaborating Centers. A total of six educational centers in ultrasound will be established in the Region by the end of 2007.

The most important international meetings, congresses, and conferences where the radiological health program was represented and where support was provided during this period were the XI Congress of the International Radiation Protection Association, in Madrid, Spain; the III Iberian Latin American and Caribbean Congress of Medical Physics, in Rio de Janeiro; the Regional CRILA Congress, in Lima; National Infrastructures for Radiation Safety: Towards Effective and Sustainable Systems, in Rabat, Morocco; and the VI and VII Regional Congresses of the International Radiation Protection Association, in Lima.

Concerning other activities, national regulations were evaluated and comments on them were sent to the Bahamas, Bolivia, Honduras, Panama, and Paraguay. A Regional compilation of the national regulations on non–ionizing radiation was completed; a radiation emergency exercise was executed jointly with the Organization of American States, in Barbados; a self-evaluation guideline to respond to radiological emergencies was prepared and sent to Peru; and a workshop for Andean countries on dangerous radioactive materials was held in Quito, Ecuador.

In addition, the PAHO radiological health program actively participates in two IAEA Regional cooperation agreements for Latin America and the Caribbean (*Acuerdos Regionales de Cooperación para América Latina y el Caribe*, ARCAL) dealing with radiology and the education of medical physicists. One of the strategic lines consists of the establishment of a formal agreement with the IAEA's Technical Cooperation Department, which will include a joint Regional project for 2007/2008 to improve the quality of radiation therapy.

At the global level, the practice of co-sponsoring relevant IAEA publications continued. PAHO participated in the 2004 version of the Joint Radiation Emergency Management Plan of the International Organizations (18). It also attended the I and II Steering Panel Committee Meetings of the International Action Plan for the Radiological Protection of Patients, in Madrid, contributing to drafting the actions for 2006 and 2007 geared to promoting education and training, providing assistance, rendering services, fostering information exchange, and coordinating research in the areas of diagnostic and interventional radiology, nuclear medicine, and radiation therapy (25). PAHO also organized and hosted the XI Meeting of the IACRS, a distinction it had not held since 1992. It also continued participating in the IAEA Radiation Safety Standards Committee (RASSC) meetings and the WHO Radiation Emergency Medical Preparedness and Assistance Network (REMPAN). The PAHO radiological health program has now begun the process of revising the BSS.

CONCLUSIONS

PAHO's radiological health program has been in existence for nearly half a century. The program has focused on specific issues in keeping with the times, as well as on the priorities of PAHO's Member States. The latter have had at their disposal the most current scientific and professional knowledge and advice available, as well as a steady partner for continuously improving their national institutions.

As new discoveries and new challenges appear, the most important needs envisaged for the immediate future are: education and training in evaluating, incorporating, and utilizing new technologies; support for strengthening radiological diagnostic and therapeutic services; support for research on analyzing and evaluating outcomes; implementing ways to safeguard patients and staff, including strengthening regulations; and improving the capacity to respond to radiological and nuclear emergencies.

With the continuing confidence and support of PAHO's Member States, the PAHO radiological health program is expected to continue to respond to their needs.

SINOPSIS

Historia del programa de radiología y radioprotección de la Organización Panamericana de la Salud

El programa de radiología y radioprotección de la Organización Panamericana de la Salud (OPS) se estableció en 1960. En ese entonces, las superpotencias mundiales se en-

frascaban en la carrera armamentista; hacían pruebas con armas nucleares en la atmósfera y los pueblos y gobiernos del mundo les temían a los efectos de la lluvia radiactiva. Además, se comenzaba a fomentar el uso pacífico de las radiaciones en la medicina, la investigación y la industria, por lo cual se necesitaba una protección adecuada contra estas nuevas formas de energía. Como se señaló en el Informe anual del Director *de la OPS, los objetivos de ese nuevo programa de la Organización eran: 1) incentivar la adopción de reglamentos aplicables al uso de las radiaciones en consonancia con las recomendaciones de la Comisión Internacional de Protección Radiológica; 2) promover la enseñanza de la física médica y de la protección radiológica; 3) ayudar a desarrollar las aplicaciones de los radioisótopos en el diagnóstico, el tratamiento y la investigación médica; y 4) impulsar las investigaciones relacionadas con el uso de las radiaciones en la medicina, la salud pública y la veterinaria.*

Durante casi medio siglo, el programa de radiología y radioprotección de la OPS ha centrado su atención en diversos temas, según las necesidades y prioridades de los Estados Miembros. Para ello siempre ha contado con personal altamente calificado capaz de asesorar a los ministerios de salud acerca de las políticas relacionadas con las aplicaciones sanitarias de las radiaciones, y a las instituciones clínicas acerca de las modalidades radiológicas diagnósticas y terapéuticas más recientes. Como en sus inicios, el programa continúa prestando atención a las siguientes necesidades de la Región: la educación y capacitación del personal de radiología para que aprenda a evaluar, incorporar y utilizar con eficacia y seguridad las nuevas tecnologías; el apoyo gerencial y técnico para fortalecer los servicios radiológicos; el asesoramiento integral orientado a establecer o mejorar los programas gubernamentales de radioprotección, incluida la adopción de legislación y reglamentación para el control de las radiaciones ionizantes y no ionizantes; el fomento de la investigación para analizar y definir prioridades; y el fortalecimiento de la capacidad institucional con miras a responder a las emergencias radiológicas y nucleares. A pesar de que surgen nuevos retos a medida que se producen nuevos descubrimientos, el Programa de radiología y radioprotección de la OPS seguirá respondiendo a las necesidades de los Estados Miembros.

Palabras clave: prestación de atención de salud, radiología, protección radiológica, radioterapia, Organización Panamericana de la Salud, Américas.

REFERENCES

1. Pan American Health Organization. Annual report of the Director, 1960. Washington, D.C.: PAHO; 1961. (Official Document No. 38).
2. Pan American Health Organization. Annual report of the Director, 1962. Washington, D.C.: PAHO; 1963. (Official Document No. 50).
3. International Atomic Energy Agency. Manual of dosimetry in radiotherapy. Vienna: IAEA; 1970. (Technical Report Series No. 110).
4. Iżewska J, Vatnitsky S, Shortt KR. Postal dose audits for radiotherapy centers in Latin America and the Caribbean: trends in 1969–2003. Rev Panam Salud Publica. 2006;20(2/3):161–72.
5. Palmer PES. Radiology and primary care. Washington, D.C.: Pan American Health Organization; 1978. (Scientific Publication No. 357).
6. Hanks G, Svensson G, eds. Quality assurance in radiation therapy: clinical and physical aspects. Proceedings of the First International Symposium on Quality Assessment in Radiation Oncology, Washington, D.C., 8–10 June, 1983. New York: Pergamon Press; 1984. (International Journal of Radiation Oncology, Biology Physics, Volume 10, Supplement 1).
7. Pan American Health Organization. Report of the Director: quadrennial 1986–1990, annual 1989. Washington, D.C.: PAHO; 1989 (Official Document No. 234).
8. Pan American Health Organization. Report of the Director: Quadrennial 1990–1993; annual 1993. Washington, D.C.: PAHO; 1993. (Official Document No. 262).
9. Pan American Health Organization. Health conditions in the Americas: 1990 edition. Washington, D.C.: PAHO; 1990. (PAHO Scientific Publication 524).
10. Pan American Health Organization. Health conditions in the Americas: 1994. Washington, D.C.: PAHO; 1994. (Scientific Publication No. 549).
11. Borrás C, Stovall J, eds. Design requirements for megavoltage X-ray machines for cancer treatment in developing countries: report of an Advisory Group Consultation. Los Alamos: Los Alamos National Laboratory; 1995. (LA-UR-95-4528).
12. International Atomic Energy Agency. The radiological accident in San Salvador. Vienna: IAEA; 1990.
13. Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Organisation, Nuclear Agency of the Organisation for Economic Co-operation and Development, Pan American Health Organization, World Health Organization. International basic safety standards for protection against ionizing radiation and for the safety of radiation sources. Vienna: IAEA; 1996. (Safety series 115).
14. Borrás C, ed. Organization, development, quality assurance and radiation protection in radiology services: imaging and radiation therapy. Washington, D.C.: Pan American Health Organization; 1997.
15. International Atomic Energy Agency. Radiological protection of patients in diagnostic and interventional radiology, nuclear medicine and radiotherapy. Proceedings of an international conference held in Málaga, Spain, 26–30 March 2001. Available from: http://www-pub.iaea.org/MTCD/publications/PDF/Pub1113_scr/Pub1113_scr1.pdf [Web site]. Accessed 15 February 2006.
16. International Atomic Energy Agency. Preparedness and response for a nuclear or radiological emergency. Vienna: IAEA; 2002.
17. Borrás C, Rudder DDG, Porte J, Archibald A, Miller C, Lokerse AF, et al. Radioactive waste management in British and Dutch Caribbean countries. In: Proceedings, International Conference on Management of Radioactive Waste from Non-Power Applications—Sharing the Experience. Vienna: IAEA; 2002. Pp. 84–89. (IAEA-CN-87/91).
18. International Atomic Energy Agency. Joint Radiation Emergency Management Plan of the International Organizations. Vienna: IAEA; 2004.
19. Pan American Health Organization. Leading Pan American health: quadrennial report of the Director 1994–1997. Washington, D.C.: PAHO; 1998. (Official Document No. 287).

20. Pan American Health Organization. Charting a future for health in the Americas. Quadrennial report of the Director. Washington, D.C.: PAHO; 2002. (Official Document No. 306).
21. Pan American Health Organization. Health in the Americas: 2002 edition. Washington, D.C.: PAHO; 2002. (PAHO Scientific and Technical Publication No. 587).
22. Borrás C. Overexposure of radiation therapy patients in Panama: problem recognition and follow-up measures. Rev Panam Salud Publica. 2006;20(2/3); 173–87.
23. Borrás C, Rudder D, Jiménez P. Use of imaging techniques in radiation oncology. In: International Atomic Energy Agency. Standards and codes of practice in medical radiation dosimetry. Proceedings of an international symposium, Vienna, 25-28 November 2002. Vienna: IAEA; 2003.
24. Fleitas I, Caspani CC, Borrás C, Plazas MC, Miranda AA, Brandan ME, et al. La calidad de los servicios de radiología en cinco países latinoamericanos. Rev Panam Salud Publica. 2006;20(2/3): 113–24.
25. International Atomic Energy Agency. International Action Plan for the Radiological Protection of Patients. Available from: http://www-ns.iaea.org/downloads/rw/radiation-safety/PatientProtActionPlangov2002-36gc46-12.pdf [Web site]. Accessed 15 February 2006.

ARTÍCULOS E INFORMES ESPECIALES

ARTICLES AND SPECIAL REPORTS

The role of professional networks in radiology services

Gray Southon[1]

Suggested citation: Southon G. The role of professional networks in radiology services. Rev Panam Salud Publica. 2006; 20(2/3):99–103.

SYNOPSIS

Recent developments in public health policy have highlighted the central role of the clinical work force in the success of policy implementation, and thus the need for effective human resource policies. Given the high level of professionalism in health services, a number of special issues arise, including the organizational structures that best support professional work. Experiences from global industries that rely on a highly expert work force show that hierarchical control structures need to be supplemented by a variety of networks. Networks are complex structures that are very different from normal hierarchies, and they need to be effectively understood. While they usually develop spontaneously, they are often not optimally structured, adequately supported, or effectively exploited by health service organizations. It is important to understand the nature of networks and how they can be promoted in order to ensure that clinicians are appropriately supported in providing and enhancing services.

Key words: health services, health personnel, community networks, group processes, organizational culture, professional autonomy, radiology.

[1] University of Auckland, School of Population Health, Auckland, New Zealand. Send correspondence to: Gray Southon, 56 Robins Rd, Tauranga, New Zealand; telephone: 64 7 5787119; cell phone: 64 211 020 977; e-mail: gray@southon.net

In health policy, the role of clinicians is commonly considered to be that of functionaries performing defined tasks as the need arises, while the principal task of management is to ensure that the staff hired is competent and that the required tasks are performed. However, some authors (1–3) have recently highlighted the fallacies of such an approach and have emphasized the need for effective human resource policies to engage with the social and political dynamics of clinical professionals. The role of the professional goes beyond merely providing services to actually defining the nature of the service required for individual patients, and it may extend to enhancing service capabilities. This paper focuses on the subject of human resource policy in the field of radiology.

The provision of radiological services depends on the capability of a number of types of professionals, particularly diagnostic and therapeutic radiologists and radiographers, as well as related staff such as medical physicists. The competence of these professionals depends not only on their initial training, but also on their desire and ability to monitor their performance, to upgrade their skills, and to adapt to local needs. Further, the effectiveness of professionals depends on their ability to integrate their services with a range of other local professional and community activities in order to accommodate the specific needs of each patient. This is the only means of ensuring that quality continuity of care can be achieved in radiology, especially in therapeutic radiology.

Such dependence on the skills and initiative of operational staff is common to many industries, and there are valuable lessons that can be drawn, particularly from large global corporations. We use these lessons to develop an understanding of the types of structures that would best enable clinical professionals to effectively contribute to the provision and reform of health services.

THE CENTRAL ROLE OF CLINICAL CAPABLITY

Clinical capability is basic to both the definition and delivery of health services. It is only through the skills, values, and commitment of professional clinicians that the appropriate service for each patient can be identified and delivered. It is clinicians who assess the nature of a patient's need, what diagnostic methods to employ, what treatments to consider, how to bring the resources of the system to bear on that need, how to work with other clinicians and services, and how to best engage the patient in light of his or her particular cultural environment (4). Such decision-making may require clinicians to balance the potentially competing interests of the patient, the system, the society, their profession, and their own personal needs. These skills depend not only on the science and "state of the art" of clinical practice but also on the local context and the way that the health service integrates with local communities. Further, by using their considerable intelligence and intimate knowledge of the task and the system, clinicians may also play a major role in enhancing the nature of the service and directing its future development.

Such realities are becoming recognized in the economic theory of social capital. Francis Fukuyama (5) notes: "The fact of the matter is that coordination based on informal norms remains an important part of modern economies, and arguably becomes more important as the nature of economic activity becomes more complex and technologically sophisticated. Many complex services are very costly to monitor and are better controlled through internalized professional standards than through formal monitoring mechanisms."

There are many ways in which effective decision-making at the clinical level is central to quality health services, and it is only through supporting such decision-making that services can be optimized.

THE ROLE OF NETWORKS

The most important organizational structure for supporting this clinical competence is the network. Networks are complexes of links among many different parties, driven largely by the interests of those parties and facilitated by trust (6). These parties may be individual clinicians, academics, departments, service providers, or other entities. Networks have always played important roles in the development and use of knowledge, in such forms as guilds, professions, associations, and, more recently, the complex of discussion groups that have developed on the Internet. Networks are central to the support and enhancement of professionalism.

There is an increasing recognition in the commercial sector of the role of networks, particularly in highly skilled professional service industries (7). Many global corporations, such as British Petroleum, Ernst & Young, Hewlett-Packard, and Xerox, have been paying much greater attention to the way that they use knowledge (8), and they are promoting networks of various types, sometimes called "communities of practice," as a means of enhancing organizational skills and capabilities (9). The IBM Center for The Business of Government has identified networks, in the form of communities of practice, to be a new tool for government managers that is capable of driving nationwide changes in government services, using the energy and commitment of operational staff (10). In the United Nations the Cardoso Report takes networks as the core structure for enabling the engagement of civil society in the UN system (11).

Networks are common in health services, and they are fundamental to service provision. Often arising naturally, networks are frequently informal and often quite ephemeral and difficult to define. They provide the potential for a flexible engagement of the enormous reservoir of interest and expertise that resides at many levels throughout the health system, coordinating diverse interests and responding to challenges as they arise. For instance, the spontaneous networks of specialists who responded to the recent SARS epidemic have been officially recognized by the World Health Organization (3). Much of the work in clinical research in diagnosis and therapy is through networks of institutions and practitioners.

Networks can take many different forms, being either formal (clearly defined and structured) or informal (often diffuse and amorphous). Networks can have a variety of functions, with some of the more important being expertise networks, referral networks, and program networks.

Expertise networks involve the sharing and development of specialized knowledge amongst groups of similarly qualified people such as radiologists and radiographers. These are often incorporated into formal structures such as colleges and societies (e.g., the International Society of Radiology

and the International Society of Radiographers and Radiological Technologists). There may also be informal associations for more specialized areas with, for example, networks of interventional radiologists, chief radiographers, breast cancer radiation oncologists, or medical physicists. Such networks play critical roles in maintaining and developing the expertise required for service provision, and they provide a sense of identity and assurance against the uncertainties of expert practice, particularly for those clinicians who are otherwise isolated (12). These uncertainties may arise from many sources, ranging from the nature of the patient, the disease, and the appropriate treatment to the political, organizational, legal, and financial environment in which clinicians work. Patients may form cancer support groups that not only become networks of people sharing their experience of the disease and treatment but also constitute a very important source of knowledge.

Referral networks enable a range of expertises to be accessed to address individual cases. For instance, a general practitioner may refer a patient to a medical oncologist, who refers him to a radiation oncologist, who treats and then refers the patient back to the medical oncologist, who then refers him to a physiotherapist to address the effects of the treatment. These networks form key coordinating mechanisms for practitioners, usually developed informally over a period of time as clinicians learn whom they can work with and trust. Radiology and oncology services often receive many of their patients through such networks, and those services may use similar networks to engage other services to address individual patient needs.

Program networks are more structured networks, commonly used in oncology services, that coordinate the different expertises required to provide for particular types of patients. Such networks may combine tertiary diagnostic and therapeutic services with primary care, community services, and mutual support groups of patients. Because of the many different specialty services involved in dealing with cancer, it is only natural that institutions work together in networks. Such networks enable the sophisticated services to be available in major centers, which work in conjunction with locally-provided lower-level services. The National Health Service of the United Kingdom has used such networks as a central component in the revitalization of cancer services (13). In diagnostic radiology, such networks enable the cooperation required for teleradiological services to operate effectively (14).

The value of networks lies in their ability to handle complex, experiential, and specialist knowledge in a way that is responsive to changing and unpredictable circumstances. Networks make possible the comparison of experiences and practices by those who know them in detail. Networks also facilitate the sharing of opinions about how to deal with a particular case, a new drug or technology, or problems with current practices. Networks can draw on expertise relevant to particular issues and local situations. Networks can be a means of distilling, consolidating, enhancing, and validating knowledge that is distributed among a wide range of people. Networks can engage people directly involved in clinical services in both assuring performance and enhancing it (12).

Networking can also enable specialist services and departments to work together cooperatively, allowing them to learn from each other in identifying inefficiencies, developing innovations, testing alternative systems, and benchmarking performance (15). Thus, the strengths of the stronger radiotherapy centers can be used to assist other centers to enhance the quality of their services.

Despite the vital role that networks play in most organizations, they are seldom effectively recognized. Organizational structure is usually presented as a hierarchy, and networks remain largely invisible. For instance, Savage (16) analyzes the way that hierarchical control has been considered the ideal for health services in the United States, but in a way that ignores the role of networks. In a major analysis of health sector worker motivation, Franco et al. (17) consider only the "alignment [of clinical attitudes] with the goals of the organization," completely ignoring the potential of wider influence of professional standards and community goals that come through networks.

This lack of attention to networks results in demands being placed on hierarchies that they often cannot fulfill. The typical hospital management, for instance, is incapable of mastering all the specialty disciplines for which they are responsible. Further, hierarchies have great difficulty in handling the multitude of problems that require in-depth practical knowledge, consistency across the system, and widespread commitment of the people involved. In health, such problems cover a wide range of quite critical issues, such as service coordination, manpower training, clinical standards, community education, and technology deployment.

On the other hand, networks can keep clinicians in touch with each other over broad regions, enabling them to learn from the best experiences of others, avoid the worst outcomes, and minimize the discrepancies in practices that inevitably develop. In this way, professional integrity and consistency can be maintained so as to enable coherent training programs and practice standards, professional mobility, and career viability. For example, these kinds of enhancements of service standards are being achieved in the Australian state of New South

SINOPSIS

El papel de las redes de profesionales en los servicios de radiología

Algunos acontecimientos recientes en el ámbito de las políticas sanitarias han puesto de relieve el papel fundamental que desempeña el personal clínico en la ejecución de dichas políticas. Es importante, por lo tanto, que las políticas de recursos humanos sean eficaces. En los servicios de salud el personal suele ser de nivel profesional en su mayor parte y, como resultado, hay varias cuestiones que es preciso examinar, entre ellas qué estructuras organizacionales conducen a un mejor desempeño profesional. Según la experiencia acumulada por industrias multinacionales con una fuerza de trabajo muy experta, las estructuras basadas en un control jerárquico tienen que suplementarse con una serie de redes de profesionales. Es preciso entender a cabalidad estas últimas, que son estructuras complejas y muy distintas de las jerarquías ordinarias. Aunque por lo general estas redes se forman espontáneamente, a menudo ni tienen una estructura óptima ni cuentan con un apoyo adecuado, a lo cual se suma que las organizaciones sanitarias raras veces saben aprovecharlas. Es importante conocer la naturaleza de las redes y saber fomentarlas a fin de conseguir que el personal clínico profesional reciba el apoyo necesario para prestar bien sus servicios y poder mejorarlos.

Palabras clave: servicios de salud, personal de salud, redes comunitarias, procesos de grupo, cultura organizacional, autonomía profesional, radiología.

REFERENCES

1. Rigoli F, Dussault G. The interface between health sector reform and human resources in health. Human Resour Health. 2003;1:9.
2. Biscoe G. Human resources: the political and policy context. Geneva: World Health Organization; 2001.
3. World Health Organization. World health report 2003: shaping the future. Geneva: WHO; 2003.
4. Cox K. Doctor and patient: exploring clinical thinking. Sydney: UNSW Press; 1999.
5. Fukuyama F. Social capital and civil society. Available from: http://www.imf.org/external/pubs/ft/seminar/1999/reforms/fukuyama.htm [Internet site]. Accessed 16 May 2005.
6. Levin DZ, Cross R, Abrams LC, Lesser EL. Trust and knowledge sharing: a critical combination. Available from: http://www-1.ibm.com/services/us/index.wss/ibvstudy/imc/a1002447?cntxt=a1000452 [Internet site]. Accessed 17 May 2005.
7. Dawson R. Living networks: leading your company, customers, and partners in the hyper-connected economy. New York: Prentice Hall; 2003.
8. Seely Brown J, Duguid P. The social life of information. Boston: Harvard Business School Press; 2000.
9. Wenger E. Communities of practice: learning, meaning, and identity. Cambridge: Cambridge University Press; 1998.
10. Snyder WM, de Souza Briggs X. Communities of practice: a new tool for government managers. Available from: http://www.businessofgovernment.org/pdfs/Snyder_report.pdf [Internet site]. Accessed 16 May 2005.
11. United Nations. We the peoples: civil society, the United Nations and global governance. Available from: http:// www.un.org/dpi/ngosection/N0437641.pdf [Internet site]. Accessed 16 May 2005. (Report A/58/817).
12. Fenton E, Harvey J, Griffiths F, Wild A, Sturt J. Reflections from organizational science on the development of primary health care research networks. Fam Pract. 2001;18(5):540–4.
13. Kerr D, Bevan H, Gowland B, Penny J, Berwick D. Redesigning cancer care. BMJ. 2002;324(7330):164–6.
14. Aas IH. Organizational cooperation in teleradiology. J Telemed Telecare. 2005; 11(1):45–50.
15. Southon G. Advancing knowledge in health: a knowledge-based health system. Available from: http://home pages.paradise.net.nz/southon/Gray/advknow.rtf [Internet site]. Accessed 4 September 2004.
16. Savage DA. Professional sovereignty revisited: the network transformation of American medicine. J Health Politics Policy Law. 2004;29(4–5):661–77.
17. Franco LM, Bennett S, Kanfer R. Health sector reform and public sector health worker motivation: a conceptual framework. Soc Sci Med. 2002;54(8):1255–66.
18. Braithwaite J, Goulston K. Turning the health system 90° down under. Lancet. 2004;364:397–9.
19. Pan American Health Organization. The World Bank and the Pan American Health Organization inaugurate health partnership for knowledge sharing and learning in the Americas [press release]. Available from: http://www.paho.org/English/DD/PIN/pr031015.htm [Internet site]. Accessed 26 June 2004.

Manuscript received on 14 December 2004. Revised version accepted for publication on 26 May 2005.

The recommended X-ray unit is known as the World Health Imaging System for Radiography (WHIS-RAD) (3, 4). In the Region of the Americas, since the 1950s the Pan American Health Organization (PAHO) has addressed the problem of effectiveness and safety in radiology departments by performing national and Regionwide surveys and by implementing quality assurance and quality control programs (5–7). (The main objectives of a quality assurance (QA) program are to improve diagnostic accuracy without using unnecessary radiation, and to minimize costs. The specific tests required to ensure effective and safe equipment performance are usually referred to as quality control (QC) tests. Sometimes, the term "quality management," encompassing both QA and QC, is used.) Establishing a comprehensive quality assurance program in radiology departments that takes into account the principles established by WHO and PAHO is considered a requirement under the guidelines contained in the *International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources* (8).

The effectiveness of diagnostic imaging services is greatly dependent on the quality of the health care provided. The existence of well-trained professionals, as well as the implementation of quality assurance programs, are essential for obtaining accurate diagnoses.

A recent PAHO assessment of imaging services in public and private hospitals in five Latin American countries revealed that very few services had implemented periodic quality control programs. The study also found that the clinical images in more than 30% of gastrointestinal tract exams and in more than 50% of lumbar spinal studies were of unacceptable quality. In the same study the accuracy of the radiological interpretation in mammography was found to depend on the experience of the physician reading the films.

Regardless of the limitations that developing countries face, they can benefit from accreditation programs if the programs are tailored to the country's specific circumstances,[3] particularly the quantity and quality of human resources and the technology available in it. The customized standards should provide a real possibility for health care improvement in the specific country by addressing the needs of the community in which the imaging services are located.

The different needs of developing and industrialized countries could be met by a tiered system, covering basic, intermediate, and advanced economies. This article presents a basic framework focused on less developed countries with basic economies. To this basic framework, each country could add further local legislative requirements or higher standards if required or requested.

While the clinical advantages of diagnostic imaging services are enormous, in practice these services could represent an unnecessary cost to the health care systems in the countries if the quality provided were unacceptable. An accreditation program represents a method for establishing and monitoring a set of quality standards (9, 10).

Although this article presents a framework based on the experience that PAHO medical physicists have acquired working in and with the countries of Latin America and the Caribbean, the proposed accreditation program could also be applied to any developing country in similar circumstances.

THE PROCESS OF DEVELOPING THE ACCREDITATION PROGRAM

Having received requests for setting standards and establishing accreditation programs in several countries, the medical physicists of PAHO's radiological health program developed a procedure to assist ministries of health to assess, certify, and monitor accreditation programs for both public and private providers of diagnostic imaging services. The main goal was to improve diagnostic accuracy and safety.

If the ministry of health of a PAHO Member State requests guidance on establishing a diagnostic imaging accreditation program, PAHO's regional advisor on radiological health works with his or her counterparts in the PAHO/WHO office in that country and assesses the feasibility and appropriateness of the request. That assessment takes into account the organization of health services and the role of governmental and private organizations in the authorization, accreditation, and/or certification of medical practices. Following that step the PAHO medical physicists analyze the available information on the country's diagnostic imaging infrastructure, equipment, and personnel. An expert team composed of PAHO staff members and/or PAHO consultants (including at least one radiologist and one medical physicist) is available when needed to carry out a country visit to update and document the situation regarding imaging and processing equipment performance, personnel availability and qualifications, maintenance and quality assurance program implementation, and compliance with radiation safety standards. The PAHO team members also interview public and private providers of imaging services to assess the technical

[3] Jiménez P, Borrás C, Fleitas I. Accreditation process of diagnostic imaging services in developing countries. International Federation for Medical and Biological Engineering (IFMBE) Proceedings. World Congress on Medical Physics and Biomedical Engineering; Sydney: World Congress on Medical Physics and Biomedical Engineering; 2003.

the program, the ministry of health should prepare a careful budget and ensure program sustainability for at least five years. When trying to convince the government to provide the needed financial support, the ministry of health can provide data on erroneous diagnoses and their consequences in terms of early death, crippling morbidity, and other social and financial costs.

AN EXAMPLE OF AN ACCREDITATION PROGRAM

General requirements for the accreditation process

A typical accreditation program includes a peer review evaluation of: (1) radiography, fluoroscopy, mammography, and ultrasound imaging and processing equipment performance; (2) physician and technologist staff qualifications; (3) implementation of quality control and quality assurance programs; and (4) image quality assessment and, where applicable, radiation dose measurements. The program is implemented and monitored by a national accreditation committee established by the ministry of health. This committee is to be composed of national experts in the different disciplines involved in imaging services, but the ministry of health may also invite foreign technical and clinical experts to participate, as needed, through the technical cooperation provided by PAHO.

The accreditation committee will initiate the process by sending an application package to the facility in order to obtain information on the number and qualifications of radiologists and radiological technologists, type and extent of quality control and quality assurance programs, and such other requirements as access to the professional services of a qualified medical physicist. Detailed information will be requested on procedure workload, reporting mechanisms, number and characteristics of diagnostic imaging units, image receptors, and methods of patient-image archiving. Instructions regarding phantom and clinical image acquisition, as well as data sheets to be submitted to the accreditation committee with each image or study, will also be included. Image quality and dose assessments are an important part of the process. They will be evaluated using specially designed phantoms (optional for ultrasound) and thermoluminescent dosimeters. The facility must submit an image of the phantom and sets of normal clinical films. Both the phantom image and the clinical images will be scored by a review panel of experts appointed by the accreditation committee.

When all stages of the evaluation are completed, the accreditation committee will issue to the lead interpreting physician of the health facility a final report that includes specific assessments and recommendations. The facility's original images will be returned along with this report. Facilities that satisfy all of the criteria will be awarded a three-year accreditation certificate by the accreditation committee, on behalf of the ministry of health, and will receive a unit decal for each approved diagnostic imaging unit. For units that are added after the accreditation has been granted, the facility is required to submit technical specifications for the unit and a copy of a medical physicist's equipment evaluation report. The accreditation committee will then request additional testing materials from the new unit. If a diagnostic modality is added to any unit, the facility is also required to notify the accreditation committee, and additional images may be required from that unit.

When facilities do not meet the accreditation criteria, the committee will make specific recommendations for improvements. These recommendations provide guidance so that a facility can meet the criteria after corrective action and reapplication. A facility that fails to satisfy the image evaluation criteria will only be required to resubmit those items that were deficient, e.g., phantom images or clinical images.

To verify that accredited facilities maintain consistent quality during the three-year accreditation period, random on-site surveys and random mail-in film checks may also be performed at any time during the accreditation period. These spot checks offer an excellent opportunity for a positive educational exchange with experts in the field. They also provide validation of the submitted information. Any facility chosen for an on-site survey will be notified in advance. The survey team will be appointed by the accreditation committee. During this survey, the site visit team will review the quality assurance program, review policies and procedures, review personnel qualifications, review the facility's clinical images and reports, and work with the facility's staff to acquire and evaluate a phantom image, along with a dose assessment of the X-ray unit.

To be eligible for accreditation, all of the facility's imaging units covered by this accreditation program must meet the performance and specification criteria included in the applicable standards of the IEC and the ISO, or the equivalent national standards. Facilities must also comply with the requirements of the *International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources* (8).

A quality assurance (QA) program should be in place. As stated by the WHO (2), quality assurance in diagnostic radiology is: "All those planned and systematic actions necessary to provide adequate confidence that a structure, system, or com-

Qualifications for physicians. To specifically address the need for high-quality radiology, the physicians supervising and/or interpreting conventional radiological examinations shall be required to meet all the following minimum criteria:

1. Shall be licensed to practice medicine, and either: (a) be certified in radiology or diagnostic radiology by a national medical board (usually established by the ministry of health), and be approved by the accreditation committee or (b) shall have a minimum of six months of documented formal dedicated training in the interpretation and formal reporting of at least 1 000 general radiographs, including patients of all ages, in a residency program approved by the accreditation committee; the program should include specific radiographic training pertinent to all body areas of which the physicians intend to interpret radiographic studies.
2. Shall have documented training in the physics of diagnostic radiography with respect to the equipment needed to safely produce such images. This should encompass physical principles of general radiography, film-screen combinations, conventional image processing, and, where applicable, digital image processing.
3. Shall have documented training in the principles of radiation protection, including instruction in radiation monitoring requirements and the hazards of radiation exposure for both patients and radiological personnel.
4. Shall have an understanding of other medical imaging modalities (fluoroscopy, computed tomography, ultrasound, magnetic resonance imaging, nuclear medicine, etc.) and their value relative to general radiography in order to best evaluate the patient's clinical symptoms.
5. If interpreting chest radiographs (and/or pediatric chest radiographs), shall have a minimum of three months documented formal training in the interpretation and formal reporting of chest radiography (and/or pediatric radiology) in a residency program approved by the accreditation committee. Such training may have taken place during the six months of other instruction in general radiography.
6. If performing and/or interpreting fluoroscopic radiographs, shall have a minimum of six months documented formal training in the interpretation and formal reporting of fluoroscopic procedures (noninvasive chest and gastrointestinal contrast studies) in a residency program approved by the accreditation committee. The program should include specific gastrointestinal training. Such training may have taken place during the six months of other instruction in general radiography.

A minimum of 200 radiographic examinations per year is recommended in order to maintain an appropriate level of expertise. If the facility performs fluoroscopy (noninvasive chest and gastrointestinal contrast studies), the performance of a minimum of 50 fluoroscopic examinations per year per physician is recommended, but not required, in order to maintain an appropriate level of expertise. If the accreditation committee finds that there are too few examinations to fulfill these recommendations, the committee will assess the situation, and may deny accreditation.

Qualifications for the radiographer or radiological technologist. The radiographer or radiological technologist must possess a degree from a program approved by the accreditation committee. The program should include a minimum of 2 000 hours of experience. It is recommended that the radiographer or radiological technologist participate in continuing education activities that include general radiography and quality control on a periodic basis, the frequency of which is to be determined by the complexity of the imaging exams to be performed.

Quality control. For the radiography/fluoroscopy portion of the accreditation program, each health care facility is required to submit documentation on what quality control tests are being performed, and their frequency. Table 1 shows recommended quality control tests and the minimum frequencies for them. A medical physicist must test the unit's performance at installation and at least annually thereafter.

To assess the technical performance under clinical situations of all equipment to which this accreditation program applies, the Radiography/Fluoroscopy Accreditation Phantom from the ACR is recommended.

Clinical images. It is not necessary to submit clinical images from every fixed radiographic unit, although phantom images must be taken from every radiographic unit. However, the radiographic unit that performs a particular imaging study most frequently should be the one from which clinical images are obtained. Sites cannot submit images performed on models or volunteers. The images to be submitted once per facility are shown in Table 2.

Specific requirements for mammography

The accreditation committee requires that a lead interpreting physician be identified by the mammography facility. Screening mammography may be performed without a physician in attendance. The accreditation committee may decide

TABLE 3. Mammography quality control tests and their minimum frequency

Test	Minimum frequency
Technologist tests	
Darkroom cleanliness	Daily
Processor quality control	Daily
Mobile unit QC[a]	Daily
Screen cleanliness	Weekly
Viewboxes and viewing conditions	Weekly
Phantom images	Weekly
Visual checklist	Monthly
Repeat analysis	Quarterly
Analysis of fixer retention in film	Quarterly
Darkroom fog	Semiannually
Screen-film contact	Semiannually
Compression	Semiannually
Medical physicist tests	
Mammographic unit assembly evaluation	Annually
Collimation assessment	Annually
Evaluation of system resolution	Annually
AEC system performance[b]	Annually
Uniformity of screen speed	Annually
Artifact evaluation	Annually
Image quality evaluation	Annually
kVp accuracy and reproducibility	Annually
Beam quality assessment	Annually
Breast exposure and AEC reproducibility	Annually
Average glandular dose	Annually
Radiation output rate	Annually
Measurement of viewbox luminance and room illuminance	Annually

[a] QC = quality control.
[b] AEC = automatic exposure control.

Specific requirements for ultrasound

The ultrasound accreditation program has four modules from which to choose: (1) obstetrical, (2) gynecological, (3) vascular, and (4) general. The general module includes upper abdominal ultrasound, female pelvis ultrasound, renal/urinary ultrasound, small parts, transrectal/prostate ultrasound, and pediatric neurosonology. A facility may apply for all four modules or for any combination of them.

Each facility seeking accreditation of ultrasound services should submit clinical images and physicians' reports to the accreditation committee. In addition, for each unit, a summary of an annual performance evaluation test should be enclosed. This summary should document the results from testing the transducers that are used for the most frequent examination(s) at the facility.

Physician reports are requested for all examinations in order to confirm the date of examination and the type of examination performed. For vascular work, where appropriate, the reports must contain results from noninvasive pressure testing, obtained either from the referral source or from actual testing performed at the site of practice. It is desirable for normal lab values for velocity measurements to appear at the bottom of reports, as a reference; this is especially helpful with carotid examinations.

Personnel qualifications. The physicians supervising and/or interpreting ultrasound examinations shall be required to show evidence of training in ultrasound in a program approved by the accreditation committee. Sonographers should be certified by a program approved by the accreditation committee. Continuing educational activities are recommended for both the physician and the sonographer.

Quality control. Routine quality control (QC) testing of the ultrasound equipment must occur regularly; a minimum requirement is annually. The same tests must be performed during each testing period so that changes can be monitored over time, and effective corrective actions taken.

For ultrasound units operating in gray-scale imaging mode, the QC program must evaluate at least the following parameters: system sensitivity and/or penetration capability, image uniformity, photography and other hard-copy recording, and assurance of electrical and mechanical safety. A low-contrast object detectability test is optional. These parameters may be assessed using commercially available phantoms. Using a phantom test object will be helpful in responding to questions about low-contrast detectability in the quality control part of the application. However, the use of a phantom test object is optional. In addition, it is recommended that users verify vertical and horizontal distance measurement accuracy when a QC program for an ultrasound unit is initiated.

On an ongoing basis, tests should be done using two probes commonly used with any unit employing more than one transducer. It is recommended that the transducers be of different scan types. One can be a linear (or curvilinear) array, and the other a sector (mechanical, phased, or vector) transducer.

Clinical images. Original ultrasound films (transparencies only) or near-original-quality copies will be accepted. Normal examinations are requested. For vascular exams, both normal and abnormal exams are required. Diagnostic physiologic and anatomic findings (especially for examinations containing abnormal findings) must be contained in the accompanying physician report. All views of an ultrasound examination must be from an examination performed on the same patient.

Clinical images will be evaluated on an objective scoring system approved by the accreditation committee.

La calidad de los servicios de radiología en cinco países latinoamericanos

Ileana Fleitas,[1] *Carlos C. Caspani,*[2] *Cari Borrás,*[1] *Maria-Cristina Plazas,*[3] *Alberto A. Miranda,*[4] *Maria-Ester Brandan*[5] *y Roxana de la Mora*[6]

Forma de citar: Fleitas I, Caspani CC, Borrás C, Plazas MC, Miranda AA, Brandan ME, et al. La calidad de los servicios de radiología en cinco países latinoamericanos. Rev Panam Salud Publica. 2006;20(2/3):113–24.

Palabras clave: radiología, servicio de radiología en hospital, radiografía torácica, mamografía, fluoroscopia, control de la calidad, América Latina.

[1] Organización Panamericana de la Salud, Washington, D.C., Estados Unidos de América. La correspondencia se debe enviar a Ileana Fleitas, PAHO/WHO, 525 Twenty-third Street, NW, Washington, D.C. 20037, United States of America. Correo electrónico: ileana@cceem.sld.cu

[2] Radiofísica Sanitaria (RFSF), Secretaría de Salud de Santa Fe, Santa Fe, Argentina.

[3] Instituto Nacional de Cancerología (INC), Ministerio de Salud, Santa Fe de Bogotá, Colombia.

[4] Instituto Boliviano de Ciencia y Tecnología Nuclear (IBTEN), Ministerio de Desarrollo Sostenible y Medio Ambiente, La Paz, Bolivia.

[5] Instituto de Física, Universidad Nacional Autónoma de México, México, D.F., México.

[6] Centro de Control Estatal de Equipos Médicos, Ministerio de Salud Pública, Ciudad de La Habana, Cuba.

RESUMEN

Objetivo. *Determinar la correlación entre ciertos indicadores de calidad para los servicios de imaginología y la certeza en la interpretación de los exámenes radiológicos para cuatro quejas frecuentes: las masas de la mama, el malestar del aparato digestivo, el dolor de espalda y los síntomas de la tuberculosis.*

Métodos. *Se evaluaron veintiséis servicios de radiología en Argentina, Bolivia, Colombia, Cuba y México. Se evaluaron los equipos de mamografía y de radiografía/fluoroscopia convencional usados en los servicios seleccionados utilizando protocolos comunes, hojas de especificaciones técnicas, instrumentos de prueba, maniquíes y sistemas de dosimetría calibrados. Los estudios se realizaron en establecimientos de complejidad media. Se obtuvo el consentimiento informado de todos los pacientes estudiados, y se garantizó la confidencialidad de los resultados. Se evaluaron y documentaron los siguientes parámetros: el tipo de establecimiento (público o privado); la población cubierta; el número de pacientes y exámenes; los equipos radiológicos, los de procesamiento de imágenes y los suministros; la educación y la capacitación del personal profesional y técnico; los programas de la garantía de la calidad y del mantenimiento preventivo, y la adherencia a las normas de seguridad radiológica. Se determinaron el funcionamiento de los equipos de rayos X, los receptores de la imagen y las procesadoras; las condiciones del cuarto oscuro y de la visualización de las imágenes; las dosis recibidas por los pacientes y la calidad de la imagen, usando parámetros uniformados en todos los casos. Los paneles independientes de radiólogos, reconocidos como expertos por la sociedad radiológica local, evaluaron la calidad de las imágenes clínicas obtenidas y realizaron una interpretación radiológica para cada paciente usando las mismas películas e historia clínica a disposición de los médicos especialistas en imaginología de la institución. El acuerdo entre los informes de los paneles de expertos y los de los radiólogos locales se tomó como un indicador de la certeza de la interpretación radiológica.*

Resultados. *Se analizaron 366 mamografías, 343 procedimientos radiológicos para las quejas del aparato digestivo, 319 exámenes de rayos X de la columna vertebral y 157 radiografías de tórax. El acuerdo entre la interpretación radiológica del panel de expertos y del médico local fue de 70% a 100%, excepto en el caso de las películas de la columna vertebral en Cuba (57,8%) y de las mamografías en México (33,3%), que el panel de expertos juzgó estaban entre las imágenes clínicas de peor calidad. Se encontró una correlación positiva significativa entre la certeza en la interpretación radiológica y la calidad de las imágenes radiológicas. La calidad de la imagen mostró una correlación positiva con el nivel de formación y capacitación de los técnicos. Los estudios que se realizaron en los servicios que contaban con equipos automáticos de revelado y que cumplieron con los indicadores establecidos para el contacto película-pantalla obtuvieron imágenes de mejor calidad y una proporción mayor de estudios con resultados concordantes. Más de 50% de los negatoscopios no cumplieron con los criterios de calidad para el brillo y la homogeneidad.*

CUADRO 1. Afecciones estudiadas, según el país y el tipo de institución (pública o privada)

Diagnóstico o síntoma	Procedimiento	Equipo	Argentina		Bolivia		Colombia		Cuba	México	
			Pública	Privada	Pública	Privada	Pública	Privada	Pública	Pública	Privada
Masas en los senos (n = 366)	Tamizaje	Mamógrafo	2	3	ND[a]	ND	2	2	ND	ND	3
	Mamografía diagnóstica	Mamógrafo	2	3	2	1	2	2	2	2	3
Trastornos gastro-intestinales (n = 343)	Enema de colon	Fluoroscopio y seriógrafo	2	2	ND	ND	2	2	4	ND	ND
	Radiografía seriada de esófago-estómago-duodeno	Fluoroscopio y seriógrafo	2	2	ND	ND	2	2	4	ND	ND
Dolor en la espalda (n = 319)	Radiografía de columna lumbosacra	Rayos X y tomógrafo computarizado	1	3	3	1	2	2	4	ND	ND
	Radiografía de columna cervical	Rayos X y tomógrafo computarizado	1	3	3	1	2	2	4	ND	ND
Tuberculosis (n = 157)	Radiografía de tórax	Rayos X	ND	ND	3	1	2	2	ND	ND	ND

[a] ND: No hay datos.

rayos X (evaluación mecánica, coincidencia de los campos luminosos y de radiación, alineación, exactitud y reproducibilidad de la tensión, exactitud y reproducibilidad del tiempo, linealidad del producto corriente-tiempo, espesor hemirreductor); las condiciones de revelado y visualización (tipo de revelado, contacto película-pantalla, luminosidad y uniformidad del brillo de los negatoscopios); y las características del personal (titulación, años de experiencia y cursos de formación continuada y estudios de protección radiológica realizados).

La selección de los pacientes

Cada país debía reclutar un mínimo de 20 pacientes por cada tipo de estudio radiológico y por cada servicio participante. La selección de los pacientes se efectuó entre julio de 2000 y febrero de 2001, según el siguiente calendario: estudios de mama (julio–septiembre de 2000), de columna vertebral (octubre–noviembre de 2000), de trastornos gastrointestinales (diciembre de 2000–febrero de 2001) y de tuberculosis (enero-febrero de 2001). Se aceptaron todos los pacientes adultos de 18 a 70 años de edad, de uno u otro sexo, que acudieron a los servicios de radiología con una prescripción para realizarse un examen diagnóstico por alguna de las afecciones abarcadas por el estudio (cuadro 1). Se excluyeron los casos de urgencia. Se obtuvo el consentimiento informado de todos los pacientes y se garantizó la confidencialidad de los resultados.

En cada país, la sociedad nacional de radiología o el organismo colegiado correspondiente conformaron un panel evaluador de expertos para cada tipo de examen radiológico a propuesta del investigador principal. Estos paneles estaban integrados por un número impar de expertos en radiología, siempre más de tres. Los expertos eran médicos especialistas en radiología o mastología con al menos 5 años de experiencia en la especialidad y probada experiencia en el diagnóstico de enfermedades vinculadas con los estudios radiológicos evaluados. En algunos casos, los paneles participaron en la evaluación de más de un tipo de estudio si contaban con los conocimientos clínicos requeridos. En total en este estudio participaron 182 técnicos y profesionales (cuadro 2).

Documentación

Cada institución describió el personal participante (radiólogos, técnicos de rayos X, enfermeros, técnicos de mantenimiento, físicos médicos y oficiales de radioprotección) y su calificación (especialización certificada, años de experiencia total y en la técnica en particular y actividades de actualización profesional realizadas en los últimos 5 años).

La protección radiológica se evaluó mediante una inspección visual especializada que valoró el

informe de las imágenes radiográficas después que lo hiciera el radiólogo local y se garantizó que ambos tuvieran acceso a la misma información. El panel diagnosticó por mayoría las enfermedades primaria y secundaria y, según la técnica empleada, evaluó la calidad general de la imagen de la radiografía (posición del paciente, llenado con el líquido de contraste, cantidad de proyecciones, y contraste y latitud de la placa radiográfica), la forma de identificación, el etiquetado de la radiografía y la presencia de artefactos. La evaluación se realizó según una escala de 1 (no útiles) a 5 (de calidad óptima). Se consideró como diagnóstico correcto el realizado por el panel de expertos. Las radiografías evaluadas por el panel como "no útiles" se consideraron también como no coincidentes (diagnóstico incorrecto).

Correlaciones estadísticas

Para el análisis estadístico se utilizó el programa estadístico SPSS, versión 10. Se estableció un nivel de significación de 0,05 y se calcularon los intervalos de confianza de 95% (IC95%). Se realizaron diagramas de dispersión, ecuaciones de regresión y análisis de la varianza entre las variables cuantificadas para determinar cuál de los indicadores de calidad se correlacionaba mejor con la coincidencia entre en el diagnóstico del radiólogo institucional y el del panel de expertos por una parte, y la calidad de la imagen de las películas clínicas evaluadas por el panel de expertos, por la otra.

RESULTADOS

Documentación

Todos los médicos que participaron en el estudio tenían más de 5 años de experiencia en su especialidad, excepto dos que realizaban estudios de mamografía en Argentina y México y tenían 1 y 2 años de experiencia, respectivamente. Todos los médicos habían recibido educación continuada, excepto en Bolivia (cuadro 3), donde los únicos con formación especializada fueron los que intervinieron en los estudios de mamografía; sin embargo, ninguno de estos últimos había recibido capacitación en protección radiológica.

Todos los técnicos participantes (llamados tecnólogos en algunos países) habían recibido entrenamiento formal (cuadro 4). Sin embargo, solo en los servicios de mamografía de Argentina, Colombia y Cuba se encontraron técnicos con formación universitaria. Todos los técnicos habían recibido algún curso de educación continuada, excepto en Bolivia, donde solo poco más de la mitad de los técnicos participantes había asistido a alguno de esos cursos.

En los centros hospitalarios participantes bolivianos que aportaron casos de tuberculosis y co-

CUADRO 3. Características de los médicos imaginólogos en los servicios que participaron en la investigación, según la especialidad y el país

Especialidad y país	No.	Años de experiencia		Especialidad	Personal capacitado (%)	Capacitación en protección radiológica, horas[a]
		Mínimo	Máximo			
Columna vertebral						
Argentina	9	5	ND[b]	Radiólogo	100	25
Bolivia	10	7	> 10	Radiólogo	20,0	25
Colombia	18	7	> 10	Radiólogo	100	20
Cuba	25	12	25	Radiólogo	100	40
Tuberculosis						
Bolivia	13	7	> 10	Radiólogo	15,3	25
Colombia	18	7	> 10	Radiólogo	100	20
Trastornos gastrointestinales						
Argentina	12	10	> 10	Radiólogo	100	25
Colombia	9	7	> 10	Radiólogo	100	20
Cuba	25	12	25	Radiólogo	100	40
Mama						
Argentina	8	2	10	3 radiólogos 5 mastólogos	100	25
Bolivia	5	10	> 10	3 radiólogos 2 mastólogos	100	0
Colombia	6	6	> 10	Radiólogo	100	20
Cuba	3	6	> 10	Radiólogo	100	112
México	9	1	> 10	Radiólogo	100	20

[a] Promedio de horas de estudio acumuladas per cápita en cualquier momento.
[b] ND: No hay datos.

contraron manuales de protección radiológica. Ninguno de los centros participantes de esos dos países contaba con programas habituales para la medición de las dosis de radiación que recibían los pacientes; solo uno de los centros de México tenía un programa de este tipo. No se informó de que hubiera algún programa de análisis del rechazo de películas en ninguno de los centros de Cuba.

Solo dos de los servicios colombianos participantes habían instaurado programas periódicos de control de la calidad para todos los equipos. Bolivia y México mostraron los mejores indicadores en cuanto al mantenimiento de los equipos y en todas sus instituciones había programas que abarcaban tanto el mantenimiento correctivo como el preventivo.

Evaluación técnica

Seguridad radiológica. En todos los países que participaron en la investigación, las normas nacionales habían adoptado los límites de dosis recomendados por las BSS para los trabajadores (7). La dosimetría del personal se llevaba a cabo mediante dosímetros termoluminiscentes con una frecuencia de recambio mensual, excepto en dos hospitales de Cuba donde se utilizaban dosímetros de película que se cambiaban cada dos meses. El análisis de los resultados de la dosimetría personal en cada servicio demostró que en ningún caso se sobrepasaron los límites de dosis para los trabajadores.

Evaluación de los equipos de rayos X. Según la evaluación realizada en cada servicio, más de 30% de las unidades de radiología convencional y fluoroscopia presentaba fallas, fundamentalmente en elementos mecánicos y geométricos. En las unidades de mamografía, la colimación del haz de radiación era inadecuada en 30% de los equipos. Además, el control automático de la exposición no logró compensar el nivel de radiación según el espesor de la mama en 25% de los equipos evaluados, lo que incidió negativamente en la densidad óptica de las imágenes.

Revelado y visualización. En los servicios de mamografía, donde la complejidad del tejido a estudiar y de las posibles alteraciones obligan a observar estándares muy elevados de calidad de la imagen y de su visualización, la mayoría de los negatoscopios se encontraban muy por debajo de la norma de 3 000 candelas por metro cuadrado, establecida por el ACR (17). Solamente un negatoscopio (en una unidad de Bolivia) tenía la iluminación, la homogeneidad y el color adecuados. En cuanto al proceso de revelado, solo 3 de las 20 reveladoras evaluadas se sometían a pruebas diarias de sensitometría y densitometría y solo 10 reveladoras eran del uso exclusivo de los servicios de mamografía, un requisito de calidad indispensable en este tipo de estudio. En total se analizaron 16 reveladoras y cuartos oscuros dedicados al resto de las enfermedades estudiadas en igual número de departamentos de radiología. En solo cinco de ellos se realizaba el control diario de las condiciones de revelado y solo en la mitad de esos servicios se habían instaurado programas de análisis del porcentaje de películas rechazadas. Los negatoscopios fueron los componentes que más fallas mostraron en todos los estudios, ya que más de 50% de ellos no cumplieron con los criterios de calidad en cuanto a brillo y homogeneidad. También se encontraron fallas en cerca de 25% de los cuartos oscuros, fundamentalmente por la entrada de luz del exterior y la intensidad excesiva de las luces de seguridad.

La dosis administradas a los pacientes. Las dosis de radiación, tanto la de entrada en la superficie del paciente como la dosis glandular promedio en el caso de las mamografías, se calcularon a partir de las lecturas realizadas con cámaras de ionización, excepto en Bolivia, donde se midieron de forma directa mediante dosímetros termoluminiscentes. En Cuba se calcularon además las dosis efectivas y las recibidas por los pacientes en los órganos. Todas las dosis —calculadas o medidas— se mantuvieron por debajo de los niveles propuestos por las BSS (7), con excepción de los estudios de tórax realizados en Bolivia, donde se utilizaron técnicas de muy baja tensión, y los estudios de columna vertebral realizados en Cuba, donde por lo general se utilizaron valores del producto corriente-tiempo mayores que los habituales.

La calidad de la imagen

En total se analizaron 366 mamografías, 343 exámenes por trastornos gastrointestinales, 319 de columna vertebral y 157 de tórax. La evaluación de la calidad de las imágenes radiográficas se basó en general en el criterio de los paneles de expertos (cuadro 6). El análisis comparativo de los informes radiológicos emitidos por el panel de expertos y por los radiólogos locales en los tres países que estudiaron casos de trastornos gastrointestinales demostró que la calidad de la imagen fue buena en menos de 70% de los estudios (69,4% en Argentina, 62,5% en Colombia y 64,5% en Cuba). A pesar de que en Cuba todos los estudios se realizaron con equipos de radiografía convencional y en Argentina y Colombia se emplearon equipos de fluoroscopia, las calificaciones fueron muy similares en los tres países. Sin embargo, esta situación parece haber inci-

los diagnósticos coincidentes correspondieron a los exámenes con una buena calidad de la imagen, según el criterio del panel.

En los servicios de mamografía, los resultados de las mediciones físicas de la calidad de la imagen con patrones de resolución se correspondieron con los obtenidos con el maniquí del ACR ($P < 0,001$). No se encontró relación alguna entre el resultado de la evaluación con el maniquí del ACR y la dosis glandular promedio ($P = 0,2$).

Se encontró una relación significativa entre la coincidencia en la interpretación radiológica del panel de expertos y el radiólogo local y los años de experiencia de este último en los estudios de mamografía ($P = 0,015$) y de columna vertebral ($P = 0,03$).

La calidad de la imagen fue directamente proporcional al nivel de formación y capacitación de los técnicos ($P < 0,024$). Además, se encontró una asociación inversa entre los años de experiencia de los técnicos y la calidad de las imágenes radiográficas en los estudios por trastornos gastrointestinales ($P < 0,001$) y de columna vertebral ($P = 0,001$). Esta relación inversa pudiera explicarse por el hecho de que los técnicos más jóvenes reciben más capacitación continuada por manifestar más interés o por los procedimientos internos que se siguen en estos departamentos. Por ejemplo, en uno de los departamentos en Cuba se realizaba habitualmente una evaluación preliminar de la calidad de las radiografías inmediatamente después del proceso de revelado y antes de enviarlas al radiólogo informante, pero estas evaluaciones se centraban en los exámenes realizados por los técnicos más jóvenes e inexpertos. Este tipo de procedimientos puede haber influido en este resultado.

La evaluación de los equipos instalados en cada servicio reveló que la certeza en la interpretación radiológica estaba asociada con el tipo de revelado ($P < 0,019$) y con el estado de la combinación película-pantalla ($P < 0,001$). Los estudios realizados en los servicios que contaban con equipos automáticos de revelado y que cumplieron con los indicadores relacionados con el contacto película-pantalla obtuvieron imágenes de mejor calidad y una mayor proporción de estudios coincidentes, mientras que los peores resultados en cuanto a la calidad de la imagen se obtuvieron en los servicios donde se efectuaba el revelado manual.

DISCUSIÓN

La evaluación de los departamentos de radiología diagnóstica es de gran importancia debido al impacto que pueden tener las interpretaciones radiológicas acertadas en el tratamiento de los pacientes, los costos de funcionamiento de estos servicios y los posibles efectos dañinos de las radiaciones ionizantes.

Aunque los estudios dosimétricos abundan, esta es la primera investigación que intenta relacionar la exactitud en la interpretación radiológica con los aspectos organizativos y dosimétricos. Estos resultados deben ayudar a establecer prioridades dentro de los programas de garantía de la calidad, basadas en la relación costo-beneficio.

De interés particular es la evaluación realizada recientemente a 61 unidades de mamografía en 11 países de América Latina y el Caribe (18), auspiciada por la OPS y el Colegio Interamericano de Radiología. La calidad de las imágenes se evaluó mediante el maniquí de acreditación del ACR y las mediciones de las dosis aplicadas, mediante dosímetros termoluminiscentes colocados sobre el propio maniquí. En general, 88% de los servicios cumplieron con los criterios de calidad de la imagen del ACR, aunque en 92% de los servicios, las dosis se encontraban por debajo de los valores recomendados en las BSS. Estos resultados son similares a los encontrados en Estados Unidos (19). Sin embargo, hay que tener en cuenta que la participación en ese estudio fue totalmente voluntaria y 66% de los servicios pertenecían a instituciones privadas. Al igual que en el presente estudio, no se halló ninguna correlación entre la calidad de la imagen y las dosis aplicadas.

El hecho de utilizar en este estudio pacientes que fueron atendidos en los departamentos de radiología como parte de su trabajo habitual, si bien complicó la recolección de todos los datos necesarios, permitió contar con una base de datos directamente vinculada a la realidad clínica que se vivía en las instituciones participantes. Por lo general, los estudios disponibles en la literatura se basaron en pacientes seleccionados según criterios de inclusión muy específicos (20). En la presente investigación multicéntrica, la utilización de pacientes sirvió además para que en varios de los departamentos participantes quedaran adoptados métodos de trabajo que ayudarán a mejorar la calidad de las imágenes radiográficas que le llegan al radiólogo informante.

Algunos autores consideran que la calidad de la imagen es el factor determinante para obtener un diagnóstico certero (21, 22), lo que quedó confirmado en este estudio. No obstante, la evaluación de la calidad de las imágenes radiográficas se basó en el criterio de los expertos y, aunque a los paneles se les pidió que siguieran los criterios de la Comisión Europea (CE) para la evaluación de la calidad de la imagen (4), no se puede asegurar que la uniformidad entre los diferentes paneles fuera la suficiente como para comparar los resultados de los cinco países. Si bien los expertos fueron respaldados por las sociedades radiológicas nacionales para garantizar

su competencia profesional, existe un nivel de desarrollo muy diferente en los diversos países participantes. Cuando se han fijado determinados umbrales de calidad para una evaluación, el criterio general de los radiólogos respecto a las imágenes es importante, pero también lo es la calidad de las imágenes que los observadores están acostumbrados a ver (20). Los resultados del presente estudio indican que no es posible comparar la calidad de las imágenes evaluadas por diferentes observadores, aun cuando se utilicen los criterios de la CE (4).

En el presente estudio, los paneles de cada país estaban compuestos por especialistas de reconocido prestigio nacional, lo que permitió a los grupos de investigadores realizar comparaciones entre los diferentes centros participantes, identificar sus propias potencialidades y debilidades y tomar medidas correctoras siempre que fue posible (10, 14, 23). Para poder comparar entre sí los resultados obtenidos en los diferentes países en el futuro, se debe contar con un solo panel de evaluación, con criterios de calidad de la imagen muy bien definidos y entrenados en el uso de esos criterios. Otra debilidad de este estudio fue que muchas de las correlaciones estudiadas carecen de poder estadístico debido al tamaño reducido de la muestra, determinado por las limitaciones financieras.

Las altas dosis de radiación para los estudios de tórax informadas en Bolivia pueden deberse al uso de técnicas de baja tensión, lo que contradice las recomendaciones de la Organización Mundial de la Salud para este tipo de estudio (24). En el caso de Cuba, donde se sobrepasaron los límites de dosis recomendados en las BSS para los estudios de columna vertebral, se utilizaron por lo general valores del producto corriente-tiempo mayores que los habituales (24), posiblemente debido a las dificultades que presentan esos equipos para regular con exactitud y reproducibilidad los tiempos de exposición.

Otras limitaciones de este estudio fueron la poca experiencia de los especialistas participantes en este tipo de investigación, la gran cantidad de variables analizadas y el hecho de que el proyecto no se diseñó inicialmente como un estudio multicéntrico. Además, los instrumentos de medición no fueron los mismos en todos los países, por lo que fue difícil uniformar los protocolos. Para subsanar esta dificultad se compraron algunos otros instrumentos de medición, lo que generó gastos adicionales en cada país y un considerable retraso en el desarrollo de la investigación.

A pesar de esas limitaciones, el presente estudio demostró que la combinación de evaluaciones físicas y clínicas es una buena vía para mejorar el resultado clínico y que este método se puede aplicar en todos los países, independientemente de sus condiciones económicas o del sistema de propiedad de los servicios (estatales, privados o parcialmente privados). La evaluación integral de los departamentos de radiología llevada a cabo en esta investigación permitió establecer, en primer lugar, que se debe prestar mayor atención a la formación continuada de los recursos humanos —especialmente de los técnicos— y que se debe dar prioridad al mantenimiento o reposición de los negatoscopios, las pantallas intensificadoras y las máquinas reveladoras.

El proyecto de investigación tuvo un impacto significativo adicional. En primer lugar, acercó a investigadores de países que se encontraban en diferentes niveles de desarrollo y que se beneficiaron del intercambio de información y experiencias. Otro elemento importante fue la colaboración entre técnicos, físicos médicos y radiólogos en cada país participante, lo que permitió que se reconociera el papel de cada especialista en el mejoramiento de la calidad de los departamentos de radiología. Finalmente, el conocimiento y la experiencia adquiridos por los investigadores de los cinco países participantes deben contribuir a mejorar el estado de los servicios de radiología en esos países y en América Latina y el Caribe.

CONCLUSIONES

Aunque muchas de las correlaciones estadísticas estudiadas carecen de poder estadístico debido al tamaño reducido de la muestra, este estudio demostró que la buena calidad de la imagen es un elemento crítico para lograr diagnósticos certeros. Se debe hacer hincapié en la formación continuada de los técnicos y en la compra y el mantenimiento de equipos y accesorios, en especial los negatoscopios, las pantallas intensificadoras y las máquinas reveladoras, por la incidencia que tienen en la calidad de las imágenes.

Como resultado de esta investigación, las autoridades nacionales han impuesto o modificado algunas de sus normas: en Argentina, el investigador principal sostuvo conversaciones con los secretarios de salud de varias provincias y le proporcionó detalles acerca de la situación de los servicios al Comité Federal de Salud, lo que llevó a elaborar un plan para solucionar los problemas encontrados; en Bolivia, a partir de los resultados obtenidos se incorporaron criterios específicos para los servicios de radiodiagnóstico como parte del Programa de Acreditación de Hospitales; en Colombia, el Instituto Nacional de Cancerología y la Sociedad de Radiología crearon un programa de garantía de la calidad y se contrató a un físico investigador para ese programa; en Cuba, el Centro de Control Estatal de Equipos Médicos pasó a formar parte del Grupo Nacional Asesor de Radio-

logía y del Programa de Detección Precoz de Cáncer de Mama, se han realizado varios cursos y talleres y se han elaborado nuevos proyectos de investigación; y en México se revisaron las normas establecidas por el Ministerio de Salud para el control de la calidad de los equipos de rayos X.

Agradecimientos. Los autores extienden su agradecimiento a todas las instituciones que participaron en este estudio. De las 182 personas que participaron en él de manera directa, los autores desean agradecer la contribución especial de: Lola Aguilar Serrano, Fernando Barrientos Zamora, Petra E. Beltrán, Lucio Ronald Berdeja Amatller, Claudia Betancourt, Solángel Bolaños, Elena Carli, Rodolfo de la Nuez Soto, Leonel Gaitán, Waldo García Riverón, Reinaldo Griñán Torres, Carmen-Rosa Guevara Ferrer, Jorge Kiguen, Roberto Lescano, Miriam Malberti, Hubaldo Martínez, Dulce-María Martínez Pereira, Edgar Medina Delgadillo, Luis-Eduardo Pedroso Mendoza, Rolando Pereiras Costa, Héctor Posso, José Luis Ramírez Arias, Jhonny Rivero Silva, Maytee Robaina García, Jaime Robinson, José L. Rodríguez, Maricel Rodríguez, Miriam Rodríguez Menéndez, César G. Ruiz-Trejo, Genaro-Rodrigo Salinas Mariaca, Margarita Serres Moret, Jorge Skvarca, Roberto Solares Amador, Luis Quevedo Sotolongo, Belkys Vásquez Ríos, Maricela Verdejo-Silva y Yolanda Villaseñor.

REFERENCIAS

1. Pan American Health Organization. Health in the Americas. 1998 ed. Washington, D.C.: PAHO; 1998. (Scientific Publication 569).
2. Pan American Health Organization. Promoting health in the Americas: annual report of the Director, 2001. Washington, D.C.: PAHO; 2001.
3. Pan American Health Organization. Health in the Americas. 2002 ed. Washington, D.C.: PAHO; 2002. (Scientific and Technical Publication 587).
4. European Commission. European guidelines on quality criteria for diagnostic radiographic images. Luxembourg: Luxembourg; 1996. (EUR 161260-EN).
5. Ritter VW, Reid Warren S Jr., Pendergrass EG. Roentgen doses during diagnostic procedures. Radiology. 1952;59: 238–49.
6. U.S. Department of Health, Education and Welfare. Population exposure to X-rays, U.S. 1970. Rockville, MD: DHEW; 1973. (DHEW Publication [FDA] 73–8047).
7. Food and Agriculture Organization, International Atomic Energy Agency, International Labor Organization, Nuclear Agency of the Organization for Economic Co-operation and Development, Pan American Health Organization, World Health Organization. International basic safety standards for protection against ionizing radiation and for the safety of radiation sources. Vienna: IAEA; 1997. (Safety Series No. 115).
8. European Union. Council Directive 97/43/ Euratom, on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure. Official Journal (European Union). 1997;L180:22–7.
9. Sáez Núñez DG, Borroto Valdés M, Mesa Hernández M, del Risco Reyna L, Borrás C. Estudio piloto de control de calidad en radiodiagnóstico de hospitales de Ciudad Habana. Resultados dosimétricos en las radiografías de tórax postero-anterior y columna lumbosacra lateral. Radioprotección.1998;6(17):16–9.
10. Guevara CR, de la Mora R, Fleitas I. Estudio de dosis en exámenes de mamografía en Cuba. Interrelación con la calidad de la imagen obtenida. Memorias del V Congreso Regional de Protección y Seguridad Radiológica; 2001 abril 29–mayo 2; Recife, Brasil. Recife: IRPA; 2001.
11. Guevara CR, de la Mora R, Fleitas I. Resultados obtenidos durante la ejecución de controles de calidad en mamografía. Memorias del Congreso Latinoamericano de Ingeniería Biomédica, mayo 23–25 de 2001, Ciudad de La Habana, Cuba. Ciudad de La Habana: SocBio; 2001.
12. Miranda Cuadros A. Evaluación de la calidad de los servicios de radiodiagnóstico en Bolivia. Informe de investigación del Programa de Subvenciones para la Investigación. Washington, D.C.: OPS; 2002. Disponible en: http://www.paho.org/Spanish/HDP/HDR/BOL-Res-3010.doc. Acceso el 26 de marzo de 2006.
13. Fleitas I, Borrás C, Brandan ME, Caspani C, Miranda A, de la Mora R, et al. Diagnostic reference levels and quality measurements in five American countries. Proceedings of the World Congress on Medical Physics and Biomedical Engineering, August 24–29 2003, Sydney, Australia. Sidney: IFMBE, IOMP; 2003.
14. Brandan ME, Ruiz Trejo C, Trujillo F, Chávez C, Montes N, Verdejo Silva M, et al. Evaluation of equipment performance, patient dose, imaging quality, and diagnostic coincidence in five Mexico City mammography services. Arch Med Res. 2004;35:24–30.
15. Pan American Health Organization. Development, quality control and radiation protection in radiological services—imaging and radiation therapy. Washington, D.C.: PAHO; 1997.
16. National Council on Radiation Protection and Measurements. Quality assurance for diagnostic imaging. Bethesda, MD: NCRP; 1988. (NCRP Report No. 99).
17. American College of Radiology. Mammography quality control manual. Reston, VA: ACR; 1999.
18. Borrás C, Mota H, Skvarca JJ. Measurements of image quality and dose in 61 mammography units in 11 countries. Proceedings of the 89th Radiological Society of North America Scientific Assembly and Annual Meeting Program, December 1–5 2003, Chicago, IL. Chicago: RSNA; 2003.
19. Suleiman OH, Spelic DC, McCrohan JL, Symonds GR, Houn F. Mammography in the 1990s: The United States and Canada. Radiology. 1999;210:345–51.
20. Lanhede B, Båth M, Kheddache S, Sund P, Björneld L, Widell M, et al. The influence of different technique factors on image quality of chest radiographs as evaluated by modified CEC image quality criteria. Br J Radiol. 2002;75: 38–49.
21. Guibelalde del Castillo E. Controles básicos de calidad de imagen con la aplicación de los criterios de la Comunidad Europea y con objetos de test. Memorias del X Congreso Nacional de Física Médica, septiembre de 1995, Salamanca, España. Salamanca: Sociedad Española de Física Médica; 1995.
22. European Commission. CEC quality criteria for Diagnostic Radiographic Images and Patient Exposure Trial. Brussels: CEC; 1990. (EUR 12952 EN).
23. Brandan ME, Caspani CEM, de la Mora R, Miranda AA, Plazas MC, Borrás C. Evaluation of diagnostic radiology services in five Latin American countries: results for mammography. Proceedings of the International Conference on Radi-

ological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy, March 26–30 2001, Malaga, Spain. Vienna: IAEA; 2001.

24. World Health Organization. The WHO manual of diagnostic imaging. Radiographic technique and projections. Geneva: WHO; 2003.

Manuscrito recibido el 14 de diciembre de 2004. Aceptado para publicación, tras revisión, el 9 de diciembre de 2005.

The quality of radiology services in five Latin American countries

ABSTRACT

Objective. To determine the correlation between certain quality indicators for imaging services and the accurate interpretation of radiological exams for four frequent complaints: breast lumps, gastrointestinal discomfort, back pain, and symptoms of tuberculosis.

Methods. Twenty-six radiology services in Argentina, Bolivia, Colombia, Cuba, and Mexico were assessed. The mammography and conventional radiographic/fluoroscopic equipment used in selected services were evaluated utilizing common protocols, data sheets, testing instruments, phantoms, and calibrated dosimetry systems. The studies were performed in medium-complexity facilities. Informed consent was obtained from all patients studied, and the confidentiality of results was guaranteed. The following parameters were documented: type of facility (public vs. private); population covered; patient workload; radiological and image-processing equipment and supplies; education and training of professional and technical staff; quality assurance and preventive maintenance programs, and adherence to radiation safety standards. The performance of x-ray units, image receptors and processors; darkroom and image viewing conditions; patient doses and image quality, were determined using standardized parameters in all cases. Independent panels of radiologists, recognized as experts by the local radiological society, assessed the quality of the clinical images obtained and performed a radiological interpretation for each patient using the same films and clinical history available to the institution's imaging physicians. The agreement between the panel of expert's reports and those of local radiologists was taken as an indicator of the radiological diagnostic accuracy.

Results. Analyses were carried out of 366 mammograms, 343 radiological procedures for gastrointestinal complaints, 319 X-rays of the spinal column, and 157 chest radiographs. The agreement between the radiological interpretation of the panel of experts and of the local physician ranged from 70% to 100%, except in the case of spinal column films in Cuba (57.8%) and of mammograms in Mexico (33.3%), which the panel of experts found to be among those having the poorest quality. There was a significant positive correlation between the accuracy of the radiological interpretation and the quality of the radiological images. Image quality showed a positive correlation with the technicians' level of education and training. Studies performed in services that had automatic film processors and that complied with the indicators established for screen-film contact yielded better images and a higher proportion of studies with concordant results. More than 50% of the viewboxes did not satisfy the quality criteria for luminance and homogeneity.

Conclusions. A good quality image is critical to achieving an accurate diagnosis. Emphasis should be placed on the continuing education of radiology technicians and on the acquisition and maintenance of adequate equipment and accessories, especially viewboxes, intensifying screens, and automatic film processors, given the impact they have on image quality.

Key words Radiology, hospital radiology department, chest radiography, mammography, fluoroscopy, quality control, Latin America.

Screening mammography: a successful public health initiative

Stephen A. Feig[1]

Suggested citation: Feig SA. Screening mammography: a successful public health initiative. Rev Panam Salud Publica. 2006; 20(2/3):125–33.

SYNOPSIS

This paper reviews the ability of screening mammography to reduce breast cancer death rates, and it discusses methods that maximize benefits and reduce false-positive interpretations in a screening program. The review covers published results from screening mammography programs conducted in Europe and North America, along with quality assurance measures designed to ensure that similar or even better outcomes will be shared by other populations of screened women. Randomized trials in Europe and the United States of America have shown the benefit from screening women ages 40-70 years. Encouraged by the success of these trials, many Scandinavian countries now offer screening mammography to their populations as a public health service. These service screening programs have reduced breast cancer deaths as much as 63% among women who were screened. In the United States, where 61.5% of women age 40 and older report having had a mammogram in the preceding year, death rates from breast cancer have been falling despite an increasing incidence of the disease. The technical quality of mammography in the United States has improved as a result of advances in mammography equipment, including the film-screen systems. Also contributing to the improvement has been the implementation of federally mandated quality control testing at each mammography facility, as required by the Mammography Quality Standards Act (MQSA), which the Congress of the United States approved in 1992. Factors that result in increased detection of early-stage cancers include better technique, use of two mammographic views per breast, annual screening intervals, and improved interpretation. Mammography is one of the 10 major subject categories on the American Board of Radiology examinations. Furthermore, MQSA requires radiologists who practice mammography to obtain continuing medical education credits and to use standard interpretation assessments on every report. Manuals for technical quality control and breast imaging reporting, as well as education and self-assessment materials on interpretation, have been developed by the American College of Radiology. Even though mammography will not detect all breast cancers, it is still the best available screening test. The American Cancer Society recommends that annual screening mammography begin no later than age 40 years.

Key words: breast neoplasms, mammography, mass screening, practice guidelines, program evaluation, United States.

The primary goal of screening mammography is to lower breast cancer mortality rates through reduction in late-stage disease. Early detection also provides a wider choice of therapeutic options such as lumpectomy rather than mastectomy. The relative sensitivity of mammography and clinical examination were assessed by the Breast Cancer Detection

[1] University of California, Irvine Medical Center, Department of Radiology, Orange, California, United States of America. Send correspondence to: Stephen A. Feig, UCI Medical Center, 101 The City Drive, Route 140, Orange, California 92868, United States; telephone: (714) 456-6905; fax: (714) 456-6932; e-mail sfeig@uci.edu

Demonstration Project, which was conducted at 29 centers throughout the United States of America from 1973 to 1981 (1). Over 280 000 women between the ages of 35 and 74 years were offered five annual screenings with both mammography and clinical examination. Almost 42% of all cancers were detected by mammography alone, 47% by both mammography and clinical examination, and almost 9% by clinical examination alone. The relative performance of mammography was best for earlier cancers such as infiltrative carcinomas measuring less than 1 cm in size and all in situ carcinomas.

RANDOMIZED CLINICAL TRIALS ON SCREENING MAMMOGRAPHY

Seven randomized clinical trials (RCTs) conducted during the past 40 years have compared deaths from breast cancer among study group women ages 40–70 years offered screening mammography and control group women. Six RCTs found that screening reduced breast cancer mortality in the entire range of ages screened. For three RCTs (Health Insurance Plan [HIP], Swedish Two-County, and Edinburgh [Scotland]) there were statistically significant reductions in breast cancer deaths, of 23%, 32%, and 20%, respectively (2–4). The Malmo, Stockholm, and Gothenburg trials in Sweden reported nonsignificant reductions of 19%, 20%, and 14%, respectively (5–7). Only one trial, the National Breast Screening Study of Canada (NBSS), was unable to demonstrate any benefit from screening (8, 9). NBSS results may be explained by poor technical quality and a faulty randomization scheme (10).

At early follow-up, no trial showed much benefit for the subset of women who entered screening between 40 and 49 years of age. Their benefit appeared later because younger women have faster breast cancer growth rates. For these growth rates, screening intervals of two years are excessively long (11, 12). Due to the relatively small number of younger women enrolled and their lower incidence of breast cancer, initial proof of benefit required pooling results from multiple trials to attain statistical significance. In 1997, a meta-analysis of women age 40–49 years at entry into all five Swedish trials found a significant, 30% reduction in breast cancer deaths (13). Subsequent long-term follow-up of three trials (HIP, Gothenburg, and Malmo) each found statistically significant breast cancer mortality reductions, of 24%, 45%, and 36%, respectively, for younger women (14–16). Thus, randomized clinical trials have proven that screening mammography will reduce deaths from breast cancer among women age 40–70 years.

VALIDITY OF SCREENING TRIAL RESULTS

On the basis of results from randomized trials that were conducted over the past quarter of a century and that involved over 500 000 women, there has been consensus in the medical community in favor of screening mammography. In the face of such near unanimous agreement, two articles published by Gotzsche and Olsen, in 2000 (17) and in 2001 (18), made the seemingly incredible claim that none of the trials provided any convincing evidence that screening prevents breast cancer deaths. The arguments and counter-arguments are complex and have been summarized in detail elsewhere (19, 20). Fortunately, the conclusions reached by Gotzsche and Olsen have all been subsequently refuted in the peer-reviewed literature (21–28).

Although the report by Gotzsche and Olsen received considerable publicity in the United States media, no medical organization or government has changed its screening policy. Indeed, after review of the Gotzsche and Olsen papers, 10 leading medical organizations in the United States reaffirmed their support of screening in a full-page advertisement in *The New York Times* on 31 January 2002. (The 10 organizations were the American Academy of Family Physicians, American Cancer Society, American College of Obstetrics and Gynecology, American College of Physicians-American Society of Internal Medicine, American College of Preventive Medicine, American Medical Association, Cancer Research Foundation of America, National Medical Association, Oncology Nursing Society, and the Society of Gynecologic Oncologists.) Also, the National Cancer Institute of the United States and the U.S. Preventive Services Task Force concluded that the results from randomized screening trials were still valid. Many groups outside the United States reached similar conclusions about screening mammography. For example, the Swedish National Board of Health and Welfare, the Danish National Board of Health, the Health Council of the Netherlands, the European Institute of Oncology, and the World Health Organization dismissed the Gotzsche and Olsen arguments and concluded that the evidence for a benefit was convincing (21).

NEGLIGIBLE RADIATION RISK FROM MAMMOGRAPHY

In comparison to the benefits, the risks from screening mammography should be negligible. Potential radiation risk from mammography should be considered, even though no woman has ever been shown to have developed breast cancer as a result of mammography, not even from multiple

examinations over many years at doses much higher than the current dose of 3–4 mGy (0.3–0.4 rad) (29). Some groups of women exposed to radiation have been found to be at increased risk for breast cancer. This has been true for survivors of the atomic bombs dropped on two Japanese cities near the end of World War II and for North American women treated with radiation therapy for benign breast conditions in the 1930s or monitored with multiple chest fluoroscopies during treatment for pulmonary tuberculosis during the same period (29). However, those populations received doses from 100 to over 1 000 rad. Numerous studies have compared the known benefits of screening with the hypothetical risks from low doses of radiation from mammography, using the conservative assumption that the risk per rad remains constant when extrapolated downward from high to low doses. Benefit/risk ratios calculated as either lives saved or years of life saved through screening vs. lives lost or years of life lost as a consequence of mammography indicate that screening mammography is safe (29–34). A 2004 report from the National Council on Radiation Protection and Measurements of the United States concludes that "the risk of radiation-induced mortality, even given a series of 30 annual screenings, is offset by even a minimal benefit in reduced breast cancer mortality from screening as low as one percent" (35).

BENEFITS FROM SERVICE SCREENING

Based on the success shown in the RCTs, all Swedish counties and many counties in Finland now offer screening mammography as a public health service to women age 40 and older. Five studies from Sweden and one from Finland show that this service screening is associated with a reduction in breast cancer mortality often exceeding the reduction found by the RCTs (36). In the counties that participated in the Swedish Two-County Trial, subsequent service screening of women ages 40–74 years reduced breast cancer deaths by 50% among the women offered screening and by 63% among those who agreed to be screened (37). Similar results were found in an expanded study involving seven Swedish counties (38).

SCREENING MAMMOGRAPHY GUIDELINES

Screening mammography beginning at age 40 is advised by the American Cancer Society (ACS), American College of Radiology (ACR), American Medical Association (AMA), National Cancer Institute (NCI), American College of Obstetrics and Gynecology (ACOG), and U.S. Preventive Services Task Force (USPSTF) (39–42). For women ages 40–49, the ACS, ACR, and AMA recommend annual screening; the ACOG, NCI, and USPSTF recommend screening every one to two years. All the organizations advise annual screening for women age 50 and older. The ACS does not stipulate any upper age limit beyond which screening should no longer be performed. Rather, the ACS maintains that screening should continue as long as a woman is in generally good health and has sufficient longevity.

TABLE 1. Breast cancer in the United States of America, with percent diagnosed by stage in 1980 and 2001, and with current five-year relative survival rates by stage at diagnosis as of 2002[a]

Stage	Stage distribution (%) 1980	Stage distribution (%) 2001	Five-year survival (%)
Ductal carcinoma in situ	3	21	100
Stage I	25	42	98
Stage II	45	25	81
Stage III, IV	14	7	26
Unstaged	13	5	56

[a] ***Source:*** National Cancer Institute, SEER database, accessed 20 April 2006. The data on five-year relative survival rates are for the period ending 31 December 2002.

EFFECTS OF INCREASED USE OF SCREENING MAMMOGRAPHY IN THE UNITED STATES

In the United States the use of screening mammography has increased continuously since 1975. Surveys performed by the National Center for Heath Statistics found that the percentage of women ≥ 40 years who reported having undergone a mammogram within the preceding two years was as follows: 28.8% in 1987, 55.8% in 1992, 66.9% in 1998, and 70% in 2000 (43). According to a survey performed in 2002, 61.5% of women in the United States age 40 and older reported that they had had a mammogram within the preceding year (44). As a result of screening mammography there has been a pronounced shift in the stage of diagnosis of breast cancer in the United States (Table 1). Intraductal carcinoma in situ (DCIS), which was rare in the premammography era, now constitutes just over 20% of the recently-diagnosed breast cancers. The proportionate representation of stage I invasive cancer has increased, while that of stages II, III, and IV has decreased.

Analyzing incidence and mortality data that are adjusted to the changes in age representation in the population provides a better assessment of how

breast cancer death rates have fallen as a result of early detection. Adjusted to a single population "standard," the incidence of invasive breast carcinoma in the United States increased by 30.9% between 1980 and 1990, and by 36.8% from 1980 to 1999. Breast cancer mortality increased by 4.4% in the 1980s but fell by 17.0% during the next decade. Based on these figures, Feig calculated that the average woman with invasive cancer in the late 1990s was 39% less likely to die from her disease than was her counterpart in the 1980s (36). If these calculations had assumed that some invasive breast cancers were prevented through mammographic detection of DCIS, the estimated benefit attributed to mammography would be even greater.

MAXIMIZING THE BENEFIT FROM SCREENING

Considering the variability in breast cancer mortality reduction among the studies that this piece has discussed, it should come as no surprise that the benefit from screening women in any country in the world may be greater than, the same as, or less than in any of the randomized trials and service screening programs. Part of the variability may be due to differences in age and risk factors among the screened populations. Most of the variation, however, would be attributable to differences in screening frequency, number of screening rounds, quality of mammography technique, and interpretation.

There is abundant indirect evidence that annual screening should lead to far greater benefit than screening every other year. This is especially true for women screened in their forties (11, 12, 42). For example, screening every two years in the Swedish Two-County Trial decreased breast cancer deaths 18% among women age 40–49 and 39% among women age 50–59. It has been calculated that annual screening for women in each of these age groups would have decreased breast cancer deaths by 36% and 45%, respectively (45).

Most screening trials used a single mediolateral oblique (MLO) view alone on all or most screening rounds. However, we now know that the number of mammographic images per breast will affect screening detection rates. Routine use of both craniocaudal (CC) and MLO views detects 7% more cancers than does an MLO view alone (11).

Overall technical quality of mammography is determined by eight separate factors: breast positioning, breast compression, image exposure, contrast, sharpness, noise, artifacts, and film labeling. Better technical quality allows increased detection rates, detection of earlier-stage disease, and fewer missed cancers (46). To promote good technical quality in the United States, the American College of Radiology has developed a list of recommended specifications for mammography equipment (47). The ACR has also published the *Mammography Quality Control Manual*, which describes: (1) methods for proper positioning and compression of the breast, (2) proper viewbox criteria for assessment of clinical image quality by the radiologist, and (3) quality control tests that need to be performed by the technologist and medical physicist on a regular basis to document proper film processing and equipment functioning (48). The routine performance of these tests is now required by United States law under the Mammography Quality Standards Act (MQSA), which was passed by the United States Congress in 1992; interim regulations became effective in 1994, and final regulations in 1999 (49). Objective data from medical physics inspections have documented improvement in film quality throughout the United States as a result of MQSA (50). Due to improvements in mammographic technique over the past 30 years, modern mammography detects earlier cancers than was possible with the randomized trials that were conducted in the 1970s and 1980s (51). Thus, modern mammography should result in even greater benefit than was shown in studies in earlier decades.

Aside from differences in screening frequency and technique, there are other reasons why randomized trials underestimate the benefit for a woman who now receives annual screening. First, randomized trials measure differences in breast cancer death rates between study group women, who were offered screening, and control group women, who were not offered screening (50). However, not all study group women accepted the offer to be screened, and many control group women obtained screening outside the trials (52). Second, screening trials consist of a limited number of screening rounds, usually three to five. Because benefit does not reach "full throttle" until later rounds, the "average" benefit from the first several rounds underestimates the gain from continual annual screening (23).

Mammography does not detect all breast cancers. Some cancers missed by mammography will be detected by clinical examination (1, 2, 53, 54). There is evidence from RCTs that when women are screened with a combination of mammography and clinical examination, clinical examination makes an independent contribution towards lowering breast cancer mortality (1, 2, 53, 54). The American Cancer Society advises women to obtain an annual mammogram and clinical breast examination beginning at age 40 (41). In addition, the ACS suggests that women should also consider performing monthly breast self-examination (BSE), although the evi-

dence in favor of BSE as a supplementary screening modality is less strong. Unless taught and performed properly, BSE may not be effective (55).

Several studies suggest that early breast cancers missed by mammography may be detected by ultrasound in dense breasts and by magnetic resonance imaging (MRI) in high-risk women (56, 57). These preliminary results need to be confirmed by larger, better-designed multicenter trials before either modality can be considered for routine screening. There are several other reasons why neither ultrasound nor MRI is currently a practical screening method for the general population. Both result in far more false-positive biopsies than mammography does. MRI requires intravenous contrast injection. Although the cost of ultrasound is similar to that of mammography (which costs around US$ 90 per exam), the cost of breast MRI is substantially higher, some US$ 1 000 to US$ 1 500 per examination. The number of MRI and ultrasound units and of adequately–trained technologists and radiologists required for population-wide screening is daunting. The equipment is very expensive, and both studies are extremely time-intensive for technologists and radiologists. Unless high-quality automated ultrasound units can be developed, screening ultrasound will not be practical.

The recent Digital Mammography Imaging Screening Trial, which was conducted by the American College of Radiology Imaging Network, found that digital mammography did not detect any more cancers in the general population than conventional screen-film mammography did (58). However, digital mammography did seem to be more sensitive than conventional mammography for women with radiographically dense breasts and for women below the age of 50 years. The X-ray dose from digital mammography is slightly lower than is the dose with screen-film mammography. However, digital mammography units cost about US$ 500 000, or six times more than conventional mammography units.

Several studies have shown that interpretation of screening mammography by two paired readers may increase detection rates by 5%–15% (59). Results with this double-reading approach vary according to the relative interpretive expertise of the two readers. The potential benefit of double reading must be weighed against increased cost, higher false-positive callback rates, and a shortage of radiologist readers.

In principle, computer-aided detection (CAD) might function as a second reader. Results from CAD studies have varied, showing a 0%–20% increased cancer detection rate (60). There is evidence that the additive value of CAD may depend on the visual skills of the radiologist (61).

Detection of early breast cancer requires a combination of high-quality radiologic interpretation, state-of-the-art equipment, and technical quality assurance programs. In the United States, mammography represents 10% of the questions on the clinical portion of the written section (part I) of the American Board of Radiology (ABR) examination, and it is one of the 10 major categories on the oral portion (part II) of the ABR exam. These examinations are usually given during the fourth year of a radiology residency, which must include three months of experience in breast imaging.

In the United States, to interpret mammograms independently, an interpreting physician must either meet initial requirements or have been grandfathered by qualifying under the interim regulations before 28 April 1999. Initial qualifications specify that the physician must have a state license to practice medicine; must be board-certified in diagnostic radiology by an organization (such as the American Board of Radiology) that is approved by the United States Food and Drug Administration, or have three months of formal training in mammography; and must have 60 category 1 continuing medical education (CME) credits in mammography, with at least 15 obtained in the three years immediately before qualifying as an interpreting physician. In addition, the physician must have interpreted, under direct supervision, 240 mammographic examinations in the six months immediately before qualifying as an interpreting physician. There is an exception for newly-board-certified diagnostic radiologists. Direct supervision means that a supervising MQSA-qualified interpreting physician reviews, discusses, and confirms the diagnosis of the physicians being supervised.

Interpreting physicians must then maintain continuing education by accruing 15 category 1 CMEs over a 36-month period, and maintain a continuing experience of interpreting a minimum of 960 mammograms in 24 months. The physician is also required to maintain a valid state license to practice medicine.

The regulations also stipulate that before independently interpreting digital mammography, a physician must have at least eight hours of training in digital mammography.

The American College of Radiology (ACR) has developed several voluntary self-assessment programs in breast imaging that include images as well as questions and answers on detection, workup, and management. There are several self-assessment syllabi volumes in breast imaging as well as a Mammography Interpretative Skills Assessment (MISA) program in CD-ROM format (62, 63). Many radiologists have found that these learning devices provide unique opportunities to develop and evaluate their own interpretive skills. A medical audit of screening outcomes represents an-

TABLE 2. Recommended results for screening outcome measurements

Parameter	Desirable goal
Positive predictive value 1 (PPV_1)[a]	5%–10%
Positive predictive value 2 (PPV_2)[b]	25%–40%
Tumors found—Stage 0 or 1[c]	> 50%
Tumors found—Minimal cancer[d]	> 30%
Node positivity[e]	> 25%
Cancers found per 1 000 screening examinations	2–10
Prevalent cancers found per 1 000 first-time screening examinations[f]	6–10
Incident cancers found per 1 000 follow-up screening examinations[g]	2–4
Recall rate[h]	≤ 10%

Sources: D'Orsi et al. (65) and Bassett et al. (66).

[a] PPV_1 = cancers/cases recommended for recall or biopsy based on abnormal screening examination.

[b] PPV_2 = cancers/cases recommended for biopsy or surgical consultation; biopsy method may be fine needle aspiration (FNA) cytology, core needle biopsy histology, or excisional biopsy.

[c] Stage 0 = ductal carcinoma in situ; Stage 1 = cancer with no evidence of lymph node metastasis.

[d] Minimal cancer = invasive cancer ≤ 1 cm or ductal carcinoma in situ.

[e] Node positivity = percent of cancers having positive lymph nodes.

[f] Prevalent cancer = cancer detected on screening among women with no prior history of screening.

[g] Incident cancer = cancer detected on screening among women with prior history of screening.

[h] Recall rate = percent of screening patients asked to return for supplementary mammographic views or ultrasound, for further evaluation of a screen-detected finding.

TABLE 3. American College of Radiology (ACR) Breast Imaging Reporting and Data System (BI-RADS) assessment categories: a standardized reporting method to provide unequivocal clinical recommendations and to facilitate imaging outcome audits

Category[a]	Recommendation
0	Need additional imaging evaluation and/or prior mammograms for comparison.
1	Negative.
2	Benign finding(s).
3	Probably benign finding. Initial short interval follow-up suggested.
4	Suspicious abnormality. Biopsy should be considered.
4a	Low suspicion for malignancy.
4b	Intermediate suspicion of malignancy.
4c	Moderate concern but not classic.
5	Highly suggestive of malignancy. Appropriate action should be taken.
6	Known biopsy. Proven malignancy. Appropriate action should be taken.

[a] Category 0 applies only to cases where breast imaging workup is incomplete; categories 1–6 are final assessment categories.

other means of monitoring and improving screening skills (64). A list of desirable goals for medical audits has been developed by the ACR (based on recommendations of the United States Agency for Healthcare Research and Quality), and is shown in Table 2 (65, 66). In some screening programs, such as the one conducted in Canada by the province of British Columbia, potential screening readers are required to take a standardized test in mammography interpretive skills (67). At present there is no similar subspecialty examination required for radiologists who want to begin reading screening mammograms in the United States.

REDUCING FALSE-POSITIVE INTERPRETATION RATES

Achieving the best tradeoff between high detection rates for early cancers and reasonably low false-positive interpretation rates should be a goal for every screening program. High sensitivity should never be achieved with the consequence of low specificity. Nor should a desire for high specificity preclude screening's basic goal of detecting early malignancy.

Formalized training in mammography interpretation can increase detection rates for early disease without any increase in false-positive biopsy rates (68). More experienced mammographers are better at finding early cancers and yet have lower callback rates for additional imaging of screen-detected findings (64). Second opinions on prebiopsy cases have been shown to reduce false-positive biopsy rates (69). Regularly scheduled mammographic-pathologic correlation conferences that review all biopsied cases provide an invaluable means for radiologists to continually improve their own interpretation performance (67). Medical audits allow radiologists to compare their own interpretive outcomes with outcomes for other radiologists in their practice, and with recommended values (66). Desirable goals for audit parameters, such as screening recall rates, detection rates for minimal cancers, and false-positive biopsy rates, are provided in Table 2.

With training, radiologists can learn to confidently identify "probably benign" lesions that have less than a 2% likelihood of malignancy. When such lesions receive short-interval follow-up rather than biopsy, false-positive biopsy rates are reduced. Only a tiny minority of such lesions will ever be biopsied as a result of subsequent change, and they are still detected at a curable stage (70).

Use of standardized assessment categories in mammography reports facilitates record-keeping for medical audits and conveys unequivocal case recommendations to the referring physician. These categories, shown in Table 3, are an integral part of the American College of Radiology Breast Imaging Reporting and Data System (65).

COST-EFFECTIVENESS OF SCREENING MAMMOGRAPHY

A recent study estimated that annual screening mammography beginning at age 40 years and continuing until age 79 years would cost US$ 18 800 per year of life expectancy saved (71). According to this study, the cost-effectiveness of screening mammography is in the same general range as that of other commonly accepted interventions such as screening for cervical cancer and osteoporosis. The cost per year of life gained from annual screening mammography is higher than that of screening for colorectal cancer, but is much lower than that of the use of seat belts and air bags in automobiles.

Although the cost per year of life gained by screening mammography is less than that of renal dialysis or heart transplants, these interventions are needed for only a tiny fraction of the population. Because screening mammography is recommended for all women age 40 and older, its total program cost must also be considered. There are 65 million women aged 40 to 89 in the United States. If every one of these women obtained an annual screening mammogram at a cost of US$ 90, the total cost would come to US$ 5.9 billion per year. The total annual cost for all United States health care expenditures, however, is even more staggering: US$ 1.4 trillion each year. Thus, even if every woman aged 40 to 89 obtained an annual mammogram, the total cost would be only 0.42% of the national expenditure on health care (72).

As a result of mammography and early treatment, most women who develop breast cancer today will not die from the disease. While breast cancer is the most common cancer among women and the second most common cause of cancer death among women, it accounts for only 3.9% of all causes of death among women in the United States (72). Nevertheless, allocation of 0.4% of all national health expenditures (or approximately 0.8% of all national health expenditures for women) to substantially reduce the death rate from a disease that accounts for 3.9% of all deaths among women would seem to be a reasonable policy.

Moreover, early detection will also reduce other health care expenditures, such as treatment of advanced primary cancers, diagnosis and treatment of distant metastases or recurrent disease, loss of work productivity, short-term disability, long-term disability, and terminal care costs.

CONCLUSIONS

There are many reasons to believe that screening mammography is capable of reducing breast cancer mortality around the world. The benefit of screening has been proven in randomized trials, and it has now been documented beyond the trials, in service screening programs. Quality assurance tests and parameters to ensure technical standards have been developed. There are also methods to teach and test interpretive expertise. False-positive interpretations, which result in excessive callbacks and biopsies, can be kept acceptably low. Radiation risks from screening are negligible compared to the known benefits from screening. Finally, screening mammography is also cost-effective.

SINOPSIS

El tamizaje mamográfico: una iniciativa de salud pública que ha dado buenos resultados

En este artículo se examina la capacidad del tamizaje mamográfico para reducir las tasas de mortalidad por cáncer de mama y se exploran los métodos de tamizaje que rinden los mayores beneficios y que reducen el número de interpretaciones positivas falsas en programas para la detección del cáncer mamario. La revisión comprende los resultados ya publicados que se han obtenido mediante los programas de tamizaje mamográfico en Europa y América del Norte, así como algunas medidas de garantía de la calidad orientadas a conseguir resultados iguales o incluso mejores en mujeres sometidas al tamizaje mamográfico en otras partes del mundo. Diversos ensayos clínicos aleatorizados en Europa y Estados Unidos de América han demostrado los beneficios de someter al tamizaje mamográfico a las mujeres entre los 40 y 70 años de edad. Alentados por estos buenos resultados, varios países escandinavos actualmente ofrecen programas de tamizaje mamográfico a toda la población femenina como parte integral de sus servicios de salud, con lo cual han logrado reducir la mortalidad por cáncer de mama hasta en 63% de las mujeres examinadas en esos programas. En los Estados Unidos, donde 61,5% de las mujeres de 40 años de edad o mayores declaran haberse sometido a una mamografía en el transcurso del año anterior, las tasas de mortalidad por cáncer de mama se han venido reduciendo pese a un aumento de la incidencia de la enfermedad. La calidad técnica de la mamografía en los Estados Unidos ha mejorado como resultado de adelantos en los equipos mamográficos, incluidos los sistemas de película y pantalla. Tales mejoras también se deben a que en cada servicio de mamografía se realizan pruebas de garantía de la calidad por exigencia del gobierno federal, conforme la Ley de Estándares de Calidad en Mamografía (Mammography Quality Standards Act), *que el Congreso de los Estados Unidos aprobó en 1992. Ciertos factores han llevado a una mayor detección de cánceres mamarios en etapa temprana: mejores técnicas mamográficas, la toma de dos proyecciones de cada seno, mamografías de tamizaje con periodicidad anual, y mejoras en la interpretación. La mamografía figura entre las 10 principales categorías temáticas comprendidas en los exámenes del Consejo Estadounidense de Radiología* (American Board

of Radiology). *Por otro lado, la MQSA exige que todo radiólogo que realiza mamografías obtenga créditos por asistir a actividades de educación continuada y que aplique criterios de interpretación normalizados en todos sus informes. Asimismo, el Colegio Estadounidense de Radiología* (American College of Radiology) *ha elaborado manuales para la garantía de la calidad técnica de las imágenes mamográficas obtenidas y los informes correspondientes, así como materiales didácticos y de autoevaluación para mejorar la interpretación. Aunque la mamografía no detecta todos los cánceres de mama, sigue siendo la mejor prueba de tamizaje que existe para detectar la enfermedad. La Sociedad Estadounidense contra el Cáncer* (American Cancer Society) *recomienda que el tamizaje mamográfico anual se inicie a más tardar a los 40 años de edad.*

Palabras clave: neoplasias de la mama, mamografía, tamizaje masivo, pautas prácticas, evaluación de programas, Estados Unidos.

REFERENCES

1. Baker LH. Breast Cancer Detection Demonstration Project: five-year summary report. CA Cancer J Clin. 1982; 32(4):194–225.
2. Shapiro S, Venet W, Strax P, Venet L. Periodic screening for breast cancer: the Health Insurance Plan project and its sequelae, 1963–1986. Baltimore: John Hopkins University Press; 1988.
3. Tabar L, Vitak B, Chen H-H, Duffy SW, Yen MF, Chiang C-F, et al. The Swedish Two-County Trial twenty years later. Radiol Clin North Am. 2000;38: 625–52.
4. Alexander FE, Anderson TJ, Brown HK, Forrest APM, Hepburn W, Kirkpatrick AE, et al. 14 years of follow-up from Edinburgh randomised trial of breast cancer screening. Lancet. 1999; 353: 1903–8.
5. Andersson I, Aspegren K, Janzon L, Landberg T, Lindholm K, Linell F, et al. Mammographic screening and mortality from breast cancer: the Malmo Mammographic Screening Trial. BMJ. 1988;297: 943–8.
6. Frisell J, Lidbrink E, Hellstrom L, Rutqvist LE. Follow-up after 11 years: update of mortality results in the Stockholm mammographic screening trial. Breast Cancer Res Treat. 1997;45:263–70.
7. Bjurstam N, Bjorneld L, Warwick J, Sala E, Duffy SW, Nystrom L, et al. The Gothenburg Breast Screening Trial. Cancer. 2001;97: 2387–96.
8. Miller AB, To T, Baines CJ, Wall C. Canadian National Breast Screening Study-2: 13-year results of a randomized trial in women aged 50–59 years. J Natl Cancer Inst. 2000;92:1490–9.
9. Miller AB, Baines CJ, To T, Wall C. Canadian National Breast Screening Study. I. Breast cancer and death rates among women aged 40–49 years. Canad Med Assoc J. 1992;147:1477–88.
10. Kopans DB, Feig SA. The Canadian National Breast Screening Study: a critical review. AJR Am J Roentgenol. 1993;161: 755–60.
11. Feig SA. Estimation of currently attainable benefit from mammographic screening of women aged 40–49 years. Cancer. 1995; 75:2412–9.
12. Feig SA. Increased benefit from shorter screening mammography intervals for women ages 40–49 years. Cancer. 1997; 80:2035–9.
13. Hendrick RE, Smith RA, Rutledge JH III, Smart CR. Benefit of screening mammography in women aged 40–49: a new meta-analysis of randomized controlled trials. Monogr Natl Cancer Inst. 1997;33: 87–92.
14. Chu KC, Smart CR, Tarone RE. Analysis of breast cancer mortality and stage distribution by age for the Health Insurance Plan clinical trial. J Natl Cancer Inst. 1998;80:1125–32.
15. Bjurstam N, Bjorneld L, Duffy SW. The Gothenburg Breast Screening Trial: first results on mortality, incidence, and mode of detection for women ages 39–49 years at randomization. Cancer. 1997;20: 2091–9.
16. Andersson I, Janzon L. Reduced breast cancer mortality in women under 50: updated results from the Malmo Mammographic Screening Program. Monogr Natl Cancer Inst. 1997;22:63–8.
17. Gotzsche PC, Olsen O. Is screening for breast cancer with mammography justifiable? Lancet. 2000;355:129–34.
18. Olsen O, Gotzsche PC. Cochrane review on screening for breast cancer with mammography. Lancet. 2001;358:1340–2.
19. Kopans DB. The most recent breast cancer screening controversy about whether mammography screening benefits women at any age: nonsense and nonscience. AJR Am J Roentgenol. 2003; 180:21–6.
20. Feig SA. How reliable is the evidence for screening mammography? Recent Results Cancer Res. 2003;163:129–39.
21. Duffy SW. Interpretation of the breast screening trials: a commentary on the recent paper by Gotzsche and Olsen. Breast. 2001; 10:209–12.
22. Duffy SW, Tabar L, Smith RA. The mammographic screening trials: commentary on the recent work by Olsen and Gotzsche. CA Cancer J Clin. 2002; 52:68–71.
23. Miettinen OS, Henschke CI, Pasmantier MW, Smith JP, Libby DM, Yankelevitz DF. Mammographic screening: no reliable supporting evidence? Lancet. 2002; 359:404–6.
24. Freedman DA, Petitti DB, Robins JM. On the efficacy of screening for breast cancer. Int J Epidemiol. 2004;33:43–55.
25. Gotzsche PC. On the benefits and harms of screening for breast cancer. Int J Epidemiol. 2004;33: 56–69.
26. Freedman DA, Petitti DB, Robins JM. Rejoinder. Int J Epidemiol. 2004;33:69–73.
27. Dean PB. Gotzsche's quixotic antiscreening campaign: nonscientific and contrary to Cochrane principles. J Am Coll Radiol. 2004;1:3–7.
28. Gotzsche PC. The debate on breast cancer screening with mammography is important. J Am Coll Radiol. 2004;1:8–14.
29. Feig SA, Hendrick RE. Radiation risk from screening mammography of women aged 40–49 years. Monogr Natl Cancer Inst. 1997; 22:119–24.
30. Law J. Risk and benefit associated with radiation dose in breast screening programmes: an update. Brit J Radiol. 1995; 68: 870–6.
31. Mettler FA, Upton AC, Kelsey CA, Ashby RN, Rosenberg RD, Linver MN. Benefits versus risks from mammography: a clinical reassessment. Cancer. 1996;776: 903–9.
32. Jansen JTM, Zoetelief J. Assessment of lifetime gained as a result of mammographic breast cancer screening using a computer model. Brit J Radiol. 1997; 70:619–28.
33. Beemsterboer PMM, Warmerdam PG, Boer R, de Koning HJ. Radiation risk of mammography related to benefit in screening programmes: a favorable balance? J Med Screen. 1998;5:81–7.
34. Mattsson A, Leitz W, Rutqvist LE. Radiation risk and mammographic screening of women from 40 to 49 years of age: effect on breast cancer rates and years of life. Brit J Cancer. 2000;82: 220–6.
35. Rothenberg LN, Feig SA, Haus AG, Hendrick RE, Howe GR, Logan-Young WW, et al. A guide to mammography

and other breast imaging procedures. Bethesda: National Council on Radiation Protection and Measurements; 2004. (NCRP Report No. 149).
36. Feig SA. Effect of service screening mammography on population mortality from breast carcinoma. Cancer. 2002;95: 451–7.
37. Tabar L, Vitak B, Chen H-H, Yen MF, Duffy SW, Smith RA. Beyond randomized trials: organized mammographic screening substantially reduces breast carcinoma mortality. Cancer. 2001;91: 1724–31.
38. Duffy SW, Tabar L, Chen H-H, Holmqvist M, Yen M-F, Abdsalah S, et al. The impact of organized mammography service screening on breast carcinoma mortality in seven Swedish counties: a collaborative evaluation. Cancer. 2002;95:458–69
39. Humphrey LL, Helfand M, Chan BKS, Woolf SH. Breast cancer screening: a summary of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med. 2002;137:347–60.
40. U.S. Preventive Services Task Force. Screening for breast cancer: recommendations and rationale. An Intern Med. 2002;137: 344–6.
41. Smith RA, Saslow D, Sawyer KA, Burke W, Costanza ME, Evans WP, et al. American Cancer Society guidelines for breast cancer screening: update 2003. CA Cancer J Clin. 2003;53:141–69.
42. Feig SA, D'Orsi CJ, Hendrick RE, Jackson VP, Kopans DB, Monsees B. American College of Radiology guidelines for breast cancer screening. AJR Am J Roentgenol. 1998;171:29–33.
43. Swan J, Breen N, Coates RJ, Rimer BK, Lee NC. Progress in cancer screening practice in the United States. Results from the 2000 National Health Survey. Cancer. 2003;97:1528–40.
44. American Cancer Society. Cancer prevention and early detection. Facts and figures 2005. Atlanta: ACS; 2005.
45. Tabar L, Larsson L-G, Andersson I, Duffy SW, Nystrom L, Rutqvist L-E, et al. Falun meeting on breast cancer screening with mammography in women aged 40–49 years: report of the organizing committee and collaborators. Int J Cancer. 1996;68:693–99.
46. Feig SA. Screening mammography: effect of image quality on clinical outcome. AJR Am J Roentgenol. 2002;178: 805–7.
47. Yaffe MJ, Hendrick RE, Feig SA, Rothenberg LN, Och J, Gagne R. Recommended specifications for new mammographic equipment: report of the ACR-CDC Focus Group on Mammography Equipment. Radiology. 1995;197:19–26.
48. Hendrick RE, Bassett LW, Botsco MA, Deibel D, Feig SA, Gray J, et al. Mammography quality control manual. Reston: American College of Radiology; 1999.
49. Monsees BS. The Mammography Quality Standards Act: an overview of the regulations and guidance. Radiol Clin North Am. 2000;38:759–72.
50. Suleiman OH, Spelic DC, McCrohan JL, Symonds GR, Houn F. Mammography in the 1990's: the United States and Canada. Radiology. 1999;210:345–51.
51. Sickles EA, Kopans DB. Deficiencies in the analysis of breast cancer screening data. J Natl Cancer Inst. 1993;85: 1621–4.
52. Morrison AS. Screening for chronic disease. 2nd ed. New York: Oxford University Press; 1992.
53. Seidman H, Gelb SK, Silverberg E, LaVerda N, Lubera JA. Survival experience in the Breast Cancer Detection Demonstration Project. CA Cancer J Clin. 1987; 37:258–90.
54. Alexander FE, Anderson TJ, Brown HK, Forrest APM, Hepburn W, Kirkpatrick AE, et al. The Edinburgh randomized trial of breast cancer screening: results after 10 years of follow-up. Br J Cancer. 1994;70:542–8.
55. Feig SA. Should breast self-examination be included in a mammographic screening program? Recent Results Cancer Res. 1990;119:151–64.
56. Berg WA. Rationale for a trial of screening breast ultrasound: American College of Radiology Imaging Network (ACRIN) 6666. AJR Am J Roentgenol. 2003;180: 1225–6.
57. Kriege M, Brekelmans CTM, Boetes C, Besnard PE, Zonderland HM, Obdeijn IM, et al. Efficacy of MRI and mammography for breast-cancer screening in women with a familial or genetic predisposition. N Engl J Med. 2004;351:427–37.
58. Pisano ED, Gatsonis C, Hendrick E, Yaffe M, Baum JK, Acharyya S, et al. Diagnostic performance of digital versus film mammography for breast-cancer screening. N Engl J Med. 2005;353(17): 1773–83.
59. Kopans DB. Double reading. Radiol Clin North Am. 2000;38: 719–24.
60. Feig SA, Yaffe MJ. Digital mammography, computer-aided detection, and other digital applications. In: Bassett LW, Jackson VP, Fu KL, Fu YS, eds. Diagnosis of disease of the breast. Philadelphia: W.B. Saunders; 2005.
61. Feig SA, Sickles EA, Evans WP, Linver MN. Re: changes in breast cancer detection and mammography recall rates after the introduction of a computer-aided detection system [letter]. J Natl Cancer Inst. 2004;96(16):1260–1.
62. Bassett LW, Feig SA, Hendrick RE, Jackson VP, Sickles EA. Breast disease (third series), test and syllabus. Reston: American College of Radiology; 2000.
63. Sickles EA. The American College of Radiology's Mammography Interpretive Skills Assessment (MISA) Examination. Semin Breast Dis. 2003;6:133–139.
64. Sickles EA, Ominsky SH, Sollitto RA, Galvin HB, Monitticciolo DL. Medical audit of a rapid-throughput mammography screening practice: methodology and results of 27,114 examinations. Radiology. 1990;15:323–7.
65. D'Orsi CJ, Bassett LW, Berg WA, Feig SA, Jackson VP, Kopans DB, et al. Breast Imaging Reporting and Data System—mammography. Fourth ed. Reston: American College of Radiology; 2003.
66. Bassett LW, Hendrick RE, Bassford TE, Butler PF, Carter D, DeBor M, et al. Quality determinants of mammography. Rockville: Department of Health and Human Services, Public Health Service; 1994.
67. Warren-Burhenne L. Screening Mammography Program of British Columbia Standardized Test for Screening Radiologists. Semin Breast Dis. 2003;6:140–7.
68. Linver MN, Paster B, Rosenberg RD, Key CR, Stidley CA, King VW, et al. Improvement in mammography interpretation skills in a community radiology practice after dedicated teaching courses: 2-year medical audit of 38,633 cases. Radiology. 1992;184:39–43.
69. Meyer JE, Sonnenfeld MR, Greenes RA, Stomper PC. Cancellation of preoperative breast localization procedures: analysis of 53 cases. Radiology. 1998; 169:629–30.
70. Sickles EA. Successful methods to reduce false-positive mammography interpretations. Radiol Clin North Am. 2000;38(4); 693–700.
71. Rosenquist CJ, Lindfors KK. Screening mammography beginning at age 40 years: a reappraisal of cost-effectiveness. Cancer. 1998; 82:2235–40.
72. Feig SA. Projected benefits and national health care costs from screening mammography. Semin Breast Dis. 2001;4: 62–7.

Manuscript received on 14 December 2004. Revised version accepted for publication on 8 August 2005.

A tomografia por emissão de pósitrons: uma nova modalidade na medicina nuclear brasileira

Cecil Chow Robilotta[1]

Como citar: Robilotta CC. A tomografia por emissão de pósitrons: uma nova modalidade na medicina nuclear brasileira. Rev Panam Salud Publica. 2006; 20(2/3):134–42.

SINOPSE

A medicina nuclear utiliza substâncias radioativas para diagnosticar e tratar doenças. Essa especialidade médica, capaz de fornecer informações fisiológicas e metabólicas sobre o corpo humano, se tornou uma ferramenta fundamental para a detecção precoce de muitas desordens, inclusive vários tipos de câncer. O presente artigo descreve os marcos históricos da medicina nuclear, os princípios físicos básicos que subjazem à tomografia por emissão de pósitrons (PET), um método de imagem usado para mapear a distribuição de radiofármacos no corpo para fins diagnósticos e terapêuticos, e o estado atual dessa modalidade no Brasil.

Palavras-chave: compostos radiofarmacêuticos, diagnóstico por imagem, PET, imagem funcional, Brasil.

A medicina nuclear é uma especialidade médica que utiliza compostos (ou moléculas) marcados com radionuclídeos, os radiofármacos, para fins de diagnóstico e terapia. Esses compostos seguem caminhos funcionais ou metabólicos específicos dentro dos pacientes, o que confere a essa modalidade diagnóstica uma característica de natureza biológica que as outras modalidades não possuem. A detecção externa da radiação emitida pelo radiofármaco permite diagnosticar precocemente muitas doenças, enquanto que as alterações anatômicas, muitas vezes, não se manifestam senão em estágios relativamente avançados, como no caso de diversos tipos de câncer.

Outra característica importante dos exames realizados com radiofármacos é a sua alta sensibilidade—isto é, é possível obter informações biológicas com concentrações de radiofármacos em níveis de nano ou picomolares. Além disso, a marcação de diferentes moléculas com um único radionuclídeo permite avaliações e estudos de um mesmo órgão ou sistema em seus aspectos tanto macroscópicos quanto moleculares. Tais estudos podem ser realizados através de imagens obtidas *in vivo* ou através de ensaios laboratoriais. Atualmente, a maior parte dos estudos radionuclídicos clínicos é de imagens, em especial as tomográficas.

Neste artigo, serão relatados, inicialmente, alguns fatos históricos sobre o desenvolvimento da medicina nuclear, seguidos de uma apresentação dos aspectos físicos da tomografia por emissão de pósitrons (*positron emission tomography*, PET); finalmente, será abordada a situação desta modalidade no Brasil.

[1] Universidade de São Paulo, Instituto de Física. Correspondência: Rua do Matão, Travessa R, 187, Cidade Universitária, Butantã, CEP 05508-900, São Paulo, SP, Brasil. E-mail: cecilcr@if.usp.br

UM POUCO DE HISTÓRIA

Pode-se dizer que a história da medicina nuclear começou com as descobertas da radioatividade natural por Henri Becquerel, em 1896, e de elementos radioativos naturais por Marie e Pierre Curie, em 1898 (descobertas pelas quais os três cientistas receberam o Prêmio Nobel de Física de 1903). Entretanto, foi o "princípio do traçador", proposto pelo químico húngaro George de Hevesy (1), em 1913, que realmente forneceu o fundamento biológico para a especialidade. Ele confirmou o princípio através de experiências com nitrato de chumbo marcado com o nuclídeo radioativo ^{210}Pb, mostrando sua absorção e seu movimento em plantas. Por esse feito, Hevesy recebeu o Prêmio Nobel de Química de 1943.

Em 1927, Herrmann L. Blumgart e Soma Weiss (2) realizaram a primeira medida da velocidade sangüínea, mediante a injeção de uma solução de radônio-C em um braço e a subseqüente verificação, com uma câmara de Wilson, de sua chegada no outro braço. Um avanço significativo na quantificação de substâncias como os hormônios no sangue foi alcançado com a técnica de ensaios radioimunológicos (*radioimmunoassay*, RIA), desenvolvida por Solomon A. Berson e Rosalyn S. Yalow (3). Por esse trabalho, Yalow foi a primeira física a receber um Prêmio Nobel de Medicina e Fisiologia, em 1977.

Em 1932, a invenção e a construção do cíclotron, por Ernest O. Lawrence e M. Stanley Livingstone (4), possibilitaram a produção de radionuclídeos artificiais, através do bombardeamento de núcleos-alvos por partículas positivas aceleradas (Prêmio Nobel de Física para Lawrence em 1939). Entretanto, a produção de quantidades suficientes de radionuclídeos para uso médico só se iniciou com o advento dos reatores nucleares, desenvolvidos durante a Segunda Guerra Mundial. O reator de Oak Ridge (Estados Unidos) começou sua produção em escala comercial em 1946, e o de Harwell (Reino Unido), em 1947.

Inicialmente, havia poucos radionuclídeos adequados para as aplicações médicas, e grande parte dos estudos clínicos enfocava a avaliação da glândula tireóide e suas disfunções, com o uso do ^{131}I na forma de iodeto. O principal detector usado era o contador Geiger-Müller, que indicava e media a presença do radiofármaco, sem, contudo, distinguir a energia da radiação gama detectada; tampouco produzia imagens da distribuição do composto.

Foi Benedict Cassen (5) quem, em 1951, ao inventar e construir o mapeador linear, deu início à era de diagnóstico por imagens radionuclídicas. Em 1958, Hal Anger (6) desenvolveu a câmara de cintilação, um sistema de formação de imagens que não exigia que o detector fosse movimentado e que apresentava maior resolução geométrica, além da possibilidade de se obter projeções diferentes de uma mesma distribuição de radiofármaco. As informações adquiridas pela câmara de cintilação eram transformadas em imagens e exibidas por um tubo de raios catódicos, de modo que podiam ser registradas em filmes ou chapas fotográficas. As modernas câmaras usadas hoje são derivadas da câmara Anger.

O grande poder diagnóstico da medicina nuclear se firmou quando Paul Harper (7) e sua equipe introduziram o radionuclídeo ^{99m}Tc como marcador. Esse nuclídeo decai por transição isomérica, emite um fóton com energia de 140 keV, bastante adequado para a câmara que Anger inventou, e possui meia-vida física de 6 horas, possibilitando estudos em intervalos de tempo razoáveis. Além disso, ele é produzido pelo gerador ^{99}Mo – ^{99m}Tc, um sistema que contém o par de radionuclídeos pai (^{99}Mo) – filho (^{99m}Tc) e que permite a separação e a extração do elemento filho. O radionuclídeo ^{99m}Tc é continuamente produzido pela desintegração do ^{99}Mo, e sua extração periódica possibilita um fornecimento constante nos próprios centros de medicina nuclear (8). Outra característica muito importante é a facilidade com que o ^{99m}Tc consegue marcar um número muito grande de fármacos, o que o torna aplicável em estudos de quase todos os órgãos e sistemas do corpo humano. Dados recentes da Sociedade de Medicina Nuclear dos Estados Unidos indicam que existem mais de 100 procedimentos diferentes na medicina nuclear para fins diagnósticos que utilizam radiofármacos específicos, que cobrem um número considerável de estudos sobre a fisiologia dos sistemas orgânicos do corpo (9).

Com o desenvolvimento dos computadores, nos anos 1960, foi possível adquirir, armazenar e processar as imagens obtidas com as câmaras de cintilação para, por exemplo, extrair parâmetros fisiológicos, corrigir distorções associadas ao processo de formação de imagens, assim como evidenciar estruturas de interesse. Na década de 1970, novos avanços em computação e, principalmente, no desenvolvimento e na implementação de métodos de reconstrução permitiram a realização de tomografias por emissão de fótons únicos (*single photon emission computed tomography*, SPECT —o que foi feito por David E. Kuhl e sua equipe na Universidade da Pensilvânia (10)— e de PET, por Gordon L. Brownell e colaboradores no Hospital Geral de Massachusetts (11, 12) e por Michael E. Phelps e colegas na Universidade da Califórnia em Los Angeles (13, 14). Vale destacar a contribuição de David Chesler (15) ao propor e reconstruir cortes tomográficos de emissão e transmissão pelo método da retroprojeção, em 1971. Variantes desse método de reconstrução ainda são muito usadas na rotina clínica.

Uma parte dos procedimentos clínicos disponíveis utiliza as projeções planas das distribuições volumétricas contendo o radiofármaco para extrair informações, enquanto que a outra faz uso das imagens tomográficas por emissão, reconstruídas a partir das projeções, para apresentar os conteúdos em cortes ou volumes.

Os estudos realizados diretamente sobre as projeções podem ser estáticos ou dinâmicos. Estes são constituídos por séries temporais de imagens que acompanham determinado processo biológico. Pelo fato de as imagens serem projeções planas, não é possível a localização precisa do radiofármaco no corpo. No entanto, a presença e a evolução temporal desse material no sistema funcional específico são informações essenciais e, não raro, suficientes para a detecção de muitas moléstias que não podem ser detectadas por outros métodos de diagnóstico por imagens. Além disso, a possibilidade de quantificar parâmetros fisiológicos com processamentos adequados torna os estudos planos particularmente úteis, por exemplo, na avaliação das funções renais e do sistema gástrico.

Desde a sua introdução em aplicações clínicas, as técnicas de tomografia por emissão, SPECT e PET, vêm suprindo a comunidade médica com informações biológicas distribuídas no espaço e no tempo. Entretanto, devido à meia-vida física extremamente curta dos emissores de pósitron viáveis e ao alto custo de implantação e execução, só nos anos 1990 a tecnologia PET se fixou definitivamente, mesmo nos países desenvolvidos, na rotina de grande parte das clínicas nucleares, com o uso da ^{18}F-fluordeoxiglicose (FDG), composto análogo à glicose, marcado inicialmente com ^{14}C por Louis Sokoloff e equipe (16) e, posteriormente, com ^{18}F por Tatuo Ido e colaboradores (17). A SPECT, por outro lado, foi absorvida de imediato, e muitos radiofármacos (a maior parte marcada com ^{99m}Tc) e procedimentos foram e continuam sendo desenvolvidos.

Associada ao desenvolvimento farmacológico, a pesquisa para melhorar a instrumentação, com o uso de detectores mais eficientes e de eletrônica mais rápida, tem impulsionado tanto a SPECT como a PET em suas aplicações. Em especial, a recente combinação da PET com a tomografia computadorizada (*computed tomography*, CT) —o sistema combinado PET/CT— por David W. Townsend e equipe, na Universidade de Pittsburgh (18), acoplando um tomógrafo por emissão de pósitrons a um outro multicortes por transmissão de raios X, permite a extração máxima dos benefícios que essas modalidades podem oferecer, em conjunto, aos médicos e seus pacientes.

Como conseqüência da evolução instrumental e farmacológica, as imagens radionuclídicas estão fornecendo informações cada vez mais em nível molecular, de modo que a escolha dos métodos de reconstrução tomográfica e as correções, assim como as quantificações em tomografia por emissão, têm merecido atenção especial por parte da comunidade. Pesquisas que enfocam a busca de resultados quantitativos mais precisos, confiáveis e rápidos estão sendo realizadas em inúmeros centros do mundo, inclusive no Brasil.

Segundo dados de 2002 da Comissão Nacional de Energia Nuclear (CNEN), existem, no território brasileiro, mais de 250 clínicas de medicina nuclear, com um número similar de câmaras SPECT, das quais cerca de 75% estão localizadas nas regiões Sudeste e Sul. Em 1998, entrou em operação, na Cidade de São Paulo, o primeiro sistema capaz de produzir imagens tomográficas com o uso de emissores de pósitron. O equipamento, uma câmara PET/SPECT, podia também ser usado para a obtenção de imagens SPECT. Atualmente, além da Cidade de São Paulo, o Rio de Janeiro e Brasília também possuem clínicas que oferecem estudos de PET.

TOMOGRAFIA POR EMISSÃO DE PÓSITRONS: ASPECTOS FÍSICOS

A tomografia por emissão de pósitrons, ou PET, como o próprio nome diz, é um mapa da distribuição de um radiofármaco emissor de pósitrons em um determinado corte do corpo.

O decaimento por emissão de pósitron pode ser descrito por,

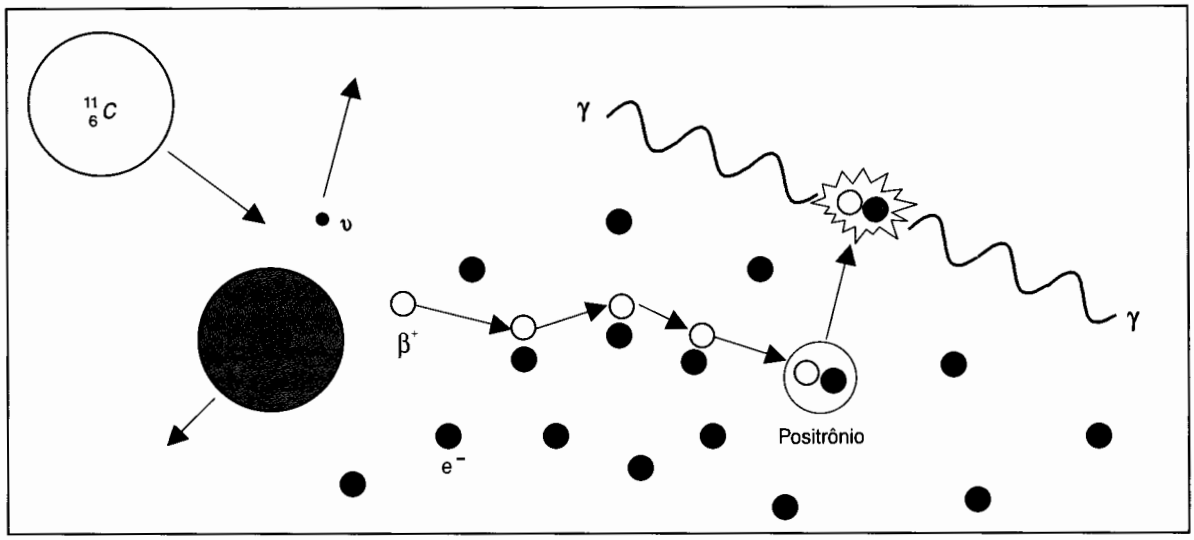
$$ {}^{A}_{Z}X \rightarrow {}^{A}_{Z-1}Y + {}^{0}_{+1}e + \upsilon, $$

onde o radionuclídeo pai ${}^{A}_{Z}X$ decai para o nuclídeo filho ${}^{A}_{Z-1}Y$, com a subseqüente emissão de um pósitron (β^+) e de um neutrino (υ).

A figura 1 ilustra o esquema de decaimento do ${}^{11}_{6}C$ para ${}^{11}_{5}B$, o caminho percorrido até a aniquilação do pósitron com um elétron do meio e a conseqüente formação do par de fótons de 511 keV cada, em direções opostas. Esses fótons são detectados externamente, e a informação é usada para a reconstrução das tomografias.

A idéia de utilizar emissores de pósitrons para detectar tumores de cérebro foi proposta, em 1951, separadamente, por Gordon L. Brownell ao neurocirurgião William H. Sweet (19), e por Frank R. Wrenn e colaboradores (20). Entretanto, somente o sistema idealizado por Brownell (21) era capaz de produzir um mapa aproximado da distribuição do radiofármaco através da detecção do par de fótons de aniquilação com dois cristais de iodeto de sódio ativado com

FIGURA 1. Tomografia por emissão de pósitrons (PET): esquema de decaimento do $^{11}_{6}C$ para $^{11}_{5}B$ e da aniquilação do pósitron com elétron e formação do par de fótons de 511 keV cada, em direções opostas[a]



[a] O positrônio é o sistema formado pelo pósitron e o elétron antes de sua aniquilação, e que resulta na produção do par de fótons.

TABELA 1. Principais emissores de pósitrons e suas características

Radionuclídeo	$T_{1/2}$ (min)	$E_{\beta+}$ max (MeV)	Alcance máximo em água (mm)
Carbono-11 ^{11}C	20,4	0,959	5,0
Nitrogênio-13 ^{13}N	9,96	1,197	5,4
Oxigênio-15 ^{15}O	2,07	1,738	8,2
Flúor-18 ^{18}F	109,8	0,650	2,4
Gálio-68 ^{68}Ga	68	1,899	9,4
Rubídio-82 ^{82}Rb	1,3	3,350	15,6

tálio [NaI(Tl)], colocados em lados opostos da cabeça do paciente e acoplados a um sistema de varredura (22). Ainda nos anos 1950, Michel M. Ter-Pogossian e William E. Powers (23) determinaram o conteúdo de oxigênio em neoplasias malignas com ^{15}O.

Os radionuclídeos emissores de pósitron usados na medicina são produzidos por cíclotrons. A tabela 1 mostra os principais desses radionuclídeos e algumas de suas características físicas. Os radionuclídeos ^{11}C e ^{15}O são de elementos constituintes de organismos vivos, fato que os torna muito adequados para a marcação de biomoléculas. Por outro lado, como suas meias-vidas físicas são muito curtas, assim como a do ^{13}N, só podem ser utilizados se o acelerador para sua produção estiver nas dependências do próprio centro diagnóstico.

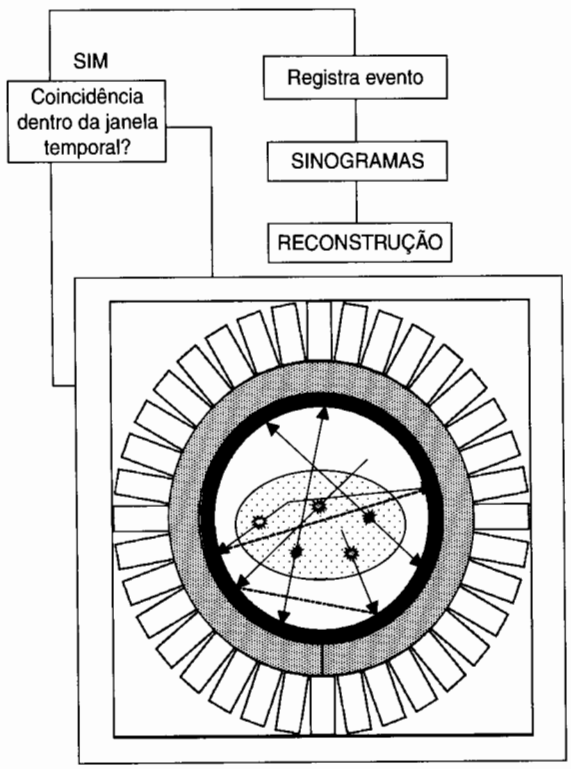
Hoje, o radionuclídeo mais usado é o ^{18}F, marcando a fluordeoxiglicose (FDG), um análogo da

glicose que é consumido por células ativas, de tal maneira que sua presença indica função metabólica tecidual. Os quase 110 minutos de meia-vida do ^{18}F permitem que a FDG marcada seja transportada a locais de exame razoavelmente afastados do centro de produção (em torno de 100 km por transporte terrestre), de modo que a PET realizada com (^{18}F)FDG é a dominante, com aplicações principalmente em oncologia e, em menor extensão, em neurologia, psiquiatria e cardiologia.

As imagens por emissão de pósitrons podem ser obtidas com dois tipos de equipamento: os sistemas dedicados e os baseados em câmaras de cintilação. Ambos utilizam a colimação eletrônica para registrar os eventos de coincidência, isto é, os pares de fótons que forem detectados em diferentes posições, dentro de um intervalo de tempo muito curto para caracterizar a coincidência, pré-definido pelo fabricante, vão constituir esses eventos. A linha que une os dois fótons detectados em coincidência define a linha de resposta, que é usada, posteriormente, na reconstrução do corte tomográfico. Se os dois fótons detectados provierem de uma mesma aniquilação, sem interagir com o meio, o evento é chamado de coincidência verdadeira, e o local de aniquilação estará sobre a linha de resposta. Se os fótons forem originados de uma mesma aniquilação, porém um deles tiver interagido com o meio, o local de aniquilação não estará mais sobre a linha de resposta e o evento é denominado espalhado. Se ambos os fótons se originarem de aniquilações diferentes, o par detectado definirá uma linha de resposta errada, resultando em um evento aleatório. A figura 2 ilustra esses eventos para um sistema dedicado, que é usado somente em estudos de PET.

Os modernos sistemas de PET dedicados são formados por mais de 15 000 elementos de detecção, dispostos em anéis adjacentes, que vão registrar os eventos de coincidência dentro de intervalos da ordem de 10 a 12 nanossegundos. Os

FIGURA 2. Esquema de detecção por coincidência (pares de fótons) em sistemas dedicados de tomografia de emissão de pósitrons (PET)[a]



[a] Linhas de resposta cheias = eventos verdadeiros; linha de resposta tracejada = evento espalhado; linha de resposta traço-ponto = evento aleatório.

elementos de detecção são pequenos cristais de cintilação, BGO ($Bi_4Ge_3O_{12}$) ou LSO [($Lu_2SiO_5(Ce)$], agrupados e acoplados a tubos fotomultiplicadores. As saídas dos tubos vão alimentar um sistema complexo de análise, discriminação e processamento que vai fornecer, no final, a imagem tomográfica. Como muitas aniquilações ocorrem simultaneamente nos volumes que contêm o radiofármaco, nem todos os eventos de coincidência registrados são formados por fótons criados na mesma aniquilação. Assim, é necessário excluir ou minimizar os eventos não-verdadeiros, para que a imagem reconstruída represente, da maneira mais próxima possível, a distribuição original.

Os sistemas baseados na câmara de cintilação são aqueles usados em SPECT dotados de circuitos de coincidência, isto é, a colimação eletrônica é instalada entre os dois detectores posicionados em oposição, permitindo o registro de eventos de coincidência e a posterior reconstrução de imagens por emissão de pósitrons. Assim, esse tipo de equipamento constitui uma alternativa ao custoso tomógrafo dedicado, principalmente quando a demanda não for suficiente para seu uso contínuo em PET. A grande diferença com relação ao tomógrafo dedicado está na menor eficiência de detecção dos fótons de 511 keV pela câmara de cintilação. Mesmo assim, em diversas situações, os resultados obtidos com sistemas PET/SPECT fornecem informações clinicamente importantes.

Ambos os sistemas, dedicado ou não, permitem a aquisição de informações nos modos 2D e 3D. Os algoritmos de reconstrução mais utilizados são os iterativos e implementados em 2D. No caso de aquisição 3D, os dados registrados são reamostrados para que se possa aplicar a reconstrução 2D, que é menos custosa computacionalmente.

Várias correções são essenciais para se garantir a qualidade das imagens reconstruídas: de decaimento, devido à meia-vida física curta do ^{18}F; de atenuação e espalhamento, para reduzir os efeitos resultantes de interações dos fótons de 511 keV com os tecidos; de eventos de coincidência aleatórios, que alocam erroneamente as origens das aniquilações; além de outras de menor impacto. Normalizações também devem ser realizadas para compensar a resposta não-uniforme do sistema de formação de imagens. Algumas dessas correções são implementadas no *hardware*, enquanto que outras são executadas via *software*, podendo ser incorporadas no próprio algoritmo de reconstrução.

É essencial que testes de calibração e controle de qualidade sejam executados periodicamente, para garantir a confiabilidade e a qualidade dos resultados, em especial se forem almejadas quantificações.

A TOMOGRAFIA POR EMISSÃO DE PÓSITRONS NO BRASIL

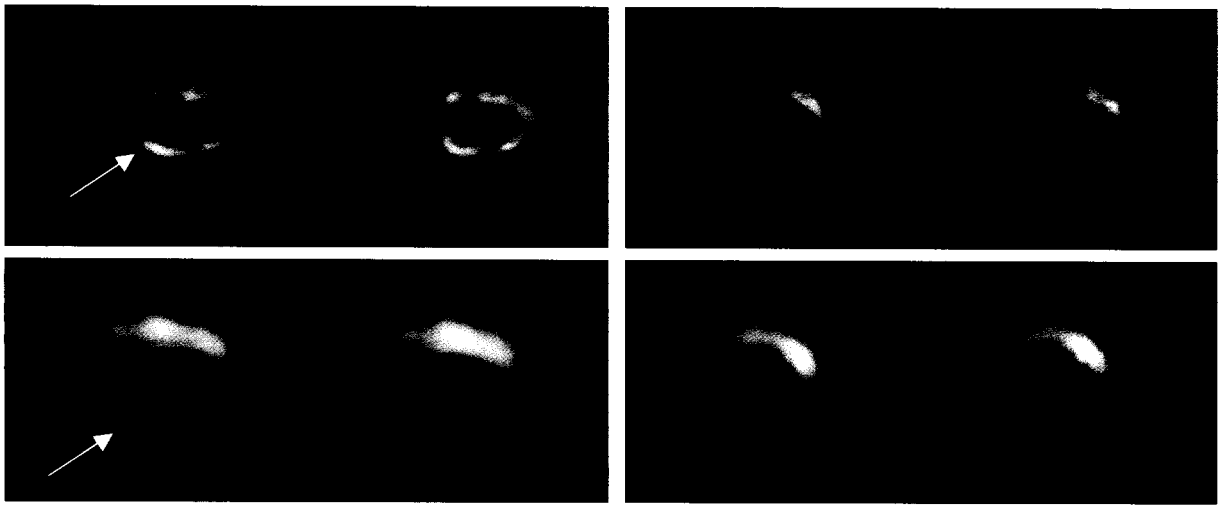
No Brasil, a tecnologia PET foi introduzida em 1998, com a instalação de uma câmara PET/SPECT no Serviço de Radioisótopos do Instituto do Coração (InCor) do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo (HC-FMUSP). Essa nova tecnologia estendeu a metodologia já bem estabelecida em SPECT a PET a um custo reduzido e sustentável quando comparado ao custo da PET dedicada, além de permitir o uso contínuo da câmara quando da ausência de fornecimento da (^{18}F)FDG. Posteriormente, outras cinco câmaras PET/SPECT foram instaladas na Cidade de São Paulo e uma na Cidade de Campinas, distante cerca de 100 km. Dessas sete câmaras, três continuam produzindo imagens PET, enquanto que as outras são usadas somente em SPECT. Atualmente, mais dois sistemas desse tipo operam nas cidades do Rio de Janeiro e Brasília.

Os sistemas PET/SPECT familiarizaram a comunidade médica brasileira com a utilização de emissores de pósitrons, principalmente do ponto de vista dos protocolos clínicos, pois, até então, todos os estudos eram feitos com compostos emissores de fótons, como o ^{99m}Tc. Estima-se que, desde a instalação da primeira câmara PET/SPECT, cerca de 5 000 exames foram realizados com esse tipo de equipamento em pacientes de todo o Brasil e de alguns países vizinhos.

No final de 2002, foi instalado o primeiro tomógrafo dedicado a PET no Serviço de Radioisótopos do InCor, substituindo o sistema PET/SPECT. Até o início de 2004, outros três sistemas, do tipo combinado PET/CT, foram instalados na Cidade de São Paulo, todos em hospitais privados. A grande vantagem desses sistemas está na aquisição de duas modalidades de imagens a partir do mesmo referencial, isto é, o paciente não é deslocado entre um exame e outro, facilitando a fusão das duas imagens para a identificação das regiões analisadas. Devido à maior sensibilidade dos sistemas dedicados, é possível realizar uma quantidade maior de exames do que com os sistemas baseados em câmaras de cintilação, fato ilustrado pelos cerca de 2 200 exames executados nos primeiros 18 meses da instalação dos sistemas dedicados.

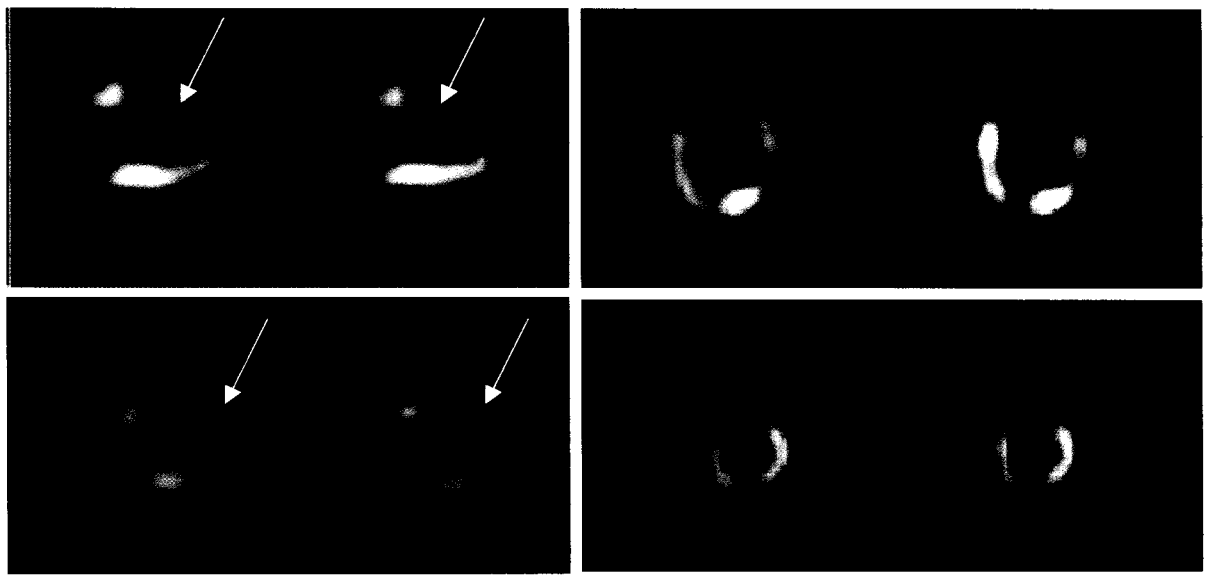
Quanto à preparação dos pacientes, novos cuidados foram introduzidos, já que a FDG é consumida por tecidos metabolicamente ativos. Além disso, a manipulação de material com produção de fótons de aniquilação de 511 keV, bem maior do que os 140 keV do fóton do ^{99m}Tc, o radionuclídeo mais usado em medicina nuclear, exigiu uma nova abordagem quanto à proteção radiológica. Por

FIGURA 3. Estudo de viabilidade do miocárdio com tomografias por emissão de pósitrons (PET) e de fótons simples (SPECT)[a]



[a] Músculo viável: as imagens de metabolismo de glicose (PET), com FDG marcada com ^{18}F (linha superior), mostram parede inferior ativa (indicada pela seta branca), enquanto que as imagens de perfusão sangüínea do miocárdio (SPECT), com tálio-201 (linha inferior, com fator de aumento maior que a linha superior), mostram a mesma parede hipoperfundida (indicada pela seta branca). As imagens foram gentilmente cedidas pelo Dr. J.C. Meneghetti, Serviço de Radioisótopos do Instituto do Coração, São Paulo (SP), Brasil.

FIGURA 4. Identificação a partir de tomografia por emissão de pósitrons (PET) de músculo não-viável para fins de revascularização do miocárdio[a]



[a] As imagens de metabolismo de glicose (PET), com FDG marcada com ^{18}F (linha superior), mostram parede anterior pouco ativa, enquanto que as imagens de perfusão sangüínea do miocárdio (SPECT), com MIBI marcado com ^{99m}Tc (linha inferior), mostram a mesma parede hipoperfundida. As imagens do lado esquerdo correspondem a cortes segundo o eixo cardíaco longo vertical, e as do lado direito, a cortes segundo o eixo cardíaco menor. A maior intensidade é representada por tonalidade mais clara, enquanto que a menor, por tonalidade mais escura. As imagens foram gentilmente cedidas pelo Dr. J.C. Meneghetti, Serviço de Radioisótopos do Instituto do Coração, São Paulo (SP), Brasil.

outro lado, a meia-vida física bastante curta facilitou o tratamento do rejeito.

A adoção de sistemas baseados em câmaras de cintilação também motivou os físicos-médicos que atuam em medicina nuclear a ampliar seus conhecimentos e adaptar procedimentos de controle de qualidade (24) e proteção radiológica, assim como desenvolver estudos e metodologias

para a quantificação (25), reconstrução totalmente 3D (26) e fusão de imagens. A grande parte dos resultados conseguidos pode ser facilmente estendida aos sistemas dedicados.

Como no resto do mundo, a grande contribuição clínica dos estudos de PET com (^{18}F)FDG no Brasil está na oncologia, para detecção, localização e estadiamento de tumores primários, diferenciação entre tumores benignos e malignos, detecção e avaliação de recorrências e metástases, diferenciação entre recorrências e alterações pós-cirúrgicas, seguimento e avaliação de procedimentos terapêuticos. Os resultados obtidos, em especial aqueles com os sistemas combinados PET/CT, têm ajudado a indicar, ajustar e, até mesmo, alterar procedimentos em pacientes com tumores de diversos tipos.

A introdução da tomografia por emissão de pósitrons, em particular o uso de sistemas PET/ CT, está propiciando uma interação maior entre médicos nucleares e radiologistas no que se refere à análise e à avaliação das imagens compostas de anatomia e fisiologia, e entre os médicos especialistas em imagens e oncologistas no que tange aos resultados obtidos. Além disso, a possibilidade de utilização direta das informações metabólicas fornecidas pelas imagens de PET, combinadas com as informações anatômicas presentes na tomografia computadorizada por raios X, está também contribuindo para tornar o planejamento radioterapêutico mais adequado a cada paciente, principalmente quanto à proteção dos tecidos sãos ao redor do tumor.

Com relação às outras aplicações, o impacto tem sido menor, um pouco mais significativo em neurologia e psiquiatria do que em cardiologia, seguindo a distribuição das aplicações em países mais experientes em tecnologia PET. As figuras 3 e 4 ilustram dois estudos da viabilidade do miocárdio: um mostra um caso de músculo viável (ou hibernante), em que a intervenção com o objetivo de revascularização pode ser bem-sucedida, enquanto que o outro mostra que a atividade celular na região com hipoperfusão é muito baixa, indicando que o músculo é pouco viável.

Vale comentar que, segundo a legislação brasileira em vigor, a produção e a comercialização de radionuclídeos são exclusividade da Comissão Nacional de Energia Nuclear (CNEN). No momento, só duas instituições produzem o radiofármaco (^{18}F) FDG no Brasil: o Instituto de Pesquisa em Energia Nuclear (IPEN/CNEN), em São Paulo (desde 1998), e o Instituto de Engenharia Nuclear (IEN/CNEN), no Rio de Janeiro (desde 2004). Esse fato limita a difusão dessa modalidade de imagem a outras regiões do território. Além disso, tal exclusividade é uma das duas causas para a tardia e lenta introdução da PET no cenário nacional. A outra razão é o alto custo da tecnologia e dos exames, que não são cobertos pelo sistema de saúde público. Dessa maneira, somente pacientes particulares e os que possuem planos de saúde que autorizam o reembolso têm acesso a essa tecnologia, que já é adotada há mais de uma década nos países desenvolvidos.

Atualmente, várias clínicas de São Paulo e Rio de Janeiro iniciaram o processo de compra de novos tomógrafos dedicados ou de sistemas PET/CT, pois a produção de (^{18}F)FDG nessas cidades já está em regime que permite um tal aumento. Além disso, a CNEN está considerando a instalação de mais dois cíclotrons, um na Região Nordeste e outro na Sudeste, com o objetivo de difundir e ampliar os estudos nessa área. Certamente, isso demandará um aumento de recursos humanos qualificados, tanto em termos de médicos especialistas como de físi-cosmédicos, radiofarmacêuticos, tecnólogos e pessoal de enfermagem, aspecto que deverá ser considerado pelas comunidades envolvidas em PET no país.

SYNOPSIS

Positron emission tomography: a new modality in Brazilian nuclear medicine

In nuclear medicine, radioactive substances are used to diagnose and treat disease. This medical specialty, that can provide information about the human body's physiologic and metabolic processes, has become a key diagnostic tool for the early detection of many different disorders, including various types of cancer. The present article describes the historical milestones in nuclear medicine; the basic physical principles underlying positron emission tomography (PET), which is an imaging method used to map the distribution of radiopharmaceuticals in the body for diagnostic and therapeutic purposes, and the current status of this modality in Brazil.

Key words: radiopharmaceuticals, diagnostic imaging, PET, functional image, Brazil.

REFERÊNCIAS

1. De Hevesy G. Radioelements as tracers in physics and chemistry. Chem News. 1913;108:166.
2. Blumgart HL, Weiss S. Studies on the velocity of blood flow. J Clin Invest. 1927;4(1):15–31.
3. Berson SA, Yalow RS, Bauman A, Rothschild MA, Newerly K. Insulin-I131 metabolism in human subjects: demonstra-

tion of insulin binding globulin in the circulation of insulin-treated subjects. J Clin Invest. 1956;35(2):170–90.
4. Lawrence EO, Livingstone MS. The production of high-speed light ions without the use of high voltage. Phys Rev. 1932; 40(1):19–30.
5. Cassen B, Curtis L, Reed C, Libby R. Instrumentation for ^{131}I use in medical studies. Nucleonics. 1951;9(2):46–50.
6. Anger HO. Scintillation camera. Rev Sci Instrum. 1958;29(1):27–33.
7. Harper PV, Beck R, Charleston D, Lathrop KA. Optimization of a scanning method using technetium-99m. Nucleonics. 1964;22(1):50–4.
8. Cherry SR, Sorenson JA, Phelps ME. Physics in nuclear medicine. 3ª ed. Filadélfia: WB Saunders; 2003.
9. Society of Nuclear Medicine. What is nuclear medicine? [folheto]. Disponível em http://interactive.snm.org/index.cfm?PageID=3106&RPID=972. Acessado em agosto de 2005.
10. Kuhl DE, Edwards RQ, Ricci AR, Yacob RJ, Mich TJ, Alavi A. The Mark IV system for radionuclide computed tomography of the brain. Radiology. 1976;121 (2):405–13.
11. Brownell GL, Burnham CA. MGH positron camera. NEREM Record. 1972; 2: 117.
12. Burnham CA, Brownell GL. A multicrystal positron camera. IEEE Trans Nucl Sci. 1972;NS-19(3):201–5.
13. Phelps ME, Hoffman EJ, Mullani NA, Ter-Pogossian MM. Application of annihilation coincidence detection to transaxial reconstruction tomography. J Nucl Med. 1975;16(3):210–24.
14. Ter-Pogossian MM, Phelps ME, Hoffman EJ, Mullani NA. A positron emission transaxial tomograph for nuclear medicine imaging (PETT). Radiology. 1975;114(1):89–98.
15. Chesler DA. Three-dimensional activity distribution from multiple positron scintigraphs. J Nucl Med. 1971;12(6): 347–8.
16. Sokoloff L, Reivich M, Kennedy C, Des Rosiers MH, Patlak CS, Pettigrew KD, et al. The [^{14}C] deoxyglucose method for the measurement of local cerebral glucose utilization: theory, procedure and normal values in the conscious and anesthetized albino rat. J Neurochem. 1977;28(5):897–916.
17. Ido T, Wan C-N, Casella V, Fowler JS, Wolf AP, Reivich M, et al. Labeled 2-deoxy-D-glucose analogs: ^{18}F labeled 2-deoxy-2-fluoro-D-glucose, 2-deoxy-2-fluoro-D-mannose and ^{14}C-2-deoxy-2-fluoro-D-glucose. J Label Compound Radiopharm. 1978;14:175–83.
18. Beyer T, Townsend DW, Brun T, Kinahan PE, Charron M, Roddy R, et al. A combined PET/CT scanner for clinical oncology. J Nucl Med. 2000; 41(8):1369–79.
19. Sweet WH. The use of nuclear disintegration in the diagnosis and treatment of brain tumor. N Engl J Med. 1951; 245(23):875–8.
20. Wrenn FR, Good ML, Handler P. The use of positron-emitting radioisotopes for the localization of brain tumors. Science. 1951;113(1940):525–7.
21. Brownell GL, Sweet WH. Localization of brain tumors with positron emitters. Nucleonics. 1953;11(11):40–5.
22. Brownell GL. A history of positron imaging. Disponível em: http://www.mit.edu/~glb. Acessado em junho de 2005.
23. Ter-Pogossian MM, Powers WE. The use of radioactive oxygen-15 in the determination of oxygen content in malignant neoplasms. Em: Radioisotopes in scientific research. Londres: Pergamon; 1958.
24. Aoki SM. Uma proposta para avaliação do desempenho de câmaras PET/SPECT [dissertação de mestrado]. São Paulo: Instituto de Física da USP; 2002.
25. Pozzo L. Tomografia por emissão de pósitrons com sistemas PET/SPECT: um estudo da viabilidade de quantificação [tese de doutorado]. São Paulo: Instituto de Física da USP; 2005.
26. Palladino FH. Reconstrução 3D de imagens em tomografia por emissão de pósitrons com câmeras de cintilação [tese de doutorado]. São Paulo: Instituto de Física da USP; 2004.

Manuscrito recebido em 14 de dezembro de 2004. Aceito em versão revisada em 22 de abril de 2005.

Las nuevas tecnologías: necesidades y retos en radioterapia en América Latina

María Esperanza Castellanos[1]

Forma de citar: Castellanos ME. Las nuevas tecnologías: necesidades y retos en radioterapia en América Latina. Rev Panam Salud Publica. 2006; 20(2/3):143–50.

SINOPSIS

La experiencia acumulada en más de un siglo de práctica de radioterapia ha puesto de manifiesto su importancia no solamente para la atención paliativa de una parte de los casos de cáncer, sino principalmente para la curación de una proporción aun mayor de esos pacientes. Teniendo en cuenta la evolución tecnológica, el acceso cada vez mayor que tienen los países en desarrollo a estos métodos y la cobertura actual en América Latina, los esfuerzos en esta área se deben dirigir a mejorar la calidad de los servicios y de los centros de radioterapia ya instalados. Para ello se debe completar su parque tecnológico, ampliar los servicios que prestan y cumplir los requerimientos mínimos de calidad establecidos para instalaciones del nivel 2. Cada centro debe estar en condiciones de realizar todas las etapas del proceso de radioterapia —desde la simulación hasta la verificación del tratamiento y el seguimiento de los pacientes— con una calidad adecuada (nivel 2). Para ello deben contar con la tecnología necesaria y con el personal debidamente capacitado. Los esfuerzos cooperativos en la Región deben tener también como prioridad contribuir a que los países adopten guías nacionales de tratamiento que contemplen todas las etapas del proceso de radioterapia y fomentar la puesta en marcha de programas validados de garantía de la calidad.

Palabras clave: radioterapia, garantía de la calidad, necesidades y demandas de servicios de salud, América Latina.

La radioterapia es un método de tratamiento de lesiones malignas en el que se utilizan principalmente radiaciones ionizantes. El método exige una infraestructura tecnológica compleja, personal especializado —tanto de médicos como de otros profesionales— y la aplicación de procedimientos y protocolos orientados a garantizar no solamente la eficacia del tratamiento antitumoral, sino también la adecuada protección de los tejidos y órganos adyacentes contra los efectos nocivos de la radiación.

El nacimiento de la terapia con radiaciones ionizantes está directamente relacionado con tres descubrimientos que ocurrieron hace más de un siglo y que tuvieron una gran repercusión en el desarrollo de la ciencia. En 1895, Wilhelm Conrad Roentgen informó del descubrimiento de "un nuevo tipo de radiación" que posteriormente se denominó rayos X; en 1896, Antoine Henri Becquerel descubrió la radiactividad natural; y en 1898, Marie y Pierre Curie produjeron por primera vez el polonio, y más tarde, el radio puro.

Esos descubrimientos tuvieron un efecto revolucionario inmediato en la concepción que la humanidad tenía acerca del mundo. Además, dieron inicio a un intenso desarrollo científico que permitió

1 Área de Física Médica, Centro Javeriano de Oncología, Hospital Universitario San Ignacio—Universidad Javeriana, Carrera 7 No. 40-62, Santa Fe de Bogotá, Colombia. Correo electrónico: esperanza.castellanos@javeriana.edu.co

comprender más profundamente la estructura submicroscópica de la materia y crear nuevas herramientas para el estudio del universo. Los rayos X también dieron origen al campo de la observación del interior del cuerpo humano y fueron reconocidos espontánea e inmediatamente por la comunidad médica como una nueva tecnología diagnóstica.

Inmediatamente se comprobó que estos novedosos rayos también tenían efectos biológicos (aparecieron zonas eritematosas y ulceraciones en la piel de los operadores de los aparatos de rayos X y de los pacientes) y surgió la idea de usarlos para tratar lesiones cancerosas. En enero de 1896, dos pacientes comenzaron a recibir tratamiento en Chicago, Illinois, Estados Unidos de América, uno de ellos por cáncer de mama; en febrero de ese año se trató a un paciente con cáncer nasofaríngeo en Hamburgo, Alemania, y en julio otro paciente con cáncer de estómago comenzó a recibir tratamiento en Lyon, Francia. Así, en un mismo año nacieron el radiodiagnóstico y la radioterapia. Posiblemente la primera curación documentada de un caso de cáncer por medio de rayos X fue el de una mujer con una lesión cutánea nasal, que fue tratada por Stenbeck en Estocolmo, Suecia, en 1899 (1).

La aparición de lesiones provocadas por la radiación aplicada a pacientes con fines diagnósticos y los resultados contradictorios obtenidos durante los primeros años en que los rayos X se usaron con fines terapéuticos llevaron a tomar algunas precauciones. La necesidad de caracterizar la cantidad y la calidad de la radiación empleada dio origen en 1896 a una nueva disciplina: la dosimetría. Gracias al estrecho trabajo de cooperación entre físicos y médicos, entre 1896 y 1904 se elaboraron técnicas dosimétricas suficientemente precisas para garantizar la reproducibilidad de las exposiciones a la radiación y evaluar la relación entre la dosis y su efecto. Esos conocimientos facilitaron el ulterior desarrollo no solo de la radioterapia, sino también de la radiología y de la medicina nuclear.

Aunque Becquerel y los esposos Curie ya habían observado en sí mismos efectos biológicos similares a los de los rayos X, el uso terapéutico de fuentes radiactivas demoró algún tiempo. En 1901, los esposos Curie prestaron fuentes de radio a algunos dermatólogos para que las emplearan con fines terapéuticos (2). Los primeros resultados fueron poco promisorios, ya que la irradiación era heterogénea, el efecto terapéutico no era suficiente y ocurrían accidentes a menudo. Los primeros resultados favorables en el tratamiento de tumores se obtuvieron en 1905 en algunos pacientes con cáncer de piel y de cuello uterino.

Esa técnica de rayos X evolucionó hasta convertirse en una subdisciplina de la radioterapia denominada teleterapia. La introducción en la práctica clínica de los haces de alta energía implicó una considerable mejoría en los resultados clínicos, mientras que la teleterapia con cobalto-60 —utilizada por primera vez en octubre de 1951— y los aceleradores de megavoltaje —introducidos en la década de 1960— se hicieron cada vez más confiables para la producción de rayos X de alta energía (2). Paralelamente se desarrollaron varias aplicaciones del radio hasta formar una nueva subdisciplina denominada braquiterapia, basada en la inserción de material radiactivo sellado en cavidades directamente adyacentes a los tumores. Esta técnica evolucionó con la introducción de diferentes materiales radiactivos, de nuevas técnicas de aplicación del material en el paciente y de métodos dosimétricos más confiables y reproducibles.

Durante los noventa años que siguieron al descubrimiento de los rayos X se observó un gran desarrollo en diversos aspectos relacionados con la radioterapia, como la radiobiología, la dosimetría, la búsqueda de materiales radiactivos adecuados para la braquiterapia y la aparición y el desarrollo, para uso médico, de los aceleradores lineales de partículas. Como consecuencia, la radioterapia ganó rápidamente aceptación a escala mundial y actualmente se la reconoce como una de las técnicas indispensables para la atención médica de los pacientes con cáncer.

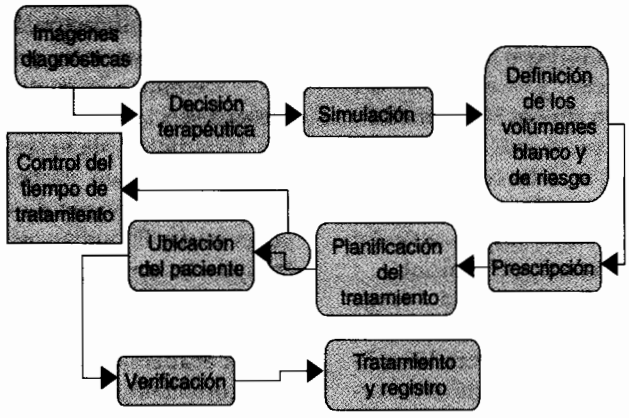
El objetivo de este artículo es identificar, a partir de los datos publicados, las necesidades más importantes e inmediatas en el campo de la radioterapia en América Latina y proponer metas concretas que ayuden a que los esfuerzos cooperativos realizados por los países y los organismos internacionales redunden en una mejoría de la calidad integral de los procedimientos radioterapéuticos.

EL PAPEL DE LA RADIOTERAPIA

Según la Organización Mundial de la Salud (OMS), el cáncer constituye una parte importante de la carga global de enfermedad en la presente década (3). Se estima que los casos nuevos de cáncer aumentarán en el mundo de 10 millones en el año 2000 a 15 millones en 2020. En los países desarrollados, el cáncer es la segunda causa más frecuente de muerte y según las pruebas epidemiológicas, la tendencia es similar en los países en desarrollo. Aproximadamente 60% de los nuevos casos de cáncer se producirán en los países de menor desarrollo en los próximos años.

Sin embargo, al menos una tercera parte de los casos nuevos de cáncer se puede prevenir mediante el control del consumo del tabaco y el alcohol, la adopción de una alimentación equilibrada y la vacunación contra la hepatitis B, entre otras medidas (3). Otra tercera parte de los casos se puede curar si se

FIGURA 1. Etapas del proceso de radioterapia moderna



logra detectar la enfermedad tempranamente y se aplica el tratamiento adecuado de manera inmediata. Cuando la enfermedad está más avanzada, se pueden aplicar técnicas eficaces, como la radioterapia, que permiten brindar un cuidado paliativo integral. El éxito de los programas de detección temprana de la enfermedad depende del uso eficaz de las diversas opciones terapéuticas.

Entre las modalidades terapéuticas más empleadas en el tratamiento del cáncer se encuentran la cirugía, la radioterapia, la quimioterapia, la terapia hormonal y la combinación de algunas de ellas. Se calcula que más de la mitad de los pacientes con cáncer necesitan tratamiento con radioterapia, ya sea sola o en combinación con la cirugía o la quimioterapia (3).

LAS NECESIDADES

La radioterapia es un proceso complejo. La experiencia acumulada en más de un siglo ha permitido establecer procedimientos y desarrollar una infraestructura tecnológica sin los cuales no es posible brindar una atención de calidad. En efecto, una vez tomada la decisión terapéutica de tratar a un paciente mediante radioterapia, se deben seguir seis etapas: la simulación, la planificación, la verificación del tiempo (o unidades de monitor), la verificación de los campos de radiación previstos, la administración de la dosis y el registro del tratamiento (figura 1).

En su informe sobre la determinación de la dosis absorbida en pacientes irradiados con rayos X o radiaciones gamma durante los procedimientos de radioterapia (4), la Comisión Internacional de Unidades y Medidas de Radiación (CIUR) concluyó que, según los estudios disponibles para ciertos tipos de tumores, es necesario aplicar la dosis al volumen que se ha de tratar con una exactitud de ±5% si se desea erradicar un tumor primario. Se debe tener en cuenta que esa tolerancia corresponde a una incertidumbre estimada aplicando intervalos de confianza de 95%, lo que corresponde a una exactitud de ±2,5% en la expresión de estos conceptos. Este criterio es demasiado estricto si se toma en cuenta la complejidad del proceso de la radioterapia (5). Sin embargo, los resultados de la radiobiología y la radioterapia modernas han confirmado la necesidad de administrar dosis con una gran exactitud, sobre todo cuando se aplican técnicas con escalamiento de dosis, es decir, dosis superiores a las definidas como estándares en la radioterapia convencional.

Por ello debe procurarse por todos los medios evitar errores sistemáticos en las diferentes etapas del proceso de radioterapia y reducir los errores aleatorios mediante buenas técnicas y procedimientos. Cada etapa desempeña un papel fundamental en el proceso completo y cualquier deficiencia en alguna de ellas puede dar origen a fallas en el resultado final.

La etapa de simulación requiere de sistemas de captura de imágenes del paciente en la posición y con los sistemas de inmovilización idénticos a los que se usarán durante el tratamiento. Para ello se debe contar con un simulador convencional o un simulador con posibilidad de realizar cortes mediante tomografía axial, o con una unidad de tomografía computarizada adaptada para simular el proceso de radioterapia. De esa manera se pueden obtener los datos anatómicos necesarios y las imágenes radiográficas o tomográficas sobre las que el médico dibuja el volumen que debe tratarse y los órganos en riesgo, para posteriormente definir las dosis necesarias en ese volumen y la máxima en dichos órganos. El resultado de esta etapa debe ser la prescripción de un tratamiento acorde con las recomendaciones de la CIUR.

La planificación del tratamiento, a cargo del físico médico, se lleva a cabo en los llamados sistemas computarizados de planificación, que modelan previamente las fuentes y los haces de radiación. Una vez definidos los campos y los haces de radiación, se

calcula la distribución de la dosis en el paciente con la ayuda de un modelo tridimensional creado con los datos del paciente. La exactitud de la distribución calculada depende de la exactitud con que se hayan modelado los haces de radiación y la anatomía del paciente y de la comprensión que el físico médico tenga del algoritmo y del programa de cálculo. Como resultado de esta etapa se debe contar con un plan de tratamiento validado por el médico especialista en radioterapia (radioncólogo) responsable del paciente, de acuerdo con su prescripción inicial.

La administración del tratamiento está a cargo del tecnólogo de radioterapia en unidades especializadas, ya sean unidades de cobalto, aceleradores lineales de partículas o sistemas de carga diferida automática para braquiterapia. En todos los casos, el tecnólogo debe reproducir los parámetros registrados en la hoja de simulación y el plan de tratamiento. Además, debe comprobar la identificación del paciente, para lo cual se recomienda que en el plan de tratamiento aparezca la fotografía de este (6).

Dados los múltiples parámetros geométricos, físicos, de posicionamiento y de accesorios que contienen el plan de tratamiento y la hoja de simulación y, en consecuencia, las múltiples fuentes de posibles errores que inciden en el proceso de administración del tratamiento, es necesario verificar los campos de irradiación antes de aplicar la dosis. Esta verificación se realiza principalmente mediante películas radiográficas y portapelículas diseñados para haces de radiación de alta energía y los llamados sistemas electrónicos de imagen portal. Estos últimos se encuentran ligados al brazo de la unidad de tratamiento y brindan una imagen en tiempo real del campo de radiación y de las estructuras abarcadas en él. Las imágenes de verificación son evaluadas por el médico radioncólogo, que propone las correcciones pertinentes y autoriza la aplicación del tratamiento. Esta verificación se debe realizar una vez por semana mientras dure el tratamiento.

La exactitud de la dosis administrada depende en gran medida de la exactitud con la que se determine la tasa de dosis de referencia del haz de radiación (resultado de la calibración) y de su constancia en el tiempo. El físico médico es el responsable tanto de la calibración como del control diario de los haces de radiación.

Por lo tanto, la radioterapia es una modalidad de tratamiento que requiere de una infraestructura tecnológica de alta complejidad, compuesta por sistemas dosimétricos que permitan caracterizar y calibrar los haces de radiación, sistemas de simulación (convencional, por tomografía computarizada o virtual), sistemas computarizados de planificación, unidades de tratamiento (de megavoltaje y de braquiterapia) y sistemas de verificación. Adicionalmente, los servicios modernos de radioterapia cuentan con una red que controla toda la información, desde la generada por los sistemas de simulación y de planificación, hasta la utilizada en las unidades de tratamiento y de verificación.

Debido a la complejidad tecnológica y a los riesgos asociados con la irradiación de los pacientes (6), la radioterapia exige un equipo de especialistas en el que deben participar radioncólogos, físicos médicos, tecnólogos de radioterapia y personal de enfermería. Es indispensable también contar con el apoyo de un servicio técnico de mantenimiento capaz de garantizar el buen funcionamiento de los equipos. Estos especialistas deben tener la competencia académica y técnica indispensable para utilizar correctamente la tecnología a su disposición, comprender a cabalidad los procedimientos en cada una de las etapas y contar con la capacidad necesaria para tomar decisiones en caso de incidentes o de situaciones críticas. Adicionalmente, como la calidad del tratamiento con radiaciones depende estrechamente de determinados factores clínicos (diagnóstico, localización del tumor, estrategia de tratamiento, verificación continua y control del paciente) y físicos (incertidumbre en el cálculo de la dosis, su optimización y verificación, y la idoneidad de los equipos dosimétricos, de cálculo y de administración del tratamiento, entre otros), todo el equipo debe trabajar de forma conjunta. Los conocimientos y la experiencia de cada uno de los miembros del equipo influirán decisivamente en la calidad del tratamiento (5) y en la seguridad del paciente (6).

Requisitos mínimos

Todos los servicios de radioterapia deben cumplir determinados requisitos mínimos para alcanzar un nivel aceptable de calidad. Cada institución debe tomar sus propias decisiones con relación al personal, los equipos, los procedimientos y las políticas, en función del número de pacientes y del tipo de enfermedades que atienda y de su organización interna, pero hay requisitos básicos propuestos por la Organización Panamericana de la Salud (OPS) (7) y el Organismo Internacional de Energía Atómica (OIEA) (5) que deben cumplir todas las instituciones.

Hasta finales de la década de 1990 se daba mayor prioridad a incrementar el número de unidades de tratamiento a fin de aumentar la cobertura de la atención de los pacientes con cáncer. Las recomendaciones recientes (5, 8) tienen en cuenta todas las etapas del proceso de radioterapia y, en consecuencia, son más exigentes en cuanto a la cantidad y la calidad del personal y de la infraestructura técnica necesaria.

En la actualidad se considera que todos los servicios de radioterapia deben contar con los siguientes elementos (5, 8):

- sistema de simulación del tratamiento y de inmovilización del paciente
- sistema computarizado de planificación de los tratamientos
- sistemas de alineamiento y localización del paciente
- unidades de tratamiento que cumplan con las especificaciones de la Comisión Electrotécnica Internacional (CEI)
- accesorios modificadores del haz de radiación
- protecciones personalizadas
- equipos de dosimetría absoluta y relativa para la calibración y el control de la calidad de las fuentes de radiación.

Las unidades de tratamiento deben ser las adecuadas para el tipo de tratamiento ofrecido por la institución y contar con un programa eficiente de mantenimiento y reparación. Estas unidades, al igual que los sistemas computarizados de planificación de los tratamientos, deben haber pasado satisfactoriamente las pruebas de aceptación y de puesta en servicio.

En cuanto al personal, todos los centros de radioterapia, independientemente de su tamaño, deben contar con radioncólogos, físicos médicos, tecnólogos de radioterapia y, en el caso de los centros de alta complejidad tecnológica, tecnólogos dosimetristas que apoyen las actividades de dosimetría clínica.

Los equipos

En 1997, la OPS propuso un esquema para calcular la necesidad de equipos de teleterapia en el mundo (7). Según este esquema, hacen falta 4 400 equipos para atender a una población de 4 400 millones de personas en la cual la incidencia de cáncer es de 75 a 150 por 100 000 habitantes, asumiendo 4,4 millones de casos nuevos de cáncer por año (de los cuales 50% requieren radioterapia) y que una máquina puede atender a 500 de esos casos. Esto significa que se debe contar aproximadamente con 1 unidad de megavoltaje por cada millón de habitantes.

Según un estudio realizado por el OIEA en 2004 (9), en 19 países de América Latina que tienen una población total de 516,7 millones de habitantes hay 710 unidades de teleterapia, es decir, 1,37 unidades de megavoltaje por millón de habitantes (entre 0 y 3,32). De estos datos se puede concluir que en América Latina existe una buena cobertura con unidades de teleterapia (superior al mínimo estimado de 1 unidad de megavoltaje por millón de habitantes), pero que su distribución es muy heterogénea. En la mayoría de los países más poblados (Argentina, Brasil, Colombia, Chile, México y Venezuela) hay más de una unidad de teleterapia por cada millón de habitantes.

Sin embargo, según esa misma fuente, más de 21% de los 470 centros estudiados son de nivel 0 (centros equipados únicamente con una unidad de teleterapia), 51% de nivel 1 (centros que cuentan con unidades de teleterapia, braquiterapia, sistemas de planificación de tratamiento y de inmovilización de pacientes, un radioncólogo y al menos un físico médico a tiempo parcial); 25% son de nivel 2 (centros que cuentan también con sistemas de simulación, posibilidades de construcción de protecciones personalizadas —protecciones con formas adaptadas a los volúmenes de interés en cada paciente— y un físico médico a tiempo completo), y solamente 3% son de nivel 3 (con capacidad de ofrecer al paciente técnicas especiales, como radioterapia por intensidad modulada, radiocirugía o radioterapia intraoperatoria) (figura 2).

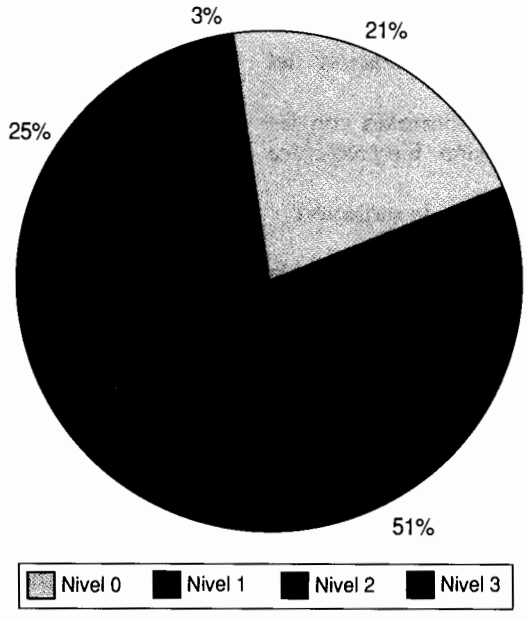
Esto indica que más de la quinta parte de los centros de radioterapia en América Latina ofrecen servicios sin el mínimo de calidad requerido y que otro 51% debe completar su equipo con sistemas de simulación y la posibilidad de protecciones personalizadas para poder ofrecer un servicio de radioterapia de buena calidad (5). En total, 72% de los centros de radioterapia de los países estudiados deben mejorar sustancialmente sus condiciones de funcionamiento.

Las llamadas nuevas tecnologías de radioterapia son los aceleradores lineales equipados con colimadores multihojas y sistemas electrónicos de imagen portal con detectores sólidos; los sistemas de simulación virtual; los sistemas de cálculo tridimensional para la distribución de las dosis; las redes de radioterapia; los sistemas de registro y verificación de los parámetros; los sistemas de seguimiento de los órganos en movimiento, y los módulos para radioterapia por intensidad modulada, entre otros.

En particular, las unidades equipadas con colimadores multihojas permiten administrar, mediante muchos haces, dosis distribuidas según la forma del volumen que se va a tratar, lo que reduce la posibilidad de que se afecten órganos críticos. La forma de los campos se transfiere por la red desde el sistema de planificación al acelerador.

De igual manera, las redes de radioterapia son indispensables para la planificación y la aplicación eficiente y exacta de un tratamiento bien conformado. Por medio de ellas, las imágenes del paciente se exportan directamente a los sistemas de planificación del tratamiento y las radiografías reconstruidas digitalmente (con la imagen de los campos conformados) se transfieren a la unidad de tratamiento. Esto facilita el control rápido y confia-

FIGURA 2. Clasificación de 470 centros de radioterapia de 19 países de América Latina según su nivel de calidad, 2004



Fuente: Organismo Internacional de Energía Atómica (9).

ble de los muchos parámetros implicados en la planificación del tratamiento y su administración.

La presencia de aceleradores con colimadores multihojas y de una red interna en los centros de radioterapia constituye la base para organizar un servicio moderno. De acuerdo con los informes presentados por los representantes de diversos países en eventos científicos regionales, solamente una pequeña parte de los centros latinoamericanos cuenta con esos elementos. A manera de ejemplo, de los 39 centros de radioterapia que funcionan en Colombia, solamente 8 tienen aceleradores con colimadores multihojas y solo 4 (alrededor de 10%) cuentan con una red informática para la radioterapia. La falta de un colimador multihojas se puede compensar con la elaboración de protecciones personalizadas hechas de una aleación denominada "cerrobend". Sin embargo, debido a la dificultad para transportarlas (por su gran peso) y a la necesidad de elaborar una protección para cada campo, por lo general no se planifica el número de campos de radiación necesarios para un tratamiento óptimo.

De manera similar, los sistemas electrónicos de imagen portal con detectores sólidos todavía son poco frecuentes en los servicios de radioterapia de América Latina debido al alto costo de esta tecnología. Siguiendo el mismo ejemplo de Colombia, solamente uno de los 20 aceleradores lineales que funcionan en ese país dispone de un sistema de imagen portal con detectores sólidos. Aunque es posible hacer una verificación adecuada del tratamiento mediante películas, es necesario esperar su revelado antes de iniciar el tratamiento.

El personal

La mayoría de los autores coinciden en que un radioncólogo puede tratar 250 casos nuevos por año (5, 7, 8). Sin embargo, según las guías nacionales europeas para la infraestructura y el personal de los servicios de radioterapia, en el Reino Unido esta cifra asciende a 350 y en Luxemburgo a 300, mientras que en Francia se recomienda que haya un radioncólogo por cada 200 a 250 pacientes en hospitales universitarios y uno por cada 300 a 400 pacientes en hospitales no universitarios (10). Por lo tanto, la referencia de contar con un radioncólogo por cada 250 pacientes se debe tomar con cautela y es preciso tener en cuenta la complejidad de la tecnología y los procedimientos establecidos en un servicio de radioterapia específico, así como las otras funciones diferentes de la atención de pacientes asignadas al personal médico.

Igualmente se recomienda la vinculación de un físico médico especialista en radioterapia por cada 400 pacientes nuevos al año (7, 8). Aunque esta recomendación está aceptada en general y se emplea al planear un nuevo servicio de radioterapia, las guías nacionales vigentes actualmente en Europa varían notablemente en este sentido: en Holanda se recomienda tener un físico médico por cada acelera-

dor lineal y uno por cada 650 pacientes nuevos al año, mientras que en Luxemburgo se debe contar con un físico médico por cada 600 y en Bélgica con uno por cada 750 pacientes nuevos al año (10).

En cuanto al personal técnico, hay consenso internacional y se recomienda contar con dos tecnólogos por cada 25 pacientes tratados diariamente por unidad de megavoltaje y con dos tecnólogos de simulación por cada 500 pacientes simulados en un año. Está aceptado que siempre deben trabajar dos tecnólogos simultáneamente en cada unidad de tratamiento (6–8) para poder garantizar la ubicación precisa del paciente (control simultáneo de los indicadores laterales de láser), su seguridad (vigilancia permanente mediante cámaras de video), el control de diferentes registros que el tecnólogo debe interpretar y diligenciar (hoja de simulación, plan de tratamiento, registro del tratamiento, imágenes portales) y la atención que necesita el paciente con cáncer.

Uno de los problemas más discutidos en reuniones y eventos regionales sobre la radioterapia es la deficiencia que se observa en el número y el nivel de formación de los físicos médicos en algunos países, particularmente en Centroamérica. De acuerdo con los datos publicados por el OIEA en 2004, de 357 físicos médicos en 19 países de América Latina, 241 habían obtenido un grado específico en física médica, en su mayor parte en Argentina y Brasil (9). Esto indica que la mayoría de los físicos vinculados a la práctica médica en el resto de los países se han formado empíricamente en los hospitales. Esta tendencia está cambiando gracias a la creación de programas de posgrado en la física de la radioterapia o la física médica (Argentina, Brasil, Colombia, Cuba, México y Venezuela) y al fortalecimiento de las legislaciones nacionales relacionadas con la acreditación de los servicios de radioterapia.

Los programas de garantía de la calidad

Cada centro de radioterapia debe contar con los medios necesarios para que la calidad de los servicios que ofrece a los pacientes siempre se mantenga dentro de los límites admitidos internacionalmente y disponer de los mecanismos necesarios para corregir desviaciones que puedan afectar al paciente (5, 7, 8). Además, debe contar con mecanismos adecuados de retroalimentación de manera que la experiencia adquirida pueda utilizarse para corregir las deficiencias y mejorar las diversas etapas del proceso. Estos elementos constituyen la base de los programas de garantía de la calidad en los servicios de radioterapia y son responsabilidad de cada institución, en particular de los administradores, los jefes de servicio, los médicos y los profesionales de las distintas áreas.

Los casos recientes de sobreexposición grave de pacientes (6) se han producido debido a la falta de programas de garantía de la calidad debidamente estructurados y funcionales. El análisis de esos accidentes demuestra que existían fallas en la aplicación de los procedimientos (particularmente el no hacer la doble verificación del tiempo de tratamiento); fallas en los mecanismos de comunicación de la información entre los miembros del equipo de trabajo; la formación insuficiente del personal (especialmente en física médica); la falta de seguimiento de los pacientes, y el incumplimiento de los protocolos de aceptación y puesta en servicio de los equipos y sistemas de planificación de tratamientos.

Para acercarse a las tasas del curación del cáncer logradas en los países desarrollados es preciso mantener servicios de radioterapia con un alto grado de precisión y fiabilidad. Tanto los aspectos clínicos (diagnóstico, toma de decisiones, indicación del tratamiento y seguimiento) como los procedimientos relacionados con los elementos físicos y técnicos del tratamiento del paciente deben controlarse minuciosamente y planificarse de manera adecuada (6, 8). En la actualidad se da una gran importancia a los aspectos físicos de la garantía de la calidad (5–8), lo que ha llevado a la OPS y al OIEA a apoyar programas de formación continuada de físicos médicos y radioncólogos en esa área y de adquisición de equipos de dosimetría y control de la calidad.Aunque se ha avanzado notablemente en la aplicación de procedimientos de garantía de la calidad de los aspectos físicos de la radioterapia, aún es necesario alcanzar un enfoque sistemático de la garantía de la calidad en todas las etapas del proceso, principalmente en sus aspectos clínicos, si se desea lograr un mejoramiento global de la calidad del tratamiento.

LOS RETOS

En la mayoría de los países de América Latina que cuentan con servicios de radioterapia desde hace muchos años, el nivel de cobertura, la organización y la estructura de los servicios disponibles actualmente indican que los esfuerzos cooperativos internacionales deben dirigirse a mejorar la calidad general de cada servicio (7, 9).

Como primera meta se debe lograr que los centros de nivel 0 y 1 (aproximadamente 72% del total) alcancen el nivel 2, de manera que puedan ofrecer servicios de radioterapia de mejor calidad. Los organismos internacionales que apoyan proyectos de cooperación entre los países deben orientar sus esfuerzos hacia el logro de esa meta antes de apoyar la creación de nuevos centros o el paso de centros del nivel 2 al nivel 3. La prioridad debe ser lograr que 90% de los centros se encuentren en el nivel 2.

En cuanto al equipamiento, otra meta prioritaria debería consistir en reemplazar los aceleradores (una vez cumplida su vida útil) por nuevas unidades de tratamiento con colimadores multihojas y redes de transferencia de datos desde el sistema de planificación del tratamiento. Esto permitiría generalizar la aplicación de la radioterapia conformacional, lo que beneficiaría a un mayor número de pacientes y aumentaría la capacidad de cada servicio. Igualmente, los equipos para instalaciones nuevas deben contar con colimadores multihojas.

Una tercera prioridad regional es la elaboración y adopción de guías nacionales de tratamiento, lo que permitiría establecer un estándar mínimo de atención, comparable entre diferentes centros. Esas guías deben normar no solamente los esquemas de fraccionamiento y de dosis, sino también la forma de simular, planificar, administrar y verificar los tratamientos, así como los métodos de seguimiento de los pacientes tratados. Esto debe hacerse tomando como base una estructura de nivel 2, ya que es la que cumple los requisitos mínimos. Las organizaciones internacionales y regionales podrían desempeñar un papel muy importante en este sentido mediante la propuesta de códigos de práctica de referencia a los ministerios de salud. Igualmente, esas organizaciones deben influir en la adopción de reglamentos nacionales que respalden el cumplimiento de esas guías o códigos de práctica.

Finalmente, los esfuerzos cooperativos deben orientarse hacia la consolidación en cada país de uno o varios (en función de la población) centros de referencia, es decir, centros que cumplan con los requisitos mínimos, que tengan y apliquen guías específicas, que cuenten con programas consolidados de garantía de la calidad y cuyo personal (médicos, físicos médicos, técnicos y de enfermería) se encuentre debidamente capacitado para la radioterapia. Estos centros serán una referencia nacional y su existencia ayudará a mejorar la calidad de los demás servicios de radioterapia.

SYNOPSIS

New technologies: needs and challenges in radiotherapy in Latin America

The cumulative experience gathered over more than a century of practice of radiotherapy has demonstrated the latter's importance not only for the palliative treatment of a fraction of cancer cases, but mainly for the curative treatment of an even greater proportion of such cases. In light of the changes in technology, the ever-increasing access developing countries to such technology, and its current coverage in Latin America, any efforts in this area should be aimed at improving the quality of the radiotherapy services and centers that are already in place. This involves developing their technological assets to the fullest, expanding their services, and complying with the minimum quality requirements established for second-level facilities. Each center should be equipped to carry out all stages of the radiotherapy process, from simulation through treatment verification and patient follow-up, with a high level of quality (level 2). To achieve this, it should possess the necessary technology and properly-trained staff that are required for the purpose. Collaborative efforts in the Region should also prioritize helping countries implement national treatment standards for all stages of the radiotherapy process and promoting the implementation of validated quality assurance programs.

Key words: radiotherapy, quality assurance, health services needs and demand, Latin America.

REFERENCIAS

1. Waltsman R. A historical review on radiotherapeutic applications. En: Bernier J, ed. Radiation oncology: a century of progress and achievement. Brussels: European Society for Therapeutic Radiology and Oncology (ESTRO); 1995.
2. Tubiana M. Les rayonnements en médicine. Pour la Science. 1996;124–30. (Dossier hors série: centenaire de la découverte de la radioactivité).
3. World Health Organization. National cancer control programmes: policies and managerial guidelines. Geneva: WHO; 2002.
4. International Commission on Radiation Units and Measurements. Determination of absorbed dose in a patient irradiated by beams of X or gamma rays in radiotherapy procedures. Bethesda, MD: ICRU; 1976. (ICRU Report No. 24).
5. Organismo Internacional de Energía Atómica. Aspectos físicos de la garantía de calidad en radioterapia: protocolo de control de calidad. Viena: OIEA; 2000. (IAEA-TECDOC-1151).
6. International Commission on Radiological Protection. Prevention of accidents to patients undergoing radiation therapy. Ann ICRP. 2002;30(3). (ICRP Publication No. 86).
7. Borrás C, ed. Organización, desarrollo, garantía de calidad y radioprotección de los servicios de radiología: imaginología y radioterapia. Washington, D.C.: Organización Panamericana de la Salud; 1997.
8. International Atomic Energy Agency. Design and implementation of a radiotherapy programme: clinical, medical physics, radiation protection and safety aspects. Vienna: IAEA; 2005. (IAEA-TECDOC-1040).
9. Zubizarreta EH, Poitevin A, Levin CV. Overview of radiotherapy resources in Latin America: a survey by the International Atomic Energy Agency (IAEA). Radiother Oncol. 2004;73:97–100.
10. Slotman BJ, Cottier B, Bentzen SM, Heeren G, Lievens Y, Van den Bogaert W. Overview of national guidelines for infrastructure and staffing of radiotherapy. European Society for Therapeutic Radiology and Oncology—Quantification of Radiation Therapy Infrastructure and Staffing Needs (ESTRO-QUARTS): Work package 1. Radiother Oncol. 2005; 75:349e1-349e6.

Manuscrito recibido el 10 de noviembre de 2005. Aceptado para publicación, tras revisión, el 15 de febrero de 2006.

Normal tissue complications after radiation therapy

Jolyon H. Hendry,[1]
Branislav Jeremić,[1]
and Eduardo H. Zubizarreta[1,2]

Suggested citation: Hendry JH, Jeremić B, Zubizarreta EH. Normal tissue complications after radiation therapy. Rev Panam Salud Publica. 2006; 20(2/3):151–60.

SYNOPSIS

This paper describes the biological mechanisms of normal tissue reactions after radiation therapy, with reference to conventional treatments, new treatments, and treatments in developing countries. It also describes biological reasons for the latency period before tissue complications arise, the relationship of dose to incidence, the effect of increasing the size of the irradiated volume, early and late tissue reactions, effects of changes in dose fractionation and dose rate, and combined chemotherapy and radiotherapy responses. Examples are given of increases in knowledge of clinical radiobiology from trials of new protocols. Potential modification to treatments include the use of biological response modifiers. The introduction of "response prediction" modifications to treatments might also be available in the near future. Finally, the paper points out that in some radiotherapy centers, the biologically-effective doses prescribed for combined brachytherapy and teletherapy treatment of cervix cancer are lower than those prescribed in other centers. This issue needs to be addressed further. The wealth of preclinical and clinical data has led to a much greater understanding of the biological basis to radiotherapy. This understanding has underpinned a variety of new approaches in radiotherapy, including both physical and biological strategies. There is also the important issue of treatment of a large number of cancers in developing countries, for which efficacious resource-sparing protocols are being continuously developed. A unified scoring system should be widely accepted as the new standard in reporting the adverse effects of radiation therapy. Likewise, late toxicity should be reported on an actuarial basis as a mandatory endpoint.

Key words: neoplasms; radiotherapy; dose-response relationship, radiation; radiation injuries.

Radiation therapy has been used for over 100 years. It is a proven method for controlling malignancies and for prolonging the life of individuals who would otherwise die from their cancer. Radiation therapy is used in somewhat more than half of all cancer treatments, and in some cases it is the preferred and most effective treatment of all. In other cases, it is used in combination with chemotherapy or surgery.

Despite their benefits, all treatments against diseases are associated with side effects to some degree. Cytotoxic treatments against cancer, including radiation therapy, cause injury to normal tissues, which ultimately limits the dose that determines the likelihood of cure.

When cancers are irradiated, some normal tissue is also irradiated, and this causes injury that gives rise to tissue reactions. In many cases, these reactions are minor and transient, but in a few cases

[1] International Atomic Energy Agency, Division of Human Health, Applied Radiobiology and Radiotherapy Section, Vienna, Austria. Send correspondence to: Dr. Jolyon H. Hendry, Applied Radiation Biology and Radiotherapy Section, Division of Human Health, International Atomic Energy Agency, Wagramer Strasse 5, P.O. Box 100, A-1400 Vienna, Austria. E-mail: j.hendry@iaea.org

[2] Hospital Pereira Rossell, Instituto de Radiología y Centro de Lucha Contra el Cáncer, Montevideo, Uruguay.

they can be prolonged and more severe. The reactions of greatest concern are those that appear months or years after therapy, making them more difficult to treat. Severe reactions in a small number of patients impose a limit on the dose that can be delivered, not just to them individually but to any patient. Physical and biological strategies are being devised to increase this limit in order to be able to deliver a higher dose in an attempt to control more cancers (tumors). One physical strategy is to reduce the irradiated volume as much as possible, so that the smaller volume can tolerate higher doses. Another strategy is to use very small dose fractions in order to exploit the greater fractionation sensitivity of late-reacting normal tissues than of tumors, so that higher tolerable doses can be accumulated resulting in more cured tumors. Three examples of biological strategies are: (1) making the radiation more effective in killing tumor cells through the utilization of the latest generation of molecular-pathway-based radiosensitizers; (2) predicting which patients will react the most, thus allowing for the remainder to be given a higher dose; and (3) applying selective targeting of radiation to the tumor cells.

MECHANISMS OF TISSUE REACTIONS

Advances in radiation technology and in radiation dose-fractionation delivery patterns, as well as the use of additional therapies, have altered the pattern of side effects (1). Historically, early skin reactions were generally dose-limiting due to the depth dose profile for orthovoltage radiotherapy. Although emphasis is still being placed on acute toxicity, today much of the focus has shifted toward late effects. Less aggressive radiotherapy protocols generally succeed in preventing severe morphological and structural changes such as fistulae and chronic ulcerations. However, irradiation may result in chronic changes in the functioning of organs such as the heart, lung, or kidney, that may become clinically manifest several years after treatment. This picture may change again with the recent advances and expected innovations in radiation and cancer biology, in functional imaging, and in radiation therapy planning and delivery. All these improvements tend to lead to an intensification of locoregional treatment.

Early tissue reactions, such as inflammation, occur within hours to several weeks after therapy due to changes in cell membrane permeability and histamine release. Subsequent early tissue reactions occur as a consequence of cell loss, causing mucositis and epidermal desquamation.

Early tissue reactions that are a result of cell loss are a feature of renewing tissues, such as bone marrow, epidermis, and mucosa. These tissues follow a hierarchical proliferative organization in which stem cells and daughter precursor cells with the ability to divide and differentiate give rise to cells which mature to form the functional end cells in tissues (2).

The sterilization of some or all of the stem and precursor cells in tissues results in early desquamatory reactions in epithelia, as well as hemopoietic depression. Such consequences ultimately result in a transitory or permanent decrease in the production of mature cells, depending on the radiation dosage level. The time course of the expression and restoration of tissue components generally depends on their normal (unirradiated) rate of renewal, and it is dose-dependent after low doses. After high doses, complete denudation of such tissues occurs at a time equivalent to the lifetime of new mature cells, including cells produced by any radioresistant precursor cells. This pattern of response has been well described for many types of renewal tissues (3, 4).

On the other hand, late tissue and organ reactions are a consequence of cellular damage and injury to a complex network of interacting populations of cells (5). Such interacting populations of cells include relatively resistant parenchymal cells, which are mainly non-dividing. However, these cells can initiate division as a consequence of slow cell depletion due to radiation-induced abortive divisions. These populations of parenchymal cells, such as those in the liver and kidney, are capable of function as well as induced multiplication. They have been called flexible populations (3), in contrast to the hierarchical populations in renewing tissues.

LATENCIES

In the case of hierarchical tissues, i.e. tissues which have a hierarchical proliferative organization, the latency period prior to the gross expression of injury is directly related to the turnover (renewal) time of the tissue. Therefore, the latency period is short for intestinal reactions because the intestinal (mucosal) tissues have a high turnover rate. The opposite can be said for skin desquamation, which has a much longer latency period. After low radiation doses there is a dose-dependent latency due to the decreasing proportion of precursor cells undergoing successful cell division (6). At high doses there is a plateau in the timing of the response, when all cells are sterilized, no matter how high the dose. In the case of slowly-proliferating flexible cell populations, there is a characteristic longer, more intense and dose-dependent latency period before expression of damage. Detailed studies on telangiectasia provide a very clear example of this effect (7). Also, there is an increasing incidence

of injury with increasing doses before the plateau in timing occurs at a very high dose (3).

From both a biological and clinical standpoint, it is useful to roughly classify normal tissue effects into early effects and late effects. Early effects are expressed during or immediately after the end of therapy; late effects may become manifest after symptom-free latency periods of months to years. Indeed, there is documented evidence that late effects continue to increase for over a decade in surviving individuals (8).

There is no consensus in the literature concerning the exact definition of "early effect" and of "late effect." Often an operational definition is used, and effects are classified based on an arbitrary cutoff for their latency period. One cutoff that has been used is 90 days after the onset of the treatment. However, it has also been proposed that late effects be defined as those that occur or that have not healed by at least 90 days after the end of therapy (9).

REACTION SCORING SCALES

There is a fairly comprehensive literature on early morbidity after both radiotherapy and chemotherapy. This has resulted in the development and implementation of comprehensive scoring systems designed for radiotherapy (such as the RTOG/EORTC (Radiation Therapy Oncology Group/European Organisation for Research and Treatment of Cancer) system) and for chemotherapy (such as the Eastern Cooperative Oncology Group Common Toxicity Criteria (CTC) or the World Health Organization system). These have been amalgamated into CTC version 2.0 (10), which is aimed at a common system that can apply to either radiotherapy or chemotherapy, individually or in combination. Recently, a more comprehensive version of the CTC criteria (CTCAE v. 3.0) addressed an increased need for more precise reporting of adverse events (11). These different systems have been used in a variety of clinical studies as well as in routine clinical practice.

Toxicity criteria for late effects are much less established than those for early effects (1). The RTOG/EORTC Late Radiation Morbidity Scoring Schema is widely used in multi-center trials in Europe and the United States of America. It is rather simple and easy to use, and it is the system usually found in the scientific literature. The most ambitious attempt so far to develop a comprehensive system for the grading and recording of late radiation effects was the "scoring system of late effects on normal tissues," or the SOMA/LENT scale (12). (SOMA is an abbreviation for "subjective symptoms, objective signs, management, and analytical measures." LENT is an abbreviation for "late effects on normal tissues.") The characteristic feature of the SOMA/LENT system is that each toxicity item is classified as subjective, objective, management-related, or analytical. In the original publication of the SOMA/LENT system, it was suggested that each individual item's score for an organ be added in order to then calculate the average score. This is clearly not a very sound system. In the case of lung reactions, for example, it was proposed to add the eight items in the SOMA part of the scale and then divide by eight. Thus, a patient dying (grade 5 per definition) from restricted pulmonary function without having developed any of the other seven signs or symptoms, or having management interventions for pulmonary injury, would get a score of 5/8, or 0.625. This value is less than that for a patient who has grade 1 signs and symptoms for all the items. One obvious idea is to record the maximum grade of any toxicity item for a specific organ or tissue and use this as the grade of toxicity (13). Thus, a patient experiencing, say, a grade 3 loss of sphincter control after radiotherapy will be recorded as having experienced a grade 3 rectal complication. This suggestion still involves a number of assumptions regarding the comparability of grades across toxicity items. From a biological perspective, it seems illogical to even attempt to pool various components of morbidity and arrive at a single number that quantifies late effects (14).

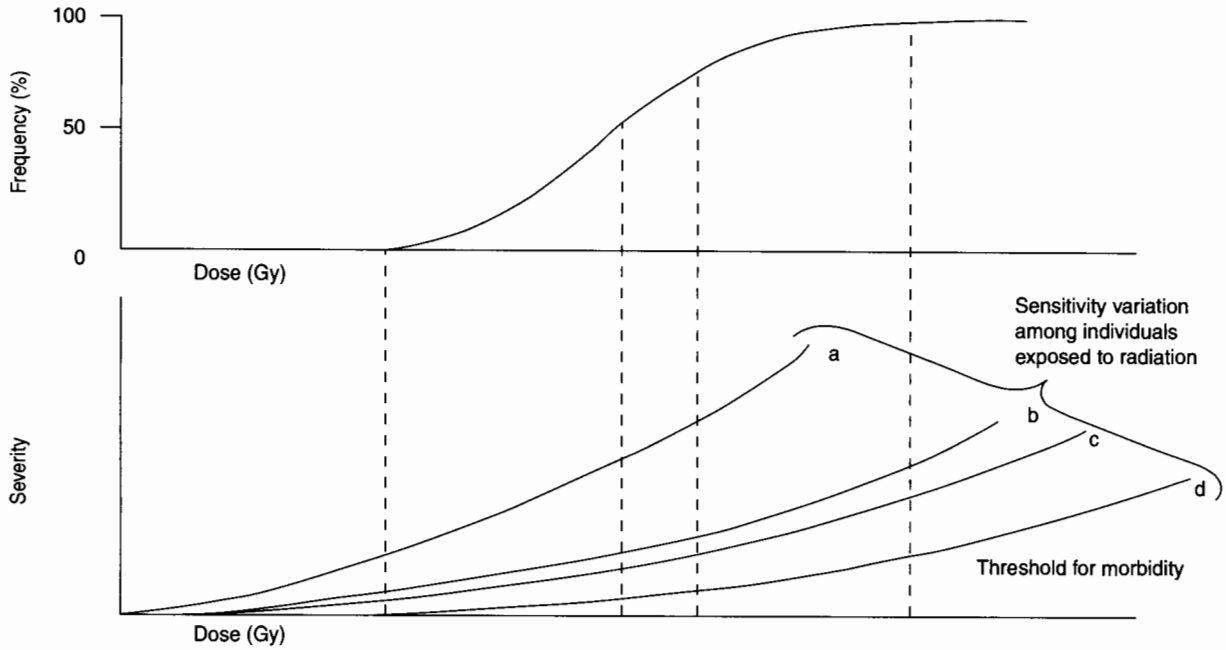
DOSE-RESPONSE CURVES

Tissue and organ reactions vary with the dose, in both severity and incidence. In general, the dose-incidence relationship will be sigmoid in shape (S-shaped) when plotted on linear axes, with the effect becoming more frequent as the dose increases. The steepness of the curve is governed largely by the degree of variation in sensitivity among the patients.

The severity of the pathological condition increases most markedly in those individuals in a subgroup who are most sensitive (Curve a in the lower panel of Figure 1), reaching the threshold of detectability at a lower dose than in the less sensitive groups (Curve b, Curve c, and Curve d in Figure 1). The dose range over which the different subgroups cross the same morbidity threshold is reflected in the upper panel of Figure 1, which shows the frequency of morbidity in the total population. That frequency reaches 100% only at the dose that is sufficient to exceed the defined threshold in all members of the population.

There are many reported examples of the steepness of dose-incidence curves for morbidity in particular tissues and organs in series of radiotherapy patients who are receiving different doses. One way to

FIGURE 1. How the incidence ("frequency" in the upper panel) of a reaction or clinically recognizable pathological condition increases as a function of dose ("dose" in the upper panel) in a population of individuals of varying sensitivities, and what the dose-severity relationship is for the component subpopulations of individuals with various sensitivities (lower panel)



describe the steepness is the absolute percentage increase in the incidence of morbidity among a population of patients when the dose is increased by 1%. Examples of this measure of steepness for different tissues in different series of patients, calculated on a common basis of 2 Gy per fraction and at the steepest part of the curve (the midpoint, of 50% incidence), are available (15). There is a wide variation in steepness due largely to the heterogeneity in the particular patient population used. However, it should be noted that, in general, the dose-incidence curves for morbidity are steeper than they are for tumor control. This indicates that there is even greater variation among patients in the response of a tumor than in the response of normal tissue.

VOLUME EFFECTS

In general, tissue reactions are greater when greater volumes are irradiated. This effect is most marked for very small volumes because the migration of cells from the edges of radiation fields affects healing in smaller volumes much more than in larger ones. For larger irradiated volumes, which are the ones most common in radiotherapy, the volume effect is less marked but still important. The presence of a volume effect is the rationale for new strategies to reduce irradiated volumes. These include dynamic imaging (used to reduce irradiated tumor margins), intensity-modulated radiotherapy (used to shape the irradiated fields more closely around the tumor), and protons (which can be used to provide a sharper edge to the irradiated volume than is possible with X rays, gamma rays, or electrons).

For skin, the tolerance of a larger irradiated region may be reduced compared to that of a smaller irradiated region, although the reaction level may be little increased. This is because the likelihood of any area within the irradiated region not healing properly increases with an increase in the number of such irradiated areas. Also, the architecture of organ systems has an influence on the volume effect. Some organ systems are comprised of functional tissue subunits arranged in parallel, such as nephrons in the kidney and alveoli in the lung. In these cases, parts of the organ can be irradiated and injured with no functional defects because the other regions can compensate. In contrast, organs or tissues comprised of functional components in a serial arrangement, such as the spinal cord, intestine, and blood vessels, can be functionally damaged to irreparable levels by injury in one small region (16).

GENERIC AND CONSEQUENTIAL LATE REACTIONS

In recent years it has become clear that late reactions in tissues and organs can be caused primar-

ily in two ways. One is through direct injury to the responsible tissues, for example, the vasculature (causing, for instance, ischemia) or stroma (fibrosis). These injuries are referred to as generic late reactions. The other is through early injury to overlying protective tissues, such as mucosa or epidermis, causing later injury in the underlying tissues. These are referred to as consequential late reactions.

Unconventional, more aggressive irradiation protocols are usually associated with an aggravation of acute reactions. Overexposures of patients, which happen occasionally, can have this same effect. Thus, aggressive irradiation protocols and the incidence of overexposure to radiation predominantly generate consequential late reactions. Such consequential late reactions are found in organ systems where the acute response is associated with an impairment of the tissue barrier against mechanical or chemical stress (17). Hence, the reactions are found mainly in the urinary and intestinal tracts, in mucosa anywhere, and to some extent in skin. The presence of consequential reactions can often confound the interpretation of late reactions when unconventional radiation protocols are used. Also, the prediction of reaction levels may be inaccurate when new schedules are trialed (18, 19). In addition, amelioration of the acute response to irradiation may be a useful approach to minimize some of the consequential late side effects of curative radiotherapy.

FRACTIONATION AND DOSE-RATE EFFECTS

The benefit of hyperfractionated treatments (using lower doses per fraction than are given with a normal schedule, and giving more treatments per day) is now well established (20). However, this has not yet led to wider application of this strategy in clinical practice. This technique prevents generic late reactions. Generic late reactions have a high fractionation sensitivity, which is characterized by a low α/β ratio in the commonly-employed linear-quadratic formalism (20). (The α/β ratio is a measure of the fractionation sensitivity of a tissue). The technique also permits the delivery of a more biologically effective dose to the tumor, while keeping the level of complications acceptably low. One milestone in this strategy was the successful implementation of the continuous hyperfractionated and accelerated radiation therapy (CHART) regimen for lung cancer and for head and neck cancer, delivering the total treatment in 12 days, with three fractions of 1.5 Gy per day (21). Another milestone was the EORTC 22791 trial of pure hyperfractionation for head and neck cancer, using conventional treatment times (22). Unfortunately, these new schedules are labor-intensive for staff and often difficult to implement in conventional radiotherapy departments. Therefore, less-modified schedules are being sought as a compromise. A recent interesting development that reverses this trend toward using hyperfractionation has to do with prostate cancer. In this case, the slow-growing tumor responds as if it were *more* sensitive to dose fraction size than even late-reacting normal tissue. Trials are being conducted to test whether high doses per fraction and fewer fractions (hypofractionation), rather than low doses per fraction, are beneficial (23, 24).

Another aspect of fractionation is the duration of the schedule. Longer schedules are beneficial in allowing regeneration of early-reacting renewing tissues, and longer schedules also reduce any consequential late reactions. However, such schedules may allow tumor cell repopulation, which is detrimental to tumor cure. It is now well established that for head and neck cancers, repopulation of tumor clonogens starts after three to four weeks of treatment (25, 26). On the other hand, accelerated (shorter) treatments, which will be completed before tumor cell repopulation becomes important, can increase acute reactions and thus may increase consequential late reactions as well.

Fractionated doses should be delivered with an interval of at least six to eight hours between fractions, so that intracellular repair is virtually complete. Otherwise, the total dose must be reduced to avoid increasing morbidity (27). However, there are data showing that even shorter interfraction intervals in hyperfractionation regimens, alone or with concurrent chemotherapy (28), have led to more acute toxicity, but not to late toxicity (29). No difference was observed between shorter and longer intervals in terms of both acute and late toxicity (30). Finally, multivariate analyses with 536 patients confirmed that the interfraction interval was not a predictor of high-grade acute or late toxicity. Additionally, recent analysis in locally advanced, unresectable (stage III) non-small cell lung cancer showed that patients treated with hyperfractionated radiation therapy using shorter interfraction intervals (4.5–5.0 hours) fared even better than patients treated with longer intervals (5.5–6.0 hours) (29). Contrary to these findings, the Radiation Therapy Oncology Group (RTOG) (31) found more high-grade late toxicity in patients with upper respiratory and digestive tract cancers treated with hyperfractionation. Due to a lack of clinical investigations in other tumor sites, every caution should be exercised when hyperfractionated regimens are planned and carried out. Another aspect of this is repair occurring during delivery of a fraction (32). If cobalt-60 is the radiation source, as in many developing countries, and it has decayed so that the dose rate is

There are few publications from developing countries reporting their results for radiotherapy outcome in cervical cancer patients. Negative results or poor outcomes are not published as often as positive or good results. That could be a reason for the paucity of such publications. Moreover, follow-ups are difficult and usually deficient, which makes it impossible to know the real situation. For example, in one study (40), with 16 patients with stage I cervical cancer, only 9 of them (56%) showed tumor control and no complications after radiotherapy. This is a lower rate of tumor control than would be expected from other published series. Such a low rate might be attributed to long overall treatment time, setup or field-margin factors, or low total biologically effective doses (40).

TRIALS AND ACCIDENTS

As mentioned above, many radiotherapy trials have been undertaken to test hypotheses about the potential benefits of modified schedules. The most successful of these trials have been based on prior knowledge and logical expectations, such as the Danish Head and Neck Cancer Study Group (DAHANCA) sequential series of trials on dose fractionation and chemoradiotherapy (41).

Other trials have been implemented because of safety legislation, and sometimes these have provided very illuminating results. One example is the use of LDR remote-controlled afterloading brachytherapy, which was introduced because of concern over the safety of staff. At the time, it was not appreciated clinically that patients' tissue reactions would be different from the reactions in normally-treated patients using the even lower dose rates produced by the manually-inserted radium sources that had been used for many years. When increasing the dose rate from approximately 50 cGy per minute to approximately 150 cGy per minute, a dose reduction of between 20% and 25% was required in order to achieve a similar low incidence of bowel and urinary morbidity (42–44). These results were consistent with findings in experimental systems as well as with clinical results for more-homogeneous interstitial irradiations. Also, for both tumor control and complications, a high α/β value and a short half-time for repair best fitted the data. This result suggested that consequential late reactions rather than generic late reactions may be responsible for the incidence of morbidity resulting from such treatments (42).

Trials such as this or CHART often provide data that give useful additional knowledge about one or more underlying parameters that govern normal tissue response. In addition, the results from cases that entail the rare overexposure of groups of patients to radiation can provide information to supplement this knowledge. For example, in a cohort of 56 cervical and prostate cancer patients in Panama, half of them received some doses per fraction approximately double those prescribed. Seventeen of the 28 overexposed patients died from 35 days to 21 months after treatment; 13 of the fatalities were caused by rectal complications (40). Survival was improved by performing colostomies. Using the doses that were actually delivered to these patients, it was possible to estimate the tolerance dose, and above this dose there were some deaths. Thus, although it is hoped that such accidents will never occur, the knowledge provided from these rare events can help strengthen the knowledge of the upper limit of the tolerable dose in conventional treatments.

RESPONSE PREDICTION AND PROTECTION OF NORMAL TISSUES

As noted above, dose-incidence curves for normal tissue injury are sigmoid in shape. The first 5% incidence is often considered a general upper limit to acceptability (except in special cases, such as paralysis, for which it is less than 1%). Less than one-fifth of this small fraction is comprised of individuals with known syndromes that predispose them to being radiosensitive. Therefore, the dose that induces, for example, a 5% incidence is denoted the tolerance dose, and all patients with a given stage of a certain type of tumor would be prescribed that dose. This means that 95% of patients do not develop a severe reaction. Therefore, in theory, a higher dose could be administered to these less sensitive patients in order to provide more effective control of their tumors (45). In order to implement this strategy, it is necessary to perform an assay to predict which patients are in the 5% category and which patients are in the remaining, 95% category. One of the problems is that there is a random statistical component to the likelihood of a particular individual placing in a given category. Analysis of the occurrence of telangiectasia of the skin in patients treated with bilateral mammary radiotherapy fields showed that as much as 90% (with 95% confidence limits of 65% and 100%) of the variability in the radioresponsiveness in the right-sided field was explained by the radioresponsiveness in the left-sided field (46). Hence, the random statistical component was fairly small, at approximately 10% of the total variation. However, this is the only example in the literature where these components of variability have been determined, and the general applicability of this result needs to be addressed for other endpoints and other tissues. To predict the nonrandom compo-

nent, many assays have been tested, from molecular to chromosomal and cellular ones, with varying degrees of success. None of them has proved sufficiently robust to allow implementation of this type of dose-prescription-variation strategy. The best assay—that is, the one with the highest positive predictive value, in this case 90%—has been the enzyme marker Transforming Growth Factor beta (TGFβ), used to predict, in a high percentage of lung cancer patients, the progression of marked radiation-induced fibrosis (47, 48).

It is increasingly recognized that the radiation response of normal tissues can be modified through the use of various agents. This could provide a strategy for all patients if the modification were selective for normal tissues and not for tumor. However, if the financial resources available are limited, this treatment should be used first with radiosensitive patients, so that the largest possible number of people would benefit for a particular given expenditure of financial resources. Early reactions in irradiated renewing tissues can be alleviated by the application of radical scavengers, such as amifostine, before irradiation. A recent randomized comparative trial confirmed that amifostine can reduce the severity and incidence of acute esophageal, pulmonary, and hematological toxicity resulting from intensive concurrent chemoradiation used for non-small cell lung cancer (49). Importantly, amifostine had no apparent effect on the survival of these patients, suggesting that it does not have a tumor-protective effect. This finding implies that therapeutic benefits should be achievable for amifostine-treated patients, and this will be tested in further clinical trials. Early tissue reactions can also be alleviated by the application of factors, in particular growth factors, after irradiation (50). These include hemopoietic growth factors in the case of bone marrow, epithelial growth factors for mucosa and epithelium, and essential fatty acids (EFAs) for skin. The mechanism is either for growth factors to accelerate the repopulation and differentiation of precursor cells, or for growth factors to help decrease the vascular component of radiation-induced injury, in the case of EFAs (51). The decreased reactions indicate that up to double the radiation dose can be tolerated by oral mucosa in the presence of keratinocyte growth factor (52). These radioprotective effects may be very useful in accelerated treatments, where early reactions are often more severe than they are in conventional treatments.

Late reactions can also be modified (50) by various vascular-associated compounds such as EFAs in the skin (51) and angiotensin II enzyme inhibitors or receptor blockers in the kidney (53). These agents at least delay the onset of functional injury, and they may also reduce its incidence. Hence, in principle, these agents might not only reduce late reactions, which are dose-limiting, but also allow for the possibility of some dose escalation. The latter, in turn, would ultimately increase tumor control rates.

RESIDUAL INJURY AND RETREATMENT

Following radiotherapy, there is a recovery of normal tissues in surviving patients, but usually not to pre-irradiation levels of tolerance. For example, skin cells may become more susceptible to mechanical trauma. Moreover, bone marrow may be compromised in terms of its stem cell content, making it more susceptible to subsequent cytotoxic agents. These results indicate that retreatment may be possible, but only through the use of lower doses. There are now many cases of recurrences treated with reasonable success. Many findings within experimental animal systems, particularly on the kidney and spinal cord, provide evidence for increasing tolerance to retreatment after the first course of irradiation (54).

CONCLUSIONS

A wealth of preclinical and clinical data has led to a much greater understanding of the mechanistic basis to radiotherapy. This understanding has underpinned a variety of new approaches in radiotherapy, including the use of both physical and biological tools that range from conformal/IMRT techniques to biological response modifiers of various types. Examples of such technically advanced approaches include the use of radiosensitizers, protectors, growth factors, and inhibitors of molecular signaling pathways.

In addition to new advances, there is also the important issue of the treatment of a large number of cancers in developing countries, where resources are often very limited. Resource-sparing protocols of hypofractionation are under development, as are designer treatments for special situations, such as the radiotherapy of cancer in radiosensitive AIDS patients.

From the clinical standpoint, recent decades have witnessed numerous clinical trials that slowly introduced first acute toxicity and then late toxicity as important endpoints in treatment outcome. The problem of the use of different scoring systems must be addressed, leading eventually to a unified scoring system that is widely accepted as the new standard in reporting the adverse effects of radiation therapy. Unfortunately, much of the work has focused on acute toxicity, as is understandable,

since it directly influences treatment delivery. This influence sometimes leads to poor compliance and treatment interruption, which negatively affect the outcome (30). Late toxicity was largely overlooked in the past, possibly due to the lack of uniform criteria for reporting it. It is now well recognized that late toxicity must indeed be reported as a mandatory endpoint on an actuarial basis. This may result in requests for prolonged follow-up, which may additionally burden both follow-up procedures and health care systems. However, if these difficulties are overcome, the ultimate benefit will be improved overall treatment outcomes.

SINOPSIS

Las complicaciones de la radioterapia en los tejidos sanos

En este artículo se describen los mecanismos biológicos que intervienen en las reacciones provocadas por la radioterapia, tanto con tratamientos convencionales como con los más nuevos, y los aplicados en países en desarrollo. Asimismo, se describen las bases biológicas del período de latencia que precede a la aparición de las complicaciones tisulares; la relación entre la dosis de radiación y la incidencia de complicaciones; las consecuencias de aumentar el volumen irradiado; las reacciones tisulares tempranas y tardías; los efectos de cambios en el fraccionamiento de las dosis y en las tasas de dosis; y las reacciones observadas al aplicar una combinación de quimioterapia y radioterapia. Se ofrecen ejemplos de nuevos conocimientos en el campo de la radiobiología clínica que se han adquirido mediante ensayos con nuevos protocolos. Entre las posibles modificaciones de los tratamientos figura el uso de modificadores de la respuesta biológica; en el futuro próximo, podría contarse también con modificaciones de los tratamientos para poder "predecir la respuesta". Por último, las dosis cuya eficacia biológica está demostrada y que están prescritas para tratar el cáncer cervicouterino usando una combinación de braquiterapia y teleterapia son menores en algunos centros que en otros, como se explica en este trabajo. El asunto debe examinarse más a fondo. Una gran abundancia de datos de carácter preclínico y clínico ha permitido comprender mucho mejor las bases biológicas de la radioterapia, y ello a su vez ha llevado a una serie de innovaciones en este campo, tanto en forma de estrategias físicas como biológicas. También es importante prestar atención al tratamiento de una gran variedad de cánceres en países en desarrollo, para los cuales continuamente se elaboran protocolos terapéuticos eficaces orientados a ahorrar recursos. Debería adoptarse en todas partes un único sistema de puntuación para documentar los efectos nocivos de la radioterapia. Asimismo, la toxicidad tardía debería ser un parámetro clínico de valoración obligatoria y figurar en las estadísticas de los resultados del tratamiento.

Palabras clave: neoplasias, radioterapia, relación dosis-respuesta en la radiación, traumatismos por radiación.

REFERENCES

1. Bentzen SM, Dörr W, Anscher M, Denham JW, Hauer-Jensen M, Marks L, et al. Normal tissue effects: reporting and analysis. Semin Radiat Oncol. 2003; 13(3):189–202.
2. Potten CS, ed. Stem cells: their identification and characterization. Edinburgh: Churchill-Livingstone; 1983.
3. Wheldon TE, Michalowski AS, Kirk J. The effect of irradiation on function in self-renewing normal tissues with differing proliferative organization. Br J Radiol. 1982;55(658):759–66.
4. Potten CS, Hendry JH, eds. Cytotoxic insult to tissue: effects on cell lineages. Edinburgh: Churchill-Livingstone; 1983.
5. Rubin P, Finkelstein JN, Williams PC. Paradigm shifts in the radiation pathophysiology of late effects in normal tissues: molecular vs. classic concepts. In: Tobias JS, Thomas PRM, eds. Current radiation oncology. Vol. 3. London: Arnold; 1997. Pp. 1–26.
6. Mason KA, Withers HR, Davis CA. Dose dependent latency of fatal gastrointestinal and bone marrow syndromes. Int J Radiat Biol. 1989;55(1):1–5.
7. Turesson I. Individual variation and dose dependency in the progression rate of skin telangiectasia. Int J Radiat Oncol Biol Phys. 1990;19:1569–74.
8. Jung H, Beck-Bornholdt HP, Svoboda V. Quantification of late complications after radiation therapy. Radiother Oncol. 2001;61:233–46.
9. Bentzen SM, Overgaard J. Clinical manifestations of normal-tissue damage. In: Steel GG. Basic clinical radiobiology. London: Arnold; 1997. Pp. 87–97.
10. Trotti A, Byhardt R, Stetz J. Common toxicity criteria: version 2.0, an improved reference for grading the acute effects of cancer treatment: impact on radiotherapy. Int J Radiat Oncol Biol Phys. 2000;47:13–47.
11. Trotti A, Colevas AD, Setser A, Rusch V, Jaques D, Budach V, et al. CTCAE v3.0: development of a comprehensive grading system for the adverse effects of cancer treatment. Semin Radiat Oncol. 2003; 13:176–81.
12. Pavy JJ, Denekamp J, Letschert J, Littbrand B, Mornex F, Bernier J, et al. Late effects toxicity scoring: the SOMA scale. Radiother Oncol. 1995;35:11–5.
13. Anacak Y, Yalman D, Ozsaran Z. Late radiation effects to the rectum and bladder in gynecologic cancer patients: the comparison of LENT/SOMA and RTOG/EORTC late-effects scoring systems. Int J Radiat Oncol Biol Phys. 2001;50:1107–12.
14. Field SB, Upton AC. Non-stochastic effects: compatibility with present ICRP recommendations. Int J Radiat Biol. 1985; 48:81–94.
15. Bentzen SM. Dose-response relationships in radiotherapy. In: Steel GG, ed. Basic clinical radiobiology. London: Arnold; 2002. Pp. 94–104.
16. Withers HR, Taylor JM, Maciejewski B. Treatment volume and tissue tolerance. Int J Radiat Oncol Biol Phys. 1988;14(4): 751–9.
17. Dorr W, Hendry JH. Consequential late effects in normal tissues. Radiother Oncol. 2001;61:223–31.
18. Kaanders JH, van der Kogel AJ, Ang KK. Altered fractionation: limited by mucosal reactions? Radiother Oncol. 1998;50:247–60.
19. Fowler JF, Harari P, Leborgne F, Leborgne J. Acute radiation reactions in oral and pharyngeal mucosa: tolerable levels in altered fractionation schedules. *Radiother Oncol. 2003;69:161–8.*
20. Stuschke M, Thames HD. Hyperfractionated radiotherapy of human tu-

mours: overview of the randomized clinical trials. Int J Radiat Oncol Biol Phys. 1997;37(2):259–67.

21. Saunders M, Dische S, Barrett A, Harvey A, Griffiths G, Palmar M. Continuous, hyperfractionated, accelerated radiotherapy (CHART) versus conventional radiotherapy in non-small cell lung cancer: mature data from the randomised multicentre trial. CHART Steering Committee. Radiother Oncol. 1999;52(2): 137–48.
22. Horiot JC, Le Fur R, N'Guyen T, Chenal C, Schraub S, Alfonsi S, et al. Hyperfractionation versus conventional fractionation in oropharyngeal carcinoma: final analysis of a randomized trial of the EORTC cooperative group of radiotherapy. Radiother Oncol. 1992;25(4):231–41.
23. Brenner DJ, Martinez AA, Edmundson GK, Mitchell C, Thames HD, Armour EP. Direct evidence that prostate tumors show high sensitivity to fractionation (low α/β ratio), similar to late-responding normal tissue. Int J Radiat Oncol Biol Phys. 2002;52:6–13.
24. Livsey JE, Cowan RA, Wylie JP, Swindell R, Read G, Khoo VS, et al. Hypofractionated conformal radiotherapy in carcinoma of the prostate: five-year outcome analysis. Int J Radiat Oncol Biol Phys. 2003;57(5):1254–9.
25. Withers HR Taylor JM, Maciejewski B. The hazard of accelerated tumour clonogen repopulation during radiotherapy. Acta Oncol. 1988;27(2):131–46.
26. Roberts SA, Hendry JH. Time factors in larynx tumour radiotherapy: lag times and intertumour heterogeneity in clinical datasets from four centers. Int J Radiat Oncol Biol Phys. 1999;45(5):1247–57.
27. Bentzen SM, Saunders MI, Dische S. Repair half-times estimated from observations of treatment-related morbidity after CHART or conventional radiotherapy in head and neck cancer. Radiother Oncol. 1999;53:219–26.
28. Jeremić B, Shibamoto Y. Effect of interfraction interval in hyperfractionated radiotherapy with or without concurrent chemotherapy for stage III nonsmall cell lung cancer. Int J Radiat Oncol Biol Phys. 1996;34:303–8.
29. Jeremić B, Milicic M, Dagovic A, Aleksandrovic J, Milisavljevic S. Interfraction interval in patients with stage III nonsmall cell lung cancer treated with hyperfractionated radiation therapy with or without concurrent chemotherapy. Final results in 536 patients. Am J Clin Oncol. 2004;27(6):616–25.
30. Jeremić B, Shibamoto Y, Milicic B, Dagovic A, Nikolic N, Aleksandrovic J, et al. Impact of treatment interruptions due to toxicity on outcome of patients with early stage (I/II) non-small-cell lung cancer (NSCLC) treated with hyperfractionated radiation therapy (Hfx RT) alone. Lung Cancer. 2003;40:317–23.
31. Cox JD, Pajak TF, Marcial VA. ASTRO plenary: interfraction interval is a major determinant of late effects, with hyperfractionated radiation therapy of carcinomas of upper respiratory and digestive tracts: results from Radiation Therapy Oncology Group protocol 8313. Int J Radiat Oncol Biol Phys. 1991;20: 1191–5.
32. Fowler JF, Welsh JS, Howard SP. Loss of biological effect in prolonged fraction delivery. Int J Radiat Oncol Biol Phys. 2004;59:242–9.
33. Hall EJ, Brenner DJ. The dose-rate effect revisited: radiobiological considerations of importance in radiotherapy. Int J Radiat Oncol Biol Phys. 1991;21(6):1403–14.
34. Nori D, Dasari N, Allbright RM. Gynecologic brachytherapy I: proper incorporation of brachytherapy into the current multimodality management of carcinoma of the cervix. Semin Radiat Oncol. 2002;12:40–52.
35. Patel FD, Sharma SC, Negi PS, Ghoshal S, Gupta BD. Low dose rate vs. high dose rate brachytherapy in the treatment of carcinoma of the uterine cervix: a clinical trial. Int J Radiat Oncol Biol Phys. 1994;28(2):335–41.
36. El-Baradie M, Inoue T, Murayama S, Tang JT, Yamazaki H, Fournier-Bidoz N. HDR and MDR intracavitary treatment for carcinoma of the uterine cervix. A prospective randomized study. Strahlenther Onkol. 1997;173(3):155–62.
37. Hareyama M, Sakata K, Oouchi A, Nagakura H, Shido M, Someya M, et al. High-dose-rate versus low-dose-rate intracavitary therapy for carcinoma of the uterine cervix: a randomized trial. Cancer. 2002;94(1):117–24.
38. Nag S, Erickson B, Thomadsen B, Orton C, Demanes JD, Petereit D. The American Brachytherapy Society recommendations for high-dose-rate brachytherapy for carcinoma of the cervix. Int J Radiat Oncol Biol Phys. 2000;48(1): 201–11.
39. Petereit DG, Pearcey R. Literature analysis of high dose rate brachytherapy fractionation schedules in the treatment of cervical cancer: is there an optimal fractionation schedule? Int J Radiat Oncol Biol Phys. 1999;43(2):359–66.
40. Borrás C, Barés JP, Rudder D, Amer A, Millán F, Abuchaibe O. Clinical effects in a cohort of cancer patients overexposed during external beam pelvic radiotherapy. Int J Radiat Oncol Biol Phys. 2004;59(2):538–50.
41. Overgaard J, Hansen HS, Specht L, Overgaard M, Grau C, Andersen E, et al. Five compared with six fractions per week of conventional radiotherapy of squamous-cell carcinoma of head and neck: DAHANCA 6 and 7 randomised controlled trial. Lancet. 2003;362(9388): 933–40.
42. Roberts SA, Hendry JH, Swindell R, Wilkinson JM, Hunter RD. Compensation for changes in dose-rate in radical low-dose-rate brachytherapy: a radiobiological analysis of a randomised clinical trial. Radiother Oncol. 2004;70(1): 63–74.
43. Leborgne F, Fowler JF, Leborgne JH, Zubizarreta E, Chappell R. Fractionation in medium dose rate brachytherapy of cancer of the cervix. Int J Radiat Oncol Biol Phys. 1996;35(5):907–14.
44. Leborgne F, Fowler JF, Leborgne JH, Zubizarreta E, Chappell R. Biologically effective doses in medium dose rate brachytherapy of cancer of the cervix. Radiat Oncol Investig. 1997;5(6):289–99.
45. Mackay RI, Hendry JH. The modelled benefits of individualizing radiotherapy patients' dose using cellular radiosensitivity assays with inherent variability. Radiother Oncol. 1999;50(1):67–75.
46. Safwat A, Bentzen SM, Turesson I, Hendry JH. Deterministic rather than stochastic factors explain most of the variation in the expression of skin telangiectasia after radiotherapy. Int J Radiat Oncol Biol Phys. 2002;52:198–204.
47. Anscher MS, Kong FM, Andrews K. Plasma transforming growth factor $\beta 1$ as a predictor of radiation pneumonitis. Int J Radiat Oncol Biol Phys. 1998;41: 1029–35.
48. Anscher MS, Marks LB, Shafman TD. Using plasma transforming growth factor beta-1 during radiotherapy to select patients for dose escalation. J Clin Oncol. 2001;19:3758–65.
49. Komaki R, Lee JS, Milas L. Effects of amifostine on acute toxicity from concurrent chemotherapy and radiotherapy for inoperable non-small-cell lung cancer: report of a randomized comparative trial. Int J Radiat Oncol Biol Phys. 2004; 58:1369–77.
50. Hendry JH. Biological response modifiers and normal tissue injury after irradiation. Semin Radiat Oncol. 1994;4(2): 123–32.
51. Hopewell JW, Robbins ME, van den Aardweg GJ, Morris GM, Ross GA, Whitehouse E, et al. The modulation of radiation-induced damage to pig skin by essential fatty acids. Br J Cancer. 1993;68(1):1–7.
52. Dorr W, Noack R, Spekl K, Farrell CL. Modification of oral mucositis by keratinocyte growth factor: single radiation exposure. Int J Radiat Biol. 2001;77(3): 341–7.
53. Moulder JE, Robbins ME, Cohen EP, Hopewell JW, Ward WF. Pharmacologic modification of radiation induced late normal tissue injury. Cancer Treat Res. 1998;93:129–51.
54. Stewart F. Retreatment tolerance of normal tissues. In: Steel GG, ed. Basic clinical radiobiology. London: Arnold; 2002. Pp. 231–40.

Manuscript received on 14 December 2004. Revised version accepted on 10 August 2005.

Postal dose audits for radiotherapy centers in Latin America and the Caribbean: trends in 1969–2003

Joanna Izewska,[1]
Stanislav Vatnitsky,[1]
and Kenneth R. Shortt[1]

Suggested citation: Izewska J, Vatnitsky S, Shortt KR. Postal dose audits for radiotherapy centers in Latin America and the Caribbean: trends in 1969–2003. Rev Panam Salud Publica. 2006; 20(2/3):161–72.

SYNOPSIS

Since 1969 the International Atomic Energy Agency and the World Health Organization (along with the Pan American Health Organization, working with countries in Latin America and the Caribbean) have operated postal dosimetry audits based on thermoluminescent dosimetry (TLD) for radiotherapy centers. The purpose of these audits is to provide an independent dosimetry check of radiation beams used to treat cancer patients. The success of radiotherapy treatment depends on accurate dosimetry. Over the period of 1969 through 2003 the calibration of approximately 5 200 photon beams in over 1 300 radiotherapy centers in 115 countries worldwide was checked. Of these audits, 36% were performed in Latin America and the Caribbean, with results improving greatly over the years. Unfortunately, in several instances large TLD deviations have confirmed clinical observations of inadequate dosimetry practices in hospitals in various parts of the world or even accidents in radiotherapy, such as the one that occurred in Costa Rica in 1996. Hospitals or centers that operate radiotherapy services without qualified medical physicists or without dosimetry equipment have poorer results than do hospitals or centers that are properly staffed and equipped. When centers have poor TLD results, a follow-up program can help them improve their dosimetry status. However, to achieve audit results that are comparable to those for centers in industrialized countries, additional strengthening of the radiotherapy infrastructure in Latin America and the Caribbean is needed.

Key words: radiotherapy, quality control, medical audit, international cooperation, developing countries, Latin America, Caribbean region.

Since 1969 the International Atomic Energy Agency (IAEA), in conjunction with the World Health Organization (WHO) (and the Pan American Health Organization (PAHO), working with countries in Latin America and the Caribbean), has operated a program to validate the calibration of radiotherapy beams used for the treatment of cancer patients with radiation therapy (1–6). Using thermoluminescence dosimeters (TLDs), this IAEA/WHO program provides an independent verification or a quality assurance (QA) audit of the dose delivered by radiotherapy treatment machines. Independent external quality audits are widely recognized as an effective method for verifying that the quality of dosimetry practice in a radiotherapy center is appropriate. Precise clinical dosimetry is essential to maximize the probability of success in cancer therapy using radiation, which demands knowing the exact radiation dose delivered to the patient's tumor. The IAEA/WHO TLD program

[1] International Atomic Energy Agency, Vienna, Austria. Send correspondence to: Joanna Izewska, International Atomic Energy Agency, Wagramer Strasse 5, 1400 Vienna, Austria.

aims at improving the accuracy and consistency of clinical radiotherapy dosimetry worldwide.

In 1991 the program was expanded to include high-energy photon beams from medical linear accelerators, in addition to those produced by cobalt-60 machines. Through this program the IAEA has also monitored the performance of secondary standards dosimetry laboratories since 1981 (7, 8). (Secondary standards dosimetry laboratories (SSDLs) are national laboratories that maintain secondary-standard-class dosimetry systems and that calibrate dosimetry instruments that are used for beam output measurements at radiotherapy centers.) The audits are coordinated with national audit networks operating in several countries, and with organizations that provide dose audits in industrialized countries (5).

The operation of the TLD program is carried out through close collaboration among the IAEA, WHO, and PAHO. Based on the requests collected by WHO and PAHO, the IAEA prepares packages with TLDs for radiotherapy centers. Each center receives two TLDs for irradiation. TLDs are in the form of capsules 2.5 cm long and 0.5 cm in diameter. They are accompanied by instructions for their irradiation, data sheets for reporting doses, and special TLD holders. WHO and PAHO distribute TLD packages to radiotherapy centers, where they are irradiated by hospital staff and returned through WHO or PAHO to the IAEA for evaluation. The dose given to the dosimeters is determined at the IAEA's Dosimetry Laboratory, and the result is compared with the dose stated by the hospital staff.

Centers are requested to irradiate the TLD using a special holder that is placed in a tank filled with water. The holder has an opening for the TLD, with the TLD being placed at a depth of 5 cm in the water. The irradiation should be done in the same way as for a patient with a tumor located at a depth of 5 cm, following the normal practice at the center and calculating the dose to the TLD the same way as for patient treatments (i.e., using routine clinical data). The TLD irradiation is to be performed either by a medical physicist, if one is available, or by other medical personnel. In the TLD data sheet the participants report data related to the treatment machines, such as the machine model, its date of installation, and the beam parameters, including the beam output as used clinically. Determination of the dose measured with an ionization chamber may be made following the TLD irradiation if the hospital has a medical physicist and dosimetry equipment available. The beam output is then calculated following a dosimetry code of practice (dosimetry protocol), and the details of the procedure are reported on the data sheet.

Discrepancies of less than 5% between the participant-stated dose and the TLD-measured dose are considered acceptable. This 5% acceptance limit defines the maximum discrepancy between stated and measured doses that does not require any further investigation. For centers with results outside the 5% acceptance limit, the IAEA has established a follow-up program that uses a second TLD check to give centers a chance to correct the discrepancy. However, if the follow-up TLD check is still unsuccessful and the errors cannot be resolved through communication with the center or by the national SSDL, on-site visits by IAEA experts in radiotherapy physics are organized to help identify and rectify the dosimetry problems.

The information that participants provide on the TLD data sheets is systematically analyzed at the IAEA. This is done in order to evaluate the status of calibration dosimetry, to trace the source of any discrepancies in the dose measurement and calculation, and to gain an understanding of the status of the use of different dosimetry equipment and procedures and various dosimetry codes of practice (protocols). Different dosimetry protocols are used in countries around the world, ranging from old exposure-based protocols of the early 1970s, through air kerma-based protocols developed in the 1980s, up to the recently-developed modern absorbed dose to water-based protocols.

This paper discusses the results of the IAEA/WHO TLD audits in Latin America and the Caribbean, taking into account the staffing and the availability and status of equipment and dosimetry practices in radiotherapy centers in those countries. The results from the TLD audits in Latin America and the Caribbean are compared with the results from other geographical regions of the world.

CALIBRATION AND QUALITY ASSURANCE OF THE IAEA TLD SYSTEM

The IAEA TLD system has been described previously (3). The calibration of the system is derived from ionization chamber measurements of the absorbed dose to water at the position of the calibration TLD. The calibration follows the IAEA TRS-398 code of practice for dosimetry in radiotherapy (9). The ionization chamber calibration is traceable to the International Bureau of Weights and Measures (*Bureau international des poids et mesures*, BIPM), which is an international organization that ensures worldwide uniformity of measurements and their traceability to the International System of Units (SI).

A thorough set of quality control procedures is maintained for the IAEA TLD system in order to

ensure its high-quality operation. In addition to internal quality control by the IAEA Dosimetry Laboratory itself, external checks of the system's performance are carried out through a program of reference TLD irradiations provided by the BIPM and several primary standards dosimetry laboratories (PSDLs). (PSDLs maintain primary standards in dosimetry. Calibration of instruments by SSDLs is traceable to primary standards.) The IAEA also exchanges dosimeters and compares measurements with other TLD-based QA networks in Europe and the United States of America. One of those networks is the ESTRO Quality Assurance (EQUAL) network for radiotherapy, which was set up for the countries of the European Union. (ESTRO is the European Society for Therapeutic Radiology and Oncology). Another of the networks is the Radiological Physics Center (RPC), which operates in North America (5). These linkages ensure that the three international TLD networks operate at similar levels of performance, based on consistent standards. In addition, a few radiotherapy centers, from different world regions, that have good records in dosimetry provide reference TLD irradiations for the IAEA, using their clinical beams. The reference irradiations by these reference institutions are synchronized in time with TLD irradiations by radiotherapy centers so that the consistency of the TLD measurements is assured for each TLD run organized by the IAEA for the centers.

The reference TLD irradiation program mentioned in the paragraph above has been carried out by the IAEA since 1997. The results of 116 irradiations by the BIPM and PSDLs during 1997–2003 showed that the IAEA TLD system performed very well. The mean of the distribution of the ratio of the IAEA's determined doses to the doses stated by the BIPM or the PSDL was 1.001, with a standard deviation of 0.008, and with all the data falling between 0.982 and 1.025. Similar to the results with the reference irradiations performed by the BIPM and the PSDLs, 260 results from the irradiations provided by the major TLD networks and reference centers showed very good international consistency in the measurement of doses for 1997 through 2003. The mean of the distribution was 1.001, the standard deviation was 0.011, and all the results fell between 0.953 and 1.033.

PARTICIPATION OF RADIOTHERAPY CENTERS IN THE IAEA TLD PROGRAM

Over the 34-year period of 1969 through 2003, the IAEA/WHO TLD program checked the calibration of 5 163 photon beams. The checks were made in 1 339 radiotherapy centers in 115 countries, in Latin America and the Caribbean (1 856 checks), the Western Pacific (1 099 checks), Europe (942 checks), Southeast Asia (632 checks), the Eastern Mediterranean (462 checks), and Africa (172 checks).

In Latin America and the Caribbean over that 1969–2003 period the 1 856 audits were conducted in 327 centers of 24 countries. These 1 856 audits comprised 36% of the 5 163 checks done around the world through the IAEA/WHO TLD program. The 1 856 figure included audits done at 73 centers in Argentina and Brazil, but those two countries later developed national TLD programs of their own and became independent of the IAEA/WHO services. The other 254 centers, in 22 countries of Latin America and the Caribbean, have continued to participate in the IAEA/ WHO TLD audits.

The respective numbers of audits in individual countries of Latin America and the Caribbean performed by IAEA/WHO in 1969–2003 varied from a few in Haiti to about 400 in Colombia. Some centers, especially newly-established ones, received TLDs only once, whereas others received TLDs up to 20 times for each beam. The number of beam checks in Latin America and the Caribbean started with 15 in 1969 and steadily increased in each subsequent decade, from approximately 220 beam checks in the 1970s, to approximately 400 in the 1980s, and to over 760 in the 1990s. For the 2000–2003 period there were 470 beam checks.

Close cooperation of the IAEA with WHO and PAHO has resulted in a systematic improvement in the return rate of irradiated TLDs from radiotherapy centers, from 60% to 70% in the early years to more than 90% at present. Currently, some geographical regions have a nearly perfect record for returning TLDs, whereas other regions are not as efficient. In some instances, due to problems with local mail services, the TLDs do not reach the centers. In other instances, the TLDs are received, but they are not irradiated and mailed back to the IAEA for analysis.

In Latin America and the Caribbean, the return rate of irradiated TLD batches has gradually improved, reaching the 95% level in 2002–2003. A disruption in the TLD distribution happened in Latin America and the Caribbean in 2001, when two batches of TLDs that two national TLD coordinators had ordered for local centers remained unirradiated due to organizational problems in these countries. These difficulties have now been resolved, and the centers in both countries have participated in TLD audits in subsequent years.

For participants around the world the typical time between the TLD irradiation and the return of irradiated TLDs through WHO or PAHO to the IAEA for analysis is about one to two months. The longest delay occurs during the collection of the ir-

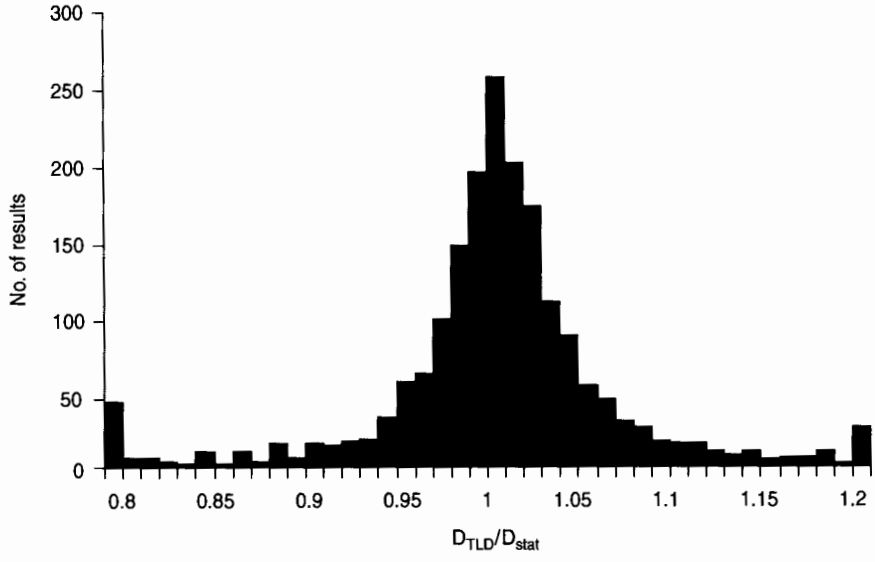
radiated TLDs by country coordinators, WHO regional offices, and PAHO. In Latin America and the Caribbean the average delay in returning the irradiated TLDs to the IAEA is approximately two months, with the delay generally in the range of one to three months, depending on the country. Unfortunately, in some countries, excessive delays are still too frequent. For example, in two countries of Latin America and the Caribbean, the delay in returning the TLD batches after the irradiation exceeded four months in 2000–2003. When errors in the radiotherapy beam calibration occurred, possibly resulting in inferior quality of patients' treatments, the errors remained unnoticed for prolonged periods. The number of patients' treatments potentially affected by poor dosimetry could be reduced if there were a more rapid resolution of the discrepancies.

RESULTS OF THE TLD AUDITS FOR RADIOTHERAPY CENTERS

Figure 1 shows the distribution of the 1 856 results in Latin America and the Caribbean for the 1969–2003 period. The histogram includes 1 458 checks of cobalt-60 (Co-60) beams and 398 checks of high-energy X-ray beams. The respective bars in the histogram indicate the ratio of the IAEA's determined dose (D_{TLD}) relative to the dose stated by the hospital (D_{stat}).

Table 1 compares the distribution of the TLD results for Latin America and the Caribbean with those for other geographical regions of the world. The table provides data for the entire 1969–2003 period as well as for just 2000–2003. As can be seen from the upper part of Table 1, the distribution of results in Latin America and the Caribbean for the period of 1969–2003 had a mean of 1.011 and a standard deviation of 0.095. The mean of the distribution of results of 1.011 differs from unity by 1.1%. As the IAEA TLD system has been verified by BIPM and PSDLs, this difference may be attributed to the differences in dosimetry equipment in radiotherapy centers and traceability of the dosimetry equipment calibration to different standards laboratories. The values include a minimum of $D_{TLD}/D_{stat} = 0.00$ (TLDs received no dose, although the data sheet indicated they had been irradiated) and a maximum of $D_{TLD}/D_{stat} = 2.19$ (by mistake, TLDs were irradiated twice). In 75% of the cases (1 388/1 856), the results were within the acceptance limit, whereas 4% (68/1 856) had major discrepancies (ones larger than 20%), indicating serious problems in dosimetry practices in those centers. In other geographical regions of the world the results were slightly better, with 78% of the checks (2 568/3 307) being successful in that same 1969–2003 period. In

FIGURE 1. Frequency distribution of the results of 1 856 IAEA/WHO thermoluminescent dosimetry (TLD) audits of radiotherapy centers in Latin America and the Caribbean, 1969–2003, for the ratios of the IAEA's determined dose (D_{TLD}) relative to the dose stated by the hospital (D_{stat})[a]



[a] The mean of the distribution was 1.011, and the standard deviation was 0.095. The minimum was 0.00 and the maximum 2.19. The two border bins show the results below 0.8 and above 1.2.

TABLE 1. Results of the IAEA/WHO thermoluminescent dosimetry (TLD) audits in Latin America and the Caribbean compared to those for other geographical regions of the world, for 1969–2003 and for 2000–2003

Period/Parameter	Latin America and the Caribbean	Other world regions	All regions
1969–2003			
Number of audits	1 856	3 307	5 163
Mean of the distribution, $\frac{D_{TLD}}{D_{stat}}$ [a]	1.011	1.012	1.012
Standard deviation	0.095	0.075	0.083
Percentage of acceptable results[b]	75%	78%	77%
2000–2003			
Number of audits	470	1 073	1 543
Mean of the distribution, $\frac{D_{TLD}}{D_{stat}}$ [a]	1.007	1.008	1.008
Standard deviation	0.085	0.072	0.076
Percentage of acceptable results[b]	87%	85%	86%

[a] $\frac{D_{TLD}}{D_{stat}}$ is the mean of the distribution of the TLD results expressed as ratios of the IAEA-determined dose (D_{TLD}) relative to the dose stated by the center (D_{stat}).

[b] The "acceptable" TLD results were those that were within a 5% limit of the TLD-measured to center-stated dose, i.e., $0.95 \leq D_{TLD}/D_{stat} \leq 1.05$.

2000–2003 the fraction of acceptable results in all regions increased compared to the results for the entire 1969–2003 period, with more noticeable improvement in Latin America and the Caribbean (increase from 75% to 87%) than in other regions (increase from 78% to 85%) (Table 1). These increases indicate an overall improvement in dosimetry practices in radiotherapy centers around the world.

Centers that have been regularly participating in the IAEA/WHO and other external dosimetry audits achieve better results than do institutions that are participating in an audit for the first time (5). In general, over the 2000–2003 period, only 78% of the radiotherapy centers in the world that received TLDs from the IAEA/WHO for the first time had results within the 5% acceptance limit, whereas 90% of the institutions participating regularly had acceptable results. The proportion of poor results with large deviations (beyond 10%) is also significantly higher for new centers than for those having participated in the audits previously. The difference between Latin America and the Caribbean and other world regions is that centers in Latin America and the Caribbean have a longer history of participating in the audits (see previous section, entitled "Participation of Radiotherapy Centers in the IAEA TLD Program"). Of the 470 beam checks performed in Latin America and the Caribbean in the 2000–2003 period, only 43 of them (9%) were from institutions participating in the IAEA/WHO program for the first time. In the same period in the other regions, 480 of the 1 043 beam checks (45%) were performed for centers participating for the first time. Compared with other regions of the world in the 2000–2003 period, fewer centers in Latin America and the Caribbean were first-time participants in the IAEA/WHO TLD program. That difference helps explain the fact that the percentage of acceptable results increased more in Latin America and the Caribbean during the last four years of that 1969–2003 period than it did in other parts of the world.

TLD RESULTS FOR THE COBALT-60 BEAMS AND THE HIGH-ENERGY X-RAY BEAMS FROM LINEAR ACCELERATORS IN 2000–2003

The 1 543 TLD results presented in the lower part of Table 1 consist of the checks of 837 Co-60 beams and of 706 high-energy X-ray beams from linear accelerators performed around the world in the 2000–2003 period. To gain a better understanding of the impact of basic radiotherapy infrastructure on the performance of radiotherapy centers in the TLD program, Table 2 analyzes the TLD results separately for Co-60 units and for linear accelerators, and it also compares the results in Latin America and the Caribbean with those for other world regions.

TABLE 2. Results of the IAEA/WHO thermoluminescent dosimetry (TLD) audits in Latin America and the Caribbean compared to those for other geographical regions of the world, for 837 Co-60 beams and 706 high-energy X-ray beams, 2000–2003

Beam/Parameter	Latin America and the Caribbean	Other regions	All regions
Co-60 beams			
Number of audits	242	595	837
Mean of the distribution, $\frac{D_{TLD}}{D_{stat}}$ [a]	1.006	1.010	1.008
Standard deviation	0.111	0.092	0.098
Percentage of acceptable results[b]	87%	78%	81%
Fraction of deviations beyond 10%	8%	10%	9%
High energy X-ray beams			
Number of audits	228	478	706
Mean of the distribution, $\frac{D_{TLD}}{D_{stat}}$ [a]	1.009	1.006	1.007
Standard deviation	0.041	0.035	0.037
Percentage of acceptable results[b]	85%	94%	92%
Fraction of deviations beyond 10%	4%	2%	2%

[a] $\frac{D_{TLD}}{D_{stat}}$ is the mean of the distribution of the TLD results expressed as ratios of the IAEA-determined dose (D_{TLD}) relative to the dose stated by the center (D_{stat}).

[b] The "acceptable" TLD results were those that were within a 5% limit of the TLD-measured to center-stated dose, i.e., $0.95 \leq D_{TLD}/D_{stat} \leq 1.05$.

Overall, the results for all regions of the world (shown in the last column of Table 2) were better for X rays from linear accelerators than for Co-60 beams, with 92% (646/706) of results within the acceptance limit for high-energy X rays, versus 81% (674/837) for Co-60 beams. Similarly, large deviations (beyond 10%) for high-energy X rays occurred on 2% of occasions (17/706) versus 9% (76/837) for Co-60 beams. This is also reflected by the standard deviations of the distributions, which are 0.037 for high-energy X rays from linear accelerators and 0.098 for Co-60 beams.

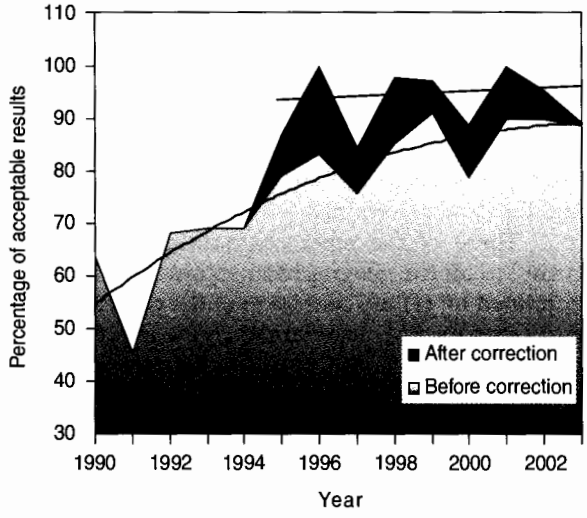
In Latin America and the Caribbean, 66 deviations outside the 5% limit were detected in 470 checks, including 32/242 deviations (13%) for Co-60 beams and 34/228 deviations (15%) for high-energy X-ray beams. Although the occurrence of the deviations is approximately the same for Co-60 units and for medical linear accelerators, the spread of the distribution for Co-60 beams is significantly larger than that for high-energy X-ray beams. This indicates that the accuracy of calibration of high-energy X-ray beams is generally better compared to that for Co-60 beams. The fraction of large deviations (beyond 10%) is higher for Co-60 beams (8%, 19/242) than for high-energy X rays (4%, 10/228), an effect that is not inherent to the machine type (linear accelerator versus cobalt machine). This result might be explained by the fact that the centers with linear accelerators are supported by better medical physics services, whereas the institutions with only Co-60 units do not always have access to well-qualified medical physicists and to dosimetry equipment. Indeed, the results for Co-60 beams in the centers that have both linear accelerators and Co-60 units are similar to the results for centers that only have linear accelerator beams.

When comparing the results of the TLD audits for 2000–2003 for Co-60 beams in different world regions, Latin America and the Caribbean had a noticeably higher fraction of acceptable results (87%, or 210/242) than did other regions (78%, or 463/595). There was a similar pattern for deviations beyond the 5% level, with it being only 13% (32/242) in Latin America and the Caribbean, compared to 22% (132/595) in other regions. Poor results are related to obsolete, malfunctioning Co-60 units and unreliable or out-of-date dosimetry systems used by medical physicists for Co-60 beam calibrations. In Latin America and the Caribbean the dosimetry equipment age and quality do not constitute a large-scale problem (see the subsection below entitled "Status of dosimetry equipment"). In addition, the age of the Co-60 units in Latin America and the Caribbean, as reported on the TLD data sheets for 2000–2003, was quite balanced, with 60% of the machines being more than 10 years old and 40% being newer than that. Of the Co-60 units, 20% of them had been installed after the year 2000, and 25% were more than 20 years old. In a few cases, poor

maintenance led to malfunctions in the radiotherapy machines, producing major TLD discrepancies.

The situation is quite different for the results of the IAEA/WHO TLD audits for high-energy X-ray beams from linear accelerators. Discrepancies in dosimetry occurred more frequently in Latin America and the Caribbean than in the other geographical regions (Table 2). In other regions the institutions operating linear accelerators are typically staffed with well-trained medical physicists and are equipped with the relevant dosimetry systems, which is not the case in some hospitals of Latin America and the Caribbean. Unfortunately, some linear accelerator-based facilities in Latin America and the Caribbean are operated without the appropriate medical physics support (see the subsection entitled "Availability of medical physics staff in radiotherapy centers"), which typically leads to poorer TLD results and may constitute a potential risk of errors in the dose delivered to patients treated at these facilities. Also, approximately 20% of linear accelerators in Latin America and the Caribbean are older than 20 years, and, if not properly maintained, they may not be as reliable as new machines.

FIGURE 2. Percentage of the results of the IAEA/WHO thermoluminescent dosimetry (TLD) audits within the 5% acceptance limit for radiotherapy centers in Latin America and the Caribbean[a]



[a] The light gray area indicates results obtained in the first check, and the dark gray area corresponds to the percentage of results that were improved in the follow-up process and that achieved the 5% acceptance level. The smooth lines refer to average values.

IMPROVEMENT OF THE TLD RESULTS IN LATIN AMERICA AND THE CARIBBEAN

There was a systematic rise in the fraction of TLD results within the acceptance limit of 5% in Latin America and the Caribbean between 1990 and 2003 (Figure 2). Although less pronounced, a similar rise occurred in other world regions over the same period. The improvement in Latin America and the Caribbean was considerable, with an increase in acceptable results from approximately 55% in 1990 to 90% in 2003. This is mainly due to greater interest in quality assurance in radiotherapy and the regular participation of centers in the TLD audit program. The rate of increase in the percentage of beams within the acceptance limit is expected to be slower in the future, as more institutions with limited resources (having no medical physicists or dosimetry equipment) join the TLD program. To bring the new participants to the level of well-performing centers, an increased allocation of resources for equipment and for training of medical physicists would be required. Since 1996 all hospitals worldwide participating in the IAEA/WHO program that have had poor TLD results have been contacted by IAEA/WHO to identify and resolve the problems in dosimetry and have been offered a second, follow-up TLD check. In instances where deviations are not corrected during the follow-up process, the next step involves support to the local medical physicists by experts in medical radiation physics, either recruited nationally or, in cases where such expertise does not exist in the country, recruited internationally. In Latin America and the Caribbean the follow-up procedures are managed by PAHO, with the help of the national TLD coordinators. In isolated cases in Latin America and the Caribbean, the IAEA directly contacted centers to assist in the resolution of the discrepancies. A few persistent deviations required the assistance of IAEA experts, who analyzed the reasons for the discrepancies during on-site visits and assisted local staff in implementing corrective actions.

Thanks to these actions by the IAEA, PAHO, and local experts, several participants in Latin America and the Caribbean improved their results in the follow-up TLD irradiation, which resulted in an increase in the fraction of acceptable TLD results for the beam calibration to approximately 95% in 1996–2003. This 95% included the correct results that did not require being followed up as well as the poor results corrected in the follow-up process. Unfortunately, 5% of the results remained uncorrected, either due to a failure to respond to the IAEA and PAHO efforts or due to local problems that could not be resolved without the allocation of additional resources.

REASONS FOR THERMOLUMINESCENT DOSIMETRY RESULTS OUTSIDE THE ACCEPTANCE LIMIT

For all data sheets, the IAEA verifies the participant's calculation of the dose delivered to the TLD based on the data reported. Any discrepancy between the dose calculated by a participant and the dose calculated by the IAEA is investigated. However, special attention is given to data sheets where discrepancies between the participant's stated dose and the dose determined with the TLD occur.

Three of the most common errors that occurred in all the geographical regions in 2000–2003 pertained to: (1) the confusion of the clinical geometry setup for TLD irradiation; (2) incorrect calculation of the irradiation time for the wrong depth, even though the TLD was placed at the prescribed depth; and (3) errors related to the combination of various mistakes in the dose calculation. More than half the deviations had reasons that could not be traced because of a lack of dosimetry data or because of an inconsistency in the data that were reported. When either the information related to the clinical output of the audited radiotherapy machine or the details of dose measurement are missing, it is not possible to provide an explanation of the deviation detected between the dose reported by the institution and the dose measured by the TLD. Some problems are caused by improper use of dosimetry equipment or poor treatment-machine conditions. Other problems are due to insufficient training of staff working in radiotherapy.

The frequencies of deviations outside the acceptance limit in Latin America and the Caribbean due to TLD setup errors were similar to those observed in other world regions during 2000–2003. However, several typical errors registered in other regions did not occur in the TLD audits in Latin America and the Caribbean. These errors occurring only in the other regions included some that were caused by incorrect use of old, exposure-based dosimetry codes of practice, misunderstanding of calibration coefficients, and incorrect use of plastic-to-water dose conversion factors for the measurements made in plastic phantoms. (Although they are not recommended by the modern dosimetry codes of practice, plastic phantoms are occasionally used for beam calibrations in centers not having the proper water phantoms.) The radiotherapy beam calibration is usually performed by medical physicists in a water phantom, and the dose calculation follows up-to-date dosimetry codes of practice that are based on air kerma calibrations or on absorbed dose to water calibrations. As noted in a subsequent subsection entitled "Use of dosimetry codes of practice for dose determination," in general, old, exposure-based dosimetry protocols are not used anymore in Latin America and the Caribbean. However, in Latin America and the Caribbean the percentage of "unknown reasons" for poor TLD results is significantly higher compared to that in other world regions, due to the large number of data sheets in Latin America and the Caribbean submitted without dosimetry data.

In several instances that took place in 1969–2003 in various parts of the world, large TLD deviations confirmed clinical observations of inadequate dosimetry practices in centers, or the deviations even uncovered accidents in radiotherapy. In an overexposure of patients in Costa Rica in 1996, more than 100 patients were given, in a one-month period, almost twice the prescribed dose (10). This resulted in the death of 42 patients within 9 months of the accident and in serious injuries to many others. In another hospital the ratios of D_{TLD}/D_{stat} varied from 0.61 to 1.20 in subsequent TLD audits, due to erratic functioning of the Co-60 shutter system, which was attributable to poor maintenance of the Co-60 unit. No output measurements had been made for a few years, and several patients treated with this Co-60 beam might have been affected. A patient underdosage that leads to a decrease in the local tumor control rate and thereby jeopardizes the success of radiotherapy treatment may not be detected by clinical observation for several years (11). If beam output measurements are not performed regularly, the TLD audit becomes a useful tool to recognize and correct the problem before clinical results are affected.

Nevertheless, poor TLD results do not always reflect errors in the beam output routinely used to treat patients in clinics. Even if TLDs indicate doses that are not consistent with the reported doses, the doses routinely given to patients might still be correct. Typically, this occurs where the TLD dose was calculated and reported in the data sheet for the specified geometry setup but, by mistake, the actual TLD irradiation was conducted using another geometry. The differences in geometry result in discrepancies between the reported dose and the TLD-measured dose. Mishaps during the TLD irradiation are not relevant to routine clinical procedures if quality control procedures for clinical dosimetry are well established and ensure that the beam data are properly implemented in the clinical routine. Problems with TLD irradiations pertain especially to the circumstances where junior physics or medical staff are given the special task of TLD irradiation without their fully understanding the instructions. A few extreme deviations that were caused by communication problems have been observed. For example, in one case, TLDs were irradiated twice, resulting in the ratio of D_{TLD}/D_{stat} being close to 2. In another cen-

ter, TLDs were irradiated with 2-Gy fractions for four days in a row, resulting in the ratio of D_{TLD}/D_{stat} being close to 4. (This result is not included in the TLD statistics reported in this report.) Fortunately, these cases had no direct clinical relevance.

DOSIMETRY INFORMATION FROM THE TLD DATA SHEETS IN 2000–2003

Of the 470 data sheets submitted by the participants of the IAEA/WHO TLD dosimetry audits in Latin America and the Caribbean in 2000–2003, the information on procedures for dose determination from ionization chamber measurements was given for only 310 of them (66%); that is, 160 data sheets were submitted without reporting data related to the beam calibration. In contrast, in other world regions, approximately 80% of the participants in the TLD audit program reported at least some dosimetry data.

Availability of medical physics staff in radiotherapy centers

The participating institutions are requested to indicate in their data sheets whether the TLD irradiation was performed by a medical physicist or by medical personnel (either a radiation oncologist or a radiotherapy technologist). With the audits in Latin America and the Caribbean in 2000–2003, the availability of a medical physicist responsible for dosimetry was confirmed in 391 of the 470 cases (83%), including 8 in which the services of a visiting physicist were used. On 79 of the 470 data sheets (17%), the centers reported no medical physicist on staff, so no beam calibration details were provided. These 79 cases were part of the 160 data sheets that were submitted without providing information on ion chamber measurements. The remaining 81 of the 470 data sheets (17%) without measurement information most likely indicate that the local medical physicist could not perform measurements due to the lack of dosimetry equipment.

Table 3 shows the distribution of the results (in terms of D_{TLD}/D_{stat}) for the centers in Latin America and the Caribbean in 2000–2003 that had a medical physicist on duty for regularly treating patients and for the centers that did not have a physicist on duty. The spread of the TLD results is smaller (standard deviation of 0.070) for institutions with medical physicists on duty than for those without such staff (standard deviation, 0.134). In addition, 89% (345/391) of the centers with medical physicists had TLD results within the acceptance limit, whereas only 70% (55/79) of the centers without a medical physicist performed successfully in this TLD audit. This compares with the worldwide average of 86% (Table 1).

TABLE 3. Results of the IAEA/WHO thermoluminescent dosimetry (TLD) audits in 2000–2003 for Latin America and the Caribbean, performed with and without medical physics support for treating patients on a regular basis, for 242 Co-60 beams and 228 high-energy X-ray beams from linear accelerators

Parameter	Medical physicist on duty	No medical physicist on duty
Number of audits	391	79
Mean of the distribution, $\frac{D_{TLD}}{D_{stat}}$ [a]	1.011	0.989
Standard deviation	0.070	0.134
Percentage of acceptable results[b]	89%	70%

[a] $\frac{D_{TLD}}{D_{stat}}$ is the mean of the distribution of the TLD results expressed as ratios of the IAEA-determined dose (D_{TLD}) relative to the dose stated by the center (D_{stat}).

[b] The "acceptable" TLD results were those that were within a 5% limit of the TLD-measured to center-stated dose, i.e., $0.95 \leq D_{TLD}/D_{stat} \leq 1.05$.

Although not shown in Table 3, there are a large number of radiotherapy centers running medical accelerators in Latin America and the Caribbean without the regular support of a medical physicist. For example, in some hospitals a visiting physicist performed the calibration of linear accelerator beams several months before the date of the TLD irradiation. Such sporadic or infrequent beam calibrations are considered inadequate. The output of radiotherapy beams should be checked on a regular basis. Both the American Association of Physicists in Medicine (AAPM) (12) and the IAEA (13) strongly recommend that radiotherapy centers implement QA programs and employ a full-time medical physicist, especially if they operate linear accelerators. Using the services of visiting physicists may be necessary in some cases due to the insufficient number of qualified medical physicists in Latin America and the Caribbean. However, the data in Table 3 show that hospitals providing radiotherapy services without medical physicists or dosimetry equipment had noticeably poorer results, which may have had a negative impact on the accuracy of the dose delivered and on patient outcomes.

Status of dosimetry equipment

As mentioned earlier, at least partial information on dosimetry equipment and procedures was given on 66% (310/470) of the data sheets obtained from Latin America and the Caribbean in 2000–

2003. The sheets indicated that the most commonly used dosimetry equipment, referred to as modern, 0.6 cm^3 Farmer-type chambers, was from well-known manufacturers such as Nuclear Enterprises or Physikalisch-Technische Werkstätten (PTW). Sometimes small waterproof chambers of 0.1–0.3 cm^3 were used for beam calibration, but they are not generally recommended by modern dosimetry codes of practice for calibrating radiotherapy beams. There are practically no users of old or atypical dosimetry equipment in Latin America and the Caribbean, whereas in other regions about 10% of the centers use obsolete or locally-made ionization chambers and electrometers. Most chambers in Latin America and the Caribbean have valid calibration certificates from SSDLs or manufacturers, with the percentage reporting calibration coefficients in terms of absorbed dose to water ($N_{D,w}$), air kerma (N_K), and exposure (N_X) being approximately 18%, 60%, and 22%, respectively.

Use of dosimetry codes of practice for dose determination

Using the data sheets from the audits carried out in Latin America and the Caribbean in 2000–2003, the physicists also provided information on the dosimetry code of practice used for dose determination, including numerical values of the correction factors and interaction coefficients applied for the calculation of absorbed dose to water from ionization chamber measurements. Table 4 shows the results (in terms of D_{TLD}/D_{stat}) for the centers using different dosimetry protocols. The results based on modern $N_{D,w}$ protocols showed a smaller standard deviation (0.021) than did the results based on N_K protocols (0.038). The groups based on old N_X protocols or "unknown" protocols had a standard deviation (0.036) that was similar to the one for the N_K protocols. These standard deviations are consistent with the results from other world regions. The use of old N_X-based protocols has practically ceased in Latin America and the Caribbean (Table 4). In comparison, approximately 10%–15% of the participants of the TLD dose quality audit in other world regions report the use of N_X-based protocols.

Table 4 shows that the air kerma-based codes of practice (IAEA TRS-277 (14) and AAPM TG-21 (15)) were the main dosimetry protocols used for radiotherapy beam calibration in Latin America and the Caribbean as of 2000–2003. The use of recently-developed absorbed dose to water-based codes of practice (IAEA TRS-398 (9) and AAPM TG-51 (16)) was limited but growing. Previous research (4) has shown that despite the differences in protocols, traceability to different laboratories, and variations in dosimetry equipment used worldwide, there is a good agreement in the determination of absorbed dose to water for photon beams when the different dosimetry protocols are used correctly. The TLD results in Latin America and the Caribbean shown in Table 4 support this conclusion.

SUMMARY AND CONCLUSIONS

Over a period of 34 years of operation, from 1969 through 2003, the IAEA/WHO TLD audits checked the calibration of approximately 5 200 photon beams in over 1 300 radiotherapy centers in 115 countries around the world. Of these beam audits, more than 1 850 of them were performed in Latin America and the Caribbean. For the 2000–2003 pe-

TABLE 4. Results of the IAEA/WHO thermoluminescent dosimetry (TLD) audits in 2000–2003 for Latin America and the Caribbean, grouped according to the dosimetry codes of practice used by the radiotherapy centers

Parameter	Dosimetry codes of practice		
	$N_{D,w}$-based[a]	N_K-based[b]	Old N_X-based or unknown[c]
Number of audits (percentage)	42 (14%)	245 (80%)	23 (6%)
Mean of the distribution, $\frac{D_{TLD}}{D_{stat}}$[d]	1.011	1.008	1.014
Standard deviation	0.021	0.038	0.036

[a] $N_{D,w}$ is ionization chamber calibration coefficient in terms of absorbed dose to water.
[b] N_K is ionization chamber calibration coefficient in terms of air kerma.
[c] N_X is ionization chamber calibration coefficient in terms of exposure.

[d] $\frac{D_{TLD}}{D_{stat}}$ is the mean of the distribution of the TLD results expressed as ratios of the IAEA-determined dose (D_{TLD}) relative to the dose stated by the center (D_{stat}).

riod, the fraction of acceptable results in all regions was higher than in previous periods, but with a more pronounced improvement in Latin America and the Caribbean than in the other regions.

The improvement in dosimetry performance in Latin America and the Caribbean has been considerable, with an increase in acceptable results from less than 60% before 1990 to about 95% in 2000–2003. This is mainly due to a greater interest in quality assurance in radiotherapy and to regular participation in the TLD audit program. For centers to reach and maintain an adequate level of dosimetry, it is important for them to regularly participate in external TLD audits. Compared to institutions that have participated in audits for a longer period of time, centers that participate in a TLD audit for the first time are less likely to achieve results within the 5% acceptance limit.

The TLD results for high-energy X rays from linear accelerators are generally better than those for Co-60 beams in all world regions. However, in Latin America and the Caribbean, discrepancies in X-ray beam calibrations occurred more frequently than in other geographical regions. This was especially true in centers where linear accelerator-based facilities were being operated without the appropriate medical physics support, which typically leads to poorer TLD results.

For the results outside the 5% acceptance limit, the IAEA has established a follow-up program, which increased the percentage of acceptable results to approximately 95% in 2000–2003 for the world overall. All centers with poor results are contacted, but some (5%) have not yet responded to efforts by the IAEA/WHO to help identify and resolve the problems.

In all world regions in 1969–2003, large deviations were observed in terms of over- and underdosage of TLDs. In several instances the overdosage confirmed clinical observations of inadequate dosimetry practices. On the other hand, a patient underdosage may not be detected by clinical observation for several years. Therefore, the TLD audit is a very useful tool for recognizing and correcting a problem before it becomes clinically evident.

In 2000–2003 the frequency of deviations outside the acceptance limit in Latin America and the Caribbean that was due to setup errors or to incorrect calculations of irradiation time was similar to the frequency found in the other world regions. However, typical errors registered in other regions, such as confusion in the use of old N_X-based dosimetry protocols and a misunderstanding of calibration coefficients, did not occur in the TLD audits in Latin America and the Caribbean. This is because old N_X-based protocols are now used less frequently, with centers in Latin America and the Caribbean switching to up-to-date N_K-based codes of practice and the recently-developed $N_{D,w}$-based codes of practice. In all world regions the institutions running radiotherapy services without qualified medical physicists and without dosimetry equipment attain poorer results than do the centers that are properly staffed and equipped. Lack of medical radiation physicists is a particularly serious problem in Latin American and Caribbean countries.

We can conclude that the unsatisfactory TLD results seen in past decades in Latin America and the Caribbean have improved considerably. Nevertheless, to achieve parity with the dose audit results for centers in the industrialized countries of North America and the European Union (5), further improvement will be needed. For this to occur, strengthening of the radiotherapy infrastructure in Latin America and the Caribbean will be required, both in terms of qualified medical radiation physics staff and appropriate dosimetry equipment.

Acknowledgements. The authors wish to thank Harald Østensen of WHO, Geneva, and Cari Borrás and Pablo Jiménez of PAHO for their involvement and personal support to the IAEA/WHO TLD program. At the IAEA, this program has been developed and carried out by several staff members over a span of 30 years. Particular credit is given to Pranabes Bera, who has performed the TLD measurements at the IAEA's Dosimetry Laboratory since 1984. The reference institutions providing irradiations for quality control of the IAEA TLD system are acknowledged for their continuing cooperation and support.

SINOPSIS

Auditorías de las dosis usadas en centros de radioterapia en América Latina y el Caribe: tendencias observadas en el período de 1969–2003

Desde 1969, el Organismo Internacional de Energía Atómica y la Organización Mundial de la Salud (junto con la Organización Panamericana de la Salud en países de América Latina y el Caribe) han puesto en marcha un programa de auditorías dosimétricas por correo que se basa en la dosimetría termoluminiscente (DTL) para servicios de radioterapia. El objetivo del programa es ofrecer una verificación dosimétrica independiente de la calibración de los haces de radiación que se usan para tratar a los enfermos de cáncer. La obtención de buenos resultados en radioterapia depende de una dosimetría exacta. Entre 1969 y 2003 se verificó la calibración de aproximadamente 5 200 haces de fotones en más de 1 300 centros de 115 países de todo el mundo. El 36% de esas auditorías se efectuaron en América Latina y el Caribe, donde a lo largo de los años se observó un mejoramiento de los resultados. Por des-

gracia, ha habido varios casos en servicios de radioterapia de varias partes del mundo en los que las grandes desviaciones de la DTL han confirmado las observaciones clínicas de prácticas dosimétricas inadecuadas e incluso de accidentes de radioterapia como el ocurrido en Costa Rica en 1996. Los hospitales o centros cuyos servicios de radioterapia funcionan sin contar con físicos médicos calificados o que carecen de equipo de dosimetría obtienen peores resultados que los dotados de personal y equipo adecuados. Cuando se obtienen malos resultados en las mediciones de DTL en un determinado centro, un programa de seguimiento puede ayudarlo a mejorar la dosimetría. No obstante, para lograr resultados de auditoría semejantes a los obtenidos por los centros de los países industrializados, es necesario seguir fortaleciendo la infraestructura de la radioterapia en América Latina y el Caribe.

Palabras clave: radioterapia, control de calidad, auditoría médica, cooperación internacional, países en desarrollo, América Latina, región del Caribe.

REFERENCES

1. Boyd AW, Eisenlohr HH. IAEA/WHO ^{60}Co teletherapy dosimetry service using mailed LiF dosimeters. A survey of results obtained during 1975–1982. Med Phys. 1983;10(4):491–2.
2. Eisenlohr HH, Jayaraman S. IAEA-WHO cobalt-60 teletherapy dosimetry service using mailed LiF dosimeters. A survey of results obtained during 1970–75. Phys Med Biol. 1977;22(1): 18–28.
3. Iżewska J, Andreo P. The IAEA/WHO TLD postal programme for radiotherapy hospitals. Radiother Oncol. 2000;54: 65–72.
4. Iżewska J, Andreo P, Vatnitsky S, Shortt KR. The IAEA/WHO TLD postal dose quality audits for radiotherapy: a perspective of dosimetry practices at hospitals in developing countries. Radiother Oncol. 2003;69:91–7.
5. Iżewska J, Svensson H, Ibbott G. Worldwide quality assurance networks for radiotherapy dosimetry. In: International Atomic Energy Agency. Standards and codes of practice in medical radiation dosimetry. Vol. 2. Vienna: IAEA; 2003. Pp. 139–55. (IAEA-CN-96/76).
6. Svensson H, Hanson GP, Zsdansky K. The IAEA/WHO TL dosimetry programme for radiotherapy centres 1969–1987. Acta Oncol. 1990;29:461–7.
7. Svensson H, Zsdansky K, Nette P. Dissemination, transfer and intercomparison in radiotherapy dosimetry: the IAEA concept. In: International Atomic Energy Agency. Measurement assurance in dosimetry. Proceedings of an international conference in Vienna, Austria, 24–27 May 1993. Vienna: IAEA; 1994. Pp. 165–76.
8. Boyd AW, Eisenlohr HH, Girzikowsky R. Postal dose intercomparison of Co-60 dosimetry using thermoluminescence dosimeters among secondary standard dosimetry laboratories. Med Phys. 1982; 9:112–3.
9. International Atomic Energy Agency. Absorbed dose determination in external beam radiotherapy. An international code of practice for dosimetry based on standards of absorbed dose to water. Vienna: IAEA; 2000. (Technical Reports Series No. 398).
10. International Atomic Energy Agency. Accidental overexposure of radiotherapy patients in San José, Costa Rica. Vienna: IAEA; 1998. (Special publication series IAEA-STI/PUB/1027).
11. Task Group on Accident Prevention and Safety in Radiation Therapy. Prevention of accidental exposures to patients undergoing radiation therapy. Ann ICRP. 2000;30(3):7–70.
12. American Association of Physicists in Medicine, AAPM Task Group 45. AAPM code of practice for radiotherapy accelerators. Report of AAPM Radiation Therapy Task Group No. 45. Med Phys. 1994; 21:1093–1121.
13. International Atomic Energy Agency. Design and implementation of a radiotherapy programme: clinical, medical, radiation protection and safety aspects. Vienna: IAEA; 1998. (IAEA-TECDOC-1040).
14. International Atomic Energy Agency. Absorbed dose determination in photon and electron beams: an international code of practice. 2nd ed. Vienna: IAEA; 1997. (IAEA Technical Reports Series No. 277).
15. American Association of Physicists in Medicine, AAPM Task Group 21. A protocol for the determination of absorbed dose from high-energy photon and electron beams. Med Phys. 1983;10:741–71.
16. American Association of Physicists in Medicine, AAPM Task Group 51. Protocol for clinical reference dosimetry of high-energy photon and electron beams. Med Phys. 1999;26:1847–70.

Manuscript received 14 December 2004. Revised version accepted for publication 20 June 2005.

Overexposure of radiation therapy patients in Panama: problem recognition and follow-up measures

Cari Borrás[1]

Suggested citation: Borrás C. Overexposure of radiation therapy patients in Panama: problem recognition and follow-up measures. Rev Panam Salud Publica. 2006;20(2/3);173–87.

SYNOPSIS

This report summarizes and analyzes the responses of various organizations that provided assistance to the National Oncology Institute (Instituto Oncológico Nacional, *ION) of Panama following the overexposure of 28 radiation therapy patients at the ION in late 2000 and early 2001. The report also looks at the long-term measures that were adopted at the ION in response to the overexposure incident, as well as implications that the incident has for other cancer treatment centers worldwide. In March 2001, the director of the ION was notified of serious overreactions in patients undergoing radiation therapy for cancer treatment. Of the 478 patients treated for pelvic cancers between August 2000 and March 2001, 3 of them had died, possibly from an overdose of radiation. In response, the Government of Panama invited international experts to carry out a full investigation of the situation. Medical physicists from the Pan American Health Organization (PAHO) were among those invited. They ascertained that 56 patients treated with partially blocked teletherapy fields for cancers of the uterine cervix, endometrium, prostate, or rectum, had had their treatment times calculated using a computerized treatment planning system. PAHO's medical physicists calculated the absorbed doses received by the patients and found that, of these 56 patients, only 11 had been treated with acceptable errors of ±5%. The doses received by 28 of the 56 patients had errors ranging from +10 to +105%. These are the patients identified by ION physicists as overexposed. Twenty-three of the 28 overexposed patients had died by September 2005, with at least 18 of the deaths being from radiation effects, mostly rectal complications. The clinical, psychological, and legal consequences of the overexposures crippled cancer treatments in Panama and prompted PAHO to assess radiation oncology practices in the countries of Latin American and the Caribbean. ION clinicians evaluated the outcome of 125 nonoverexposed patients who had been treated in the same time period and for the same cancer sites as the overexposed patients. The clinicians uncovered a larger recurrence of cervical cancers than expected. The finding prompted PAHO to launch an initiative for the accreditation of radiation oncology centers in Latin America and the Caribbean, working in collaboration with professional societies for radiation oncologists, medical physicists, and radiotherapy technologists. The Latin American Association for Radiation Oncology* (Asociación Latinoamericana de Terapia Radiante Oncológica) *has established an accreditation commission. Accreditation will require that centers implement a comprehensive radiation oncology quality assurance program that follows international guidelines. Statistical data on patient outcomes will be collected in order to document needs in radiotherapy centers in Latin America and the Caribbean and to define future strategies for cancer treatment.*

Key words: pelvic neoplasms, radiotherapy, radiation injuries, quality control, Panama.

[1] Pan American Health Organization, Washington, D.C., United States of America. Send correspondence to: Dr. Cari Borrás, 1501 44th Street, N.W., Washington, D.C. 20007, United States; e-mail: cariborras@starpower.net.

TABLE 1. Chronology of events related to the investigation of the overexposure of radiation therapy patients at the National Oncology Institute (*Instituto Oncológico Nacional*, ION) of Panama

Time period	Event
March 2001	• Patient overreactions first reported; 3 deaths had occurred • The ION medical physicists identify 28 cases with dosimetry errors • The Ministry of Health of Panama requests assistance from the Pan American Health Organization (PAHO) • PAHO's medical physicists calculate that the radiation dose received by the first deceased patient is more than double the prescribed value
April 2001	• PAHO's medical physicists calculate absorbed doses of 28 patients • Experts from the M.D. Anderson Cancer Center confirm ION/PAHO findings and explain error with treatment planning system manufactured by Multidata Systems International Corporation
May 2001	• The ION reports problem to the Panamanian regulatory authority for radiation safety • The International Atomic Energy Agency (IAEA) sends expert mission at the regulatory authority's request • PAHO's lead medical physicist joins the IAEA team
June–September 2001	• PAHO's medical physicists calculate 11 patients' brachytherapy doses • PAHO's lead medical physicist reviews 530 patients' physics charts • The United States Food and Drug Administration (FDA) investigates the Multidata software • The IAEA publishes experts' report, *Investigation of an Accidental Overexposure of Radiotherapy Patients in Panama*
2002	• ION's clinicians and PAHO's medical physicists undertake joint study of dosimetry and clinical outcome of 153 patients • PAHO launches initiative on accreditation of Latin American and Caribbean radiation oncology centers
May 2003	• FDA issues an injunction to stop Multidata from manufacturing and distributing radiation therapy medical devices in the United States • Criminal trial of three local physicists starts in Panama
June 2004	• *Clinical effects in a cohort of cancer patients overexposed during external beam pelvic treatment*, article by PAHO and ION staff members, is published
November 2004	• Two of the indicted physicists are sentenced to four years in prison and barred from practicing their profession for seven years; they appeal the sentence. The third physicist is acquitted.

Cancer is the leading cause of death in Panama. In a country with a population of some 2.8 million, more than 4 000 new cancer cases are diagnosed each year (1). Treatments include surgery, chemotherapy, and radiation therapy. The country's largest radiation therapy institution is the National Oncology Institute (*Instituto Oncológico Nacional*). The ION is also Panama's only public radiation therapy institution.

The radiological health program[2] of the Pan American Health Organization (PAHO) started providing technical assistance to the ION in November 2000 to review their plans to acquire new linear accelerators and expand the ION's radiation oncology services. In March 2001, Panama's Ministry of Health (*Ministerio de Salud de la República de Panamá*) asked PAHO to investigate some serious overreactions—including three deaths—among cancer patients undergoing radiation therapy treatment. PAHO's medical physicists[3] carried out the investigation using information on radiation therapy treatment techniques and data from copies of patient charts provided by the clinical and medical physics staff at the ION. The actual chronology of the investigation is shown in Table 1.

After reviewing 530 treatment charts at the ION, PAHO's lead medical physicist ascertained that between 1 August 2000 and 2 March 2001, 478 cancer patients were treated at the ION. The cancer site treatment distribution for those 478 persons, according to ION's records, was: 71 breast, 40 brain, 38 lung, 67 head and neck, 3 bladder, 96 cervix, 13 colon, 19 endometrium, 48 prostate, 6 pelvis, and 77 other sites. Of these patients, 191 received teletherapy pelvic irradiation treatments, and 60 of them also received brachytherapy insertions. Of the

[2] The author, a medical physicist, was working in PAHO's radiological health program as a staff member until 2003, and as a consultant thereafter.

[3] At the time, a second medical physicist, Damian Rudder, was working in PAHO's radiological health program as a consultant.

191 patients, 153 of them were irradiated for tumors of the cervix, endometrium, uterus, prostate, or rectum. (This tumor site classification is the one used by the ION.) Until August 2000, these pelvic cancers had been treated with anterior/posterior (AP/PA) and lateral radiation fields without shielding blocks. To protect part of the small bowel and the femoral heads, in August 2000 the technique was modified to include corner blocks. A fifth block was sometimes also used to protect scar tissue in those patients who had undergone hysterectomies as part of their cancer treatment.

This modified treatment procedure was discontinued at the end of March 2001, after three deaths had occurred. By that time, the ION medical physicists had identified 28 patients who might have been overexposed. This paper reports on the managerial and dosimetric aspects of the investigation carried out by PAHO medical physicists in collaboration with the ION, and the resulting measures taken to alleviate the problem at the ION and to prevent a similar mishap elsewhere in the future. The dosimetric results were presented at medical physics conferences in 2001[4] and 2002.[5] The clinical outcome of the cohort of 153 patients treated for the same cancer sites was published in 2004 (1).

THE INVESTIGATION

Logistical aspects of radiation oncology at the National Oncology Institute

In 1999, the ION moved all its services except radiation therapy from its location on Justo Arosemena Avenue in Panama City to the old Gorgas Hospital, located in Ancón, a neighborhood of Panama City located in the old Panama Canal Zone.[6] The Gorgas Hospital had been a United States Army hospital before it was transferred to the Panamanian Government in 1997. When under United States Army control, the Gorgas Hospital had had a cobalt therapy room for radiation therapy treatments. Unfortunately, the structural shielding in the treatment room did not meet the 1995 Panamanian radiological protection regulations.[7] Modification of the existing room would have required significant structural changes, which the architects contracted by the Ministry of Health of Panama decided were too difficult and costly to implement. Therefore, the Ministry of Health decided to keep the external beam therapy treatments in the old facility on Justo Arosemena Avenue, while brachytherapy treatments, patient hospitalization, and clinical follow-up of patients were to be performed in the remodeled Gorgas Hospital. The Gorgas Hospital became the new "National Oncology Institute." At the end of 1999, a project was developed by the ION to relocate the radiotherapy services into this remodeled facility and to purchase new, modern radiotherapy equipment. In December 2000, the Ministry of Health approved the project.[8]

While the new radiotherapy facility was being built, external beam therapy treatments were given at the Arosemena Avenue site, from 6 a.m. to 9 p.m., using only a Theratron 780C cobalt unit, the source of which had been replaced in April 2000. In the same facility there was also a decommissioned ATC/9 Picker unit. The staff consisted of five radiation oncologists, six radiotherapy technicians, and three medical physicists. The radiation oncologists rotated between the two hospital facilities. Two of them were assigned to the Arosemena Avenue site for a month in two work shifts. The idea was that a radiation oncologist should always be present while patients were being treated, but, in practice, there was no physician on site after 6 p.m.

The treatment planning information for both external beam and brachytherapy treatments was kept in the "physics" patient data sheet at the Arosemena Avenue site. Clinical patient management was recorded in a "clinical" data sheet, which was kept in the Gorgas Hospital facility. Patients were seen at the Gorgas Hospital in the middle and at the end of the treatment, usually not by the same radiation oncologist who had prescribed the treatment.

Treatment and dosimetry protocols

Treatment planning and dose prescription were done at the Arosemena Avenue facility. Following published techniques (2, 3), most patients were treated with multiple fields on a daily basis, five days per week. Four of the five ION radiation oncologists treated pelvic fields without shielding blocks; the other oncologist required at least four blocks for the AP/PA fields. Between 1 August 2000 and 2 March 2001, a total of 153 ION patients were irradiated for tumors of the cervix, endometrium, uterus, prostate, or rectum; 56 of the 153 were treated using shielding blocks. Their can-

[4] Borrás C, Rudder D, Amer A, Hendry J. Sobreexposición de pacientes de radioterapia en Panamá—aspectos dosimétricos. On: CD-ROM. 2° Congreso Iberolatinoamericano y del Caribe de Física Médica. Caracas: ALFIM; 2001.

[5] Borrás C, Rudder D, Barés JP, Millán F. Overexposure of radiotherapy patients in Panama. [Abstract]. Med Phys. 2002:29(6);1326.

[6] Personal communication, Juan Pablo Barés, ION.

[7] República de Panamá. Ministerio de Salud. Resolución No 27. (De 24 de octubre de 1995). "Por medio de la cual se adopta las normas básicas de protección radiológica no. 110."

[8] Personal communication, Juan Pablo Bares, ION.

cer site distribution was as follows: 23 cervix, 20 prostate, 7 endometrium, 3 uterus, and 3 rectum. These 56 patients constitute the patient cohort of this investigation.

A review of the treatment charts—including the isodose distributions—for these 56 patients showed that all the pelvic irradiations used multiple treatment fields, but not all of the fields were blocked. For example, oblique fields and boost fields were not blocked, and that was also true in some cases for lateral fields. External beam doses prescribed for patients with cancer of the cervix, endometrium, or rectum were around 50 Gy, with a central boost of 10–20 Gy for patients who only partially responded to the treatment. Prescribed doses to prostate tumors were 45–50 Gy to large field sizes, followed by a 20-Gy boost to a reduced field box technique or skip scan rotation, totaling between 65 and 70 Gy to the center of the tumor. Prescribed dose fractions ranged from 1.8 to 2 Gy per fraction. The radiation oncologists at the ION prescribed the dose either to the intersection of the radiation beams or to the isodose level that involved the tumor. The ION medical physicists performed the dosimetry calculations with a computerized radiation therapy treatment planning system (TPS) manufactured by Multidata Systems International Corporation (Saint Louis, Missouri, United States of America), with the isodose distributions and treatment times being generated using the "External Beam" Version 2.1.1 software for that TPS.

Depending on the stage of the disease, cancers of the cervix and the endometrium were treated both by external beam radiation therapy and by brachytherapy. Of the 56 patients in this study, 17 of them had received brachytherapy as well as external beam therapy. Brachytherapy was delivered using a manual afterloading technique with cesium-137 sources in Suit-Delclos applicators. The number, activity, and placement of the sources used depended on the clinical conditions (1).

According to Panamanian radiation protection regulations,[9] patients undergoing brachytherapy treatments or nuclear medicine therapy procedures using iodine-131 needed to be hospitalized in specially shielded rooms. There were only four of these rooms in the new Gorgas site. Because of the large number of iodine-131 patients, the availability of these rooms for brachytherapy patients was limited. As a consequence, brachytherapy treatments could not be given in the middle of the external beam treatment course or immediately after completing it, as many other institutions do. Often, brachytherapy was scheduled two to three months afterwards, when insertion in the uterine canal was difficult, and was frequently not done. To compensate for this lack of sources in the uterine canal, external beam fields were given a dose higher than recommended in published protocols (3). Patient treatment protocols were not documented, and individual patient cases were not referred to a tumor board, where the optimal treatment modality for that patient could have been considered by a multidisciplinary group of cancer physicians.

Starting in January 2001, brachytherapy insertions were quantified from a dosimetric point of view. The applicators loaded with dummy sources were inserted manually by a radiation oncologist in a minor surgery room at the new Gorgas site. The position of the applicators within the patient was then checked with a portable X-ray machine in the presence of a medical physicist, who filled out the appropriate data forms. Once the insertion geometry was approved by the radiation oncologist, the films were taken by the medical physicist to the Arosemena site and digitized into the TPS. Doses were individualized depending on the clinical stage of the disease. A typical prescription was 40 Gy to Point A (4); external beam doses to the whole pelvis were between 40 and 45 Gy. The TPS software program calculated doses to specified points, such as point A, the bladder, and the rectum, and displayed the isodose curves.

Identification of the computational error

The first step taken in March of 2001 by the PAHO medical physicists, when they were alerted to a potential overexposure of patients treated with the cobalt-60 therapy unit at the ION, was to assess whether there had been a problem with the calibration of the unit, as had happened in Costa Rica in 1996 (5, 6). The ION was participating in the postal audit of the World Health Organization (WHO) and the International Atomic Energy Agency (IAEA) that verifies the calibration of radiotherapy beams in hospitals, using thermoluminescent dosimetry (TLD). Therefore, the PAHO medical physicists reviewed the TLD results for the ION cobalt-therapy unit. The last verification, which had been carried out in August 2000, had given an error of 4%, which was within the 5% tolerance specified by the IAEA.

The PAHO medical physicists then calculated the dose to the first patient who had died in December 2000, using data from a copy of his treatment chart, made available by the ION. The physicists determined that the patient had received a

[9] Personal communication, Eloy Gibbs, Caja del Seguro Social de Panamá, Departamento de Salud Radiológica, technical unit empowered by the Ministry of Health (the radiation regulatory authority) to develop and implement radiation protection regulations.

dose of 94 Gy, more than twice the prescribed dose of 40 Gy.[10] By mid-April 2001, the PAHO medical physicists calculated the doses received by 28 patients selected by the ION physicists as having possibly been overexposed. It is not known what criterion the ION physicists used for the selection. The standard of practice for dose delivery accuracy, set in 1976 by the International Commission on Radiation Units and Measurements, is ± 5% (7). The PAHO physicists found out that, except for one patient who had not completed the treatment at the ION, the delivered doses for the other 27 patients had errors that ranged from 10% to more than 100%.[11] (In this paper, percentage error is defined by the difference between delivered dose and prescribed dose, divided by the prescribed dose, multiplied by 100).

At the end of April 2001, a team of experts from M.D. Anderson Cancer Center, in Houston, Texas, United States of America, was invited to Panama by the ION's director to investigate the problem. Those experts determined that the algorithm used in the TPS software gave treatment times differing by a factor of about two, depending on how the data for the partially shielded treatment fields were entered into the computer program.[12] The instructions from the TPS manual were to enter the coordinates of the perimeter of the unshielded field and then to digitize one block at a time, to a maximum of four blocks. However, digitizing each block separately was time-consuming, and some of the radiation oncologists at the ION wanted to treat some cervix cancer patients with five blocks (one in each corner of the field and one over the hysterectomy scar). Therefore, the ION physicists circumvented the Multidata TPS software block entry limitations by digitizing all the blocks in a continuous fashion, as if it were a single block. When the outside and inside perimeters of the field were entered into the computer program in the same direction (performing a double loop), the computed treatment times were double those obtained when the outside perimeter was digitized in one direction and the inside perimeter in the reverse direction. The Multidata system did not alert the user that an improper data sequence had been entered.

These findings were confirmed in May 2001 by an IAEA expert team, which was sent to Panama at the request of the Panamanian regulatory authority for radiation safety (8). As the Ministry of Health of Panama had also invited PAHO, the IAEA team was joined in Panama by the PAHO lead medical physicist.

Dose calculations

The dosimetric assessment by the PAHO medical physicists fell into two categories: (1) external beam dosimetry for the 56 patients treated for cancer of the cervix, endometrium, uterus, prostate, or rectum and (2) brachytherapy dosimetry for 17 female patients treated for cancer of the cervix and/or endometrium. The dosimetry calculations, first performed in March and April 2001 at the PAHO Headquarters in Washington, D.C., were refined in the following months by this author after analysis of the information she had collected at the ION in May–June 2001. During that visit to Panama, she had reviewed 530 patient charts, from which a patient database, including dosimetric and clinical parameters, was generated.

External beam dosimetry methodology

The doses received by the 56 patients were assessed by performing manual point dose calculations at the point of intersection of the radiation beams. The following data were taken from the patients' charts for each treatment field: field sizes, attenuation factors for any beam modifiers used (e.g., blocking and/or wedges), depth of the point of intersection of the treatment fields from the patient's skin surface, treatment times, and radiation output of the cobalt-60 unit. Backscatter factors and percentage depth doses to the points of calculation for each treatment field were taken from published tables (9). Calculations were also performed for all patients whose clinical outcomes showed significant complications, for unusually heavy patients, and on a spot-check basis. Each patient record was carefully reviewed. Since patient field sizes and depths were similar, the parameter most closely examined was the treatment time per dose fraction for each field.

By May 2001 the ION physicists had produced two sets of isodose distributions for each of the 28 overexposed patients. One set, generated at the onset of treatment, was the result of entering the block coordinates by the double-loop method. For the second set, which was generated retrospectively, the block coordinates were entered individually. The two sets of isodoses were analyzed by the PAHO medical physicists. Figure 1 compares the resulting isodose distributions for a particular patient when the coordinates for the shielding blocks

[10] Borrás C. Preliminary point dose calculations for patients treated at the National Oncology Institute of Panama. Washington, D.C.: Pan American Health Organization; 2001. (PAHO report to the ION).

[11] Borrás C. Patient dosimetry at the National Oncology Institute of Panama. Washington, D.C.: Pan American Health Organization; 2001. (PAHO report to the ION).

[12] Aguirre F, Almond P, Lindberg R. Report of a consultation visit to the National Oncology Center, Panama City. Panama City; 2001. (Expert team report to the ION).

FIGURE 1. Comparison of isodose distributions for a rectum four-field treatment plan for a radiation therapy patient when the coordinates for the shielding blocks were incorrectly entered in the computerized radiation therapy treatment planning system using the double-loop method (Figure 1a) and when the coordinates for each block were correctly digitized individually (Figure 1b), with the block configuration given in Figure 1b for both treatment plans, National Oncology Institute, (*Instituto Oncológico Nacional*, ION) of Panama, 2000–2001

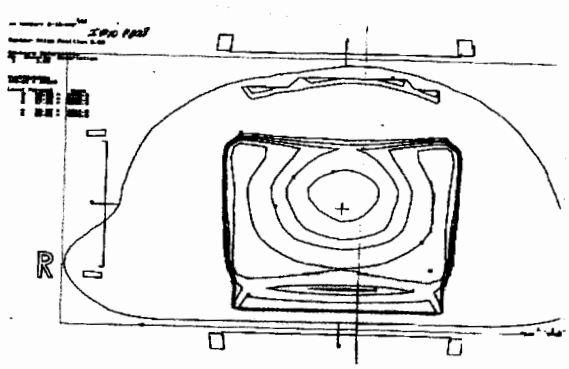


FIGURE 1a. Double-loop method; the computed treatment time per dose fraction was 1.01 minute

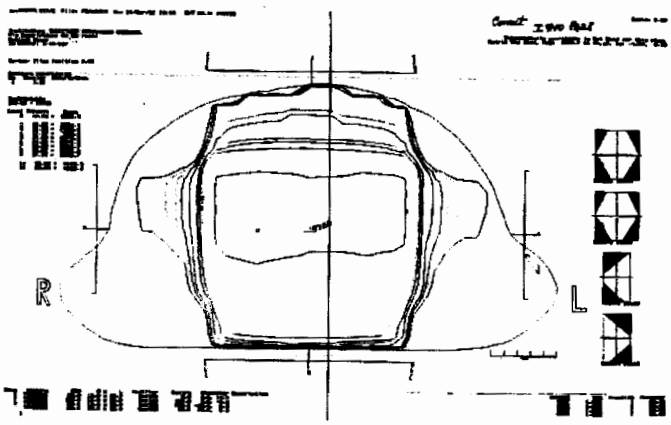


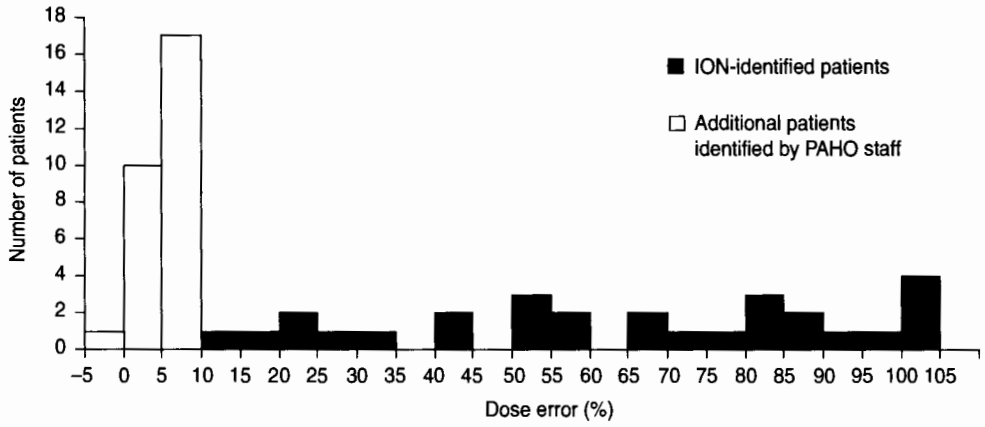
FIGURE 1b. The coordinates for each block entered separately; the computed treatment time per dose fraction was 0.50 minute

were entered in the TPS using the double-loop method (Figure 1a), and when the coordinates for each block were digitized individually (Figure 1b). (This isodose distribution was chosen by this author as the most illustrative example among the two sets of isodose distributions that the ION physicists had generated for each of the 28 patients they studied.) The ION physicists did not notice that the shape of the isodoses generated by the double-loop method (Figure 1a) did not resemble typical isodose curves for that particular type of treatment (Figure 1b). Had they realized this at the time the patients were treated, they would have uncovered the problem with the TPS sooner.

Manual calculations were done for the 17 patients who had received brachytherapy, using the data supplied with the patients' charts, including the number of sources used, their arrangement, and their activity (10). Assuming typical anatomical dimensions (1), doses were determined to point A, the bladder, and the rectum. The ION brachytherapy prescription, in mgh of radium, was converted into Gy by multiplying the mgh by 0.9, following Perez et al. (11).

As was mentioned earlier, 153 ION patients were irradiated for tumors of the cervix, endometrium, uterus, prostate, or rectum between 1 August 2000 and 2 March 2001; 56 of these 153 patients were treated using shielding blocks and had their treatment times improperly calculated. However, not all of these incorrect treatment-time calculations led to doses exceeding the ± 5% accuracy tolerance. By chance, the double-loop calculation method was used only in half of the 56 cases. Teletherapy and approximate brachytherapy absorbed doses to the tumors of these 56 patients have been published (1). Figure 2 is a histogram of the percentage errors found in the teletherapy absorbed doses received by the 56 patients whose treatment times were calculated by digitizing the blocked field using a single outline. The histogram shows the number of patients with absorbed dose errors, with 5%-error intervals; the absorbed dose errors range from –5% to +105%. The mean error for the doses received by the

Figure 2. Errors in absorbed doses of teletherapy treatments received by 56 patients (percentage error (%) = [(delivered dose – prescribed dose)/prescribed dose] × 100), National Oncology Institute (*Instituto Oncológico Nacional*, ION) of Panama, 2000–2001



28 patients identified by the ION physicists as overexposed (their treatment times had been calculated by the double-loop method) had a mean value of +65%, with a standard deviation of 29%. Among these 28 patients, there was one who had initiated prostate treatment in November 2000 at the ION and, because of intestinal complications, interrupted his treatment after six sessions and completed the treatment at a private center shortly thereafter. At that private center the medical physicist (the same medical physicist working at the ION) calculated the treatment time by taking the ratio of dose rates of the ION cobalt unit and that of the private center cobalt unit, without realizing that an error had occurred in the original treatment time determination. An earlier report (8) indicated that the patient had not completed the treatment and therefore had not been overexposed. The PAHO medical physicists found out that, while the prescribed dose was 65 Gy, the dose received was 93 Gy (1), not 19.35 Gy, as originally reported (8).

The mean absorbed dose error for the 28 additional patients identified by the PAHO physicists as having had their treatment times also calculated by the TPS was +6%, with a standard deviation of 2.5%. These patients also had their block coordinates entered as a single outline, but the internal and external perimeters of the blocked field were digitized in reverse directions.

In summary, of the 56 patients, only 11 received doses within the accepted ± 5% tolerance. How many were overexposed? Did the ION physicists use the +10% error as the criterion for overexposure? The International Commission on Radiological Protection (ICRP) says that "10% or more overdosage should be detected by a well-trained clinician, based upon an unusually high incidence of adverse patient reactions" (12). The Nuclear Regulatory Commission of the United States used to call a 10% deviation between a prescribed and delivered dose a "misadministration" (13), but because of the potential implication of "malpractice," the term "medical event" is now used, with a 20% tolerance for an overall treatment, and 50% for a dose fraction in a series (14).

In order to be consistent with previous publications (1, 8, 15), this paper will use the term "overexposed patients" to refer to the cohort of 28 patients originally identified by the ION physicists as overexposed.

CLINICAL DOSE EFFECTIVENESS AND EVALUATION OF OVEREXPOSED PATIENTS' CLINICAL OUTCOME

From a radiobiological perspective, total absorbed doses are not the only important variable; high doses per fraction enhance the radiobiological response, especially for late-responding normal tissues (16). To take this fact into account, clinical dose-effectiveness calculations use the concept of biologically effective dose (BED). The BED is the maximum dose equivalent using very low doses per fraction or low dose rates. This useful concept incorporates in the calculations the estimated cell repair times, and allows comparisons to be made of the effects of doses delivered using different fractionation regimes. It also allows external beam and brachytherapy doses to be combined. Alternatively, both treatment doses can be converted to the equivalent dose delivered in conventional 2-Gy fractions (1).

Status of overexposed patients by May 2002

The clinical dose effectiveness and the clinical outcome of the 56 patients included in this study were determined as part of a clinical investigation of a total of 153 patients who had received external beam radiotherapy to the pelvis at the ION during the same time period, August 2000 to March 2001; that information was published in June 2004 (1). The investigation was performed along the lines established by the IAEA for the overexposed patients one year earlier (8), but it extended the study by analyzing normal tissue (colon and bladder) reactions using both the RTOG (17) and the LENT/SOMA (18–20) scoring methods. (RTOG and LENT/SMA are the acronyms for "Radiation Therapy Oncology Group" and "late effects on normal tissues"/"subjective symptoms, objective signs, management, and analytical measures")

By May 2002, 17 of the 28 overexposed patients had died within 35 days to 21 months after being treated. Thirteen of the fatalities were caused by rectal complications. Death started occurring when rectal doses reached the equivalent of 70–80 Gy in 2-Gy fractions (rectal BED values greater than 120-130 Gy). After doses equivalent to 130 Gy in 2-Gy fractions (rectal BED values of 200 Gy), all the patients died (1). The patients who died in the first few months after treatment had severe injury in the small and large intestine, which resulted in a high level of secondary sepsis. The patients who died later, approaching one year after radiotherapy, had damage in the large bowel, resulting in obstructions, necrosis, and perforation (1). Two of the three patients who had been treated with five blocks instead of four survived longer, as did the patients who had received colostomies (1).

Status of overexposed patients after May 2002

The surviving patients continued to be followed up clinically at the ION. Information on their status was obtained by the author in June 2004, November 2004, and August 2005. By June 2004, 21 of the 28 overexposed patients had died. Seventeen of these deaths could be ascribed to radiation effects.[13] There was also additional morbidity. One of the cervical cancer patients, who had received an absorbed dose of 92 Gy to the pelvis from the external beam treatment and 25 Gy from brachytherapy, developed spastic gait in August 2002, 23 months after the end of the teletherapy treatment. She was diagnosed with bilateral motor and sensory radiculopathy affecting L1–L4. In February 2003, the neurophysiological lumbosacral plexopathology was confirmed and attributed to the radiation therapy overexposure. By April 2004, 32 months after the end of the radiation therapy treatment, the patient had developed total paraplegia of the lower limbs. By November 2004, she had died; the exact date of her death was not recorded at the ION.

By August 2005, 23 patients had died, at least 18 of them from radiation effects, mostly rectal complications. The 5 surviving overexposed patients continue being followed up by and receiving medical care from ION physicians. Their clinical condition, as of August 2005, is shown in Table 2.[14] The patients all suffer from gastrointestinal ailments; one of them had to undergo a colostomy. Based on previous clinical experiences (21), they are expected to develop more late effects over the coming years.

Comparison with overexposure in Costa Rica in 1996

The morbidity and mortality found in the Panama study are consistent with the data in the literature (12, 22, 23). Of particular interest, because of its geographical and cultural proximity, is the Costa Rica case that occurred in 1996 (5, 6).

In the San Juan de Dios Hospital, a facility of the Costa Rica Social Security Agency (*Caja Costarricense de Seguro Social*) in San José, Costa Rica, a physicist made a mistake in the calibration of a cobalt-60 unit. He interpreted decimals of minutes as seconds, and provided the facility with dose rate charts that were in error by 45%. The miscalculation resulted in the overexposure of 114 radiotherapy patients between 26 August and 27 September 1996. The overexposure was studied by PAHO and the IAEA (5, 6). Patient outcome was evaluated weeks after (5), one year after (6), and two years after (24, 25) the completion of the radiotherapy treatment. Of the 114 overexposed patients, 35 of them had received pelvic doses from 40 to 70 Gy in numbers of fractions ranging from 12 to 25, and doses per fraction from 2.7 to 5 Gy, about 60% higher than prescribed. Six of these patients died between 6 weeks and 13 months after treatment from one or more of the following complications: bowel fistulas, perforation, intestinal necrosis, and peritonitis. These complications were the same as the ones that occurred in the overexposed patients in Panama (1), but the morbidity and mor-

[13] Personal communication, Fernando Millán and Juan Pablo Barés, ION, November 2004.

[14] Personal communication, Juan Pablo Barés and Fernando Millán, ION, August 2005.

TABLE 2. Radiotherapy doses that had been prescribed and received at the National Oncology Institute (*Instituto Oncológico Nacional*, ION) of Panama between August 2000 and March 2001 and the clinical condition of the five surviving overexposed patients as of August 2005

Patient number[a]	7	13	15	18	24
Cancer site	Endometrium	Prostate	Endometrium	Prostate	Uterine cervix
Prescribed tumor absorbed dose (Gy)					
Teletherapy	50	45	45	45	45
Brachytherapy	18	–[b]	14	–	21
Received tumor absorbed dose (Gy)					
Teletherapy	79	54	77	54	49
Brachytherapy	16	–	13	–	19
Biological effective dose (BED) (Gy)					
Tumor: $\alpha/\beta = 10$; ($\alpha/\beta = 1.5$)	123	71 (167)	116	73 (132)	83
Bladder: $\alpha/\beta = 5$	152	88	141	92	98
Rectum: BED_1 $\alpha/\beta = 10$	118	71	112	73	77
Rectum: BED_2 $\alpha/\beta = 3$	186	110	174	118	116
2-Gy/fraction dose-equivalent (Gy)					
Tumor: $\alpha/\beta = 10$; ($\alpha/\beta = 1.5$)	102	59 (71)	97	61 (78)	69
Bladder: $\alpha/\beta = 5$	108	63	101	66	70
Rectum: BED_1 $\alpha/\beta = 10$	98	59	94	61	64
Rectum: BED_2 $\alpha/\beta = 3$	111	66	104	71	69
Clinical findings as of August 2005	Diffuse pain of the gastrointestinal tract	Surgery for cancer of ascending colon; stable condition	Frequent urinary infections; vaginal fistula	Colostomy for actinic colitis	Stable condition

[a] The patient numbers are taken from Table 2 of Borrás et al. (1).
[b] The "–" symbol indicates that the patient did not receive brachytherapy.

tality in Costa Rica were less severe than in Panama because the doses were lower.

PLANNED ACCREDITATION PROGRAM FOR LATIN AMERICAN AND CARIBBEAN RADIATION ONCOLOGY CENTERS

The clinical study performed in May 2002 and published in June 2004 (1) had a cohort of 153 patients; 28 of them constituted the overexposed group, and 125 made up the control group. Clinical follow-up was performed on 98 of these 125 patients. The most interesting finding was the high incidence of tumor recurrence among patients in this control (non-overexposed) group with cervical and endometrial cancer, especially for cancer stages 1 and 2 (1). This suggested that either the teletherapy field margins were not set up optimally (26) or that the doses were not high enough (27). The latter conclusion is supported by the fact that tumor activity was found only among patients who had no rectal complications. However, both the teletherapy and brachytherapy absorbed doses were within published recommended ranges (2–4). Recurrences for cancer of the cervix have been reported extensively (28–31). The literature review of Hendry et al. (32) indicates that there is a 5.6% loss of tumor control for each week of additional treatment duration. This amounts to a 22% loss of tumor control for each month of additional treatment duration. Hence, the gap of one or more months between the teletherapy and brachytherapy treatments, caused by the scarcity of hospital beds in the specially shielded rooms at the Gorgas Hospital, could well have had a detrimental effect on the outcome. Perez et al. showed that after the initial treatment for cancer in any stage, 80% of recurrences appear within 24 months (33).

The unexpectedly high level of cervical cancer recurrence among the ION patients prompted the PAHO medical physicists to evaluate cancer recurrence in other cancer centers in Latin America and the Caribbean, and to compare those findings with published results. The PAHO medical physicists contacted the officers of two radiation oncology professional societies, the Group of Iberian and Latin American Radiation Oncologists (*Círculo de Radioterapeutas Ibero-Latinoamericanos*) and the Latin American Group of Brachytherapy-Oncological Radiation Therapy (*Grupo Latinoamericano de Curieterapia-Radioterapia Oncológica*). The PAHO medical physicists also contacted the directors of some large radiation oncology facilities, including the National Cancer Institute of Colombia, where a comprehensive evaluation of its 43 radiation oncology centers had been conducted with PAHO's support (34). The PAHO medical physicists hoped to be

able to collect data from these professional societies and national cancer institutes that would allow them to analyze the results of representative clinical quality-assurance practices, in particular those dealing with patient follow-up.

The evaluation of the Colombia radiation oncology centers showed that the centers did not have documentation on long-term patient follow-up (34). The officers of the two radiation oncology professional societies reported the same kind of information: In most countries of Latin America and the Caribbean, assessment of clinical outcome, and therefore of radiotherapy success or failure, is performed by the referring physicians.

This prompted PAHO in 2002 to launch an initiative on the accreditation of radiotherapy departments in Latin America and the Caribbean. This was done in collaboration with the two radiation oncology societies mentioned above, and with two other organizations, the Latin American Medical Physics Association (*Asociación Latinoamericana de Física Médica*) and the International Society for Radiographers and Radiological Technologists. The objective of the initiative was to promote a cultural change in the countries of Latin America and the Caribbean, towards an acceptance of external evaluations of radiation oncology services as a mechanism for raising and standardizing the quality of radiation oncology practices.

In 2005 the two Latin American and Caribbean radiation oncology societies merged to form one association, the Latin American Radiation Oncology Association (*Asociación Latinoamericana de Terapia Radiante Oncológica*) (35). To improve the quality of standards in the health care of cancer patients undergoing radiation therapy treatments in Latin America and the Caribbean, the Association officers decided to set up the "Commission on Accreditation of Radiation Oncology Centers." The Commission's goal is to increase the survival rates for and the quality of life of oncological patients, by better controlling tumors and by reducing the complications and toxicity due to radiation therapy.

The Commission on Accreditation is expected to be fully functional by 2007. The Commission's first task is to develop accreditation criteria for all the stages of the radiotherapeutic process: clinical history, diagnosis and staging of the disease, therapeutic decision, localization/simulation of the treatment, physical and clinical dosimetry, teletherapy/brachytherapy treatments, and clinical follow-up and statistics. Of main concern is the adequacy of treatment protocols. Are patients receiving doses high enough to ensure cancer control and to improve survival? Are radiation oncologists reluctant to cause even a small and normally acceptable percentage of patient overreactions? Are radiation oncologists prescribing doses lower than what is recommended in the literature? Is the fear of violating radiation safety regulations affecting decisions regarding patient treatment?

The Commission on Accreditation will pay particular attention to clinical patient follow-up procedures in order to ensure that radiation late effects are documented, and that appropriate patient support is provided. Centers will only be accredited if they have implemented a comprehensive quality assurance program that follows international guidelines (36–38). Statistical data on patient outcome will be collected in order to document needs in Latin American and Caribbean radiotherapy centers and to define future strategies for cancer treatment. The Commission will also identify a cadre of radiation oncology experts to audit the centers that wish to be accredited.

CONSEQUENCES OF THE PANAMA OVEREXPOSURES

The lessons from the Panama overexposures are not limited to how to manage the affected patients. Regulatory authorities in Panama and in the United States and two international organizations launched a series of investigations to help prevent future occurrences of this type of "accident." A key question is, were all the overexposures at the ION really an "accident"? And what does "accident" mean? One dictionary defines "accident" as "chance or what happens by chance." The IAEA defines "accident" as "any unintended event, including operating errors, equipment failures, or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety" (12). The ICRP defines the term as "an unintended event that has or may have adverse consequences" (22). When dealing with medical exposures, both the IAEA and the ICRP also use the term "accidental medical exposures." One of the connotations is that of a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner. In these latter definitions, "accidental" has the connotation of unintended and not unexpected, with an emphasis on the difference between prescribed and delivered. Somehow it is assumed that the prescribed dose is correct and that "adverse effects" are rare. However, to cure cancer, a certain percentage of "adverse effects" may occur in normal tissues at a level that is accepted in medical practice. This includes up to 1% of patients who are very radiosensitive because of various repair-deficiency

TABLE 3. Major accidental exposures of radiotherapy patients that have happened around the world over the last three decades[a]

Type of accident	Country	Year(s)	Patients overdosed or underdosed
Miscalibration of cobalt-60 units	United States	1974–1976	426 overdosed
	Germany	1986–1987	86 overdosed
	United Kingdom	1988	207 overdosed
	Costa Rica	1996	114 overdosed
Hardware/software problems with linear accelerators	Canada and United States	1985–1987	3 overdosed
	Spain	1990	27 overdosed
	Poland	2001	5 overdosed
Low dose rate brachytherapy problems	United Kingdom	1988–1989	14 underdosed 12 overdosed
	United States	1992	1 overdosed
Treatment planning errors	United Kingdom	1982–1990	1 045 underdosed
	United States	1987–1988	33 overdosed
	Panama	2000–2001	28 overdosed

[a] The data presented in the table come from IAEA (12) and ICRP (22).

syndromes.[15] Both the IAEA and the ICRP have published reports that illustrate different types of accidents and their root causes (12, 22). Table 3 lists major instances of radiotherapy accidents that have happened around the world over the last three decades. While most of the incidents involve overexposures, there have also been several instances of patients being underdosed, leading to lack of cancer control. The most notable case of underexposure occurred from 1982 to 1990 in the United Kingdom, at the North Staffordshire Royal Infirmary, in the city of Stoke-on-Trent in the county of Staffordshire. It was due to an incomplete understanding and testing of a treatment planning system (12). Of the 1 045 improperly treated patients, 492 of them developed local recurrences (39).

Cancer recurrence is not the concern of radiation regulatory authorities. Those regulatory authorities only investigate overexposures (often without understanding the clinical aspects of radiation therapy), and they assign the responsibilities for patient treatment to the physicists performing the dosimetry. Two key publications, the *International basic safety standards for protection against ionizing radiation and for the safety of radiation sources* (40) and the *EU Council Directive 97/43/Euratom* (41), emphatically state that medical exposures are the responsibility of the medical practitioner prescribing or delivering the dose. However, since errors are clearly dose-related (5, 6, 8, 12, 22, 24, 25), physicists are being taken to court for radiation therapy overexposures, while the physicians in charge are not being charged (42–45).

Regulatory actions

The Panamanian regulatory authority for radiation safety investigated the overexposures immediately after receiving notification from the ION. The "lessons learned" generated a series of corrective actions, among them stringent requirements for the establishment of quality assurance and quality control programs, and for adequate training of professionals of the ION's radiation oncology department (46).

The Center for Devices and Radiological Health of the United States Food and Drug Administration (FDA), which oversees medical devices, approved Multidata's TPS software in 1997. In May–June 2001, right after the FDA became aware of the Panama overexposures, the FDA sent examiners to investigate Multidata. The FDA found that Multidata had received at least six complaints about calculation errors related to the failure of the firm's radiation treatment planning software to correctly handle certain types of blocks (polygons) (47). The FDA also found out that even the most recent version of Multidata's TPS algorithm was capable of the same error. Consequently, the FDA forced the company to issue a warning to all its TPS

[15] Hendry JH, Zubizarreta EH. Variation in biologically-effective dose (BED) prescriptions among centres using brachytherapy/external-beam treatment of cervical cancer [abstract]. Radiother Oncol. 2004: 73(Supplement 1):S19.

users, in order to prevent any other accidental overexposures (48).

The FDA found that Multidata had failed to: (1) establish, maintain, and follow procedures to control the design of the radiation treatment planning software in order to ensure that the specifications were met; (2) establish and follow procedures for taking preventive and corrective action; (3) establish and follow procedures for investigating all complaints; and (4) adhere to other standard good manufacturing practices. In addition, the firm failed to identify the root cause of the software code problems when they were brought to the company's attention.

The Nuclear Regulatory Commission (NRC) of the United States published the findings of the IAEA investigation in an "information notice" dated 20 November 2001. The NRC sent the notice to all its medical licensees, and attached the June 2001 and August 2001 "urgent notices" that Multidata had sent to its customers in response to the FDA's action (49).

Legal actions

On 18 May 2004 a court trial for the three ION physicists began in Panama City. The prosecutor had asked for them to be convicted of second-degree murder. Neither the ION nor the five radiation oncologists involved were charged. On 18 November 2004 it was announced that one of the physicists was acquitted, but the other two were found guilty, sentenced to four years in prison, and barred from practicing their profession for seven years (45). They have initiated an appeal process, but they are very worried, given the precedent established by the Costa Rica case.

The trial for the Costa Rican physicist who had miscalibrated the cobalt therapy unit began on 26 February 2000, in the presence of 35 surviving patients and the relatives of 80 patients who had died. He was accused of negligence in 30 homicides and 59 radiation injuries. He was also accused of falsifying documents and of using false documents. On 30 July 2001 he was absolved of the latter two charges, but he was found guilty of 14 homicides and 50 radiation injuries. He was sentenced to six years in prison and barred from practicing his profession for five years. The plaintiffs had also sued the Costa Rica Social Security Agency, claiming that the indemnifications paid to them by the Agency did not preclude them from obtaining additional compensation from the Agency in connection with the overexposures. The court ruled against the plaintiffs and in favor of the Agency. Both decisions were appealed to the Supreme Court of Costa Rica. On 12 August 2003 the Supreme Court upheld the verdict and the sentence of the lower court regarding the physicist's culpability. The Supreme Court, however, overturned the lower court's decision precluding the plaintiffs from seeking additional compensation from the Agency (44). This decision cleared the way for surviving patients or their heirs to file suit against the Agency in civil court.

Plaintiffs from Panama also sued Multidata, both in the state of Missouri (United States) and in Panama. The Missouri court dismissed the action, concluding that the case could have and should have been brought up in Panama. The court cited a variety of reasons, such as the fact that the ION could not be sued in Missouri and that it would be highly inconvenient to conduct pretrial discovery if the case were pending in the United States (50). The Panamanian court dismissed the charges brought against Multidata, saying that the case had been filed in two courts simultaneously (43). Now that the case has been dismissed in the United States, the plaintiffs are free to again sue Multidata in Panama. Depending on the outcome of the litigation, the potential judgment could be substantial. In the Stoke-on-Trent (United Kingdom) case, 80 of the 492 patients who developed local recurrences sued the North Staffordshire Health Authority, alleging that tumor recurrence was due to underexposure. They won the suit and were awarded a total of £2 million (39).

THE NATIONAL ONCOLOGY INSTITUTE TODAY

Many things have changed at the ION since the patient overexposures occurred. The radiation oncology department has moved into a new building within the remodeled Gorgas Hospital. New treatment rooms have been built with the structural shielding specified by the Panamanian regulations. Thanks to a donation of US$ 6.5 million made by the Government of Taiwan to the Government of Panama, the equipment now consists of three linear accelerators (two of them with dual energy photons and electrons), a superficial X-ray machine, a simulator, and a treatment planning system. Except for the superficial X-ray machine, all the units are networked. Access to a computed tomography scanner for virtual simulation is also available. The staff consists of six radiation oncologists, five physicists, four dosimetrists, and 12 radiation therapy technologists. The ION also has a radiological protection department, with 1.5 full-time-equivalent staff. The quality and safety of the radiation therapy procedures are monitored by the Inter-institutional Committee on Radiological Protection and Quality Control (*Comité*

Interinstitucional de Protección Radiológica y Control de Calidad), which meets weekly. The Committee is composed of members of the ION's radiology, radiation oncology, nuclear medicine, and radiological protection departments, and it is chaired by the ION's director. Although it was established in response to the radiotherapy overexposures, it now oversees all the activities that involve ionizing radiation.

CONCLUSIONS

The Panamanian overexposure incident is perceived as one of the worst radiation therapy accidents ever. It had devastating consequences, not just for the patients but also for the practice of radiation therapy in Panama. As had happened in other patient overexposures, such as the ones in Costa Rica, patients in Panama began avoiding the public institution and instead sought treatment in private facilities. They did not realize, however, that because of staffing shortages, the same radiation therapy personnel worked in both the public and private facilities.

While the Panama overexposures were caused by a violation of the TPS instructions, a good software program would have alerted the user that the procedure was not authorized. In any case, treatment times generated by a TPS require manual verification. However, no TPS quality control existed at the ION, even though a comprehensive report on quality assurance for TPSs was available at the time (51). This experience prompted the IAEA to publish a report that describes how to commission a TPS, and with what frequency its algorithms should be tested (52).

There were other factors that contributed to the error with the TPS at the ION. One was the large patient workload, with more than 70 patients per machine per day. Another factor was that teletherapy treatments were done in one hospital (where the physics charts were kept), and brachytherapy treatments and patient follow-up were done (and clinical charts kept) in another hospital. The shortage of medical physics staff also played a significant role.

Radiation-safety regulatory authorities investigate accidental medical exposures, focusing on overexposures. However, the most interesting finding in Panama was the high level of recurrence of cervical cancer among the patients for whom no unacceptable error in dose delivery had occurred. The finding prompted PAHO to launch an initiative for the accreditation of radiation oncology centers in Latin America and the Caribbean. Accreditation will require that the centers implement a comprehensive radiation oncology quality assurance program that follows international guidelines. Statistical data on patient outcome will be collected in order to document needs in Latin American and Caribbean radiotherapy centers and to define future strategies for cancer treatment (1). The newly–established Commission on Accreditation should ensure that cancer patients are treated with doses that are not only "safe" but effective.

Acknowledgements. We are indebted to the staff of the ION, especially to Juan Pablo Barés, who was the director of the ION and who encouraged this research, as well as the radiation oncology personnel, who kindly made procedure information and patient data available. We thank Damian Rudder, who, while at the Pan American Health Organization, performed all the absorbed dose calculations; Jolyon Hendry, who reviewed earlier drafts of this work and offered helpful suggestions throughout; and William Roventine, who reviewed the last drafts.

SINOPSIS

La sobreexposición de pacientes tratados con radioterapia en Panamá: reconocimiento del problema y medidas de seguimiento

Este informe resume y analiza la respuesta de varias organizaciones que brindaron asistencia al Instituto Oncológico Nacional (ION) de Panamá después de la sobreexposición de 28 pacientes sometidos a radioterapia que ocurrió en el ION a finales de 2000 y principios de 2001. Además, se examinan las medidas de largo plazo adoptadas en el ION en respuesta al accidente de sobreexposición y las implicaciones que tiene este accidente para todos los centros de tratamiento oncológico en el mundo. En marzo de 2001 se le comunicaron al director del ION las reacciones adversas graves sufridas por algunos pacientes sometidos a radioterapia contra el cáncer. De los 478 pacientes tratados entre agosto de 2000 y marzo de 2001 por cánceres localizados en la región pélvica, tres habían fallecido, presumiblemente por sobredosis de radiación. A raíz de ello, el Gobierno de Panamá invitó a expertos internacionales a realizar una investigación a fondo de la situación. Entre los especialistas invitados se encontraban físicos médicos de la Organización Panamericana de la Salud (OPS), quienes comprobaron que 56 pacientes con cáncer cérvico-uterino, de endometrio, de próstata o de recto tratados mediante campos de teleterapia parcialmente bloqueados recibieron dosis calculadas mediante un sistema computarizado de planificación de tratamientos. Los físicos médicos de la OPS comprobaron que solo 11 de esos 56 pacientes recibieron una dosis absorbida dentro de los límites aceptables de ±5%. Veintiocho de los 56 pacientes recibieron dosis con errores entre +10 y +105%. De esos 28 pacientes que fueron sobreexpuestos, según los físicos del ION, 23 murieron antes de septiembre de 2005; de ellos, 18 murieron a causa de los efectos de las radiaciones, principalmente complicaciones rectales. Las consecuencias clínicas, psicológicas y jurídicas de esta sobreexposición menoscabaron gravemente los tratamientos contra el cáncer en Panamá y llevaron a la OPS a examinar de cerca las prácticas de ra-

dioterapia oncológica en América Latina y el Caribe. Los médicos del ION evaluaron los resultados del tratamiento de 125 pacientes atendidos en ese mismo intervalo de tiempo por los mismos tipos de cáncer sin haber sufrido sobreexposición y encontraron una tasa de recurrencia de cáncer cervicouterino mayor de la esperada. Esto llevó a la OPS a lanzar una iniciativa para la acreditación de los centros de radioterapia oncológica en América Latina y el Caribe, en colaboración con las sociedades profesionales de radioncólogos, físicos médicos y tecnólogos de radioterapia. La Asociación Latinoamericana de Terapia Radiante Oncológica estableció una comisión de acreditación que exigirá que los centros establezcan programas integrales de garantía de la calidad en radioterapia oncológica según los lineamientos internacionales. Asimismo, se recogerán datos estadísticos acerca de los resultados observados en los pacientes tratados para documentar las necesidades de los centros de radioterapia en América Latina y el Caribe, con vistas a definir futuras estrategias en el tratamiento del cáncer.

Palabras clave: Neoplasias pélvicas, radioterapia, traumatismos por radiación, control de calidad, Panamá.

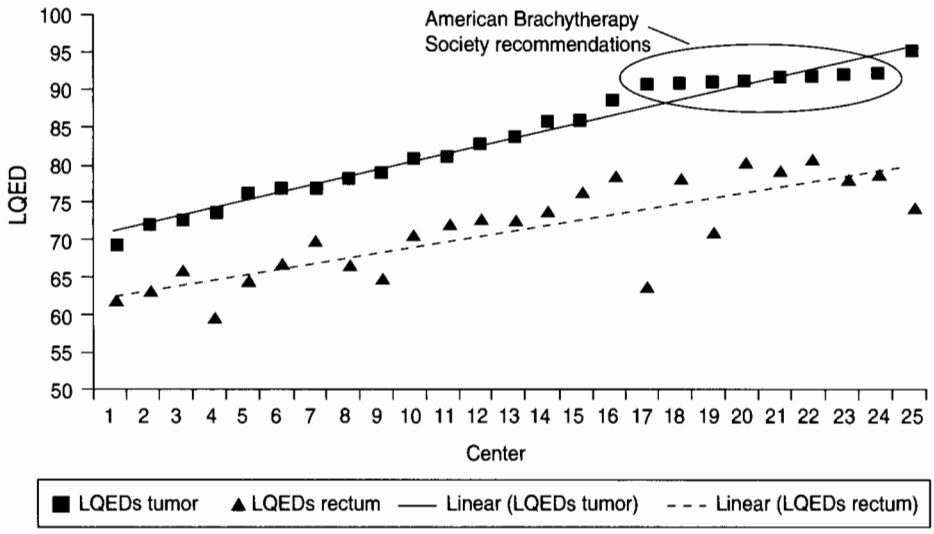
REFERENCES

1. Borrás C, Barés JP, Rudder D, Amer A, Millán F, Abuchaibe O. Clinical effects in a cohort of cancer patients overexposed during external-beam pelvic radiation therapy. Int J Radiation Oncology Biol Phys. 2004:59(2);538–50.
2. Fletcher GH, ed. Textbook of radiotherapy. 3rd ed. Philadelphia: Lea & Febiger; 1980.
3. Perez CA, Brady LW, eds. Principles and practice of radiation oncology. 3rd ed. Philadelphia: Lippincott Williams & Wilkins; 1998.
4. World Health Organization. Radiotherapy in cancer management: a practical manual. London: Chapman & Hall Medical; 1997.
5. Borrás C. Radiation therapy overexposure. In: Amaral, ECS, Belém Ferreira LMJ, eds. REMPAN 97 proceedings: Seventh Coordination Meeting of World Health Organization Collaborating Centers in Radiation Emergency Medical Preparedness and Assistance Network. Rio de Janeiro: Instituto de Radioproteção e Dosimetria; 1997. Pp. 67–9.
6. International Atomic Energy Agency. Accidental overexposure of radiotherapy patients in San Jose, Costa Rica. Vienna: IAEA; 1998.
7. International Commission on Radiation Units and Measurements. Determination of absorbed dose in a patient irradiated by beams of x- or gamma-rays in radiotherapy procedures. Washington, D.C.: ICRU; 1976. (Report 24).
8. International Atomic Energy Agency. Investigation of an accidental overexposure of radiotherapy patients in Panama. Vienna: IAEA; 2001.
9. British Journal of Radiology. Central axis depth dose data for use in radiotherapy. London: The British Institute of Radiology; 1996. (The British Journal of Radiology Supplement 25).
10. Young MEJ, Batho HF. Dose tables for linear radium sources calculated by an electronic computer. Brit J Radiol. 1964; 37:38–44.
11. Perez CA, Breaux S, Madoc-Jones H, Camel HM, Purdy J, Sharma S, et al. Correlation between dose and tumor recurrence and complications in carcinoma of the uterine cervix: stage I and II-A. Int J Radiat Oncol Biol Phys. 1979;5: 373–82.
12. International Atomic Energy Agency. Lessons learned from accidental exposures in radiotherapy. Vienna: IAEA; 2000. (Safety Reports Series No. 17).
13. United States, Nuclear Regulatory Commission. Code of Federal Regulations, Title 10: Energy, Part 35: medical use of byproduct material. Washington, D.C.: NRC; 1980. (45 FR 31704, 10 CFR 35.41).
14. United States, Nuclear Regulatory Commission. Code of Federal Regulations, Title 10: Energy, Part 35: medical use of byproduct material. Washington, D.C.: NRC; 2002. (67 FR 20370, 10 CFR 35.2).
15. Vatnitsky S, Ortiz Lopez P, Iżewska J, Meghzifene A, Levin V. The radiation overexposure of radiotherapy patients in Panama. Radiother Oncol. 2001;60: 237–8.
16. Thames HD, Hendry JH. Fractionation in radiotherapy. London: Taylor and Francis; 1987.
17. Cox JD, Stetz J, Pajak TF. Toxicity criteria of the Radiation Therapy Oncology Group (RTOG) and the European Organization for Research and Treatment of Cancer (EORTC). Int J Radiat Oncol Biol Phys. 1995;31(5):1341–6.
18. Rubin P, Constine L, Fajardo LF, Philips TL, Wasserman TH. Overview: Late Effects of Normal Tissues (LENT) scoring system. Int J Radiat Oncol Bio Phys. 1995;31(5):1041–2.
19. Pavy JJ, Denekamp J, Letschert J, Littbrand B, Mornex F, Bernier J, et al. Late effects toxicity scoring: the SOMA scale. Int J Radiat Oncol Bio Phys. 1995;31(5): 1043–7.
20. International Journal of Radiation Oncology Biology Physics. LENT SOMA scales for all anatomical sites. Int J Radiat Oncol Biol Phys. 1995;31(5):1049–93.
21. Jung H, Beck-Bornholdt HP, Svoboda V, Alberti W, Herrmann T. Quantification of late complications after radiation therapy. Radiother Oncol. 2001;61:233–46.
22. International Commission on Radiological Protection. Prevention of accidental exposures to patients undergoing radiotherapy. A report of the International Commission on Radiological Protection. Ann ICRP. 2000;30(3):7–70.
23. United Nations Scientific Committee on the Effects of Atomic Radiation. Sources, effects and risks of ionizing radiation. 1988 report to the General Assembly, with annexes. New York: United Nations; 1988.
24. Mettler FA, Landberg T, Nénot JC, Medina-Trejos F, Ching R, Garcia I, et al. A 2-year medical follow-up of the radiotherapy accident in Costa Rica. In: Gusev IA, Guskova AK, Mettler FA, eds. Medical management of radiation accidents. Boca Raton: CRC Press; 2001. Pp. 299–311.
25. Cosset JM. ESTRO Breur Gold Medal Award Lecture 2001: irradiation accidents—lessons for oncology? Radiother Oncol. 2002;63:1–10.
26. Zunino S, Rosato O, Lucino S, Jauregui E, Rossi L, Venencia D. Anatomic study of the pelvis in carcinoma of the uterine cervix as related to the box technique. Int J Radiat Oncol Biol Phys. 1999;44: 53–9.
27. Brady LW, Perez CA, Bedwinek JM. Failure patterns in gynecologic cancer. Int J Radiat Oncol Biol Phys. 1986;12: 549–57.
28. Sakurai H, Mitsuhashi N, Takahashi M, Akimoto T, Muramatsu H, Ishikawa H, et al. Analysis of recurrence of squamous cell carcinoma of the uterine cervix after definitive radiation therapy alone: patterns of recurrence, latent periods and prognosis. Int J Radiat Oncol Biol Phys. 2001;50:1136–44.
29. Perez CA, Breaux S, Madoc-Jones H, Bedwinek JM, Camel HM, Purdy JA, et al. Radiation therapy alone in the treatment of carcinoma of uterine cervix. I. Analysis of tumor recurrence. Cancer. 1983;51:1393–1402.
30. Lanciano R. Optimizing radiation parameters for cervical cancer. Semin Radiat Oncol. 2000;10(1):36–43.
31. Fyles A, Keane TJ, Barton M, Simm J. The effect of treatment duration in the

local control of cervix cancer. Radiother Oncol. 1992;25(4):273–9.
32. Hendry JH, Bentzen SM, Dale RG, Fowler JF, Wheldon TE, Jones B, et al. A modelled comparison of ways to compensate for missed treatment days in radiotherapy. Clin Oncol (R Coll Radiol). 1996;8(5):297–307.
33. Perez CA, Grigsby PW, Castro Vita H, Lockett MA. Carcinoma of the uterine cervix. I. Impact of prolongation of overall treatment time and timing of brachytherapy on outcome of radiation therapy. Int J Radiat Oncol Biol Phys. 1995; 32:1275–88.
34. Instituto Nacional de Cancerología, Ministerio de la Protección Social, Organización Panamericana de la Salud/ Organización Mundial de la Salud. Evaluación de los servicios de radioterapia en Colombia. Santa Fe de Bogotá: Instituto Nacional de Cancerología; 2005.
35. Asociación Latinoamericana de Terapia Radiante Oncológica. ALATRO. Asociación Latinoamericana de Terapia Radiante Oncológica. Available at: http:// www.alatro.org/ [Web site]. Accessed 11 July 2006.
36. World Health Organization. Quality assurance in radiotherapy: a guide prepared following a workshop held at Schloss Reisenburg, Federal Republic of Germany, 3–7 December 1984, and organized jointly by Institute of Radiation Hygiene and World Health Organization. Geneva: WHO; 1988.
37. Hanks G, Svensson G, eds. Quality assurance in radiation therapy: clinical and physical aspects. Proceedings of the First International Symposium on Quality Assessment in Radiation Oncology. New York: Pergamon Press; 1984. (International Journal of Radiation Oncology, Biology, Physics, Volume 10 Supplement 1).
38. Borrás C, ed. Organization, development, quality assurance and radiation protection in radiology services: imaging and radiation therapy. Washington, D.C.: Pan American Health Organization; 1997.
39. Alexander Harris Solicitors. Patients given wrong dose of radiation. Available from: http://www.alexharris.co.uk/page/_Radiotherapy_110.asp [Web site]. Accessed 11 August 2005.
40. Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Organisation, Nuclear Agency of the Organisation for Economic Co-operation and Development, Pan American Health Organization, World Health Organization. International basic safety standards for protection against ionizing radiation and for the safety of radiation sources. Vienna: IAEA; 1997. (International Atomic Energy Agency Safety Series 115).
41. European Commission. Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom. Available from: http://survey.ear-online.org/ national_societies/EU_CouncilDirective. pdf [Web site]. Accessed 13 July 2006.
42. Sociedad Española de Física Médica. El accidente del acelerador lineal en el Hospital Clínico de Zaragoza. Madrid: SEFM; 1991.
43. Borrás C. Medical physicists' roles and responsibilities in accidental medical exposures. In: Ng KH, Jamal N, Muhammad SN, eds. Proceedings of the 3rd South-East Asian Congress of Medical Physics (SEACOMP) and 4th Asian-Oceanian Congress of Medical Physics (AOCMP). Kuala Lumpur: Department of Radiology, Faculty of Medicine, University of Malaya; 2004.
44. Costa Rica, Corte Suprema de Justicia. Sala Tercera de la Corte Suprema de Justicia, San José. Exp: 97-000347-0201-PE. Res: 2003-00685. Available from: http:// www.poder-judicial.go.cr/salatercera/ jurisprudencia general/2003/0685-03. doc [Web site]. Accessed 11 August 2005.
45. Diaz C. JM. Cuatro años de prisión para físicos del ION. El Panamá América-EPASA. Available from: http://www. elpanamaamerica.com.pa/archive/1118 2004/nation05.shtml [Web site]. Accessed 11 July 2006.
46. Gibbs E, Douglas A. Lessons learned from the regulatory control of the accidental exposure of radiotherapy patients occurred in Panama. In: International Atomic Energy Agency. International Conference on National Infrastructures for Radiation Safety: towards effective and sustainable systems. Vienna: IAEA, 2004. Pp. 524–7. (IAEA-CN-107/127).
47. Gage D, McCormick J. "We did nothing wrong." Why software quality matters. Available from: http://www.baseline mag.com/print_article2/0,1217,a= 120920,00.asp [Web site]. Accessed 11 August 2005.
48. United States, Center for Devices and Radiological Health. FY 03 CDRH annual report. Available from: http:// www.fda.gov/cdrh/annual/fy2003/ fy2003.pdf [Web site]. Accessed 11 August 2005.
49. United States, Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards. Update on radiation therapy overexposures in Panama. Washington, D.C.: NRC; 2001. (Information Notice 2001-08, Supplement 2).
50. FindLaw for Legal Professionals. Opinion. Missouri Court of Appeals Eastern District. Natacha Chandler, et al., Appellants, v. Multidata Systems International Corp., Inc., et al., Respondents. Available from: http://caselaw.lp.findlaw.com/scripts/getcase.pl?court=mo&vol=/appeals/052005/&invol=ed84192_ 2005 [Web site]. Accessed 11 July 2006.
51. Fraass B, Doppke K, Hunt M, Kutcher G, Starkschall G, Stern R, et al. American Association of Physicists in Medicine Radiation Therapy Committee Task Group 53: quality assurance for clinical radiotherapy treatment planning. Med. Phys. 1998:25(10);1773–829.
52. International Atomic Energy Agency. Commissioning and quality assurance of computerized planning systems for radiation treatment of cancer. Available from: http://www-pub.iaea.org/ MTCD/publications/PDF/TRS430_ web.pdf [Web site]. Accessed 11 August 2005. (IAEA Technical Report Series No. 430).

Manuscript received 14 December 2004. Revised version accepted for publication 20 April 2006.

FIGURE 2. Values of linear-quadratic equivalent dose (LQED) in Gy for cervical tumor dose prescriptions (solid squares and upper, solid line) and for calculated rectal doses (triangles and lower, dashed line) among 25 radiotherapy centers around the world



reduced, then the dose per fraction may need to be increased to compensate for the decreased effectiveness of the radiation. The same applies to more sophisticated technology, such as intensity-modulated radiation therapy (IMRT). With prolonged fraction delivery needed to execute sophisticated IMRT plans, a loss of biological effect may occur.

The influence of repair has been observed in numerous detailed studies using cell cultures or animal systems, particularly during irradiation at low dose rates (32). Brachytherapy treatments are one of the cornerstones of the treatment of cervical cancer, often in addition to external beam therapy (33). The brachytherapy is delivered using either low-dose-rate (LDR) irradiation (between 0.5 and 1.5 Gy per hour) in two sessions or, increasingly more commonly, several high-dose-rate (HDR) sessions (~100 cGy per minute). The total dose is adjusted accordingly to give the same acceptable low level of morbidity, which is predominantly rectal injury. HDR is not better than LDR for these treatments (34), but it gives an acceptable result, and more patients can be treated with the equipment, although more staff resources are needed.

Around the world, LDR brachytherapy is being gradually replaced by HDR brachytherapy. Some randomized trials have shown that HDR can be as effective as LDR in terms of tumor control and late complications (35–37), but no formal trials have been performed to test different HDR schedules. The American Brachytherapy Society (ABS) published guidelines about dose and fractionation (38), based on a review of HDR schedules (39).

We have collated known dose prescriptions for cervical cancer used in 25 radiotherapy centers around the world. These dose prescriptions were converted to values of linear-quadratic equivalent dose (LQED) for the dose to the tumor (by convention, quoted at point A) and the lower dose received by the rectum (assuming 70% of the point A dose in the rectal wall). The conversion was done by calculation, using the LQ formalism and the following parameter values: α/β for tumor = 10 Gy, half time of repair = 1.5 hours; α/β for rectum = 3 Gy, half time of repair = 1.5 hours. The 25 values of tumor LQED were placed in ascending numerical order from the lowest to the highest, and the tumor LQED values were then plotted in Figure 2 along with their corresponding values of LQED for the rectum. The prescriptions used a variety of high-dose-rate treatments (21 schedules) and low-dose-rate treatments (4 schedules), plus external beam therapy. Trend lines are shown for visual clarity, and the centers using the ABS-recommended dose prescriptions for cervical cancer are circled. When the dose prescriptions are compared in terms of LQED, there is up to 25% less dose prescribed in those centers on the left side of Figure 2 compared to the higher doses on the right (including the ABS values, which are circled). As there exists some fear about the risk of increased late effects with the use of high-dose fractions in high-dose-rate cervical brachytherapy, it is possible that some of these lower-LQED schedules have been designed with excessive prudence. Randomized trials will be needed to determine the schemes with the optimal dose and fractionation.

La regulación de la protección radiológica y la función de las autoridades de salud

César F. Arias[1]

Forma de citar: Arias CF. La regulación de la protección radiológica y la función de las autoridades de salud. Rev Panam Salud Publica. 2006;20(2/3):188–97.

SINOPSIS

En este artículo se presenta una breve síntesis de la evolución de la protección contra las radiaciones ionizantes y se hace una interpretación de su filosofía actual. Se analiza el papel decisivo que deben desempeñar las organizaciones reguladoras en protección radiológica y la importante contribución que pueden brindar las autoridades sanitarias. Estas deberían participar activamente al menos en tres aspectos: la promoción de la educación formal del personal de salud en lo concerniente a la protección radiológica, la atención médica de las personas sobreexpuestas accidentalmente y la protección radiológica de los pacientes en relación con los procedimientos radiológicos. Para lograr esos objetivos, los profesionales sanitarios han de tener los conocimientos necesarios en materia de protección radiológica, promover el uso de los equipos adecuados y aplicar los procedimientos necesarios de garantía de la calidad. La apropiada intervención de las autoridades nacionales de salud puede contribuir en gran medida a reducir las dosis innecesarias en los procedimientos médicos con fuentes de radiación y reducir la probabilidad de que ocurran accidentes radiológicos en este campo.

Palabras clave: radiación ionizante, protección radiológica, control de la radiación, reglamentos.

La posibilidad de obtener imágenes del interior de la materia sorprendió al mundo cuando Wilhelm Conrad Roentgen descubrió los rayos X en la Universidad de Würzburgo, Alemania, en 1895. Un año después, Antoine Henri Becquerel comenzó a explorar otro fenómeno que Marie Curie denominó más tarde "radiactividad". Todos ellos fueron acreedores del Premio Nóbel de Física en reconocimiento a descubrimientos que abrían un amplio campo al conocimiento y a la imaginación.

En la actualidad, innumerables aplicaciones derivadas de aquellos primeros conocimientos son práctica habitual en diversas áreas de la producción, la investigación y —de manera muy especial— la medicina. Pocos descubrimientos han tenido un impacto tan grande en el campo médico. La radiología convencional, la tomografía computarizada, la radiología intervencionista, las técnicas de medicina nuclear, la tomografía por emisión de positrones y la radioterapia con fuentes radiactivas y aceleradores de partículas son procedimientos frecuentes en la medicina moderna.

Sin embargo, casi a raíz de su descubrimiento se hizo evidente que los rayos X y la radiactividad también podían causar daños a la salud. Ya en 1896 se observaron problemas de depilación, eritemas, quemaduras, amputaciones —e incluso la muerte— en las personas que empleaban tubos de rayos

[1] Departamento de Física, Universidad de Buenos Aires, Paseo Colón 850, CP1063, Buenos Aires, Argentina. Correo electrónico: carias@fi.uba.ar

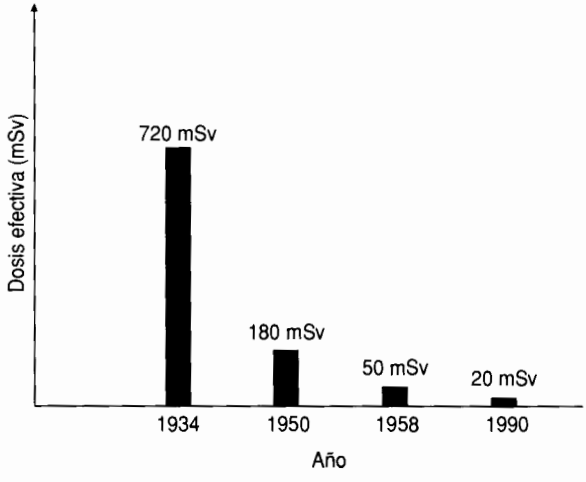
X y materiales radiactivos en sus investigaciones. A medida que los pioneros de la radiología sufrían afecciones o morían prematuramente, los científicos comprendieron una contradictoria realidad: estos nuevos descubrimientos que podían contribuir a salvar la vida también podían destruirla.

En este artículo se presenta una breve síntesis de la evolución de las medidas de protección contra las radiaciones ionizantes y se hace una interpretación de la filosofía actual al respecto. Además, se analizan la importancia de contar con organizaciones reguladoras que sean eficaces en este sentido y la significativa contribución que pueden aportar las autoridades de salud, especialmente en la protección de pacientes sometidos a procedimientos médicos de diagnóstico o a tratamientos en que se emplean fuentes de radiación ionizante.

ORIGEN Y EVOLUCIÓN DE LA PROTECCIÓN RADIOLÓGICA

En la figura 1 se resume la evolución de los límites de dosis, concepto central de la protección radiológica, es decir, de la disciplina dedicada a la protección de las personas contra los peligros de las radiaciones. Sin embargo, para interpretar correctamente esta figura es necesario comprender cómo ha progresado el conocimiento en radiobiología, el significado de las magnitudes y unidades de medida adoptadas para correlacionar la exposición a las radiaciones con sus riesgos y los criterios adoptados a lo largo del tiempo en torno a la protección de las personas (1, 2).

FIGURA 1. Límites de exposición anual recomendados para los trabajadores por la Comisión Internacional de Protección Radiológica, 1934–1990[a]



Fuente: Datos tomados de las referencias 1 y 2.
[a] En la actualidad está vigente el límite establecido en 1990.

Los rayos X, las emisiones radiactivas (alfa, beta y gamma, entre otras) y las partículas resultantes de reacciones nucleares (como los neutrones, los protones y los deuterones) pueden afectar a la salud de las personas —aun cuando la energía absorbida sea muy pequeña— debido a la capacidad que poseen estas radiaciones de ionizar los átomos que encuentran en su trayecto, peculiaridad que les valió la denominación de radiaciones ionizantes. Las moléculas que poseen átomos ionizados aumentan su reactividad química y pueden provocar alteraciones en las estructuras celulares, siendo de particular importancia las que ocurren en las moléculas de ácido desoxirribonucleico (ADN). Otras radiaciones electromagnéticas de mayor longitud de onda —y por consiguiente de menor energía fotónica—, denominadas radiaciones no ionizantes, no tienen esa posibilidad y solo pueden afectar a la salud mediante otros procesos biofísicos que requieren niveles de exposición miles de veces superiores en términos de la energía absorbida (3).

Los efectos de las radiaciones ionizantes y el inicio de la protección radiológica

Los médicos fueron los primeros en emplear fuentes de radiaciones ionizantes para realizar exploraciones radiológicas y también en sufrir los daños provocados por las radiaciones. Esto llevó a que en el Segundo Congreso Internacional de Radiología, celebrado en Estocolmo, Suecia, en 1928, se recomendara la creación de un organismo internacional para ocuparse de este problema. Así nació la protección radiológica como disciplina y se creó un organismo que en la actualidad se denomina Comisión Internacional de Protección Radiológica (CIPR).

Durante el Primer Congreso Internacional de Radiología, celebrado en Londres, Reino Unido, en 1925, se había creado la Comisión Internacional de Unidades y Medidas de Radiación (CIUR) con el fin de proponer magnitudes y unidades de medida apropiadas para evaluar la exposición a las radiaciones. Tanto la CIUR como la CIPR —dos organizaciones nacidas de la radiología médica— han contribuido a definir las magnitudes y unidades que se emplean en la protección radiológica (cuadro 1).

Algunos experimentos llevados a cabo en animales e investigaciones realizadas con personas expuestas a radiaciones ionizantes por razones médicas o laborales han contribuido a conocer los efectos biológicos de dichas radiaciones. Sin embargo, la mayor investigación epidemiológica llevada a cabo hasta la fecha es la realizada en las poblaciones japonesas de Hiroshima y Nagasaki con la participación de los sobrevivientes de las explosiones atómicas de agosto de 1945. En ese estudio, que aún no ha concluido, han participado alrededor de 86 000 per-

CUADRO 1. Magnitudes y unidades empleadas en la protección radiológica

Dosis absorbida en un órgano: relación entre la energía total de radiación absorbida por un órgano o tejido y la masa del mismo.
Unidad: gray (Gy), equivalente a 1 julio/kg

Dosis equivalente en un órgano: dosis de radiación absorbida en un órgano o tejido, ponderada según la efectividad relativa del tipo de radiación. El factor de ponderación varía entre 1 y 20.
Unidad: sievert (Sv), equivalente a 1 julio/kg

Dosis efectiva: suma de las dosis equivalentes recibidas por todos los órganos y tejidos de una persona, ponderadas según la radiosensibilidad relativa de cada órgano o tejido.
Unidad: sievert (Sv), equivalente a 1 julio/kg

Dosis efectiva colectiva: se clasifica la población expuesta en varios grupos según la dosis efectiva media recibida y se define la dosis colectiva como la suma de los productos de las dosis efectivas medias en cada grupo por el número de personas que integran ese grupo.
Unidad: sievert-persona (Svp)

Fuente: Datos tomados de las referencias 1 y 4.

sonas. Además, como consecuencia del accidente nuclear que ocurrió en 1986 en Chernobyl, antigua Unión Soviética, se ha reunido información importante sobre la incidencia de cáncer de tiroides en niños y niñas expuestos a las radiaciones.

En 1955, la Organización de las Naciones Unidas creó el Comité Científico para el Estudio de los Efectos de las Radiaciones Atómicas (ONU/CCEERA) con el fin de recopilar información sobre ese particular. Desde entonces, este comité publica periódicamente informes sobre las fuentes de radiación existentes en el mundo, los niveles de exposición de las personas y los resultados de las investigaciones sobre los efectos de la radiación en la salud (5).

¿Se pueden evitar del todo los efectos de las radiaciones ionizantes?

Esta pregunta refleja la esencia del problema atañente a la filosofía de la protección radiológica. Ciertos efectos denominados "deterministas", tales como la esterilidad, la catarata, el eritema, los trastornos hematopoyéticos y el síndrome agudo por radiación, pueden evitarse del todo si las dosis que reciben las personas no sobrepasan determinados umbrales; estos son de alrededor de 0,5 gray (Gy) en el caso de la exposición aguda y de 0,1 Gy en el de la exposición crónica. Sin embargo, otros efectos llamados "estocásticos" (la inducción del cáncer y algunos trastornos hereditarios) no pueden evitarse por completo. No hay datos comprobatorios que permitan establecer una dosis umbral para la aparición de estos efectos y se considera que cualquier exposición a las radiaciones ionizantes, por pequeña que sea la dosis, contribuye a aumentar la probabilidad de inducción de cáncer y, si la exposición es de las gónadas, también de trastornos hereditarios. Los términos "determinista" y "estocástico" aluden a la naturaleza pronosticable o probabilística de estos efectos.

Según estimaciones de la CIPR, los trabajadores que se exponen a dosis pequeñas y a tasas de dosis de radiación bajas en su lugar de trabajo tienen una probabilidad de 4% de morir de un cáncer radioinducido por cada sievert (Sv) de dosis efectiva recibida (1). En el caso de miembros de la población en general, que en algunas circunstancias pudieran verse expuestos a dosis pequeñas y a tasas de dosis de radiación bajas, la probabilidad de morir de un cáncer inducido por las radiaciones es de 5% por cada Sv de dosis efectiva recibida. Estas cifras se conocen como coeficientes de riesgo y la diferencia entre los valores correspondientes a los trabajadores y a personas de la población en general se debe a que en la categoría de los "trabajadores" no se incluye a los menores de 18 años de edad, cuya sensibilidad a las radiaciones es mayor. Estas cifras podrían verse ligeramente modificadas en las nuevas recomendaciones generales de la CIPR, no solamente debido a la actualización de la información epidemiológica, sino a una posible revisión del criterio empleado para definir los coeficientes de riesgo.

Hasta el momento no se han comprobado efectos hereditarios en la descendencia de las personas expuestas a las radiaciones; sin embargo, estudios realizados en animales permiten suponer que esos efectos estocásticos pueden ocurrir también en los seres humanos. Se estima que la relación entre los efectos hereditarios observados en la primera generación y la dosis de radiación es 10 veces menor que la relación entre los efectos cancerígenos y la dosis (6).

Por lo tanto, los efectos estocásticos de las radiaciones no se pueden evitar por completo si la exposición no es nula. A los fines de la protección radiológica se acepta la hipótesis de que la probabilidad de que ocurran estos efectos aumenta en proporción con las dosis cuando estas y las tasas de dosis son pequeñas.

LA PROTECCIÓN RADIOLÓGICA EN LA ACTUALIDAD

Las últimas recomendaciones generales elaboradas por la CIPR sobre la protección radiológica datan de 1990 (1) y se ha anunciado su actualización para fines de 2006 o principios de 2007. Aunque no se esperan cambios sustanciales en cuanto a la filosofía de la protección radiológica, es posible que en las nuevas recomendaciones generales se modifique el énfasis que antes se ponía en algunos conceptos.

Las bases filosóficas de la protección radiológica

Los riesgos asociados con la exposición a las radiaciones dependen de las dosis de radiación que reciben las personas expuestas. Por lo tanto, para reducir esos riesgos se deben reducir las dosis que se reciben y la exposición innecesaria a las radiaciones.

La protección de las personas contra los diversos riesgos originados en el medio ambiente laboral o público siempre se ha basado en el establecimiento de límites a la presencia de sustancias contaminantes o a la exposición individual. Si bien en sus inicios la protección contra las radiaciones ionizantes se rigió por ese criterio, a partir de la década de 1970 el concepto de límite comenzó a concebirse como una referencia de riesgo máximo, tolerable solo en situaciones excepcionales. El protagonismo en la filosofía de la protección radiológica se desplazó entonces gradualmente hacia la justificación de las prácticas basadas en el uso de fuentes de radiación y la optimización de la protección radiológica.

Para un organismo internacional no es una tarea sencilla recomendar valores límites de riesgo. El conocimiento actual sobre los efectos de las radiaciones ionizantes en los seres humanos se aplica a diversas culturas y nacionalidades pero, a pesar del llamado proceso de globalización, la situación económica y social de los diversos países es extremadamente desigual. Si los límites recomendados fueran muy bajos, muchos países no podrían adoptarlos debido al alto costo que implicaría la protección, mientras que la recomendación de límites elevados no contribuiría a disminuir los riesgos en grado significativo. En ambos casos, las recomendaciones resultarían desacertadas. Ante este dilema, la CIPR decidió recomendar límites de riesgo intermedios y aplicar principios de justificación y optimización.

Dado que toda exposición a las radiaciones implica cierto riesgo, la aceptación del uso de las fuentes de radiaciones debe verse justificada por los beneficios que aporta a toda la sociedad o a una parte de ella. Por ejemplo, en la década de 1940, algunas zapaterías empleaban equipos de fluoroscopia con rayos X para determinar el tipo de calzado adecuado para cada cliente y hasta hace unos 15 años se montaban fuentes radiactivas en los extremos de algunos pararrayos, a pesar de que nunca se logró demostrar que esto aumentara su eficacia durante las tormentas eléctricas. En la actualidad, tales aplicaciones de las fuentes de radiación no se consideran justificadas y no se autorizan.

Optimizar la protección significa comprender que el uso de las fuentes de radiación conduce a la exposición inevitable de algunas personas que estarán tanto mejor protegidas cuanto menor sean las dosis de radiaciones que reciben, y actuar en consecuencia. Pero, ¿hasta dónde se deben reducir las dosis? La respuesta no la pueden proporcionar solamente los estudios científicos; también es necesario tener en cuenta las condiciones económicas y sociales imperantes en cada país.

No les corresponde a los organismos internacionales determinar el grado de esfuerzo económico que cada país debe realizar para proteger a sus ciudadanos contra un riesgo laboral o ambiental. Por consiguiente, el concepto de optimización es un criterio genérico —sin alusiones a valores específicos— que ha pasado a tener mayor trascendencia que los límites numéricos. Según la CIPR, se deben reducir las dosis individuales de radiación, el número de personas expuestas y la probabilidad de que ocurran exposiciones accidentales tanto como sea razonablemente posible (por debajo de los límites) teniendo en cuenta los factores económicos y sociales, es decir, las restricciones económicas y las necesidades de la sociedad (1). De este modo, los organismos internacionales compatibilizan su responsabilidad de ofrecer la mejor recomendación con la ineludible realidad de que lo mejor no es igual para todos. Queda a criterio de cada país definir sus objetivos en materia de protección radiológica tomando los límites recomendados como una cota superior. Solo en casos excepcionales, una persona quedaría expuesta a riesgos cercanos a los límites.

Cuando una fuente de radiación funciona en condiciones normales —es decir, cuando la exposición de las personas ocurre según lo planificado— se puede controlar el riesgo radiológico mediante la aplicación de los límites de dosis y las restricciones derivadas de los procesos de optimización. Los límites de dosis aplicables a los trabajadores y a los miembros del público son distintos, debido a que la relación riesgo-beneficio es diferente en cada uno de estos grupos. Las dosis que las personas reciben debido a la exposición a las radiaciones de carácter natural y las que reciben durante los procedimientos radiológicos con propósitos médicos no se deben contabilizar a efectos de la aplicación de los límites.

En el cuadro 2 se resumen los valores de los límites anuales de dosis recomendados por la CIPR en 1991. Estos límites no establecen una frontera entre el riesgo y la seguridad, sino que indican los valores de riesgo máximos tolerables recomendados por la CIPR. En el mismo cuadro se indican los valores de la probabilidad de morir de un cáncer inducido por la radiación, correspondientes a los límites de dosis, según los coeficientes de riesgo indicados por esa entidad (1). Muchos países han adoptado estos valores límite y se espera que se ratifiquen en la próxima edición de las recomendaciones de la CIPR.

Otro objetivo de la protección radiológica es reducir los riesgos asociados con los accidentes radiológicos. La CIPR ha introducido la expresión

CUADRO 2. Límites anuales de dosis efectiva recomendados por la Comisión Internacional de Protección Radiológica y riesgos asociados

Grupo poblacional	Límite de dosis efectiva	Riesgo anual de morir[b]
Trabajadores	20 mSv[a]	8 por cada 10 000 trabajadores
Miembros de la población	1 mSv	5 por cada 100 000 personas

Fuente: Datos tomados de la referencia 1.
[a] Promedio de las dosis efectivas recibidas en 5 años.
[b] Riesgo anual de morir de un cáncer inducido por radiaciones si se recibe una dosis anual de radiación igual al límite de dosis efectiva.

"exposición potencial" para aludir a la exposición originada durante situaciones accidentales hipotéticas y a partir de 1990 ha prestado una atención especial a la prevención de los accidentes con fuentes de radiación (7, 8). Con tal propósito recomienda el criterio de reducir la probabilidad de que ocurran accidentes mediante sistemas de seguridad apropiados, de modo que los riesgos radiológicos derivados de situaciones accidentales en que pueda estar involucrada una fuente de radiación sean del mismo orden de magnitud que los riesgos asociados con la exposición a las radiaciones en condiciones de operación normal de dicha fuente (8).

A pesar de los reparos formulados por la CIPR acerca de la naturaleza colectiva del criterio de optimización durante el proceso de revisión de las actuales recomendaciones (9), no cabe duda de que la aplicación conjunta y sistemática de los criterios de limitación de dosis y optimización ha constituido una estrategia eficaz para reducir los riesgos asociados con las radiaciones. Según las estadísticas compiladas por el ONU/CCEERA a partir de la información brindada por las autoridades nacionales, se observa que los valores de dosis de radiación recibidas por los trabajadores muestran una tendencia decreciente a lo largo de las últimas décadas, al menos en los países que cuentan con estructuras reguladoras apropiadas. Esos datos indican que la dosis efectiva promedio recibida anualmente por los trabajadores de distintos países se ha reducido 33% en 30 años (5). Sin embargo, se debe tener en cuenta que no todos los países cuentan con mecanismos para documentar las dosis ocupacionales y, por lo tanto, en tales casos no se tiene información sobre la evolución de las mismas.

¿Consideraciones individuales o colectivas?

Desde 1976, la CIPR promueve el empleo de otro indicador del nivel de protección radiológica: la dosis colectiva. La dosis colectiva consiste esencialmente en la suma de las dosis efectivas que reciben las distintas personas que trabajan con procesos en que se utilizan fuentes de radiación (dosis colectiva ocupacional), o la suma de las dosis efectivas que reciben o recibirán en el futuro los miembros de una población como consecuencia del funcionamiento de una instalación con fuentes de radiación (dosis colectiva del público). La dosis colectiva se expresa en sievert-persona (Svp). Para facilitar su cálculo, se clasifica a la población expuesta en grupos según los niveles de dosis efectiva media y se la define formalmente como se menciona en el cuadro 1.

La dosis colectiva se utiliza como indicador del detrimento colectivo que la exposición a las radiaciones ionizantes puede provocar en un grupo de trabajadores o en la población en general. Su validez está condicionada por las hipótesis de linealidad y de ausencia de umbral aplicables a los efectos estocásticos, por lo que el concepto de dosis colectiva puede emplearse solamente cuando las dosis y las tasas de dosis individuales son bajas. La amplia aceptación que ha ganado este concepto se debe a que permite comparar la eficacia de diferentes estrategias de protección radiológica aplicables a una misma fuente, así como los efectos radiológicos adversos provocados por diferentes fuentes (cuadro 3).

En el proceso de revisión llevado a cabo por la CIPR durante los últimos años se ha cuestionado (9) y revalorizado (10) este concepto. Cabe suponer que en sus próximas recomendaciones la CIPR

CUADRO 3. Dosis efectivas anuales promedio y dosis efectivas colectivas mundiales anuales correspondientes a la exposición natural y a la exposición artificial por diversas causas

Fuentes de exposición en el mundo	Dosis efectiva anual per cápita (mSv)	Dosis efectiva colectiva mundial (millones de Svp)
Radiación natural	2,4	14 400
Radiodiagnóstico médico	0,4	2 400
Pruebas nucleares en la atmósfera	0,005	30
Accidente de Chernobyl, antigua Unión Soviética	0,002	12
Producción de energía nuclear	0,0002	1,2

Fuente: Datos tomados de la referencia 5.

mantendrá el concepto de la dosis colectiva, aunque probablemente con algún condicionamiento.

EL EQUILIBRIO ENTRE LOS BENEFICIOS Y LOS RIESGOS: LA REGULACIÓN

La protección radiológica no debe reducirse a la formulación de buenos propósitos. ¿Cómo lograr que el diseño, la construcción, la operación y el desmantelamiento final de una instalación cumplan con los recaudos técnicos necesarios? La capacitación y el entrenamiento de las personas implicadas es, sin duda, una condición esencial, pero no es suficiente. Es necesario que en cada país funcione una organización independiente para supervisar el cumplimiento de los principios y las normas específicas, es decir, una autoridad reguladora en materia de protección radiológica. Su organización es responsabilidad de los gobiernos y los organismos internacionales especializados pueden brindar asistencia al efecto.

En las Américas, la Organización Panamericana de la Salud (OPS) ha colaborado desde la década de 1960 con los Estados Miembros en la elaboración de normas de protección radiológica y en el desarrollo de actividades de control de las fuentes de radiación (11). En 1997, la OPS publicó un libro con abundante información sobre la organización y el desarrollo de los servicios de imaginología y radioterapia, en el que se presentan los principales conceptos sobre protección radiológica y aspectos reguladores (12).

El Organismo Internacional de Energía Atómica (OIEA), junto con la OPS, la Organización Mundial de la Salud (OMS), la Organización Internacional del Trabajo (OIT) y la Organización de las Naciones Unidas para la Agricultura y la Alimentación (FAO), así como la Agencia Nuclear de Energía (NEA) de la Organización de Cooperación y Desarrollo Económicos, han elaborado varios documentos orientados a apoyar el establecimiento de organizaciones reguladoras nacionales. El primero de ellos, "Normas básicas internacionales para la protección contra las radiaciones ionizantes y la seguridad de fuentes de radiación" (NBIS) (13), que se publicó en inglés en 1996 y en 1997 en castellano, constituye una guía práctica para la estructuración de las normas de protección radiológica y las funciones reguladoras en los países.

El OIEA brinda asistencia a los Estados Miembros que la requieran para la creación y el desarrollo de organizaciones reguladoras de la protección radiológica mediante el llamado Proyecto Modelo. En la actualidad, 13 países latinoamericanos participan en ese proyecto[2].

[2] Para mayor información se puede consultar la página del OIEA en Internet http://www.iaea.org

Los gobiernos y las funciones reguladoras

Los gobiernos deben prestar atención a asuntos muy disímiles y administrar los recursos de los países para satisfacer las necesidades básicas de sus pueblos de acuerdo con el grado de desarrollo alcanzado. Cabe preguntarse, ¿en qué medida la atención de los riesgos asociados con la evolución de la tecnología puede ser un objetivo central en países donde las necesidades elementales —como la atención médica o el saneamiento básico— no están satisfechas aún? ¿Qué prioridad puede tener un programa de protección radiológica en tales circunstancias?

Sin embargo, es frecuente encontrar instalaciones médicas con fuentes de radiación ionizante de cierta complejidad en países que tienen grandes carencias tecnológicas. Por lo tanto, el análisis no debe estar dirigido a considerar la prioridad que puede tener un programa de protección radiológica en el contexto del desarrollo general de un país, sino en el marco del desarrollo de un campo específico de aplicación de las fuentes de radiación en ese país. Los costos de protección radiológica y del sistema regulador deben formar parte de los costos de la tecnología que emplea tales fuentes y, desde esa perspectiva, tales costos son relativamente bajos.

No todos los países cuentan con organismos reguladores apropiados. En algunos casos esto puede atribuirse a una subestimación de los riesgos asociados con las fuentes de radiación ionizante. Sin embargo, no es desdeñable la exposición de la población provocada por las fuentes artificiales de radiación, en particular las de uso médico (cuadro 3), a lo que deben agregarse los numerosos accidentes que se producen en el mundo con fuentes industriales y médicas. Los accidentes ponen en evidencia la existencia de fallas extremas en los sistemas de seguridad radiológica, pero cabe suponer que fallas menos graves —que impliquen sobreexposiciones menores— pueden pasar inadvertidas o no notificarse.

Las autoridades reguladoras

En muchos países, la regulación de la protección radiológica se organizó a medida que se desarrollaban las aplicaciones con fuentes de radiación ionizante y materiales nucleares. En la mayoría de los casos, la organización de la regulación recayó en los organismos de energía atómica o sus equivalentes. Sin embargo, en algunos países los organismos de salud asumieron esa responsabilidad. Durante las últimas décadas aumentó la convicción de que los organismos reguladores debían constituir estructuras gubernamentales diferentes de las instituciones que empleaban fuentes de radiación o que promovían su uso y gradualmente se fueron creando estructuras reguladoras independientes en varios paí-

ses. Es facultad de cada país decidir la organización más apropiada para sus condiciones específicas.

Las autoridades reguladoras deben establecer normas de protección radiológica y verificar su cumplimiento durante todas las etapas de desarrollo de las diferentes prácticas que empleen fuentes de radiación ionizante. Estas autoridades deben tener la suficiente capacidad de acción técnica, legal y ética que les permita ejercer su autoridad sobre las personas y entidades encargadas de tales prácticas. El principal mecanismo con que cuentan las autoridades reguladoras para aplicar su autoridad consiste en un sistema de licencias institucionales que autorizan tener, utilizar, transferir y trasladar fuentes de radiación ionizante o realizar cualquier operación con ellas. Estas autorizaciones o licencias institucionales están condicionadas al cumplimiento de determinados requisitos de diseño y operación de las instalaciones, equipos y fuentes. Además, es preciso contar con un sistema de autorizaciones o licencias personales que se otorgan al personal según su nivel de capacitación y entrenamiento en protección radiológica y en la práctica específica en que utilizarán las fuentes de radiación.

Las autoridades reguladoras no se pueden limitar a cumplir funciones administrativas, sino que deben estar en condiciones de evaluar la protección y la seguridad radiológicas en el ámbito de cada fuente y en las condiciones particulares de cada tipo de práctica, y de exigir las mejoras que resulten necesarias. Esto solo es posible si se cuenta con personal profesional y técnico altamente capacitado, con experiencia en la protección radiológica y —lo que no es menos importante— experiencia en la operación del tipo de instalaciones que se supervisa.

Se debe recordar que en condiciones normales, las dosis de radiación que reciben las personas no provocan alarma sensorial ni manifestaciones clínicas inmediatas, aunque ello no significa que los riesgos sean nulos ni pequeños. Por consiguiente, la autoridad reguladora debe exigir que cada instalación cuente con sistemas de vigilancia radiológica que permitan evaluar las dosis de radiación recibidas por las personas.

Desde la publicación de las NBIS (13), el OIEA, junto con los demás organismos responsables de esa publicación, ha promovido el fortalecimiento de estructuras reguladoras nacionales y ha brindando asistencia técnica al respecto. La Conferencia Internacional sobre Infraestructuras Nacionales Reguladoras en Seguridad Radiológica, celebrada en Rabat, Marruecos, en septiembre de 2003, constituye una prueba de la importancia que se le otorga a la regulación (14).

LA FUNCIÓN DE LAS AUTORIDADES DE SALUD

Las funciones de las autoridades nacionales de salud en el proceso de regulación difieren según el país. Sin embargo, las autoridades sanitarias tienen la responsabilidad de emitir opiniones autorizadas en materia de salud, así como las autoridades reguladoras en protección radiológica tienen la misión de preservar la salud de las personas ante este riesgo específico. Por ello, independientemente de cómo se estructuren las funciones reguladoras en un país, las autoridades sanitarias no deberían estar desvinculadas del sistema regulador. Su opinión especializada puede contribuir de manera importante a validarlo.

Las autoridades de salud pueden participar activamente al menos en tres aspectos de la protección radiológica: la promoción de la educación formal del personal de salud en lo concerniente a la protección radiológica, la atención médica de las personas sobreexpuestas y la protección radiológica de los pacientes.

Formación del personal de salud

La formación universitaria y los procesos formales de entrenamiento para los profesionales de la salud deben aportar los conocimientos necesarios sobre el empleo de las radiaciones ionizantes en las aplicaciones médicas, sus riesgos y beneficios. En el caso de los especialistas, esto se debe complementar con una profunda capacitación y un intenso entrenamiento en las aplicaciones médicas específicas. Los físicos médicos son indispensables en los servicios de radioterapia, conviene su presencia en los de medicina nuclear y deberían asesorar en los de radiodiagnóstico. Aunque esta no es una especialidad nueva, en algunos países no se cuenta con un número suficiente de físicos médicos ni con instituciones apropiadas para su formación. Las autoridades de salud pueden contribuir de un modo importante al desarrollo, la consolidación y el reconocimiento de esta especialidad.

La atención médica de las personas sobreexpuestas a radiaciones

Otro aspecto en el que las autoridades de salud deberían desempeñar un papel protagónico es la atención médica de las personas sobreexpuestas accidentalmente. La evaluación diagnóstica, la estrategia terapéutica que debe seguirse y las derivaciones apropiadas incumben directamente a los profesionales de la salud y deben planificarse estableciendo los acuerdos correspondientes con las instituciones médicas involucradas.

La protección radiológica de los pacientes

Las fuentes de radiación ionizante de uso médico son las más numerosas y las que contribuyen

en mayor medida a la exposición artificial de la población (cuadro 3). En la actualidad hay más de un millón y medio de fuentes de radiación ionizante declaradas en el mundo, tanto para diagnóstico como para tratamiento médico, y con ellas se realizan más de dos mil millones de procedimientos anualmente (cuadro 4). Además de provocar la inevitable exposición de los trabajadores y de algunos miembros de la población —como todas las fuentes de radiación ionizante—, estas fuentes están concebidas para irradiar deliberadamente a determinadas personas: los pacientes. La CIPR ha dedicado una docena de publicaciones al tema de la protección de los pacientes y en una de ellas (15) ha sintetizado los criterios apropiados para las prácticas de diagnóstico y tratamiento.

La protección radiológica del paciente está relacionada con el ejercicio de la profesión médica. En ocasiones, los organismos reguladores se limitan a sí mismos en aras de no "invadir" el campo médico (16) y se produce entonces un vacío que ningún organismo cubre. Por ello es deseable que las autoridades de salud se interesen especialmente en la protección radiológica del paciente y establezcan una acción coordinada con los organismos reguladores.

¿Cómo proteger a personas irradiadas deliberadamente?

Para obtener una imagen radiológica o tratar un tumor es indispensable que el paciente reciba cierta dosis de radiación. Puede entonces hacerse referencia a una dosis necesaria. Sin embargo, en ocasiones la exposición es mayor que la requerida para el procedimiento o se exponen tejidos que están fuera del campo de interés, lo que genera una dosis innecesaria. No se pueden establecer límites de dosis para los pacientes, ya que la relación dosis-beneficio es diferente en cada caso. Los conceptos de justificación y optimización adquieren entonces mayor importancia: el médico debe analizar la justificación de cada procedimiento que prescribe y el equipo médico especializado que lo realiza debe optimizarlo (16).

CUADRO 4. Principales equipos médicos que emplean radiaciones ionizantes y número de procedimientos realizados anualmente en el mundo

Aplicación médica	Número de equipos
Radiodiagnóstico (1 910 millones de procedimientos por año)	
Convencional	700 000
Tomografía computarizada	34 000
Mamografía	40 000
Radiodiagnóstico dental (520 millones de procedimientos por año)	
Convencional	900 000
Medicina nuclear (32 millones de procedimientos por año)	
Escáner rectilíneo, cámara gamma	14 000
Tomografía por emisión de positrones	300
Radioterapia (4,7 millones de tratamientos por año)	
Rayos X	5 000
Cobalto	4 000
Acelerador lineal	5 000

Fuente: Datos tomados de la referencia 5.

La optimización está estrechamente relacionada con la calidad de los procedimientos. En algunas instituciones las dosis son hasta 10 veces mayores que las empleadas en otras para realizar estudios radiodiagnósticos equivalentes desde el punto de vista de la información obtenida. Esto significa que la dosis innecesaria puede ser muy elevada en algunos casos. Se debe tener en cuenta que la dosis colectiva mundial generada por los procedimientos de radiodiagnóstico médico es la mayor de las atribuibles a la exposición artificial a las radiaciones ionizantes (cuadro 3). Se puede suponer que si se lograra mejorar la calidad de los procedimientos radiológicos se podría reducir la correspondiente dosis colectiva mundial al menos a la mitad sin menoscabar los beneficios del radiodiagnóstico.

Las dosis efectivas individuales en los procedimientos de radiodiagnóstico pueden variar, según el tipo de estudio, desde decenas de μSv hasta más de 100 mSv. Algunas técnicas pueden originar dosis absorbidas de 10 a 100 mGy en algunos tejidos, como la tomografía computarizada (17), o de 1 Gy o más en la piel, como la radiología intervencionista (18). En ocasiones, la dosis absorbida puede sobrepasar los umbrales de los efectos deterministas y producir lesiones en los pacientes.

En radioterapia, las dosis prescritas para el tratamiento de los tumores son elevadas (entre 20 y 85 Gy). La eficacia de estos procedimientos depende en gran medida de la exactitud con que se irradia al paciente y del grado en que se logra minimizar la exposición de los tejidos sanos, es decir, depende tanto del valor de la dosis como de la localización del campo de irradiación. Dosis superiores a la prescrita aumentan el riesgo de lesiones y muerte provocadas por las radiaciones, mientras que dosis inferiores aumentan el riesgo de un tratamiento ineficaz. La desviación aceptable para minimizar estos efectos indeseables es de 5%.

Accidentes con fuentes médicas

En un estudio realizado por el OIEA en el que se investigaron 90 accidentes relacionados con la radioterapia en diversos países, los errores detectados de sobreexposición son tres veces más numerosos que los de subexposición (19). Esta asimetría podría relacionarse en parte con el hecho de que la detec-

ción de sobreexposiciones se ve favorecida por reacciones clínicamente observables en el paciente, en tanto que la subexposición no produce manifestaciones clínicas, aunque puede dar lugar a un tratamiento menos eficaz y a la posible muerte del paciente por la evolución de su enfermedad. Esas consecuencias, aunque graves, pueden no ser tan patentemente atribuibles a subexposiciones provocadas por errores en los procedimientos.

Durante la última década, en las Américas se han producido dos accidentes con fuentes de radioterapia que han provocado la muerte de decenas de pacientes por sobreexposición (20, 21). Graves fallas condujeron a esos accidentes. Cabe preguntarse, ¿cuántos casos sin detectar o sin notificar pueden haber ocurrido en el mundo, con desviaciones menos patentes en los valores de las dosis, pero con un detrimento significativo de la eficacia de los tratamientos?

El empleo de un medio terapéutico como la radiación se justifica si el procedimiento se planifica con la mejor técnica disponible y se aplica con la mayor calidad (22). La prevención de accidentes en la práctica de la radioterapia vincula estrechamente dos especialidades: la protección radiológica y la física médica (23).

El plan de acción internacional para la protección radiológica de los pacientes

En marzo de 2001 se celebró en Málaga, España, la Conferencia Internacional sobre Protección Radiológica del Paciente, patrocinada por varias organizaciones internacionales (OIEA, OMS, OPS, entre otras). Como resultado de esa conferencia se aprobó un plan de acción internacional para la protección radiológica de los pacientes (24) que contempla, entre otras, las acciones siguientes:

- promover la educación y el entrenamiento de médicos clínicos, especialistas, tecnólogos, enfermeros, físicos médicos, radiofarmaceutas, diseñadores de equipos, ingenieros de mantenimiento, administradores, entre otros, en la protección radiológica, el control de la calidad y la reducción de las dosis innecesarias y de los riesgos de exposición accidental en las aplicaciones médicas
- promover el intercambio de información sobre esos temas entre instituciones de diversos países
- promover el reconocimiento de la importancia de los tecnólogos en la protección radiológica de los pacientes y mejorar su capacitación
- promover el reconocimiento de la importancia de los físicos médicos como profesionales de la salud
- preparar guías apropiadas destinadas al personal de los servicios médicos que emplean fuentes de radiación
- reconocer que existen aspectos relacionados con la transferencia de equipos de segunda mano a países en desarrollo que inciden en la protección radiológica y proporcionar guías destinadas a los donantes de equipos de segunda mano, los receptores y las organizaciones intermediarias. En particular se debe tomar en cuenta la necesidad real del país receptor, la provisión de herramientas, accesorios; piezas de recambio y manuales; la formalización de acuerdos para las pruebas de aceptación, instalación y mantenimiento, y el entrenamiento en el uso de equipos con sus dispositivos específicos de protección.

Se espera que las autoridades de salud conozcan este documento y participen activamente en la puesta en práctica de estas acciones.

CONCLUSIONES

Lejos estaban Roentgen y Becquerel de imaginar la extraordinaria expansión de las aplicaciones prácticas de sus descubrimientos. Pero en la actualidad no se desconocen, como en aquellos tiempos, los riesgos asociados con esos fenómenos y no se justifica que las prácticas con fuentes de radiación ionizante, que tantos beneficios pueden aportar, provoquen daños por la falta de medidas eficaces de protección radiológica y de procedimientos adecuados de garantía de la calidad.

Ese equilibrio entre beneficios y riesgos se puede controlar mediante sistemas reguladores nacionales adecuados. Es responsabilidad de los gobiernos crear condiciones jurídicas y administrativas apropiadas para que las autoridades reguladoras de la protección radiológica lleven a cabo su labor eficazmente.

Las autoridades de salud, aun cuando no ejerzan funciones reguladoras directas en esta materia, pueden contribuir de un modo importante mediante su acción coordinada con los órganos reguladores para proteger la salud de los trabajadores y miembros de la población contra los riesgos que implican las fuentes de radiaciones ionizantes. También deberían cumplir una importante función en la organización de los medios necesarios para la atención de personas sobreexpuestas por accidentes con fuentes de radiación. Pero cabe esperar que las autoridades sanitarias desempeñen un papel protagónico en la protección de los pacientes debido a su relación directa con la profesión médica. Para ello, deben contar con profesionales sanitarios con conocimientos en materia de protección radiológica, promover el uso del equipo adecuado y aplicar procedimientos apropiados de garantía de la calidad.

La intervención oportuna de las autoridades nacionales de salud puede contribuir en gran me-

dida a reducir las dosis innecesarias en las prácticas médicas con fuentes de radiación y reducir las probabilidades de que ocurran accidentes radiológicos en este campo.

SYNOPSIS

Regulating radiological protection and the role of health authorities

This article summarizes the development of protection against ionizing radiation and explains current thinking in the field. It also looks at the decisive role that regulatory agencies for radiological protection must play and the important contributions that can be made by health authorities. The latter should take an active part in at least three aspects: the formal education of health personnel regarding radiological protection; the medical care of individuals who are accidentally overexposed, and the radiological protection of patients undergoing radiological procedures. To this end, health professionals must possess sufficient knowledge about radiological protection, promote the use of proper equipment, and apply the necessary quality assurance procedures. Through their effective intervention, national health authorities can greatly contribute to reducing unnecessary doses of radiation during medical procedures involving radiation sources and decrease the chances that radiological accidents will take place.

Key words: radiation, ionizing; radiation protection; radiation control; standards.

REFERENCIAS

1. International Commission on Radiological Protection. The 1990 recommendations of the International Commission on Radiological Protection. Ann ICRP. 1991;21:1–3. (ICRP Publication No. 60).
2. Taylor L. Radiation protection standards. London: CRC Press; 1971.
3. Skvarka J, Aguirre A. Normas y estándares aplicables a los campos electromagnéticos de radiofrecuencias en América Latina: guía para los límites de exposición y los protocolos de medición. Rev Panam Salud Publica. 2006;20(2/3):205–12.
4. International Commission on Radiation Units and Measurements. Quantities and units in radiation protection dosimetry. Oxford: ICRU; 1993. (ICRU Report No. 51).
5. Comité Científico de las Naciones Unidas para el Estudio de los Efectos de las Radiaciones Atómicas. Informe 2000. Viena: UNSCEAR; 2000.
6. Comité Científico de las Naciones Unidas para el Estudio de los Efectos de las Radiaciones Atómicas. Informe sobre efectos hereditarios. Viena: UNSCEAR; 2001.
7. International Commission on Radiological Protection. Protection from potential exposure: a conceptual framework. Ann ICRP. 1993;23:1. (ICRP Publication No. 64).
8. International Commission on Radiological Protection. Protection from potential exposures: application to selected sources. Ann ICRP. 1997;27:2. (ICRP Publication No. 76).
9. Clarke R. The evolution of the system of radiological protection: the justification for new ICRP recommendations. J Radiol Prot. 2003;23:129–42.
10. Arias C. ICRP versus ICRP: challenges for future ICRP recommendations. Proceedings of the XI International Congress of Radiation Protection, Madrid, May 2004. Madrid: Sociedad Española de Protección Radiológica; 2004.
11. Hanson G, Borrás C, Jiménez P. History of the radiological health program of the Pan American Health Organization. Rev Panam Salud Publica. 2006;20(2/3): 87–98.
12. Organización Panamericana de la Salud. Organización, desarrollo, garantía de calidad y radioprotección en los servicios de radiología: imaginología y radioterapia. Washington, D.C.: OPS; 1997.
13. International Atomic Energy Agency. Normas básicas internacionales para la protección contra las radiaciones ionizantes y la seguridad de las fuentes de radiación. Viena: OIEA; 1996. (Colección Seguridad No 115).
14. International Atomic Energy Agency. Findings and recommendations of the International Conference on National Infrastructures for Radiation Safety; 2003 Sept; Rabat, Morocco. Vienna: IAEA; 2004.
15. International Commission on Radiological Protection. Radiological protection and safety in medicine. Ann ICRP. 1996; 26(2):1–47. (ICRP Publication No. 73).
16. Arias C. Regulatory functions and medical exposure. Proceedings of IX International Congress of Radiation Protection; 1996 Apr; Vienna, Austria. Vienna: Austrian Association for Radiation Protection; 1996.
17. International Commission on Radiological Protection. Managing patient dose in computed tomography. Ann ICRP. 2000; 30(4):1–45. (ICRP Publication No. 87).
18. International Commission on Radiological Protection. Avoidance of radiation injuries from medical interventional procedures. Ann ICRP. 2001;30(2):1–67. (ICRP Publication No. 85).
19. International Atomic Energy Agency. Lessons learned from accidental exposures in radiotherapy. Vienna: IAEA; 2000. (Safety Report Series No. 17).
20. International Atomic Energy Agency. Accidental overexposure of radiotherapy patients in San José, Costa Rica. Vienna: IAEA; 1998.
21. International Atomic Energy Agency. Investigation of an accidental exposure of radiotherapy patients in Panama. Vienna: IAEA; 2003.
22. International Commission on Radiological Protection. Prevention of accidents to patients undergoing radiation therapy. Ann ICRP. 2001;30(3):1–70. (ICRP Publication No. 86).
23. Arias C, Piumetti E, Sanchez G. Medical sources and radiological accidents. Proceedings of the World Congress on Medical Physics and Biomedical Engineering, 1994 Aug; Rio de Janeiro, Brazil. Rio de Janeiro: Brazilian Society of Medical Physics; 1994.
24. International Atomic Energy Agency. International action plan for the radiological protection of patients. Vienna: IAEA; 2002.

Manuscrito recibido el 14 de diciembre de 2004. Aceptado para publicación, tras revisión, el 30 de agosto de 2005.

Counseling patients exposed to ionizing radiation during pregnancy

Robert L. Brent[1]

Suggested citation: Brent RL. Counseling patients exposed to ionizing radiation during pregnancy. Rev Panam Salud Publica. 2006;20(2/3);198–204.

SYNOPSIS

Health physicists and knowledgeable clinicians have the responsibility to counsel women of reproductive age about the reproductive risks of ionizing radiation exposure before conception or during pregnancy. It is important to realize that lay individuals have many misconceptions about the reproductive risks of ionizing radiation. Many patients who have already had or will undergo some type of radiological test are apprehensive about the reproductive and developmental risks of diagnostic radiological procedures. Epidemiological studies and animal studies indicate that high exposures of ionizing radiation can cause miscarriage, congenital malformations, growth retardation, stillbirth, and cancer. With the exception of cancer, there are threshold exposures for those outcomes, with exposures below certain radiation doses not increasing the reproductive or developmental risks. The threshold exposure for birth defects at the most sensitive stage of development is 0.2 Gy, and the threshold for growth retardation and miscarriage is even higher. However, embryonic loss can occur from low exposures during the preimplantation and presomite stages of development ("the all or none period"). This is a stage when the embryo is more likely to die than survive malformed. The most sensitive period for the induction of mental retardation is from the 8th week to the 15th week of gestation. The threshold for deterministic effects increases after early organogenesis and also as the exposure is protracted, e.g., with radionuclides or multiple radiological procedures. Awareness that the threshold dose for developmental effects increases as the fetus develops complicates counseling because we do not have definitive data on threshold exposures at all stages of gestation. Ionizing radiation exposures prior to pregnancy represent a very low risk for the increased incidence of genetic disease in the offspring of the parents who have had radiation exposures to the ovary or testes. Counseling patients requires knowledge of embryology, genetics, radiation teratology, and the principles of teratology in order for the counselor to provide sympathetic, accurate, scholarly advice.

Key words: pregnancy; pregnancy outcome; radiation, ionizing; abnormalities; risk factors; teratogens; counseling.

Health physicists and knowledgeable clinicians have the responsibility to counsel women of reproductive age about the reproductive risks of ionizing radiation exposure that occurs either before conception or during pregnancy. Medical personnel need to realize that lay individuals have many misconceptions about the reproductive risks of ionizing radiation. Further, many patients are apprehensive about the reproductive and developmental risks of diagnostic radiological procedures. Counseling patients requires knowledge of embryology, genetics, radiation teratology, and the principles

[1] Thomas Jefferson University, Philadelphia, Pennsylvania, United States of America, and Alfred I. duPont Hospital for Children, Wilmington, Delaware, United States. Send correspondence to: Robert L. Brent, Room 308 R/A, Alfred I. duPont Hospital for Children, Box 269, Wilmington, Delaware 19899, United States; telephone: 302-651-6888.

of teratology in order for the counselor to provide sympathetic, accurate, scholarly advice. This paper will help inform medical personnel about the real risks to the embryo from ionizing radiation, provide suggestions on counseling patients, recommend procedures to follow when evaluating a patient, and offer guidance on when to schedule elective X-ray studies that are needed.

RISKS TO THE EMBRYO FROM IONIZING RADIATION

There is no question that an acute exposure to ionizing radiation above 0.5 Gy represents a significant risk to the embryo, regardless of the stage of gestation (1–8). The threshold dose for low linear energy transfer ionizing radiation that results in an increase in major anatomical congenital malformations is approximately 0.2 Gy. Although congenital malformations are unlikely to be produced by radiation during the first 14 days of human development, there would be a risk of embryonic loss if the dose were high. From approximately the 18th day to the 40th day postconception, the embryo is at risk for an increased frequency of anatomical congenital malformations if the embryonic exposure is greater than 0.2 Gy. Studies in mice have reported rib variation or other skeletal variations below 0.2 Gy, but these studies cannot be translated to human risks. The embryo maintains an increased susceptibility to central nervous system (CNS) effects, e.g., major CNS malformations early in gestation and mental retardation and microcephaly in midgestation. Of course, with very high doses, e.g., an exposure to a few Gy in the latter part of gestation, there can be a decrease in intelligence. While it is true that the embryo is sensitive to the deleterious effects of these mid-range exposures of ionizing radiation, the measurable effects decrease as the exposure approaches the usual exposures that the embryo receives from diagnostic radiology procedures, which are predominantly less than 0.05 Gy. In fact, many studies indicate that the threshold for most embryonic radiation effects is in the 0.2-Gy range, and that this threshold for deterministic effects is raised by protraction of the radiation exposure (9, 10). For example, following several clinical diagnostic radiological procedures occurring over a period of days, the exposure may be greater than 0.05 Gy (8). In this case, the counselor can more readily reassure the patient that the reproductive risks are not increased because the exposure was protracted. The newer techniques using CT scans have the potential for exposing the embryo or fetus to doses above 0.05 Gy, although there has been a major effort by the radiologists and manufacturers to reduce the exposure from CT scans (11–14).

That is why the recommendation of most official organizations, including the National Council on Radiation Protection and Measurements (NCRP), indicate that exposures of 0.05 Gy or less will not increase the risk of birth defects or miscarriage (3, 7, 8). However, when the exposure exceeds the threshold dose, the risks of radiation exposure to the human embryo include embryonic loss, growth retardation, congenital malformations, microcephaly and mental retardation, infertility, and carcinogenesis (with the magnitude of the oncogenic risk to the fetus being controversial) (15–18).

Except for carcinogenesis, all of those effects are threshold phenomena. Therefore, radiation exposure below 0.05 Gy represents no measurable increased deterministic risks to the embryo. Even if one accepts the controversial concept that the embryo is more sensitive to the carcinogenic effects of radiation than the child is, the risk at these low exposures is much smaller that the spontaneous risks (Table 1). Furthermore, other studies (16–18) indicate that the estimate of the risk of radiation-induced leukemogenesis made by Stewart et al. (15) is exaggerated.

Table 1 presents the spontaneous risks facing an embryo at conception and the additional risks that would come from a low exposure of ionizing radiation (0.05 Gy). The hazards of exposures in the range of diagnostic radiology (0.2 mGy–0.05 Gy) represent an extremely low risk to the embryo, when compared with the spontaneous mishaps that can befall human embryos. Approximately 15% of clinically recognized pregnancies abort spontaneously, but many more pregnancies do not survive even to the first missed menstrual period. Human infants have a 3% major malformation rate at term, which rises to approximately 6% once all minor and major malformations are recognized. In spite of the fact that doses of < 0.05 Gy can produce cellular effects and the fact that diagnostic exposures during pregnancy may have a small risk of malignancy in the child, the maximum theoretical risk to human embryos exposed to doses of 0.05 Gy or less is extremely small. When the risks are explained to the patient, the family with a wanted pregnancy invariably continues with the pregnancy. It is of interest that most mothers who have been exposed to ionizing radiation during their pregnancy are concerned about all congenital malformations. However, if they are concerned about cancer, it is primarily a concern about childhood leukemia. The risk of leukemia following fetal exposures from diagnostic radiological studies is a small fraction of the spontaneous leukemia risk, even when the risk published by Wakeford and Little (18) is utilized, and the risks estimated by other investigators (16–17) are lower than those of Wakeford and Little.

The difficulty that frequently arises is that the risks from diagnostic radiation are evaluated out-

TABLE 1. Spontaneous risks facing an embryo at conception and the additional risk that would come from a low exposure of ionizing radiation (0.05 Gy)[a]

Type of risk	Spontaneous risks facing an embryo at conception (0 rad exposure)	Additional risk from a 0.05-Gy exposure
Risk of very early pregnancy loss, before the first missed period	350 000/10^6 pregnancies	0
Risk of spontaneous abortion in known-pregnant women	150 000/10^6 pregnancies	0
Risk of major congenital malformations	30 000/10^6	0
Risk of severe mental retardation	5 000/10^6	0
Risk of childhood leukemia/year	40/10^6/year	<?1–3/10^6/year
Risk of early- or late-onset genetic disease	110 000/10^6	Very low risk; the risk is in the next generation and is not measurably increased with small populations
Prematurity	40 000/10^6 pregnancies	0
Growth retardation	30 000/10^6 pregnancies	0
Stillbirth	20-2 000/10^6 pregnancies	0
Infertility	7% of couples	0

[a] Modified from Brent (4) and Brent (5).

side the context of the significant normal risks of pregnancy. Furthermore, many physicians approach the evaluation of diagnostic radiation exposure with either of two extremes: a cavalier attitude, or panic. The usual procedures in clinical medicine are ignored, and an opinion based on meager information is given to the patient. Frequently, it reflects the physician's bias about radiation effects, or his or her ignorance of the field of radiation biology. In our consultation records—obtained from the Internet, telephone contacts, and correspondence over the past five decades—we have records of patients who, following radiation exposure from a very low-exposure diagnostic radiological procedure, were not properly evaluated, but were advised to have an abortion.

COUNSELING PATIENTS ABOUT REPRODUCTIVE AND DEVELOPMENT RISKS

The responsibility for evaluating risks of environmental toxicants to the pregnant patient and her embryo may be that of the family physician, obstetrician, radiologist, or health physicist. When evaluating the risks of ionizing radiation, the counselor can be faced with various clinical situations. Four types of encounters are briefly described in the following paragraphs.

The first situation involves a pregnant or possibly pregnant patient who presents with clinical symptoms that need to be evaluated. What is the appropriate utilization of diagnostic radiological procedures that may expose the embryo or fetus to ionizing radiation? A pregnant or possibly pregnant woman complaining of gastrointestinal bleeding or pain or an abdominal or pelvic mass that cannot be attributed to pregnancy deserves the appropriate studies—including radiological ones—to diagnose and treat her clinical problems. The studies should be performed in a timely and appropriate manner in order to minimize the exposure and maximize the goal of making the correct diagnosis. The studies should be performed at the time they are clinically indicated, whether or not the woman is in the first or second half of the menstrual cycle. Furthermore, these studies should not be relegated to one portion of the menstrual cycle. The first half of the menstrual cycle is a time when the woman is not pregnant. Conception occurs midway during the menstrual cycle. The second half of the menstrual cycle is when the embryo has not yet initiated differentiation and is less sensitive to the teratogenic effects of radiation, although it is more sensitive to the lethal effects of radiation. Animal studies indicate that the threshold for lethality during this very early stage of development is above 0.1 Gy, but one cannot apply these results directly to the human embryo.

In another example of this first situation, if a radiologist has been asked to perform an elective radiological diagnostic study for employment or follow-

up that is not an emergency, then the approach should be different. The radiological study can be postponed until the beginning of the next menstrual period. If the patient and physician are certain the patient is not pregnant or has a negative pregnancy test and has not had intercourse for a lengthy period, then the elective examination can be performed at that time. The situation is complicated when the woman has irregular menstrual cycles. In that situation, the diagnostic study can be performed after the next menstrual cycle begins. However, even in that situation, a pregnancy test should be performed.

A second clinical situation that the counselor may face is that the patient has completed a diagnostic procedure that has exposed her uterus to ionizing radiation, such as a procedure needed to rule out a gastrointestinal disease because of abdominal pain. The examination revealed that the patient had a duodenal ulcer. The procedure was necessary, but the patient now believes she was pregnant at the time of the procedure. If you are the counselor, what is the proper response to this situation?

Explain that you would have proceeded with the necessary X-ray diagnostic test whether she was pregnant or not, since diagnostic studies that are indicated in the mother have to take priority over the possible risk to her embryo, because almost no diagnostic studies increase the developmental risks to the embryo. At this time, obtain the calculated dose to the embryo and determine the woman's stage of pregnancy. If the dose is below 0.05 Gy (that is, 0.05 Sv, or 5 rads), you can inform the mother that her risks for birth defects and miscarriage have not been increased. In fact the threshold for these effects is 0.2 Gy or greater, thus the 0.05-Gy exposure is far from the threshold exposure.

A third clinical situation that the counselor may face is that a woman delivers a baby with a serious birth defect. On her first postpartum visit, the woman recalls that she had a diagnostic X-ray study early in her pregnancy. What is your response when she asks you whether the baby's malformation could be caused by the radiation exposure? In most instances, the nature of the clinical malformation will rule out radiation teratogenesis. Radiation-induced malformations have a confined group of malformations that identifies the radiation teratogenic syndrome, and many malformations have never been reported even following intrauterine radiation exposures that are known to produce congenital malformations. In this situation a clinical teratologist or radiation embryologist could be of assistance. On the other hand, if the exposure is below 0.05 Gy or even 0.10 Gy, it would not be scientifically supportable to indicate that the radiation exposure was the cause of the malformations. As mentioned before, the threshold for major malformations is 0.20 Gy. Dose, timing, and the nature of the malformation would enter into this analysis. A genetic disease is diagnosed with approximately 15% to 25% of malformed children. If that is the case, the malformations could not have been caused by an intrauterine exposure to ionizing radiation.

For a counselor the most difficult situation of the four possible ones mentioned here is when external radiation therapy or high exposures of radionuclides have been utilized in a pregnant woman or in a woman who became pregnant during the therapy. While this is a serious situation, there are instances when the exposure to the embryo is low. Low exposures to the embryo may occur when radiation therapy is directed toward the head, neck, upper chest, or the extremities. Administered radionuclides are special problems because each radionuclide has a different half-life, metabolism, and excretion. Therefore, each patient needs the expert evaluation of a competent medical or health physicist to determine what the fetal exposure will be or has been, depending on the nature of the radiation exposure. Rarely, the patient may have received the course of therapy or be in the middle of the therapy when the pregnancy is discovered. That can be very upsetting to both the patient and physician. The exposure to the fetus can be calculated and appropriate counseling can be delivered. When the radiation therapist knows that the patient is pregnant, then the situation is much more advantageous, because the fetal exposure can be estimated before the onset of therapy.

In order to appropriately and more completely respond to all these situations, the counselor should rely on the extensive amount of information that has accumulated on the effects of radiation on the embryo. In fact, there is no environmental hazard that has been more extensively studied or on which more information is available (2–8).

Case report

The following consultation occurred by telephone. Unfortunately, it is not an uncommon occurrence among the thousands of consultations that the author has performed. A 27-year-old woman (gravida 3, para 2, abortus 0) called on a Friday afternoon because she was eight weeks pregnant and was scheduled for a therapeutic abortion on Monday morning. The paternal family did not accept abortion as an option, which caused much dissension within the family. Her obstetrician and a pediatric genetic counselor had advised her to have a therapeutic abortion because at the time of conception she had had several X-ray examinations of the abdomen, and the obstetrician and the counselor

were concerned that the embryo would be malformed. Dosimetry had not been performed, and an evaluation had not been initiated. It took about 10 minutes on the telephone, by taking a reproductive history, to determine that she became pregnant after the diagnostic radiation studies had been completed, and that her two boys had developmental problems (hemangioma and pyloric stenosis). The radiology department was contacted, and they had already calculated a fetal exposure that was < 0.01 Gy. The advice that was given to the patient over the telephone was that the outcome of the pregnancy still had the background risk for reproductive and developmental risks: 30 major malformations per 1 000 births as a minimum, and 15% for miscarriage. She canceled the abortion, and later delivered a normal, full-term girl. This case history illustrates the inadequate amount of data that was collected by the physicians before counseling the patient.

EVALUATING THE PATIENT

Case histories similar to the case just discussed have been frequently referred to our laboratory at the Thomas Jefferson University or to the duPont Hospital for Children. In most instances the dose to the embryo is < 0.05 Gy, and frequently it is < 0.01 Gy. Our experience has taught us that there are many variables involved in radiation exposure to a pregnant or potentially pregnant woman. Therefore, there is no routine or predetermined advice that can be given in this situation. However, if the physician and the health physicist take a systematic approach to the evaluation of the possible effects of radiation exposure, they can help the patient make an informed decision about the pregnancy. This systematic evaluation can begin only when the following 10 essential pieces of information have been obtained: (1) stage of pregnancy at the time of exposure; (2) menstrual, medical, and reproductive history; (3) date of conception (sometimes the patient knows when she conceived); (4) previous pregnancy history; (5) family history of congenital malformations and reproductive problems; (6) other potentially harmful environmental factors that occurred during the pregnancy; (7) ages of the mother and father; (8) types, dates, and number of any radiation studies performed; (9) calculation of the embryonic exposure by a medical or health physicist or a radiologist who is familiar with this type of evaluation; and (10) status of the pregnancy (wanted or unwanted).

The information contained in the evaluation should be communicated to the patient so that the family can arrive at a decision. The physician should also place a summary in the medical record stating that the patient has been informed that every pregnancy begins with a background risk of problems and that the decision to continue the pregnancy does not mean that the counselor is guaranteeing the outcome of the pregnancy. In each pregnancy, the individuals involved will need to make a decision about using amniocentesis or ultrasound to evaluate the fetus.

DIAGNOSTIC OR THERAPEUTIC ABDOMINAL RADIATION IN WOMEN OF REPRODUCTIVE AGE

In women of reproductive age it is important for the patient and physician to be aware of the pregnancy status of the patient before performing any type of X-ray procedure in which the ovaries or uterus will be exposed. If the embryonic exposure will be 0.05 Gy or less, the radiation risks to the embryo are small when compared with the spontaneous risks (Table 1). Even if the exposure is 0.10 Gy, this exposure is below the threshold or no-effect dose of 0.2 Gy for congenital malformations. It is important to discuss the risks of radiation as part of the *preparation* for the X-ray studies, at a time when both the physician and patient are aware that a pregnancy exists or may exist. The pregnancy status of the patient should be determined and noted.

Because the risk of 0.05 Gy is so small, the immediate medical care of the mother should take priority over the risks of diagnostic radiation exposure to the embryo. X-ray studies that are essential for optimal medical care of the mother and evaluation of medical problems that need to be diagnosed or treated should not be postponed. Once a diagnosis has been made, elective procedures, such as employment examinations or follow-up examinations, need not be performed on a pregnant woman, even though the risk to the embryo is very small. If other procedures (e.g., ultrasound) can provide adequate information without exposing the embryo to ionizing radiation, they of course should be used. Naturally, there is a period when the patient is pregnant but the pregnancy test is negative and the menstrual history is of little use. However, the risks of 0.05 Gy or less are extremely small during this period of gestation (the "all or none period," that is, the first two weeks post conception) (1) (Table 1).

Scheduling elective X-ray studies

In those instances in which elective X-ray studies need to be scheduled, it is difficult to know whether to schedule them during the first half of the menstrual cycle (before ovulation) or during the second half of the cycle (when most women will not

be pregnant, but could be pregnant). Both the genetic risks of diagnostic exposures to the oocyte and the embryopathic effects on the preimplanted embryo are extremely small, especially at low exposures. Also, there are no data available to compare the risk of 0.05 Gy to the oocyte (first half of the menstrual cycle) to the risk of 0.05 Gy to the preimplanted embryo (second half of the menstrual cycle, following fertilization). If the diagnostic study is performed in the first 14 days of the menstrual cycle, should the patient be advised to defer conception for several months, based on the assumption that the deleterious effect of radiation to the ovaries decreases with increasing time between radiation exposure and a subsequent ovulation? The physician is in a quandary because he or she is warning the patient about a very low risk. On the other hand, avoiding conception for several months is not an insurmountable hardship, as indicated in the following quote from the Biological Effects of Ionizing Radiation (BEIR) committee report (2): "It is not known whether the interval between irradiation of the gonads and conception has a marked effect on the frequency of genetic changes in human offspring, as has been demonstrated in the female mouse. Nevertheless, it may be advised for patients receiving high doses to the gonads (> 0.25 Gy) to wait for several months after such exposures before conceiving additional offspring."

Because the patients exposed during diagnostic radiologic procedures absorb considerably less than 0.25 Gy, the recommendations to perform all diagnostic elective radiological studies in the first half of the menstrual cycle may be unnecessary.

The importance of determining the pregnancy status of the patient

Why expend energy to determine the pregnancy status of the patient if exposures < 0.05 Gy do not measurably affect the exposed embryos, and if it is recommended that diagnostic procedures be performed at any time during the menstrual cycle if necessary for the medical care of the patient?

There are various reasons why the physician and the patient should share the burden of determining the pregnancy status before performing an X-ray or nuclear medicine procedure that exposes the embryo. One key reason is that if the physician includes the possibility of pregnancy in the differential diagnosis, a small percentage of diagnostic studies may no longer be necessary. Early symptoms of pregnancy may mimic certain types of gastrointestinal or genitourinary disease. Another essential reason is that if the physician and the patient are both aware that pregnancy is a possibility, the physician can explain the necessity of the procedure and answer questions about the risks. It is more likely that the patient will be reassured, having discussed these issues, if she subsequently proves to be pregnant.

Carefully evaluating the reproductive status of women undergoing diagnostic procedures will prevent many unnecessary allegations of malpractice (19). Surprise and anxiety stimulate many lawsuits. In some instances, the jury that considers the lawsuit is not concerned with cause and effect but with the fact that something was not done properly by the physician (20, 21). In this day and age, failure to communicate adequately can be interpreted as less-than-adequate medical care. These factors are eliminated if the patient's pregnancy status has been evaluated properly and the situation has been discussed with the patient. The patient will have more confidence if the decision to continue the pregnancy is made before the medical X-ray procedure is performed, because the necessity of performing the procedure will have been determined with the knowledge that the patient was pregnant.

SINOPSIS

El asesoramiento de pacientes expuestas a radiaciones ionizantes durante el embarazo

Los físicos que trabajan en el ámbito de la salud y los clínicos que tienen conocimientos de radiología tienen la responsabilidad de asesorar a las mujeres de edad fecunda acerca de los riesgos reproductivos de la exposición a radiaciones ionizantes antes de la concepción o durante el embarazo. Es importante entender que las personas legas albergan muchas nociones equivocadas acerca de los riesgos asociados con ese tipo de radiaciones. Muchas pacientes que ya se han sometido o serán sometidas a algún tipo de prueba radiológica les temen a los correspondientes riesgos reproductivos y a las posibles consecuencias de estas pruebas diagnósticas para el desarrollo fetal. Según estudios epidemiológicos y con animales, un alto grado de exposición a radiaciones ionizantes puede provocar un aborto, anomalías congénitas, retraso del crecimiento, muerte fetal y cáncer. A salvedad de esto último, hay umbrales de exposición establecidos en relación con cada uno de estos problemas, y una exposición por debajo de ciertas dosis de radiación no se asocia con ninguna elevación del riesgo de sufrir daños reproductivos o del desarrollo. El umbral de exposición asociado con anomalías congénitas durante la etapa del desarrollo de mayor vulnerabilidad es de 0,2 Gy, y el umbral en el caso del retraso del crecimiento y del aborto espontáneo es aun mayor. No obstante, la pérdida de un embrión puede ocurrir incluso a dosis bajas durante las fases del desarrollo que preceden a la implantación o en la fase presomática (el llamado período de "todo o nada"). Esta es la etapa en que un embrión corre un mayor riesgo de morir que de sobrevivir con malformaciones. El período de mayor vulnerabilidad para la inducción de retraso mental dura desde la octava hasta la decimoquinta semana de gestación. El umbral para la aparición de efectos deterministas aumenta después de la embriogénesis temprana y a medida que la exposición se prolonga, sea, por ejemplo, por el uso de radio-

núclidos o durante una serie de procedimientos radiológicos. El saber que la dosis umbral que afecta al desarrollo aumenta a medida que crece el feto complica el asesoramiento porque no tenemos datos contundentes acerca de los umbrales de exposición para todas las etapas de la gestación. Las exposiciones a radiaciones ionizantes antes del embarazo acarrean un riesgo muy pequeño de que aumente la frecuencia de enfermedades genéticas en hijos/hijas de madres que han recibido radiaciones en los ovarios o de padres que las han recibido en los testículos. Para asesorar a las pacientes hay que tener conocimientos de embriología, genética y teratología de la radiación y saber los principios de teratología, a fin de poder aconsejar con empatía, exactitud y dominio académico de la materia.

Palabras clave: embarazo, resultado del embarazo, radiación ionizante, anomalías, factores de riesgo, teratógenos, aconsejar.

REFERENCES

1. Wilson JG, Brent RL, Jordan HC. Differentiation as a determinant of the reaction of rat embryos to x-irradiation. Proc Soc Exp Biol Med. 1953;82:67–70.
2. Committee on the Biological Effects of Ionizing Radiation. Effects on populations of exposure to low levels of ionizing radiation. Washington, D.C.: National Academy Press; 1980.
3. National Council on Radiation Protection and Measurements. Basic radiation criteria. Washington, D.C.: NCRP; 1971. (Report No. 39).
4. Brent RL. Radiation and other physical agents. In: Wilson JG, Fraser FC, eds. Handbook of teratology. Volume 1. General principles and etiology. New York: Plenum Press; 1977. Pp. 153–223.
5. Brent RL. Utilization of developmental basic science principles in the evaluation of reproductive risks from pre- and postconception environmental radiation exposures. Teratology. 1999;59(4):182–204.
6. Brent RL. The effects of embryonic and fetal exposure to x-rays and isotopes. In: Barron WM, Lindheimer MD, eds. Medical disorders during pregnancy. 3rd ed. St. Louis: Mosby Yearbook; 2000. Pp. 586–610.
7. National Council on Radiation Protection and Measurements. Medical radiation exposure of pregnant and potentially pregnant women. Washington, D.C.: NCRP; 1977. (Report No. 54).
8. Mettler FA Jr, Brent RL, Streffer C, Wagner L. Pregnancy and medical radiation. Tarrytown: Elsevier Science; 2000. (Annals of the ICRP, Vol. 30(1), Publication 84).
9. Brent RL. The response of the 9½ day-old rat embryo to variations in dose rate of 150 R X-irradiation. Radiat Res. 1971;45: 127–36.
10. Brizzee KR, Brannon RB. Cell recovery in foetal brain after ionizing radiation. Int J Radiat Biol. 1972;21:375–8.
11. Mettler FA, Wiest PW, Locken JA, Kelsey CA. CT scanning: patterns of use and dose. J Radiol Prot. 2000;20(4): 353–9.
12. Wiest PW, Locken JA, Heintz PH, Mettler FA Jr. CT scanning: a major source of radiation exposure. Semin Ultrasound CT MR. 2002;23(5):402–10.
13. Ravenel JG, Scalzetti EM, Huda W, Garrisi W. Radiation exposure and image quality in chest CT examinations. AJR Am J Roentgenol. 2001;177(2):279–84.
14. Brenner DJ, Elliston CD, Hall EJ, Berdon WE. Estimated risks of radiation-induced fatal cancer from pediatric CT. AJR Am J Roentgenol. 2001;176(2): 289–96.
15. Giles D, Hewitt D, Stewart A, Webb J. Malignant disease in childhood and diagnostic irradiation in utero. Lancet. 1956;271(6940):447.
16. MacMahon B, Hutchison GB. Prenatal X-ray and childhood cancer: a review. Acta Unio Int Contra Cancrum. 1964;20: 1172–4.
17. Boice JD Jr, Miller RW. Childhood and adult cancer after intrauterine exposure to ionizing radiation. Teratology. 1999; 59(4):227–33.
18. Wakeford R, Little MP. Risk coefficients for childhood cancer after intrauterine irradiation: a review. Int J Radiat Biol. 2003;79:203–9.
19. Brent RL. The effect of embryonic and fetal exposure to X-ray, microwaves, and ultrasound: counseling the pregnant and nonpregnant patient about these risks. Semin Oncol. 1989;16(5): 347–68.
20. Brent RL. Litigation-produced pain, disease and suffering: an experience with congenital malformation lawsuits. Teratology. 1977;16:1–14.
21. Brent, RL. Medicolegal aspects of teratology. J Pediat. 1967;71:288–98.

Manuscript received on 14 December 2004. Revised version accepted on 22 March 2005.

Normas y estándares aplicables a los campos electromagnéticos de radiofrecuencias en América Latina: guía para los límites de exposición y los protocolos de medición

Jorge Skvarca[1] *y Aníbal Aguirre*[2]

Forma de citar: Skvarca J, Aguirre A. Normas y estándares aplicables a los campos electromagnéticos de radiofrecuencias en América Latina: guía para los límites de exposición y los protocolos de medición. Rev Panam Salud Publica. 2006;20(2/3):205–12.

SINOPSIS

Las nuevas tecnologías que utilizan campos electromagnéticos (CEM) ofrecen a la humanidad inmensos beneficios. Además de emplearse en la transmisión de energía eléctrica, las telecomunicaciones y en equipos industriales, médicos y electrodomésticos, los CEM tienen otras muchas y muy diversas aplicaciones. Algunos estudios demuestran que la exposición a los CEM podría producir efectos adversos a la salud, como cáncer y cambios en el comportamiento de las personas. Aunque hasta el presente no se ha demostrado que la exposición a CEM de baja intensidad provoque estos efectos, se trabaja por lograr un consenso científico al respecto y por establecer normas de seguridad adecuadas. La responsabilidad de desarrollar y promover los estándares de seguridad ha recaído fundamentalmente en organizaciones y agencias especializadas reconocidas internacionalmente; sin embargo, las autoridades sanitarias nacionales deben participar activamente en ese proceso. La Organización Panamericana de la Salud ha decidido promover investigaciones científicas y epidemiológicas con vistas a proponer guías y estándares armonizados. Algunos países de América Latina, como Argentina, Bolivia, Brasil, Chile, Colombia, Costa Rica, Ecuador, México, Perú y Venezuela ya cuentan con leyes específicas, aunque generalmente parciales o incompletas, basadas en las recomendaciones internacionales. En este artículo se describen las normas establecidas en América Latina y se analizan los diferentes enfoques de cada una de ellas.

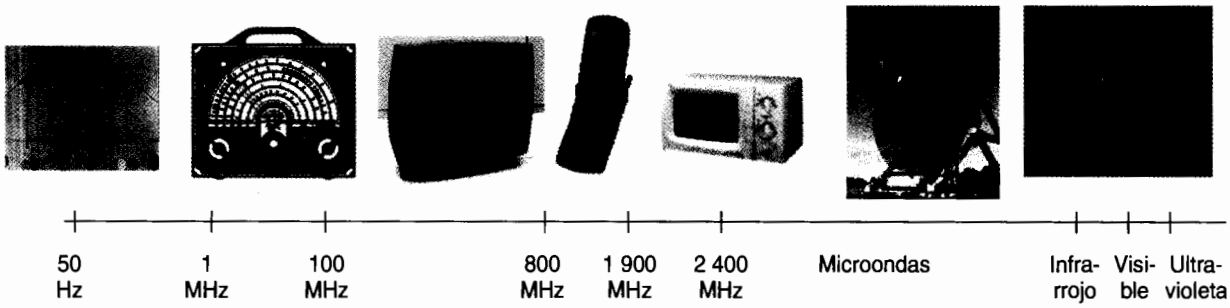
Palabras clave: normas de calidad ambiental, campos electromagnéticos, exposición a la radiación.

Los problemas asociados con el uso de las radiaciones no ionizantes han cobrado importancia a medida que aumenta la utilización de las fuentes que las generan. Entre estas fuentes se encuentran las líneas de transmisión de energía eléctrica (1) y las estaciones de transformación que generan campos de muy baja frecuencia (50–60 Hz), las fuentes de alimentación conmutadas, las estaciones de radiodifusión de amplitud modulada (525–1 735 kHz), las estaciones de radiodifusión de frecuencia modulada (88–108 MHz), las estaciones de televisión "por aire" en las bandas de frecuencias muy altas (VHF) y ultraaltas (UHF) y los sistemas de comunicación móviles por celdas (800 y 1 900 MHz), la soldadura por radiofrecuencia de uso industrial, los equipos de tecnología médica que utilizan radiaciones de radiofrecuencias y los rayos láser y del espectro ultravioleta cercano en sus diversas aplicaciones clínicas, entre otros (figura 1). Los dispositivos de mantenimiento de energía eléctrica que al cargarse generan grandes campos estáticos, los sistemas de resonancia magnética nuclear y los ferro-

[1] Departamento de Electrónica, Facultad de Ingeniería de la Universidad de Buenos Aires, Buenos Aires, Argentina. La correspondencia se debe dirigir a: Jorge Skvarca, Moreno No. 1652, Buenos Aires, CP 1093, Argentina. Correo electrónico: jorgesk@hotmail.com

[2] Cátedra de Sistemas Inalámbricos, Facultad de Ingeniería de la Universidad de Buenos Aires, Buenos Aires, Argentina.

FIGURA 1. Espectro electromagnético de las radiaciones ionizantes



carriles eléctricos por corriente continua (de 0 Hz), si bien no se propagan por ser estáticos, también son objeto de estudio de los especialistas en radiaciones no ionizantes.

Los campos electromagnéticos (CEM) generados por las mencionadas fuentes en los grandes centros urbanos han dado origen a las disciplinas que estudian la acción de las radiaciones no ionizantes sobre las personas, así como la compatibilidad y la interferencia electromagnéticas con equipos y sistemas electrónicos o electromecánicos.

En el presente artículo se examina la problemática que plantea el uso de las radiaciones no ionizantes en América Latina y el Caribe, se analizan las normas establecidas para proteger a la población contra estas radiaciones y sus fundamentos y se expone la legislación al respecto adoptada por algunos países latinoamericanos.

LAS RADIACIONES NO IONIZANTES

Para este análisis se tomaron en cuenta solo las fuentes emisoras de radiaciones no ionizantes destinadas a los servicios de comunicaciones (de 30 kHz a 300 GHz). Se debe destacar que las radiaciones provenientes de fuentes de menor frecuencia merecen igual atención; sin embargo, el análisis detallado de sus particularidades excede el alcance del presente trabajo.

Magnitudes y unidades de campos electromagnéticos

Los CEM de radiofrecuencias y microondas (de 0,3 GHz a 300 GHz) se caracterizan mediante la intensidad del campo eléctrico (E), expresada en voltios por metro (V/m), y la intensidad del campo magnético (H), medida en amperios por metro (A/m) o en teslas (T). El flujo de energía de la onda electromagnética, conocido como densidad de potencia, se propaga perpendicularmente a estos dos componentes y se cuantifica mediante un parámetro conocido como vector de Poynting (S). La longitud de onda (λ) de la propagación y su frecuencia (f) son dos características relacionadas entre sí por la velocidad de propagación de las ondas electromagnéticas (c), que es igual a la velocidad de la luz en el vacío (300 000 km/s).

Otro aspecto importante relacionado con los efectos biológicos de las radiaciones no ionizantes provocados por la interacción de los campos de radiofrecuencias con sistemas biológicos es la tasa de absorción específica, que está dada por la energía absorbida por unidad de tiempo (potencia) expresada en vatios (W) por unidad de masa corporal en kilogramos (W/kg). La tasa de absorción específica es la unidad dosimétrica empleada para cuantificar los efectos biológicos y definir los límites de exposición.

La necesidad de una norma

Si en un punto urbano se detecta un CEM proveniente de una emisora de radio de frecuencia modulada y de una radiocelda de telefonía móvil cercana, cabe preguntarse: ¿Cuál es el nivel de CEM permitido? ¿Qué diferencia hay entre el CEM proveniente de la estación de frecuencia modulada y el proveniente de la radiocelda? ¿La radiocelda y la estación de frecuencia modulada están situadas en lugares adecuados? ¿Cómo se deben medir los CEM para poder caracterizarlos correctamente?

Para responder a estas preguntas se deben tener en cuenta las normas que establecen las condiciones y parámetros fundamentales para el trabajo con radiaciones no ionizantes (2), entre ellos:

- los valores de exposición máxima permitida para un espectro de frecuencias dado;
- los lugares donde se pueden emplazar los sistemas que emiten radiaciones y las condiciones que deben cumplir;

- los procedimientos (protocolos de medición) que deben emplearse para caracterizar los CEM, a fin de obtener valores confiables que puedan compararse con las normas que establecen los niveles de exposición máxima permitida.

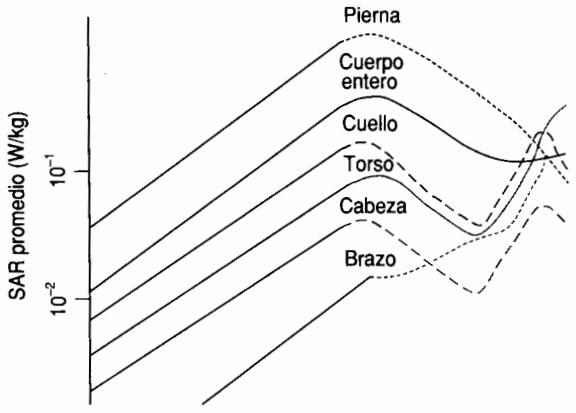
La elaboración de estas normas corresponde a diferentes ramas institucionales; sin embargo, establecer los valores máximos permitidos de exposición es competencia de las autoridades sanitarias (nacionales e internacionales), especialmente de las dedicadas a la aplicación de técnicas vinculadas con la radiofísica y la biocompatibilidad electromagnética (3). No obstante, la elaboración de las normas que regulan los procedimientos y la ubicación de los sistemas de transmisión es competencia de entidades especializadas designadas por los Estados para controlar y regular los servicios de comunicaciones, y pueden seguir o no las pautas internacionales. Por su parte, el establecimiento de los protocolos de medición es tarea tanto de los organismos de control sanitario como de las autoridades de control de las comunicaciones y en su elaboración deben participar académicos, científicos y técnicos —tanto nacionales como extranjeros— a fin de garantizar que el sistema de control se base en valores confiables que permitan fiscalizar correctamente la intensidad de los CEM.

LOS EFECTOS ASOCIADOS Y LA POLÍTICA DE CONTROL DE RIESGOS

La necesidad de contar con una norma que establezca los valores de exposición máxima permitida se debe a los trastornos que las radiaciones no ionizantes pueden ocasionar en los organismos vivos. Según la Organización Mundial de la Salud (OMS) estos efectos se clasifican como biológicos cuando la exposición a un CEM produce alteraciones en algún sistema biológico, tales como cambios en la concentración o el transporte de alguna sustancia. Los efectos biológicos pueden sobrepasar el umbral que el cuerpo humano puede compensar y así menoscabar la salud. Estos efectos sanitarios adversos por exposición a radiofrecuencias y microondas pueden ser térmicos o atérmicos.

Los efectos térmicos son el resultado de la interacción entre un CEM y un sistema biológico, con la posterior transformación de la energía electromagnética del campo en energía térmica debido a las pérdidas dieléctricas y resistivas que sufren los tejidos biológicos. Esto provoca el incremento de la temperatura, ya sea en la zona irradiada por el CEM o en todo el organismo, en dependencia de las condiciones de exposición y de la frecuencia del CEM. Los efectos térmicos más estudiados están relacionados

FIGURA 2. Variación de la tasa de absorción específica (SAR[a]) promedio según la frecuencia y la zona del cuerpo irradiada



Fuente: Referencia 6. (Reproducido con permiso del Ministerio de Salud y Acción Social de la República Argentina).
[a] Por la sigla inglesa correspondiente a *specific absorption rate*.

con el deterioro o la pérdida de la visión y de la fertilidad, ya que al estar el cristalino y las gónadas en zonas de poca irrigación sanguínea, el calor generado por la acción del CEM no se disipa con facilidad.

Los efectos atérmicos se producen como resultado de la exposición a CEM de muy baja intensidad sin elevación de la temperatura en los sistemas biológicos. Si bien los efectos nocivos del efecto atérmico no se han podido corroborar mediante grandes estudios epidemiológicos, uno de los problemas de mayor actualidad relacionado con las radiaciones no ionizantes es el análisis de la exposición prolongada a la radiación de baja intensidad y su posible asociación con algunas afecciones endocrinas, malformaciones congénitas, cambios de carácter (efectos etológicos) y el cáncer.

Las normas que fijan los valores de exposición máxima permitida a las radiaciones no ionizantes de distintas frecuencias en la mayoría de los países se basan en los efectos térmicos, es decir, para cada grupo de frecuencias se fija un valor de exposición máxima permitida por debajo del cual la absorción promedio del CEM por el cuerpo humano no representará un incremento nocivo de la temperatura (en general de alrededor de 0,1 °C). De esta forma se pueden elaborar gráficos que ilustren el comportamiento de la tasa de absorción específica (SAR, por la sigla inglesa correspondiente a *specific absorption rate*) en función de la frecuencia y se pueden fijar los valores permitidos de densidad de potencia, de campo eléctrico y de campo magnético, ya sea para trabajadores (exposición a CEM durante 8 horas diarias) o para el público en general (exposición a CEM de duración indefinida) (figura 2).

De acuerdo con los efectos mencionados anteriormente y a fin de evitar el daño que la exposición a los CEM podría provocar, en los últimos 25 años se han definido criterios y límites de exposición de carácter obligatorio que ayudan a reducir los riesgos asociados con la exposición a los CEM.

Debido a la falta de consenso acerca de las normas que se deben adoptar —y hasta que diversos estudios epidemiológicos aún no concluidos permitan establecer los criterios más racionales— se han establecido principios de cumplimento voluntario (4) que pueden contribuir a reducir al mínimo los daños ocasionados por las emisiones de radiofrecuencias.

1. Principio de precaución o de incertidumbre científica. Según este principio, se deben tomar precauciones para evitar la exposición a los CEM hasta que los conocimientos científicos y la información epidemiológica permitan definir de manera más precisa los efectos de los CEM, incluso de las emisiones de baja intensidad o de la exposición a largo plazo.
2. Principio de prudencia. Establece que se deben tomar medidas de protección de bajo costo que permitan disminuir la intensidad de los CEM.
3. Principio de exposición tan baja como sea razonablemente posible. Se debe tratar de emplear la menor potencia posible para una tarea dada. Este es un principio de precaución conocido en el campo de las radiaciones ionizantes y que se adoptó como política para el control de los riesgos por radiaciones no ionizantes.

Estos principios no establecen ni recomiendan valores máximos o mínimos, sino que enuncian conceptos que pueden interpretarse subjetivamente. Como resultado, en la actualidad se ha desatado un gran debate sobre el alcance y la aplicación de cada uno de ellos (5).

LOS LÍMITES DE EXPOSICIÓN A LAS RADIACIONES NO IONIZANTES

Al igual que para las radiaciones ionizantes, para las radiaciones no ionizantes se han establecido límites de exposición para personas expuestas en su profesión y para el público. El uso de radiofrecuencias con fines médicos se excluye de este análisis, ya que no puede establecerse un límite para los pacientes expuestos a las radiaciones —tanto para el diagnóstico como para el tratamiento— porque el beneficio que se espera es superior al posible daño ocasionado.

Para ilustrar la forma en que se regula la exposición a las radiaciones no ionizantes, se expondrá con mayor detalle la situación existente en Argentina. Los límites de exposición promulgados por el Ministerio de Salud y Acción Social de ese país mediante la Resolución 202/95 se basaron en la propuesta de la Dirección Nacional de Calidad Ambiental, adscrita a la Secretaría de Salud (6–7), y aunque fueron concebidas mucho antes que los recomendados por la Comisión Internacional de Protección contra Radiaciones no Ionizantes (CIPRNI) (8), son muy parecidos.

La exposición ocupacional

El criterio empleado para determinar el límite de exposición para las personas expuestas a radiofrecuencias por razones de trabajo se basó en una jornada laboral de 40 horas semanales (con breves períodos de exposiciones elevadas) durante 50 semanas al año. Se les debe informar claramente a los trabajadores de los posibles riesgos asociados con sus ocupaciones (9). Los límites de exposición ocupacional se aplican en dependencia de la frecuencia de la exposición del cuerpo completo.

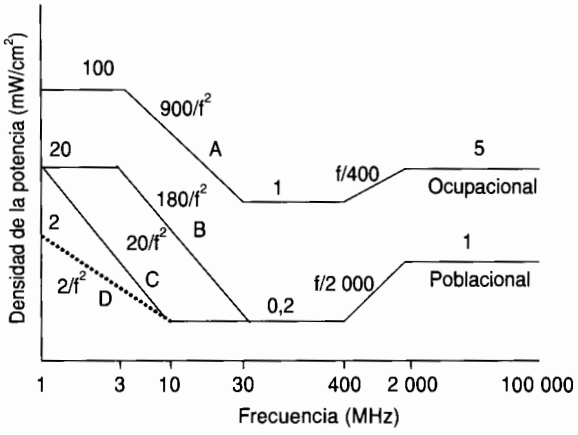
Estos límites de exposición ocupacional equivalen aproximadamente a la densidad de potencia de una onda plana incidente necesaria para producir una SAR promedio de cuerpo completo de 0,4 W/kg (una SAR de 4 W/kg provoca un aumento de la temperatura corporal de aproximadamente 1 °C).

El valor mínimo de la densidad de potencia para la exposición ocupacional es de 1,0 mW/cm^2, lo que coincide con el espectro de frecuencias donde el cuerpo humano se comporta como una antena receptora ideal (figura 3). Como se sabe, la energía radiante se transmite y se recibe a través de elementos llamados antenas. Las configuraciones y dimensiones de las antenas dependen de diversos factores, como la frecuencia y su polarización, y en el caso más simple son irradiantes verticales (cualquier elemento conductor) con una longitud acorde con la frecuencia de emisión. Una persona de aproximadamente 1,80 metros de altura puede comportarse como una antena ideal de 0,25 longitud de onda en determinado espectro de frecuencias (por ejemplo, 40 MHz) y por lo tanto puede absorber con mayor eficiencia la energía irradiada.

La exposición poblacional

La población en general —que obviamente es mucho más numerosa que la población expuesta a las radiaciones por razones laborales— puede correr riesgos que por lo general no se pueden controlar individualmente. Por ello se establece que los valores límite de exposición de la población en ge-

FIGURA 3. Valores límite para la densidad de potencia según la frecuencia (f) en Argentina[a]



[a] Estas curvas reflejan el valor promedio de la densidad de potencia medida durante 6 minutos para entornos ocupacionales o durante 30 minutos para entornos poblacionales.

Leyenda:

Curva A: Representa los valores límite de exposición para entornos ocupacionales con una exposición diaria de 8 horas.

Curvas B y C: Representan los valores límite de exposición para entornos poblacionales con una exposición diaria de 24 horas, que entrarán en vigencia con el aumento planificado de nuevas fuentes radiantes, produciéndose un mayor nivel de exposición para el público. Cuando el aumento de las fuentes es significativo, se toma como referencia la curva C en lugar de la B.

Curva D: Se aplica a entornos poblacionales cercanos a campos de antenas de frecuencia media.

(Reproducido con permiso del Ministerio de Salud y Acción Social de la República Argentina).

neral deben ser la quinta parte de los valores límite aceptados para la exposición ocupacional en la mayor parte del espectro (de 10 MHz a 300 GHz) y equivaler a la densidad de potencia de una onda plana incidente necesaria para producir una tasa de absorción especifica promedio de cuerpo completo de 0,08 W/kg (figura 3).

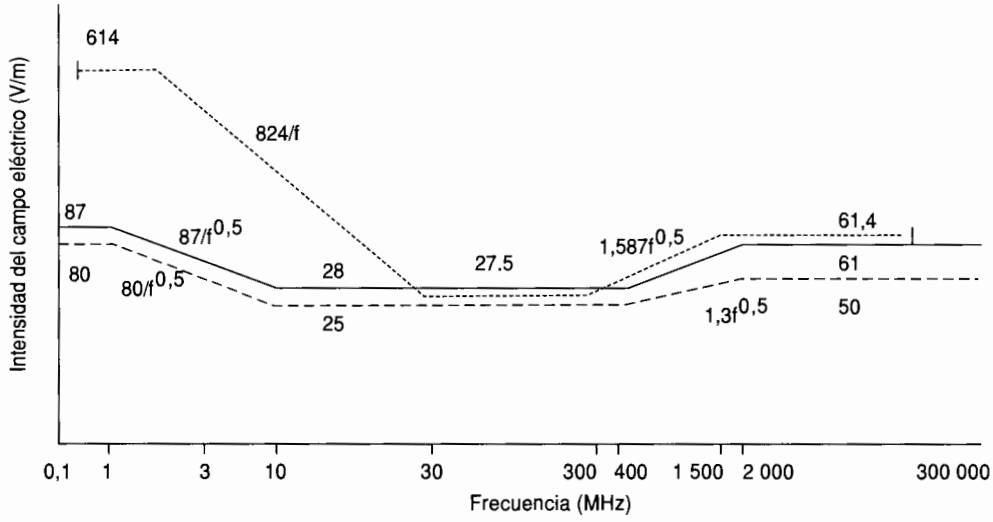
Cuando los campos están cercanos se observa una distorsión del campo de radiofrecuencias, por lo que la exposición límite se debe determinar según la intensidad (E) y el vector (H) del campo magnético (figuras 4 y 5).

LOS PROTOCOLOS DE MEDICIÓN

Para que las normas que regulan la exposición máxima permitida a las radiaciones no ionizantes tengan utilidad práctica, se debe establecer una metodología de medición que permita determinar correctamente los valores de los CEM o su densidad de potencia (10).

En los centros urbanos pueden emplearse CEM de distintas frecuencias, pertenecientes a distintos servicios, por lo que es posible que en un punto dado se sienta de manera simultánea el efecto de más de una fuente. A fin de realizar una caracterización con la mayor precisión posible, a continuación se enumeran las reglas básicas que se

FIGURA 4. Valores de exposición máxima permitida para campos eléctricos en el espectro de radiofrecuencias y microondas en entornos poblacionales, según la frecuencia (f)



Leyenda:

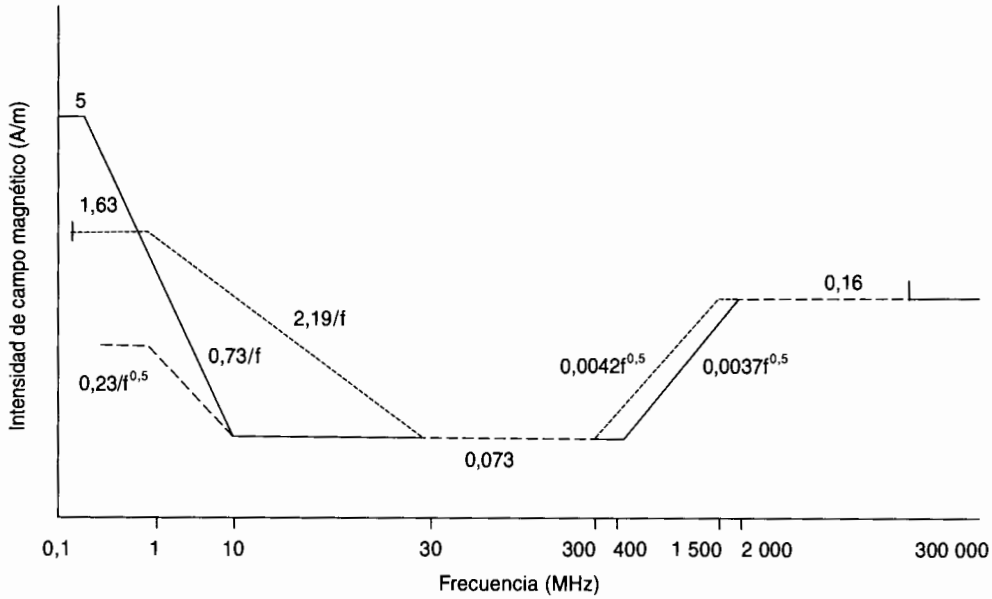
..... Valores fijados por la norma de Bolivia, tomados de la Comisión Federal de Comunicaciones de los Estados Unidos de América (FCC);

—— Valores fijados por las normas de Argentina, Brasil y Perú, todos coinciden con los valores CIPRNI;

------ Valores fijados por la norma de la Republica Bolivariana de Venezuela.

(Reproducido con permiso del Ministerio de Salud y Acción Social de la República Argentina).

FIGURA 5. Valores de exposición máxima permitida para campos magnéticos en el espectro de radiofrecuencias y microondas en entornos poblacionales según la frecuencia (f)



Leyenda:

..... Valores fijados por la norma de Bolivia, tomados de la Comisión Federal de Comunicaciones de los Estados Unidos de América (FCC); valores fijados por las normas de Brasil, Perú y Venezuela, coincidentes con los valores CIPRNI.

—— Valores fijados por la norma argentina (de 1MHz en adelante coincide con la CIPRNI);

------ Valores coincidentes en todas las normas.

(Reproducido con permiso del Ministerio de Salud y Acción Social de la República Argentina).

deben tener en cuenta para medir correctamente los parámetros de los CEM.

Por lo general, los puntos de medición en los centros urbanos no suelen ser zonas abiertas en las que los CEM se reciben de forma directa, sino puntos donde el CEM resultante se construye mediante la suma vectorial de los múltiples efectos que provocan los obstáculos circundantes. Ya sea en lugares cerrados —como un hospital, un colegio o una vivienda— o en zonas de tránsito —como una calle de la ciudad o un parque—, el punto de medición se ve afectado por diversos CEM provenientes de distintas fuentes conocidas previamente o no.

La medición del valor individual de los campos eléctrico y magnético, o de la densidad de potencia asociada con el CEM se puede realizar mediante la integración por banda ancha o por banda angosta.

La integración por banda ancha se realiza mediante monitores de radiación con sondas isotrópicas sensibles a los campos eléctricos o magnéticos, en dependencia de la magnitud que se desee medir. Estos equipos ofrecen el valor resultante de la integración de todos los componentes del campo (eléctrico o magnético, según el caso) en las tres direcciones principales y captan todas las emisiones provenientes de los distintos servicios y fuentes, aunque no pueden discriminarlas. Por tanto, el método de integración por banda ancha solo permite obtener un valor total de los campos actuantes, sin una discriminación espectral.

Cuando es necesario identificar las fuentes que emiten radiaciones en un punto dado, se debe utilizar el método de integración por banda angosta. Esta técnica utiliza un analizador de espectro capaz de integrar la potencia de las emisiones, pero cuenta además con un conjuntos de antenas de parámetros conocidos, calibradas en el entorno espectral de trabajo, que le permite caracterizar cada una de las fuentes emisoras, aunque sean de distintos servicios. De esta forma se puede saber qué componente del campo (eléctrico o magnético, en dependencia de la antena utilizada) aporta cada una de las emisiones.

Una vez escogido el método de medición apropiado, se debe prestar atención al tipo de tarea o actividad que se realiza en el punto que se desea

caracterizar. Si está ubicado dentro de una institución dedicada a la salud o a la educación, es estrictamente necesario realizar la medición en el lugar donde se encuentra el paciente o el alumno, según el caso, pues se deben medir los campos a la altura en que la persona realiza sus tareas. Estas particularidades deben mencionarse explícitamente en el protocolo de medición.

Además, se debe establecer que solo se utilicen instrumentos calibrados y respaldados con certificados de validez internacional, de manera que las mediciones presenten un grado de exactitud adecuado, independientemente del organismo o del profesional que las realice. Esto permitirá comparar los valores con los de otros estudios y perfeccionar la técnica.

NORMAS ESTABLECIDAS EN AMÉRICA LATINA

Solo diez países latinoamericanos poseen normas que regulan las dosis de exposición permitida a las radiaciones no ionizantes. Algunos establecieron los valores límite según las recomendaciones del Instituto Nacional de Normas de los Estados Unidos de América (*American National Standards Institute*, ANSI) aprobadas en 1974 por su Comité C-95. En 1991, el ANSI recomendó su nuevo estándar C-95.1-1991, en el que estableció el límite de exposición ocupacional de 1 mW/cm^2 en el espectro de frecuencias de 30 a 300 MHz. Solamente Bolivia adoptó el estándar del ANSI de 1991, basado en límites de la Comisión Federal de Comunicaciones de los Estados Unidos de América (*Federal Communications Commission*, FCC) (11), mientras que los otros países establecieron normas basadas en las recomendaciones del CIPRNI de 1998 (12). Algunas normas, como la de Chile, no tienen representación en frecuencias y solo fijan valores puntuales. A continuación se resume la información disponible.

Argentina. Resoluciones del Ministerio de Salud, MS 202/1995, y de la Secretaría de Comercio, SeCom 530/2000. Los límites ocupacionales y públicos son similares a los de las normas de la CIPRNI y se presentan en las figuras 2 y 3.

Bolivia: Estándar Técnico de la Superintendencia de Telecomunicaciones, SITTEL 2002/0313.

Brasil: Resolución 303 del 2 de julio de 2002 de la Agencia Nacional de Telecomunicaciones (*Agência Nacional de Telecomunicações*, ANATEL) que regula los límites de exposición a campos eléctricos, magnéticos y electromagnéticos en el espectro de radiofrecuencias entre 9 kHz y 300 GHz. Se basa en los límites recomendados por la CIPRNI.

Chile: Decreto 594/00 Salud, Título 4, sobre la contaminación ambiental y Resolución 505/00 de la Subsecretaría de Telecomunicaciones, SUBTEL.

Colombia: Norma Técnica UIT K52, basada en los límites recomendados por la CIPRNI.

Costa Rica: Resolución No 2896-98 de la Sala Constitucional que establece protocolos de medición para las líneas de alta tensión.

Ecuador: Norma Técnica que establece los límites de máxima exposición permitida, aprobada en 2004. Se basa en los límites recomendados por la CIPRNI.

México: La Comisión Federal de Telecomunicaciones de México, COFETEL, reitera en su Programa Nacional de Normalización 2005 (PNN-2005) la necesidad de aprobar una norma oficial mexicana (NOM) que regule las radiaciones no ionizantes en todo el espectro radioeléctrico. Este reclamo, planteado hace varios años en la NOM-126, refleja la preocupación social expresada por sectores cada vez más amplios de la población.

Perú: Decreto Supremo del Ministerio de Transportes y Comunicaciones, MTC 038-2003, sobre la adopción de límites de exposición en el espectro de radiofrecuencias de 9 kHz a 300 GHz. Se basa en los límites recomendados por la CIPRNI.

Venezuela: Norma del Comité Venezolano para Normas Industriales, COVENIN: Norma Venezolana Covenin, NVC 2238-00. Es una norma nacional que fija los límites de máxima exposición permitida.

Como se puede observar, los países que han aprobado recientemente normas con los límites de exposición máxima permitida se han basado en las recomendaciones del ICNIRP o de la FCC.

Como conclusión, se puede afirmar que las normas y estándares empleados en algunos países de la Región se deben actualizar, completar y armonizar, de manera que abarquen todo el espectro de radiofrecuencias. Los países que aún no cuentan con este tipo de normas o están en el proceso de modernizarlas pueden utilizar como marco general la información actualizada y armonizada que brinda la Organización Mundial de la Salud mediante su proyecto internacional sobre CEM, que se basa en los principios de precaución, prudencia y exposición tan baja como sea razonablemente posible.

SYNOPSIS

Norms and standards for radiofrequency electromagnetic fields in Latin America: guidelines for exposure limits and measurement protocols

New technologies that use electromagnetic fields (EMF) have proved greatly beneficial to humankind. EMF are used in a variety of ways in the transmission of electrical energy and in telecommunications, industry, and medicine. However, some studies have shown that EMF could be detrimental to one's health, having found an association between exposure to EMF on the one hand, and the incidence of some types of cancer as well as behavioral changes on the other. Although so far there is no concrete proof that exposure to low-intensity EMF is hazardous, researchers continue to study the issue in an attempt to reach a consensus opinion and to establish safety standards. While developing and establishing such norms and standards have traditionally been the responsibility of international specialized agencies, national health authorities should take an active part in this process. Currently the Pan American Health Organization is promoting scientific research, often in the form of epidemiologic studies, in order to propose uniform norms and standards. Some Latin American countries, including Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Mexico, Peru, and Venezuela, have already enacted incomplete or partial legislation based on recommended international standards. This article describes the norms established in Latin America and the particular approach taken by each country.

Key words: environmental quality standards, electromagnetic fields, radiation exposure, Latin America.

REFERENCIAS

1. United States of America, National Institute of Environmental Health Sciences, U.S. Department of Energy. Preguntas y respuestas sobre los CEM: campos eléctricos y magnéticos asociados con el uso de la energía eléctrica. Washington, D.C.: U.S. Department of Energy; 1995.
2. United States of America, Federal Communications Comission, Office of Engineering and Technology. Evaluating compliance with FCC Guidelines for Human Exposure to Radiofrequency Electromagnetic Fields. Washington, D.C.: Federal Communications Comission; 1997. (OET Bulletin No. 65).
3. Portela A. Fundamental and applied aspects of non-ionizing radiation. New York: Plenum Press; 1974.
4. World Health Organization. Establishing a dialogue on risk from electromagnetic fields. Radiation and environmental health. Geneva: World Health Organization; 2002.
5. Foster KH, Vecchia P, Repacholi MH. Science and the precautionary policy. Science. 2000; 288:979–81.
6. Portela A, Skvarca J, Matute Bravo E, Loureiro L. Volumen I: Manual de estándares de seguridad para la exposición a radiofrecuencias comprendidas entre 100 kHz y 300GHz. En: Prospección de radiación electromagnética ambiental no ionizante. Buenos Aires: Secretaría de Salud; 1988.
7. Portela A, Skvarca J, Matute Bravo E, Loureiro L. Volumen II: Radiación de radiofrecuencias: consideraciones biofísicas, biomédicas y criterios para el establecimiento de estándares de exposición. En: Prospección de radiación electromagnética ambiental no ionizante. Buenos Aires: Secretaría de Salud; 1988.
8. Repacholi MH. IRPA guidelines on protection against non-ionizing radiation. New York: Pergamon Press; 1991.
9. United States of America, Institute of Electrical and Electronics Engineers. IEEE recommended practice for radio frequency safety programs, 3 kHz to 300 GHz. New York: IEEE; 2006. (IEEE Std C95.7).
10. United States of America, Institute of Electrical and Electronics Engineers. IEEE recommended practice for measurements and computations of radio frequency electromagnetic fields with respect to human exposure to such fields, 100 kHz–300 GHz. New York: IEEE; 2006. (IEEE Std C95.3).
11. United States of America, Institute of Electrical and Electronics Engineers. IEEE standard for safety levels with respect to human exposure to radio frequency electromagnetic fields, 3 kHz to 300 GHz. New York: IEEE; 2006. (IEEE Std C95.1).
12. Comisión Internacional para la Protección de las Radiaciones no Ionizantes. Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz). Health Physics. 1988;74(4):494–522.

Manuscrito recibido el 14 de diciembre de 2004. Aceptado para publicación, tras revisión, el 9 de marzo de 2005.

GUÍA ABREVIADA PARA LA PRESENTACIÓN DE MANUSCRITOS

El documento "Guía para autores", que se encuentra en Internet en la página web de la *Revista Panamericana de Salud Pública/Pan American Journal of Public Health* (RPSP/PAJPH) situada en http://journal.paho.org/, describe en detalle los tipos de manuscritos que pueden considerarse para publicación y las normas para redactarlos. Los manuscritos que no sigan las normas básicas indicadas no se considerarán para publicación ni se someterán a revisión por pares.

1. Se admiten originales en español, inglés o portugués. Los manuscritos enviados para publicación no pueden haber sido publicados total o parcialmente con anterioridad ni en formato impreso ni electrónico. Si existe alguna publicación anterior basada en los mismos datos, los autores están obligados a dárselo a conocer a la Redacción y a mandarle a esta una fotocopia del material publicado. Ningún manuscrito que haya sido presentado a la RPSP/PAJPH podrá ser enviado a otras revistas simultáneamente. Una vez aprobada la publicación en la RPSP/PAJPH, todos los derechos de reproducción total o parcial pasarán a la Organización Panamericana de la Salud (OPS).

2. Los originales se enviarán por medio de Manuscript Central, sistema para la presentación y revisión de manuscritos en línea. Puede ir directamente a Manuscript Central (http://mc.manuscriptcentral.com/rpsp) o entrar por conducto de la página web de la revista. Las consultas sobre el estado de los manuscritos debe hacerlas el autor directamente por medio del mismo sistema.

3. Los trabajos deben referirse a temas de salud pública dentro del campo de actividades de la OPS. No deben contener declaraciones ni alusiones políticas.

4. En general, los textos no deben tener más de 15 a 20 páginas a doble espacio en caracteres de 12 puntos de estilo Times New Roman o Arial. Si en el texto aparece material traducido de otra lengua, envíese también copia del original.

5. La Redacción de la revista aceptará o rechazará los originales en función de las recomendaciones de los revisores, la calidad científica del estudio y su idoneidad para la revista. En los manuscritos aceptados se realizarán las modificaciones editoriales que se estimen necesarias, y la Redacción se reserva el derecho de no publicar un manuscrito si los autores no contestan a cabalidad las preguntas planteadas por el editor. Una vez editado, el texto final se enviará a los autores para su aprobación antes de mandarlo a composición tipográfica.

6. Los trabajos que representan investigaciones originales deben seguir el formato estándar IMRYD (introducción, materiales y métodos, resultados y discusión). Todo manuscrito debe incluir un resumen estructurado de un máximo de 250 palabras que describa claramente los siguientes: objetivos y diseño del estudio; medio en que se realizó; participantes y método de muestreo; intervenciones; variables de principal interés; resultados; conclusiones; recomendaciones. Los trabajos de revisión deben tener secciones que expliquen los objetivos de la revisión, fuentes usadas, criterios de selección, términos de búsqueda, compendio y síntesis de datos, y conclusiones, todo lo cual deberá abreviarse en el resumen estructurado. Los trabajos para la sección de "Temas de actualidad" y de "Opinión y análisis" deben acompañarse de un resumen sin estructurar.

7. Las referencias deberán estar en el estilo de Vancouver (números arábigos consecutivos en paréntesis dentro del texto y lista numerada al final, en página aparte). Cada referencia tiene que estar completa: nombre e iniciales de cada autor; título del artículo o libro en el idioma original; nombre entero de la revista con números del volumen y páginas o ciudad de publicación del libro, nombre de la editorial y fecha de publicación.

8. Las figuras y los cuadros con sus leyendas y títulos respectivos se colocarán en páginas aparte, numeradas consecutivamente y agrupadas después de las referencias. Cada figura o cuadro debe mencionarse por lo menos una vez en el cuerpo del manuscrito.

9. El autor recibirá varios ejemplares del número de la revista en el que se publique su artículo.

CONDENSED GUIDELINES FOR MANUSCIPT PREPARATION

The document "Guidelines for authors," which is on the webpage of the *Revista Panamericana de Salud Pública/Pan American Journal of Public Health* (RPSP/PAJPH), located at http://journal.paho.org/, describes in detail the types of manuscripts that will be considered for publication and the guidelines that should be followed in their preparation. Manuscripts that do not comply with the basic guidelines will not be considered for publication nor will they be sent for peer review.

1. Original papers written in English, Portuguese, or Spanish will be considered. Manuscripts submitted for publication must not have been published elsewhere in whole or in part, in either print or electronic format. If the same data has appeared in a prior publication, the authors are under obligation to notify the journal and include with their submission a photocopy of the previously published material. While a manuscript is being considered for publication in the RPSP/PAJPH, it should not be submitted to another publisher. Once the manuscript is accepted for publication, the Pan American Health Organization (PAHO) reserves all rights of reproduction, in part or in toto.

2. The original manuscript should be submitted through Manuscript Central, an online manuscript submission and peer review system. This can be done directly through Manuscript Central (http://mc.manuscriptcentral.com/rpsp) or via the journal's website. Authors should use the system to inquire about the status of their manuscripts.

3. The subject of the paper should pertain to public health or related matters, within the scope of the activities of the Pan American Health Organization. Papers should not contain any political statements or references.

4. In general, the text should not exceed 15 to 20 double-spaced pages in 12-point Times New Roman or Arial type. If the paper is a translation of all or part of another work, a copy in the original language should also be sent.

5. PAHO reserves the right to accept or reject any paper based on the recommendations of its peer reviewers, scientific rigor, and suitability for the journal. Papers are accepted with the understanding that they are subject to editorial revision as deemed necessary, and the journal reserves the right to refuse to publish a manuscript if its authors do not satisfactorily reply to the editor's queries. When the paper is ready for typesetting, the primary author (or another author designated to receive correspondence) will receive the final text for approval.

6. Papers reporting original research findings should follow the IMRAD format (introduction, materials and methods, results, and discussion). All research manuscripts should include a structured abstract (maximum 250 words) clearly describing the objectives and design of the study, the context in which it was carried out, its participants and sampling method, interventions, main outcome measures, results, conclusions, and recommendations. Review articles should contain sections dealing with objectives, sources, selection criteria, search terms, compilation and interpretation of data, and conclusions; this information should likewise be summarized in the structured abstract. Papers submitted for the "Current Topics" and "Opinion and Analysis" sections of the journal should be accompanied by an unstructured abstract.

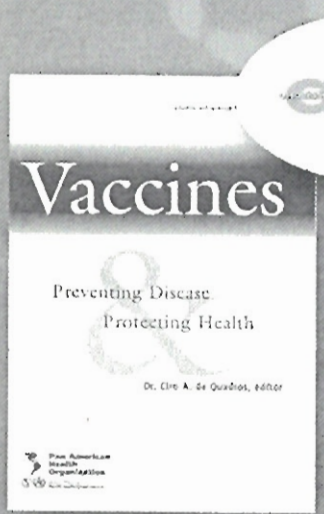
7. References should follow the Vancouver style (consecutive Arabic numerals in parenthesis within the text and a numbered list on a separate page at the end of the text). Each reference must be complete: name and initials of author(s); title of paper or book in its original language; complete name of journal plus volume number and pages, or city of publication, name of publisher, and date of publication.

8. Each figure or table, with its respective caption and title, should appear on a separate page, numbered sequentially with an Arabic number, and attached after the references. Each figure or table must be mentioned at least once in the text.

9. Upon publication, the primary author will receive several copies of the issue of the journal in which the article appears.

The scientific community recognizes PAHO PUBLISHING:

EXCELLENT... TRUSTWORTHY... USEFUL

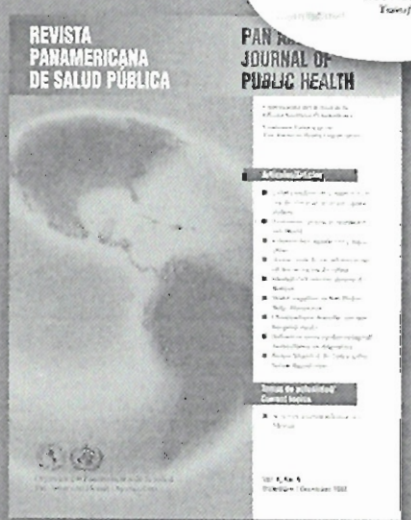


Recognized for "excellence and its unique contribution to scholarly publishing in the medical sciences" by the Association of American Publishers

BMA

Awarded "high commendation" by the British Medical Association

ISI
Web of KNOWLEDGE.
Transforming Research



Selected for coverage by the Institute for Scientific Information as "one of the world's most important and influential research journals"

Pan American Health Organization

Regional Office of the World Health Organization

http://www.paho.org/publishing

Acerca de la OPS La Organización Panamericana de la Salud (OPS) es un organismo internacional integrado por los Estados y territorios del continente americano. Su secretaría, la Oficina Sanitaria Panamericana, funciona simultáneamente como Oficina Regional de la Organización Mundial de la Salud (OMS) para las Américas y tiene por misión brindar apoyo técnico a sus países miembros y fomentar la cooperación entre ellos, a fin de lograr condiciones ambientales y de desarrollo humano sostenible que les permitan alcanzar la meta de salud para todos y por todos. La OPS tiene, además de su Sede en Washington, D.C., numerosas oficinas de representación en los países y varias instituciones científicas denominadas centros panamericanos. También cuenta con el apoyo técnico de centenares de centros colaboradores designados por la OMS.

ORGANIZACIÓN PANAMERICANA DE LA SALUD
525 TWENTY-THIRD STREET, N.W.
WASHINGTON, D.C. 20037, E.U.A.

About PAHO The Pan American Health Organization (PAHO) is an international agency composed of the States and territories of the Americas. Its secretariat, the Pan American Sanitary Bureau, is also the Regional Office of the World Health Organization (WHO) for the Americas, and its mission is to cooperate technically with its member countries and to stimulate cooperation among them so that, by attaining a healthy environment and sustainable human development, they may achieve health for all and by all. PAHO has, in addition to its Headquarters in Washington, D.C., numerous country offices and several scientific institutions known as Pan American centers. It also receives technical support from hundreds of collaborating centers designated by WHO.

PAN AMERICAN HEALTH ORGANIZATION
525 TWENTY-THIRD STREET, N.W.
WASHINGTON, D.C. 20037, U.S.A.

ISSN 1020-4989