

The art of medicine

The art of public health: pneumococcal vaccine coverage in Mexico

If the art of medicine involves making hard choices about how to improve individual health using evidence but facing uncertainty, then the art of public health involves making hard choices about improving population health and distributing it fairly under conditions of limited evidence, uncertainty, social and political constraints, and professional incentives that may be in conflict with fairly maximising population health. To illustrate the kind of public health choices a health minister faces, we focus on a current controversy in Mexico. Given a prior decision to fund the heptavalent pneumococcal conjugate vaccine (PCV7), should Mexico deliver the pneumococcal vaccine in the two primary doses plus one booster regimen—the international standard of care for which there is a better evidence base—or, should Mexico provide the two primary doses while investing the resources for the booster dose in another intervention, such as the purchase of a vaccine for influenza A H1N1 or the screening and treatment of anaemia, which arguably offers a greater health benefit than does the pneumococcal booster dose? After laying out the facts of the case, we analyse the ethical issues raised by the policy options facing the health ministry. This Mexican case highlights the general challenges facing health ministers worldwide who need to make difficult decisions quickly, under political pressure and resource constraints and without an optimum level of evidence.

Beginning in 2004, the Mexican Ministry of Health took steps that led to the commitment to provide the pneumococcal vaccine as part of its package of essential services. In late 2008, encouraged by the Mexican Association of Pediatrics, the ministry reopened the discussion about whether a booster dose at 12–15 months should be included in the regimen. In July, 2009, a group of national and international experts on immunology,

epidemiology, pneumococcus, ethics, and economics met to discuss this proposal and to provide recommendations to the National Vaccination Council (CONAVA). The participants were told that the health budget was being cut in the face of the financial crisis and that the funds that could be used to purchase the third dose could alternatively be used to purchase vaccine against influenza A H1N1. Just before the meeting, the PCV7 manufacturer offered the government the third dose of the vaccine at half price. The economic analysis presented to the meeting suggested that, at current prices, pneumococcal vaccination is probably not sufficiently cost-effective to justify its purchase by Mexico. The incremental cost-effectiveness of the third dose, even at half price, was still not sufficiently cost-effective, but it was marginally more cost-effective than the previous two. At the end of the discussion, the group reached the partial consensus that two plus booster doses were clearly preferred, resources permitting, but if sufficient funds were not available, that universal coverage with two doses was preferred to partial coverage with two plus booster doses. However, most members of the group were uncomfortable about endorsing a two dose regimen, as opposed to a two plus booster dose regimen, because it was felt to violate the widely accepted “standard of care”. A written report of the conclusions of the discussions of the expert group was presented to CONAVA, which in turn voted 24:1 to recommend to the Minister of Health the inclusion of the booster dose of PCV7.

A Minister of Health’s decision space is generally constrained by political and budgetary decisions made by others. Ethically informed choices by ministers must be made in this feasible space. In 2008, the Mexican Ministry of Health decided to purchase the pneumococcal vaccine with funds from the Seguro Médico para una Nueva Generación, a new health insurance programme that provides coverage for all newborn babies without employer-related insurance. As an expansion of the vaccine programme, this decision redefined the Minister’s decision space by requiring him to use these funds for vaccine purchases for children. In light of these constraints and his budget, consider the Minister’s options: he can fund either the pneumococcal vaccine in the two plus booster dose regimen or two doses plus influenza A H1N1 vaccine. If he chooses to fund the two plus booster dose regimen, the standard of care in most high-income countries would be achieved, presumably with less threat to professional obligations and pride. However, fewer lives may be saved than if the resources consumed by the booster dose were used for influenza A H1N1 vaccine purchase instead. Of course, there was at the time uncertainty about the safety and efficacy of the as yet untested influenza A H1N1 vaccine. Still, if the vaccine proves safe and effective, then almost



Corbis

certainly it would save more lives at lower cost than the pneumococcal booster dose. Moreover, funding influenza A H1N1 seems to be fairer. Since children are at greater risk of dying from influenza A H1N1 than pneumococcal pneumonia under the current two-dose schedule, they have stronger claims for protection from H1N1 and meeting stronger claims is the fairer choice. Disagreement might arise about this choice because we compromise the standard of care for pneumococcal vaccine if we pursue the influenza A H1N1 option. We also face the objection that we have clearer clinical trial evidence of the effectiveness of the pneumococcal vaccine than we do of the influenza A H1N1 vaccine at this time, and arguably the “burden of proof” falls on those who would aim for less certain expected gains, even if greater.

Limiting the debate to how to best use funds for vaccination ignored potentially better, alternative uses of these funds. For example, it took the option of expanding treatment for childhood anaemia off the table even if, as the evidence suggests, it would produce a greater benefit at lower cost. Had this option been on the table, however, because it involves a choice between lifesaving benefits for fewer versus more modest health benefits for a larger number, then there might well be considerable ethical disagreement about which of these outcomes is more acceptable.

Ethical priority setting in public health is thus of critical importance. We focus on several ways the decisions open to the Minister were constrained to yield suboptimal choices from the perspective of improving population health and distributing it fairly. The initial decision to offer the pneumococcal vaccine was politically driven from outside the Ministry of Health and was not based on a decision about how to use resources to best promote population health. At the manufacturer’s price, the estimated cost-effectiveness exceeded three times gross domestic product per capita and the cost doubled the vaccine budget. Funding for it was not sustainable within the vaccine budget, so funds intended for other interventions were reallocated to the vaccine budget.

Precedence is thus crucial in public health decision making. If only evidence mattered to policy, each country would consider the available evidence in the context of its situation and choose the option that is most likely to equitably maximise population health. However, if high-income countries have already made a decision, then the burden of proof required to take a different decision for Mexico is much greater. It is not clear how much this is an issue of national pride, individual professional reputation, or the perception that making the wrong decision, when it follows precedent, is not censured, whereas making the wrong decision and bucking precedent, is highly censured. Such respect for precedent may help if the Mexican context is similar to that of high-income countries and they can make better-researched recommendations. However, if a different choice is best in the Mexican context, then respecting precedent can be damaging. In addition, the argument was voiced at the

expert meeting in July, 2009, that the burden of proof should fall on those who challenge the body of evidence that exists about safety and efficacy. The argument makes us unduly risk averse: if there is a minor benefit of a booster dose, but the minor benefit is relatively certain, then favouring a somewhat lower probability of achieving a much greater benefit seems too risky. With such stringent burden of proof, countries are stuck in a Catch-22: the lack of relevant evidence impedes the implementation of policies that would generate evidence.

The Mexican case also illustrates how professional incentives may be in conflict with fairly maximising population health. At the expert meeting, considerable attention focused on the fact that alternative uses of resources for a booster dose would mean Mexico does not meet the standard of care for the PCV7 vaccine. The standard of care, however, is based on the epidemiology, disease burden, and resources available in high-income countries. Although available evidence suggests that a third dose is beneficial, it also suggests that more children’s lives can be saved by other uses of the resources. Moreover, the alternative use is fairer to people at comparable risk. Thus the “universal” standard of care invoked by various advocacy groups, including paediatricians, reflect judgments about how to maximise the benefit derived from a technology but not how to optimally improve population health.

These arguments mean Mexico may miss an opportunity to compare administering a booster dose to some parts of the population while not giving it to the rest. The world might then learn how important the booster dose and the standard of care are. That would benefit many millions of people elsewhere, as well as lead to wiser decisions by donors of vaccines to poor countries. When resources are scarce, and competing demands are compelling, then better evidence from Mexico comparing alternatives would help meet the burden of proof, which should fall on those making claims on resources rather than on those suggesting deviation from standards set in high-income countries. Such an approach would also place strong price pressure on technologies of marginal cost-effectiveness. Many ethical trade-offs and disagreements arise in decisions about public health. A fair, deliberative process offers health ministries an opportunity to wrestle with these complex issues and to make difficult decisions, which, while still often imperfect, draw legitimacy from the fair conditions under which they were made.

**Norman Daniels, Atanacio Valencia-Mendoza, Adriane Gelpi, Mauricio Hernandez Avila, Stefano Bertozzi*

Department of Global Health and Population, Harvard School of Public Health, Boston MA 02115, USA (ND); GSAS, Harvard University, Boston, MA, USA (AG); Center for Evaluation Research and Surveys, National Institute of Public Health, Cuernavaca, Mexico (AV-M); Secretariat of Health, Mexico, DF, Mexico (MHA); and National Institute of Public Health, Cuernavaca, Mexico (SB) ndaniels@hsph.harvard.edu

Further Reading

Norman D. *Just Health: Meeting Health Needs Fairly*. New York: Cambridge University Press, 2008.

Daniels N, Sabin JE. *Setting Limits Fairly: Learning to Share Resources for Health*, 2nd edn. New York: Oxford University Press, 2008.

Goldblatt D, Southern J, Saha S, et al, for the Cost Work Group, Third US Preventive Services Task Force. The art and science of incorporating cost effectiveness into evidence-based recommendations for clinical preventive services. *Am J Prev Med* 2001; **20**: 36–43.

van Gils EJM, Veenhoven RH, Hak E, et al. Effect of reduced-dose schedules with 7-valent pneumococcal conjugate vaccine on nasopharyngeal pneumococcal carriage in children: a randomized controlled trial. *JAMA* 2009; **302**: 159–67.

Whitney CG, Piliashvili T, Farley MM, et al. Effectiveness of seven-valent pneumococcal conjugate vaccine against invasive pneumococcal disease: a matched case-control study. *Lancet* 2006; **368**: 1495–502.

Zimmerman R, Jackson R. Vaccine policy decisions: tension between science, cost-effectiveness and consensus. *Am Fam Physician* 2001; **63**: 1919–23.