Non-consensual research - what are your views?

The question "Should adults who cannot give informed consent to their participation be research participants?" is complex and multi faceted. This article discusses the consultation being undertaken by HDC into the law regarding non consensual research.

The Code of Health and Disability Services Consumers' Rights (the Code) came into force in 1996, following an inquiry led by Judge Dame Silvia Cartwright into cervical cancer research conducted at National Women's Hospital. The research involved withholding treatment from women with cervical abnormalities without their knowledge or consent. The Cartwright Report led to a number of reforms aimed at ensuring the protection of consumers' rights, including the introduction of the Code. The Code turned 20 in July 2016, and throughout those 20 years New Zealand has been a leader in the field of rights for people who receive health and disability services.

The right to make an informed choice and give informed consent before receiving health or disability services, including participating in research, is the cornerstone of the Code. The maxim "nothing about us without us" is an essential part of the culture of New Zealand's health and disability sector.

In some circumstances it is appropriate and lawful to provide health or disability services to a consumer without consent. An example is the provision of emergency life-saving treatment to an unconscious patient.

It is more complex to decide whether it is appropriate to enrol a person who cannot give consent to be a research participant. This issue could arise in a number of circumstances, including when the person is unconscious in an Emergency Department, is a patient in an ICU, is severely intellectually disabled or has advanced dementia.

Right 9 of the Code states that the rights in the Code extend to circumstances where a person is participating in, or it is proposed that the person will participate in, research. At present, pursuant to Right 7(4) of the Code, research on a person who is unable to give consent can take place only if participation in the research is in **that person's best interests**. In addition, if the person's wishes are known they must be complied with or, if the person's wishes are not known, available suitable persons interested in the welfare of the person must be consulted.

For enrolment in research to be in the person's best interests, that course of action must be better than the available alternatives. A fundamental problem with the best interests test is that the outcome of research is uncertain- frequently the risks and benefits are speculative. Furthermore, it would seem that research where the protocol incorporates a placebo or control group cannot be in the best interests of all the participants.

Recently, it has been argued that New Zealand's laws regarding non-consensual research are too restrictive, and prohibit studies that could lead to significant improvements in health and disability services. It has been suggested that research conducted on consumers who cannot give informed consent may provide valuable information about the conditions that cause consumers to lack or lose capacity, and about the diagnosis, treatment, care and needs of such consumers; and that, in some cases, that information may not be obtainable through research which only includes consumers who are able to give informed consent.

At present, non-consensual research that is not intended to provide a benefit to an individual participant but nevertheless may provide important information of benefit to others cannot proceed because it does not meet the standard of being in the participant's best interests.

It is important for everyone to have access to the benefits of research. However consumers who are unable to make informed decisions for themselves are particularly vulnerable to abuses of their rights and interests. The Code must continue to protect consumers from such abuses.

I will not be recommending any change to the current laws unless I believe there is a necessity to do so. To help me determine whether there is a need for change, I have commenced a public consultation. The consultation gives me an opportunity to learn more about what New Zealanders currently think about non-consensual research. The consultation will continue until 30 April 2017 and will focus on two fundamental questions: are New Zealand's current laws regarding non-consensual research appropriate and, if not, how should they be amended?

The consultation document and response form are available on www.hdc.org.nz. These are complex but important matters and I encourage people to express their views and make a submission.

Anthony Hill, Health and Disability Commissioner
Dr Cordelia Thomas, Associate Health and Disability Commissioner

NZ Doctor, 12 April 2017