Ethical issues in immunisation: Special issue for Journal of Paediatrics and Child Health

Provisional title: Consent and public engagement in an era of expanded childhood immunisation

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Abstract
Childhood immunisation programs have seen well-heralded successes in disease control. An increasing number of scheduled vaccines, narrowing risk–benefit ratios, and public attention to vaccine safety raise new questions about consent. We first explore the challenges that this highly dynamic environment poses for valid consent. Then we broaden this discussion to wider public engagement by suggesting how the public – the bearers of vaccine risk and benefit – can be better involved in immunisation policy.

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The public health achievements of immunisation are well-recognised, with remarkable success in eradication or control of diseases such as smallpox, polio, pertussis, measles, mumps, rubella, hepatitis B, tetanus, diphtheria and *Haemophilus influenzae* type b (Hib). Further health benefits are expected. Novel technologies have enabled development of vaccines against a widening array of diseases including human papillomavirus (HPV), and herpes zoster. Vaccines against pathogens as diverse as human immunodeficiency virus, malaria, tuberculosis, herpes simplex virus, dengue fever, Ross River virus, *Staphylococcus aureus* and *Clostridium difficile* are at varying stages of development. Existing programs continue to be updated with new combination vaccines, such as measles-mumps-rubella-varicella (MMRV), or vaccines for a wider number of disease strains, such as 13-valent pneumococcal vaccine, and novel delivery systems are being tested.

The control of infectious diseases that immunisation has achieved, along with the increased number of vaccines offered in childhood schedules, have brought with them new challenges for how we communicate the benefits and risks of immunisation. This article considers the ethical and policy implications of developments in immunisation, for both individual consent and societal involvement in decision making, and offers some recommendations for how policy and practices can meet these challenges.

1. Individual consent

In western society, it is broadly accepted in ethics, law and health care that individuals should be able to make decisions about their own health care in ways that reflect their needs, wishes and values. In health care, the provision of consent is the means by which people actualise their autonomy (self-rule or self-determination), by authorising what happens to them and who touches them. For consent to be valid, patients (or their parents) must be competent to make the decision, sufficiently informed, understand the information provided and be able to act freely and voluntarily.

The contemporary environment in which immunisation programs are administered presents a series of challenges to ensuring valid consent. One of these lies in managing the volume of information about each vaccine as schedules become increasingly ‘crowded’, and a second lies in accommodating different lay and public health views about the relative merits of immunisation where the risk–benefit ratios of immunisation are less stark and/or less apparent.

**Managing the volume of information**

There is an increasing number of vaccines recommended for children as part of national programs. The Australian National Immunisation Program Schedule currently has 6 recommended vaccines against 13 diseases. This compares with 3 vaccines against 9 diseases prior to 1994. Public and immunisation provider concerns about this increase are evident; up to one-third of parents and health professionals...
feel that children receive too many vaccines\textsuperscript{6,7} and there is evidence that parents are becoming increasingly selective about whether their child has all vaccines on offer and they tend to be more wary of newer vaccines.\textsuperscript{8,9}

Ensuring valid consent for each new vaccine is increasingly difficult as this requires that, for each vaccine, parents must be provided with sufficient information about their material risks and benefits. This is particularly the case for parents of children aged under 5 years (given the sheer number of recommended vaccines) and for parents of medically at-risk and Indigenous children who have more vaccines recommended for them. Health professionals must also contend with scientific uncertainty about some of the rare but serious diseases associated with vaccination where causation is difficult to establish. They must also manage the volume of information potentially required and their own sometimes limited knowledge of vaccines.\textsuperscript{10} Given these challenges, it is hardly surprising that studies suggest that in practice the ethical and legal standards of consent are often not met.\textsuperscript{11,12}

Some have suggested that this results from the absence of clear and consistent policies and processes for risk communication surrounding immunisation. Health professionals and consumers have argued that the absence of sufficient, rigorous and consistent information about the relative risks and benefits of immunisation undermines public trust in immunisation (as a whole) and undermines the ability of individuals to make informed decisions.\textsuperscript{13,10} This criticism has been most keenly expressed when genuine vaccine safety signals arise or when a parent believes they were insufficiently warned about a vaccine reaction.\textsuperscript{14}

In response to such concerns and to the medico-legal issues arising from them, in some countries, such as the United States, it is mandatory to provide consumers with a Vaccine Information Sheet (VIS) at each medical encounter.\textsuperscript{11} However, as is the case with any textual health information, the VIS relies on a standard literacy level and cannot replace the patient–provider relationship – which forms the basis of discussions about immunisation. Furthermore, even where such information is available, many parents will also desire a verbal discussion about risk,\textsuperscript{15} particularly those whose educational or cultural background makes written materials less accessible or less appropriate. Other parents – up to half in some surveys - may prefer to leave decisions to the health provider, and may request minimal information about immunisation, other than a reassurance that it is ‘beneficial’ and ‘safe’.\textsuperscript{16} (BMRB Social Research, \textit{Childhood immunisation: Wave 24 report – England and minority ethnic respondents}, Unpublished report, 2004)

But while there is merit in standardising immunisation information and in providing information through different genres, in many ways such strategies misunderstand the principles of consent. There is no legal or ethical obligation to provide \textit{all} information about a vaccine – only to provide information that is \textit{material} (of value or importance) to the patient/consumer or parent.\textsuperscript{5} And this, in the end, only becomes clear through interaction between the health provider and patient/parent.
Indeed, risk communication in a clinical encounter is more than simply a ‘top-down’ supply of information. It is an exchange between a health care provider and patient/parent, an ongoing discussion built upon trust and the expectation of care, and an ongoing and integral part of the therapeutic relationship. This perspective acknowledges that both providers and parents have responsibilities. While providers need to give information and elicit concerns and questions, parents need to communicate their information needs. In this way, providers can identify parents with high information needs and pay appropriate attention to a comprehensive risk discussion if it is needed.

Morally and clinically robust health communication is difficult and time-consuming and ensuring time for this discussion within the constraints of the contemporary health care system remains a constant challenge. For this reason, the burden of informing patients should be shared by a range of health services, not just the individual immunisation provider. Parents should, and often do, have the opportunity to receive verbal and written information about immunisation in the antenatal period, in maternity units, and from community health services. At the point where parents have contact with vaccine providers, such as in GP waiting rooms, sufficient materials should be provided prior to a vaccine being given. Additional efforts to facilitate valid consent in patients/parents with low levels of literacy and/or numeracy, and for those who do not have English as their primary language, need to be further developed and made widely available, including expansion of interpreter services, interactive internet resources, capacity-appropriate decision-aids and information sheets in multiple languages.

**Balancing risks and benefits for individuals and communities**

The second challenge for consent relates to narrowing risk-benefit profiles. In the developed world, endemic and highly infectious diseases are now largely controlled by immunisation; in this environment, new vaccines, while cost-effective as public health measures, tend to be for diseases that cause comparatively less mortality and morbidity, such as varicella-zoster.

While, for the most part, health professionals can generally assume that parents would make decisions to vaccinate their children against diseases such as polio, pertussis, diphtheria, tetanus, measles, mumps, rubella and Hib based upon a rational assessment that the benefits of immunisation far outweighed the risk, it is no longer clear that parents will always make the same decision about newer vaccines — where the risk–benefit ratio is lower and/or where infection may be neither very prevalent nor lethal. This same rationale may also hold for older vaccines when a previously endemic disease such as polio becomes well-controlled or is declared eliminated from a region such as is currently the case for polio in the Western Pacific region.

The possibility that existing or newer vaccines might not offer the same balance of benefits over risks becomes even more challenging because population-wide immunisation programs have benefits that are more than simply the sum of the benefits for vaccinated individuals. For mass immunisation programs, building
population or ‘herd’ immunity can protect not only those who are immunised, but those who are not. In other words, those who are directly protected by immunisation shield those who have not been vaccinated from getting the disease, such as babies too young to have received full protection or those unable to be vaccinated for medical reasons. People who exempt their child from immunisation, therefore, may still gain benefits from the widespread immunisation of those around them without their child facing any of the risks. This is known as the ‘free rider’ problem.

In many ways, of course, the ‘free rider’ behaviour is understandable, because it is largely impossible for an individual who decides not to be vaccinated to see the nearly imperceptible effect that his or her behaviour has on everyone. The problem is, however, that if enough people choose not to be vaccinated, population immunity will fall to levels at which outbreaks may occur which will affect those who have not been vaccinated, and those who have (since no vaccine offers 100% protection). Thus, while a decision not to vaccinate may be rational for the individual who makes it, it can lead to harms for whole populations.

In some countries enforcement of immunisation has helped to manage this problem. In Australia high immunisation coverage has been achieved through a range of non-legislative strategies including provision of free vaccines under the National Immunisation Program, financial incentives for immunisation providers and parents, tracking of coverage through the Australian Childhood Immunisation Register, school exclusion for unvaccinated children during outbreaks, and education.

Nevertheless, the question remains of how to ensure valid consent while upholding population health. While concern has been expressed (at least at a public policy level) that the public benefit of population immunity is sufficiently great that communication about the risks of vaccines should be moderated, in fact the limited existing literature suggests that (1) the few parents who decline vaccination for their children rarely do so out of a conscious decision to free ride - they simply do not think vaccines are safe nor effective and (2) parents who lean towards vaccination are able to take account of information about both individual and societal risk and benefit and, at least for established vaccines, tend to accept the arguments in favour of immunisation. The problem, however, is that as risk–benefit ratio narrows, it becomes easier to understand decisions to refuse immunisation, harder to judge such decisions as morally ‘free riding’, and more difficult to sustain arguments in favour of mandating such vaccines. This suggests that clinical decisions about immunisation will inevitably turn on decisions that are made about immunisation policy and the support of the community for those decisions. In the final section we consider why community involvement in, and support for, immunisation policy is important, what it requires and how it might be achieved.

2. Community consent and vaccine policy
The inclusion of vaccines in a national program has traditionally involved the deliberations of expert advisory committees who weigh up the benefits of a vaccine relative to its costs and make recommendations to government. These
deliberations typically consider the following: burden of disease, economic evaluation, vaccine safety, vaccine effectiveness, feasibility of recommendation, recommendations of other countries, feasibility of local vaccine production, and public perceptions. Recommendations regarding new vaccines may be made with varying levels of evidence and scientific certainty, particularly with regards such factors as correlates of protection, the extent and length of protection, and the risk of rare but serious reactions.

These systems are comprehensive and appropriate but could be further improved by more deliberative processes of public engagement. Primarily this is because in every situation, irrespective of the strength of evidence, policy decisions will involve trade-offs and value judgements. For example, there are values at play when deciding whether to vaccinate a group where gains are more marginal but still potentially important (e.g. rubella and HPV vaccination of boys); in choosing between different outcomes (e.g. which outcomes of pertussis should be prioritised in choosing the vaccine schedule), and in decisions about which rates of serious side effects are acceptable (e.g. the rate of febrile convulsions from influenza vaccination or intussusception from rotavirus vaccination). Indeed, contrary to popular belief, as ‘evidence’ really refers to ‘fact’ plus ‘value’, it is inevitable that value judgements, and occasionally political pressure, will come into play in deliberations about immunisation policy. Furthermore, as governments are empowered to make decisions in terms of the public interest it is also inevitable that groups of experts or sometimes individuals will be the ones who make judgements about what outcomes should be prioritised and what level of risk is acceptable.

Because the harms and benefits of vaccines are borne by the entire community and decisions about vaccines are often made under conditions of epidemiological uncertainty, in ethical terms a strong case can be made for including the community in deliberations about policy and practice. In recent years, this case has been increasingly recognised and a range of strategies have been used to achieve it, including lay membership of expert panels, community surveys, broad community engagement processes, public meetings, citizens’ juries and consensus conferences.

Each of these approaches has advantages and disadvantages. Lay membership of expert panels is a common approach in immunisation policy development. Here, an individual becomes the focal point through which the wider community’s values and perspective are channelled. That individual will inevitably have specific interests and perspectives and they are usually not sufficiently resourced to gauge, and then represent, the views of the entire community. Social research methods, such as focus groups, surveys and choice experiments, can provide more representative information about likely or actual public responses to policy initiatives, but may reflect only uninformed community opinion about matters that are scientifically and socially complex. Community consultation through submissions and committees of inquiry can collect views from a more informed public, but tend to prejudice the views of a vocal minority. While deliberative processes, such as consensus conferences and citizens’ juries, may provide inputs into policy decisions that are
more informed and more reflective of community values, they also are open to the criticism of selection bias and generalisability and are resource intensive.\textsuperscript{37, 38} Despite such drawbacks, however, the development of immunisation policy, particularly in areas where the trade-off between public good and personal choice is stark, would surely benefit from community participation via processes of deliberative democracy.

Finally, listening and valuing the input of citizens will become increasingly important as vaccines continue to attain their success and we see a growing focus on vaccine safety. For it is in such processes that governments can better understand lay perspectives, build mutual trust and engender a more productive conversation that works towards the ultimate goal of public health and wellbeing.

**Conclusion**
Recent developments in childhood immunisation programs present unique challenges – the number of vaccines on offer continue to increase, while at the same time the risk–benefit ratios of some vaccines become increasingly narrow. In this setting it is increasingly difficult to balance competing demands – public health imperatives for high uptake of immunisation, requirements for valid consent, and respect for personal choice. But there is no option but to address these challenges as consent remains the cornerstone of respect for autonomy in health care and is one of the foundations upon which public trust in immunisation is maintained.
References


