The Federation's Pages

WFPHA: World Federation of Public Health Associations
www.wfpha.org
Bettina Borisch, Federation's Pages Editor

Journal of Public Health Policy (2011) **32,** 135–141. doi:10.1057/jphp.2010.48;
published online 6 January 2011

Public health: How much evidence is needed to support our policies?

Public health professionals are frequently asked to provide the scientific evidence for policy decisions. Evidence-based policy is, somehow, the extension of the idea of evidence-based medicine. However, public health decisions must be made even if there are no sufficient data or in the absence of scientific proof.

Some examples include the following questions. Should mammography for breast cancer screening be recommended, and covered by insurance?[1] If yes, which age groups should be included in this recommendation?[2,3] Should we mandate influenza vaccination for health workers?[4] How can we tell?

The difficulty of these, and other such controversial public health and health policy questions, has a number of components.[5] Do the available data allow us to conclude that a given intervention brings any net benefit to individuals? If yes, is this expected benefit large enough, is it likely enough, and would it accrue to enough people, to be worth having? Do we have enough evidence to support this conclusion? Given what else we could have done instead with the same resources, is the expected benefit *still* worth having? If we conclude that a recommendation should be made,

The content of The Federation's Pages is selected and edited by the WFPHA and not reviewed by JPHP.

how strong should it be, and when can a public health intervention be mandated?

Sufficiently robust data are clearly important for answering all of these questions; just as clearly, however, they are not sufficient. The first question, whether or not an intervention brings *any* benefit, can be answered better in a rather straightforward manner if we have more and better data. When grounded in sufficient research, answers to this question can be true. Answers to all the other questions, however, have strong value content requiring ethical, and sometimes political, exploration. Answers to these questions, strictly speaking, cannot be true or false: what they can be is right or wrong. And even that cannot always be determined once and for all. In making decisions in public health and health policy, then, we must also address the following questions: How much benefit does an intervention need to bring in order to be recommended? How much evidence do we need to reach a conclusion? How much constraint may we apply in implementing an intervention? How should we go about making decisions on all of these questions?

How Much Net Benefit?

When asking if an intervention is worthwhile, we aim to use interventions that we consider to be relevant to individuals' health, and to avoid using those that bring insufficient advantages to persons to make them worth their time, efforts, and risks.

Once the benefit expected from an intervention has been assessed, however, knowing if this benefit is sufficient for the intervention to be implemented will further require that there be an agreement on the level of expected benefit, which we *require.* If data show the intervention to have no benefit, knowing whether the intervention should be implemented is easy: it should not. Similarly, we would all agree that, where data show substantial benefit to a sufficient number of individuals, an intervention should be implemented. When, however, is an intervention beneficial *enough*? Answers to this question reflect values and priorities: how much weight we give to the expected benefit, to the risks involved, to this intervention as opposed to other things on which we could be spending time and resources.

The trade-offs involved in implementing an intervention must also be judged acceptable. An intervention may be sufficiently beneficial to be indicated if it were free, and nevertheless not be worthwhile given the resources and other interventions we would need to forgo in order to use it. Examples such as routine combined anti-aggregation[6] are good

illustrations. In practice, this may not even be a direct question of financial cost.[7] Such trade-offs are often expressed in terms of Quality Adjusted Life Years (QALYs). A threshold is then invoked: usually, it is assumed that interventions which cost less than $50 000 per QALY gained should be implemented, those which cost more than $100 000 per QALY are too expensive, and judgment should be exercised in between. Despite its apparent basis in facts, however, this threshold was never agreed upon as a threshold.[8] Deciding how much we are willing to spend for the benefit of 1 year in good health is an assessment of values requiring us to think through our priorities. Relying on a 'traditional' threshold simply makes it an unexamined one.

How Much Evidence?

Deciding how much evidence is enough again entails a value judgment, which can vary in different circumstances. We – rightly – require stronger evidence for claims that seem to contradict existing knowledge, and this is straightforward: the burden of proof rests with those who make a claim *against* existing evidence. We also, however, often require stronger evidence for claims that, if they were true, could mean that we should take actions that we do not like, or that we find ethically problematic. This second situation is very different, in that its crucial aspect is not factual uncertainty, but disagreement about a value-laden or politically fraught decision. In such cases, calls for stronger data can represent efforts to avoid discussion of the underlying ethical or political issue. Extreme examples include the 'moving targets' strategy of vaccination opponents, whose constant calls for stronger data on ever changing questions are simply another way of expressing a disapproval of vaccination that has nothing to do with knowledge or data. More reasonably, the question of prior testing of H1N1 vaccine safety was an important part of the 2009 debate on vaccination campaigns.[9] The question of how much evidence was to be considered enough regarding a vaccine developed over a short timeline, in a situation where the risk of disease was uncertain, is a difficult one indeed. This example illustrates how debates regarding acceptability of the amount of data are influenced by disagreement over ethical and political aspects of the situation. Individuals more reluctant to consider the targeted disease an important threat to human health will be more likely to be wary of the dangers of vaccination, and thus to call for more safety data.

Discussions of this sort, where uncertainty about risks is central, are often couched in terms of the 'precautionary principle'. Often misunderstood as a prescription for a 'wait and see' strategy, this principle

is in fact intended to function as a 'move to a proactive strategy of anticipating and preventing the actualization of threats by mandating precautionary measures'.[10] Importantly, it cannot be applied unless the risk invoked has at least some plausibility. Neither can it represent a call for absolute certainty,[11] nor a ban on all research that might shed light on the invoked risk. At bottom line, this principle shifts the burden of proof from those who would invoke a risk to those who would deny it. It represents a guide to what we should believe, rather than a guide to what we should do.[12] As much of the debates surrounding its application illustrate, it does not provide a threshold to determine how much evidence is enough.[13] Again, this is a value judgment, which requires a separate assessment.

How Much Constraint?

When a conclusion has been reached, on the basis of evidence deemed sufficient, that an intervention would indeed be sufficiently beneficial, questions arise as to how we may implement it. When should a public health measure be recommended, and when should it be mandated? Public health has been criticized on the grounds of paternalism, and alternately has found advocates to argue that paternalism in public health can be justified in some circumstances.[14] This is a complex debate including questions regarding the basis of rights to infringe upon liberty,[15] and the value of health relative to other valued aspects of our lives.[16]

Without going into more detail than the scope of this article allows, two points are important here. First, some public health interventions arguably enhance individuals' ability to make choices, rather than curtailing it.[17] This places such interventions beyond the scope of the constraint problem. Second, how much constraint is justified is again an ethical and political question on which additional data will usually bring little to bear.

How Should We Decide?

Questions raised by public health and health policy interventions are often couched in terms of data. These questions, however, often raise more ethical and political issues than scientific ones. This difference is not trivial. The distinction between facts and values, which seems so straightforward in philosophical discussions[18] can be more difficult to keep in mind in public health debates.

Why might that be? First, understanding data in public health may truly be more difficult than in other areas of medicine, as 'the distribution

of health both affects and is affected by the distribution of other goods'.[16] This leads to legitimate concerns regarding insufficient data or insufficient understanding of existing data. Second, where disagreements or power differentials exist regarding public health decisions, calling for stronger data may sometimes simply signify dissent. This amounts to avoiding the real issue. Finally, opening up an ethical dilemma in public health is genuinely difficult: we have no fixed threshold for any of the questions outlined in this article, and must yet make decisions that will affect others. What do we mean by health? Can we infringe on liberty for it? Can we give it priority to 'other goods that a just society should be trying to secure for its citizens'?[16] If so, to what degree, and for how much benefit? When are we sufficiently certain of the existence and degree of this benefit, and of the risks? And are these risks and benefits equally distributed? It is, perhaps, unsurprising that calls for ever stronger data sometimes replace head-on discussion of our ethical and political uncertainties, especially regarding issues where admitting uncertainty may not only be a personal difficulty but also a political risk.

Therefore, how should we decide? That these are not questions of fact does not mean that we may decide them in an arbitrary manner. Indeed, public health ethics, the examination of the ethical issues arising in public health and health policy, is currently receiving growing attention as its specificities become clearer.[16] At minimum, we should certainly not attempt such decisions if we are shirking discussion of the values involved,[19] including values that could help us decide when enough evidence is available.[12] We should be aware that all of these questions involve thresholds, and that we have no entirely objective manner of defining where those thresholds ought to be. Some form of common agreement is, thus, the firmest grounding we can give them. This makes discussing them crucial. But we can only do this if we recognize these questions for what they are: not issues of scientific fact, but issues of right and wrong.

Samia A. Hurst
Institute for Biomedical Ethics, Geneva University Medical School
E-mail: samia.hurst@unige.ch

Bettina Borisch
Institute for Public Health, Geneva University Medical School

Alex Mauron
Institute for Biomedical Ethics, Geneva University Medical School

Contact:
WFPHA Contact Information:
c/o Institute for Social and Preventive Medicine, University of Geneva, CMU, 1, rue Michel Servet, CH-1211 Genève 4, Switzerland
E-mail: geneva@wfpha.ch
Website: www.wfpha.org

Acknowledgement

This work was funded by the Institute for Biomedical Ethics and by the Institute for Social and Preventive Medicine at the University of Geneva, and by the Swiss National Science Foundation (grants 3200B0-107267/2 and 3233B0-107266/2). The funding sources were not involved in the study design, in the collection, analysis, and interpretation of data, in the writing of the report, or in the decision to submit the paper to WFPHA.

References

1. Gotzsche, P.C. and Olsen, O. (2000) Is screening for breast cancer with mammography justifiable? *The Lancet* 355: 129–134.
2. Nelson, H.D. *et al* (2009) Screening for Breast Cancer: Systematic Evidence Review Update for the US Preventive Services Task Force. Rockville, MD: Agency for Healthcare Research and Quality. Evidence Review Update. (Prepared by the Oregon Evidence-based Practice Center under contract 290-02-0024 with the Agency for Healthcare Research and Quality).
3. Hellquist, B.N. *et al*. (2010) Effectiveness of population-based service screening with mammography for women ages 40 to 49 years: Evaluation of the Swedish Mammography screening in young women (SCRY) cohort. *Cancer*, advance online publication, 29 September 2010; doi: 10.1002/cncr.25650.
4. Maltezou, H.C. *et al*. (2010) Determinants of intention to get vaccinated against novel (pandemic) influenza A H1N1 among health-care workers in a nationwide survey. *Journal of Infection* 61: 252–258.
5. Hurst, S.A. (2010) Clinical indication as an ethical appraisal: The example of imaging before middle ear surgery. *ORL: Journal for Oto-Rhino-Laryngology and Its Related Specialties* 72: 138–143, discussion 144.
6. Gaspoz, J.M. *et al* (2002) Cost effectiveness of aspirin, clopidogrel, or both for secondary prevention of coronary heart disease. *New England Journal of Medicine* 346: 1800–1806.
7. Hurst, S.A. and Danis, M. (2007) A framework for rationing by clinical judgment. *Kennedy Institute of Ethics Journal* 17: 247–266.
8. Ubel, P.A., Hirth, R.A., Chernew, M.E. and Fendrick, A.M. (2003) What is the price of life and why doesn't it increase at the rate of inflation? *Archives of Internal Medicine* 163: 1637–1641.
9. Schwarzinger, M., Flicoteaux, R., Cortarenoda, S., Obadia, Y. and Moatti, J.P. (2010) Low acceptability of A/H1N1 pandemic vaccination in French adult population: Did public health policy fuel public dissonance? *PLoS One* 5: e10199.

10. Petrenko, A. and McArthur, D. (2009) Between same-sex marriages and the large hadron collider: Making sense of the precautionary principle. *Science and Engineering Ethics* 16: 591–610.
11. Harris, J. and Holm, S. (2002) Extending human lifespan and the precautionary paradox. *Journal of Medicine and Philosophy* 27: 355–368.
12. Peterson, M. (2007) Should the precautionary principle guide our actions or our beliefs? *Journal of Medical Ethics* 33: 5–10.
13. Goldstein, B.D. (2007) Problems in applying the precautionary principle to public health. *Occupational and Environmental Medicine* 64: 571–574.
14. Nys, T. (2008) Paternalism in public health care. *Public Health Ethics* 1: 64–72.
15. Selgelid, M. (2009) A moderate pluralist approach to public health policy and ethics. *Public Health Ethics* 2: 195–205.
16. Wilson, J. (2009) Towards a normative framework for public health ethics and policy. *Public Health Ethics* 2: 184–194.
17. Hale, B. (2010) Respecting autonomy in population policy: An argument for international family planning programs. *Public Health Ethics* 3: 157–166.
18. McCullough, L.B., Coverdale, J.H. and Chervenak, F.A. (2004) Argument-based medical ethics: A formal tool for critically appraising the normative medical ethics literature. *American Journal of Obstetrics and Gynecology* 191: 1097–1102.
19. Hurst, S.A., Reiter-Theil, S., Slowther, A.M., Pegoraro, R., Forde, R. and Danis, M. (2008) Should ethics consultants help clinicians face scarcity in their practice? *Journal of Medical Ethics* 34: 241–246.