

Informed choice and mass immunization programmes

The school-based phase of the HPV (human papillomavirus) immunization programme which will provide Gardasil vaccine for girls from 12 years old is about to start. Given the debate on the failure of informed consent processes with the MeNZB immunisation programme, and a troubling start to the national HPV immunization programme launched in September last year, it is timely to raise concerns about the fate of informed choice and consent in the school-based phase of the programme. **Christy Parker** looks at some of the ethical issues surrounding mass immunization programmes targeting children and young people and argues that the principles of informed choice and consent must not be compromised by population health objectives.

During the last 50 years mass immunization programmes have been effective in protecting people against infectious diseases alongside other public health measures. However, while successful, these programmes have remained controversial often with fierce debate over both the context and their implementation (Verweij & Dawson, 2004). There are two major groups of ethical issues around which most of the controversy centers. The first relate to the development, introduction, and availability of new vaccines. There is much debate about the principles that should be applied in deciding which programmes are funded, about how these decisions are made, and by whom (Verweij & Dawson, 2004). The role of pharmaceutical companies who stand to make millions, or even billions, in decisions about national vaccination programmes is particularly contentious. Broader debates about the safety and efficacy of vaccines also continue to be very active.

The second major group of ethical issues, and the ones which are the focus of this article, concern the implementation of vaccination programmes: the means used to achieve high vaccination uptake, and the information and communication processes involved (Verweij & Dawson, 2004). When extraordinarily high immunization targets, aggressive marketing campaigns, and one sided information resources are employed, they risk undermining consumers rights to informed choice and informed consent (See Box). There is an inherent tension between these rights, and the objectives of population health which seek the highest uptake of interventions (such as screening or immunizations) to reduce the incidence of a disease across the whole population. The tension is further complicated when an intervention is aimed at children and young people and the right to informed choice and informed consent includes their parents.

Informed choice and consent are not niceties in New Zealand; they are enshrined in law through the Code of Health and Disability Services Rights. The Code of Rights, which became law in 1996 confers a number of rights on all consumers of health and disability services in New Zealand, and arose out of the Cartwright Inquiry with its damning findings about the treatment of women with cervical cancer at National Women's Hospital, a scandal termed the 'Unfortunate Experiment'. Rights six and seven of the code define health and disability services consumers rights to full information to enable them to make an informed choice and give their informed consent for any proposed health intervention. Right six is the right to be fully informed. The consumer can expect an explanation of the options available including an assessment of the expected risks, side effects, benefits, and costs of each option. Right six also stipulates:

Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.

Right seven outlines the right to make an informed choice and give informed consent.

International research has explored this tension and the ways that the communication and implementation of childhood immunization programmes, aimed at maximising uptake, can undermine consumers (or their parents) rights to make an informed choice. Offering practitioners financial incentives to meet high uptake targets works to undermine informed consent processes, especially when practitioners also believe that it is their moral responsibility to ensure children are immunized. Alderson et al (1997) asked primary health care practitioners in the United Kingdom about their views on childhood immunization and how targets with financial incentives might affect parents choice. They found that official targets and guidelines, as well as one-sided information resources, had a significant impact on how these practitioners approached informed choice and informed consent in vaccination programmes. Almost all of the practitioners which included GPs, practice nurses and health visitors felt obliged to carry out government policy even if they felt this was damaging to their patient relationships. One GP stated:

I feel angry about targets. My relationship with patients is becoming increasingly damaged. I think, increasingly, things like coercive consent will become a problem; they'll see me more as a policeman, not a doctor[r] (Alderson et al, 1997: 96)

Many practitioners also described a special moral duty to children which superseded the rights of parents to make an informed choice. It was apparent that policies encouraging high uptake lent institutional support to these attitudes. The comments of one GP were particularly concerning:

My duty is to the child, and not to have the child immunized because of grandmother's prejudice is unacceptable as far as I'm concerned. [I]f a child comes in and I notice the child hasn't had them, I sometimes will do them opportunistically. I think targets have improved rates. There's no doubt that money talks, and it's meant a lot of GPs have got themselves sorted out.

The reluctance to provide full information and facilitate discussion about the risks and benefits of immunization for fear that parents would not make the right choice was reported by many practitioners, leading one practitioner to state rather revealingly consent is about compliance, we need to do more work on how to get them to comply, to take it up. Parents who chose not to have their children immunized tended to be seen as irresponsible and/or irrational.

The recent MeNZB immunization programme was a worrying local example of the fate of informed choice and consent when the goal of childhood immunization programmes is to achieve the highest possible uptake and fast. When the \$220 million dollar campaign finished in May last year, parents were shocked to discover that few of the children immunized during the campaign remained immune to Meningococcal B. Uncertainties about how long immunity would last were not adequately communicated to parents in the rush to achieve high uptake targets, and most parents thought that their children would be immune for life. The failure of informed choice and consent processes is not just a violation of health consumers rights as enshrined in law, it is dangerous. Parents, believing their children are immunized against Meningococcal B, are less likely to be alert to signs of this deadly disease.

Claims that fear-mongering and bullying tactics were used to intimidate parents into having their children immunized were reported throughout the MeNZB campaign, and many parents reported a lack of reliable and unbiased information to assist their decision making process. The approach to informed choice and consent during the school-based phase of the programme was particularly concerning to many parents. An October 2007 study published in the New Zealand Medical Journal found that parents had a largely unfulfilled desire for reliable, valid and balanced information about the MeNZB vaccine (Watson et al, 2007). Parents, whether they decided to immunize or not, frequently described the Ministry of Health media publicity as scare mongering controlling people through fear fear driven

not balanced and one-sided. Even parents with a more positive view made comments such as presenting the Government's received view and needing in some way to twist it to force people to immunize. Those parents with school aged children reported concerns about the graphic nature of information given to children at school, in most cases without parental consent; the use of child-based incentives; and the short time frame given to parents to sign consent forms, all of which left parents feeling like they were being pressured into giving their consent (Watson et al, 2007).

The roll out of the HPV immunization programme since September 2008 has also raised concerns that the approach to its implementation undermines health consumers' ability to make an informed choice about the vaccine. The Gardasil vaccine, which targets four types of the human papillomavirus associated with cervical cancer, some vulval and vaginal cancers, and genital warts, is being offered to all women aged 9-26, and is controversial for a number of reasons. These include the vaccine's infancy and the suspicion that it was rushed to the market ahead of competitors for commercial gain with inadequate evidence of its efficacy and safety. Once again there are unanswered questions around how long the vaccine will offer immunity. HPV vaccination programmes are also solely targeting girls and women when HPV infection is present in boys and men and is associated with other cancers and genital warts. HPV is thus a sexual health issue, **not** a women's health issue and young women should not have to bear the burden for reducing the incidence of HPV related diseases. Further we risk sending young women the message that they alone are responsible for sexual health. Gardasil is also one of the most expensive vaccine ever sold and the programme will cost hundreds of millions of dollars- prompting questions about the gains given that women still need regular cervical smears with or without the vaccine. The HPV immunization programme is being introduced in two phases, the first phase introduced in September last year through GPs and primary health care practices for women born in 1990 and 1991, and the second school based phase late in term one of this year for girls aged 12 to 18.

Concerns about the implementation and communication of the HPV immunization programme echo those of the MeNZB campaign and centre around the marketing of the vaccine; the one-sided nature of the information resources available to young women and their parents; and the involvement of the pharmaceutical company- CSL Biotherapies- in delivering the programme. The decision to market the HPV vaccine as the 'cervical cancer vaccine' is factually incorrect and obstructs consumers' ability to understand the relationship between HPV, cervical cancer and Gardasil. The information resources are also woefully inadequate and fail to communicate uncertainties about how long the vaccine will confer protection, and that 90% of HPV infections are cleared by the body naturally within two years. The ethics of aggressive marketing campaigns selling vaccines as 'cool' to young women are questionable- peer pressure should not be used as a strategy to encourage vaccine uptake. The Auckland District Health Boards 'One For The Girls' information website about the HPV programme is an example of the emphasis on marketing over clear and honest evidence-based information to assist decision making. CSL's biotherapies 'Remind me' compliance programme alerts young women by email or text when their follow up vaccines are due. It is unethical for pharmaceutical companies with major financial interests in vaccine uptake to have this role, and the resulting direct contact with young health consumers.

Ethical issues aside, safety is a major issue if aggressive one-sided marketing campaigns and poor information resources reduce young women's ability to make a meaningful informed choice about Gardasil. Young women must understand that they will still need to have regular cervical smears because Gardasil does not offer lifetime protection from cervical cancer (as parents believed with meningococcal B). Gardasil does not protect against all cancer causing types of HPV and it is unknown how long immunity will last- experience tells us the duration of immunity is likely to be shorter than first thought. If young

women do not understand the limitations of Gardasil there is a major risk that they may not participate in New Zealand's excellent cervical screening programme. Given the uncertainties about the duration of immunity, there is a real risk that by the time many of the very young women who have the vaccine are sexually active they may no longer be protected from any of the strains of HPV. In the worst case scenario, if these young women do not have regular smears believing that they are protected from cervical cancer we could actually see an increase in the incidence of cervical cancer. Good information when it comes to health choices is a serious business.

As we prepare to launch the HPV programme in our schools, it is timely that we look seriously at the level of education and the information resources we provide to the huge numbers of young women we plan to vaccinate in the course of these programmes. Consumers must have easy access to full information and the opportunity to make an informed choice about vaccines, especially when a vaccine is controversial. Consumers' rights to do so are fundamental to health service delivery in this country. Verweij and Dawson (2004) argue that analysis and discussion of the ethical issues should be part of any justification of mass immunization programmes, perhaps especially for those targeting children and young people. Alderson et al (1997) urge policy makers to take parents' concerns and questions about vaccination seriously and to include them in these discussions, acknowledging them as the experts in caring for their children. We must remember that parents are the first to see the impact of vaccines on their children's health. Alderson et al (1997) also urge the development of detailed information booklets with clear summaries of research reviews, statistics and suggested questions to discuss rather than relying on marketing resources that appeal to parents' guilt and fear, or to the culture of

Finally, serious questions need to be asked about how we measure success in immunization programmes. It's too easy and extremely dangerous to set high targets for uptake and to see this as success or good practice by health professionals. Best practice should be measured by the number of people who have been given enough information, time to discuss this information, and who make a meaningful informed choice, whether this be to accept or decline the intervention. Despite laudable objectives, we shouldn't be bullied into accepting anything less.

References

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