

IMMUNIZATION

[Archived] Immunization: Comments on MacDonald, Halperin, and Rodewald

David M Salisbury, CB, FRCP, FRCPCH, FFPH

Department of Health, London, United Kingdom

October 2005

Introduction

The linked papers from MacDonald, Halperin, and Rodewald provide an overview of childhood immunization from three authors who have extensive experience in immunization service provision, policy development and implementation, and vaccine and vaccination research. The distinction between vaccine and vaccination research is significant: the introduction of new vaccines requires that they be extensively researched, especially for their safety and effectiveness; the successful maintenance of immunization programs requires that the process of vaccination itself be researched. The latter includes research into the contributions health-care providers make to the process of delivering and administering vaccines, and the increasingly important interplay of the vaccine recipients, or their care-provider, in the immunization process.¹

In times of high disease prevalence, fears of disease are prevalent. Within today's increasingly risk-averse society, once diseases are rare and no longer feared, fears over vaccine safety become predominant, surpassing the fears of the diseases that the vaccines are intended to prevent.² Thus, a perverse situation can arise when parents reject vaccination, perceiving the

dangers of vaccination to be more relevant to their decision- making than the fears of diseases that could potentially kill or permanently damage their children.³ Once diseases have become rare, parents can avoid any risks of vaccination, presuming that their children are safe through the contribution of those who have vaccinated their children. This option is short-sighted: if enough parents act in this way, then there will be sufficient susceptible children to sustain transmission of infection, which in turn may lead to more serious disease if it affects children at older ages.⁴

Research and Conclusions

MacDonald, Halperin, and Rodewald cover broadly similar topics. MacDonald concentrates on describing the provision of immunization in Canada; Halperin covers similar ground, describing immunization arrangements in Canada, but also reviews research – exclusively into vaccine safety issues; and Rodewald brings a U.S. perspective, drawing attention to the need for operational research in support of immunization programs.

Each author starts with the statement that immunization is one of the most cost-effective public health interventions. This is true because the long-established vaccines have traditionally been cheap and the diseases they prevented plentiful and serious. Under such circumstances, their use will be cost-effective when compared with other health interventions. However, as new vaccines are developed, they are coming to market at increasingly high prices,⁵ in part reflecting the high costs to industry of their development and the increasing cost of their manufacture, as regulatory authorities require higher standards of compliance with good manufacturing practice requirements. In the case of a vaccine to prevent rotavirus diarrhoea, a condition that affects almost all children but only mildly in industrialized countries, the greatest contribution towards its cost-effectiveness will be from the reduction of societal costs (e.g. economic costs as a consequence of parents taking time from work to care for ill children), not the disease costs. It should be noted that in developing countries this same disease kills millions of children annually.⁶ The vaccine's availability in such countries will only come about if low prices there can be offset against high prices in industrialized countries, thereby possibly undermining their cost-effectiveness. In countries where vaccines are provided by national authorities, their prospects for introduction will be less promising if they do not compare well against other possible health interventions that can be obtained at lower cost. Thus, research on vaccination is increasingly bringing together disciplines of mathematical modelling to assess the impacts of varying strategies, along with economic analyses of such differing strategies.⁷

MacDonald and Halperin both draw attention to the need for consistency in recommendations on vaccination, noting either varying national level recommendations or varying degrees of implementation of national recommendations at the local (provincial/territorial) level. Based on such disparities, MacDonald makes a strong plea for a national immunization strategy for Canada that would resolve problems of disparities between federal and local recommendations and provide consistent funding for all localities. Rodewald specifically draws attention to the adverse impacts that vaccine shortages have had in the U.S. and the need for a national program to purchase and stockpile vaccines to minimize fluctuations in their availability.

All three authors draw attention to issues of vaccine safety, emphasizing the adverse consequences of parental fears over safety concerns, especially when the bases for their fears may be groundless. Each quotes the putative association between MMR vaccine and autism, with Halperin reviewing much of the evidence that argues against such an association. More recent research, notably from Japan,⁸ pointing to increases in autism — despite the withdrawal of MMR (mumps, measles and rubella) in that country — adds to the assurances that the association is false. But some serious adverse events do very rarely occur after immunization and Halperin describes the process through which such events can be monitored in Canada. However, the Canadian scheme⁹ does not allow for estimates of the vaccine-attributable risk of such events, only the overall risk. There are techniques for measuring attributable risks,¹⁰ and although Halperin refers to results from such methods, techniques for assessing risks are most important in the current context of immunization research.

MacDonald, Halperin, and Rodewald in turn point to the need for policy-makers and program managers to communicate effectively with parents about immunization in order to inform parents' decision-making processes. MacDonald and Halperin both refer to the experiences in the former Soviet Union with the resurgence of diphtheria to exemplify this importance, citing the abandonment of routine immunization as the root cause of that epidemic. However, the causes were more complex than a failure to impress on parents the importance of routine immunization.¹¹ While Halperin quotes studies that investigate the contributions that particular health-care professionals can make, and the importance of specific communication materials,¹² MacDonald takes the opposite view, that what matters is giving information to parents, and that the mode of the message is less important.¹³ The Canadian authors also point to the work that has been done in Canada in producing materials to help parents with decision-making on immunization, but cite no evidence of how the material has been evaluated, or of its impact. In the United States, one

study that sought to investigate parents' attitudes to routine immunization¹⁴ was modelled on the routine surveys that are undertaken twice-yearly in the United Kingdom and are used to inform the communications strategy for that immunization program.^{15,16} In addition to routine U.K. surveys of parents' attitudes, similar surveys are done of health-care professionals,¹⁷ and all immunization promotion materials are extensively pre-tested and the impacts of such materials evaluated. These forms of operational immunization research are going to become more important as immunization programs face increasing pressures, especially through doubts over the need for immunizations and their safety.

Implications

Immunization programs are now highly effective in controlling or even eradicating communicable diseases. New vaccines are being introduced, but these are proving to be much more expensive than long-established products, and the previous criteria of cost-effectiveness may not be so readily demonstrated. In the absence of many of the historically feared diseases, new fears over vaccine safety are becoming paramount, and may even threaten the success of long-established programs. Research designed to gain a better understanding of parents' and health professionals' attitudes is becoming increasingly important.

References

1. Salisbury DM, Yarwood J. Public perception of immunisation. *Lancet* 2004;363(9417):1324.
2. Salisbury DM. The consumers' perspective. In: de Quadros CA, ed. *Vaccines: Preventing disease and protecting health*. Washington, DC: Pan American Health Organization; 2004:310-317.
3. Chen RT, Davis RL, Sheedy KM. Safety of immunizations. In: Plotkin SA, Orenstein WA. *Vaccines*. 4th ed. Philadelphia, Pa: Saunders; 2004:1557-1581.
4. Anderson RM, May RM. Immunization and herd-immunity. *Lancet* 1990;335(8690):641-645.
5. National Cervical Cancer Coalition. A vaccine every woman should take. Available at: http://www.nccc-online.org/view_news.php?nid=24. Accessed August 17, 2005.
6. Widdowson MA, Bresee JS, Gentsch JR, Glass RI. Rotavirus disease and its prevention. *Current Opinion in Gastroenterology* 2005;21(1):26-31.
7. Melegaro A, Edmunds WJ. Cost-effectiveness analysis of pneumococcal conjugate vaccination in England and Wales. *Vaccine* 2004;22(31-32):4203-4214.
8. Honda H, Shimizu Y, Rutter M. No effect of MMR withdrawal on the incidence of autism: a total population study. *Journal of Child Psychology and Psychiatry* 2005;46(6):572-579.
9. Scheifele DW, Halperin SA, CPS/Health Canada, Immunization Monitoring Program, Active (IMPACT). Immunization Monitoring Program, Active: a model of active surveillance of vaccine safety. *Seminars in Pediatric Infectious Diseases*

2003;14 (3):213-219.

10. Farrington CP, Nash J, Miller E. Case series analysis of adverse reactions to vaccines: A comparative evaluation. *American Journal of Epidemiology* 1996;143(11):1165-1173.
11. Dittmann S, Wharton M, Vitek C, Ciotti M, Galazka A, Guichard S, Hardy I, Kartoglu U, Koyama S, Kreysler J, Martin B, Mercer D, Ronne T, Roure C, Steinglass R, Strebel P, Sutter R, Trostle M. Successful control of epidemic diphtheria in the states of the former Union of Soviet Socialist Republics: Lessons learned. *Journal of Infectious Diseases* 2000;181(Suppl 1):S10-S22.
12. Ritvo P, Irvine J, Klar N, Wilson K, Brown L, Bremner KE, Rinfret A, Remis R, Krahn MD. A Canadian national survey of attitudes and knowledge regarding preventative vaccines. *Journal of Immune Based Therapies and Vaccines* 2003;1(1):3. Available at: <http://www.jibtherapies.com/content/1/1/3>. Accessed August 17, 2005.
13. Bjornson GL, Scheifele DW, Gold R. Assessment of parent education methods for infant immunization. *Canadian Journal of Public Health-Revue Canadienne de Santé Publique* 1997;88(6):405-408.
14. Gellin BG, Maibach EW, Marcuse EK. Do parents understand immunizations? A national telephone survey. *Pediatrics* 2000;106(5):1097-1102.
15. Salisbury DM. Development of immunization policy and its implementation in the United Kingdom. *Health Affairs* 2005;24(3):744-755.
16. Yarwood J, Noakes K, Kennedy D, Campbell H, Salisbury DM. Tracking mothers' attitudes to childhood immunisation, 1991 to 2001. *Vaccine*. In press.
17. NHS Immunisation Information. Health professionals survey 2004. Available at: <http://www.immunisation.nhs.uk/newsitem.php?id=49>. Accessed August 17, 2005.