

24 June 2020

Hon Jenny Salesa, Associate Minister of Health

Dear Hon Jenny Salesa

Letter concerning the importance of research with adults who cannot provide informed consent

I am writing to you as the Chairperson of the National Ethics Advisory Committee (NEAC).

On 28 May 2020 I met with you and informed you of NEAC's intention to write to you about research with adults who cannot provide informed consent. The Health and Disability Commissioner (the Commissioner) publicly consulted on changes to the application of the Code of Health and Disability Services Consumers' Rights (the Code) to health and disability research involving adult consumers who are unable to consent to their participation in the research. Those consumers might, for example, be unconscious, or have significant cognitive impairments that prevent them from understanding the implications of the decision to participate.

On 29 April 2020 NEAC met with Dr Cordelia Thomas, Associate Commissioner and Ms Rose Wall, Associate Commissioner from the Office of the Health and Disability Commissioner (HDC) to discuss the HDC's recently released report on health and disability research with adult participants who are unable to provide informed consent (the report).

During the meeting the HDC informed NEAC that progressing the report would be halted until after the election, and that it would be up to the new Commissioner to take the work forward.

NEAC strongly supports a change in the law, and while NEAC does not agree with every recommendation that the Commissioner makes, they support the continuation of the work that is required to change the current legal environment for research with adults who cannot provide their own consent. Below are reasons why NEAC believe you should consider this work as a priority for NEAC, the HDC and the Ministry of Health following the election and the appointment of a new Commissioner.

Unknown risks in standard of care – the evidence gap

Protection of the rights and health of individuals and communities to which they belong is the starting point for discussions when discussing research with adults who cannot consent. However, this important consideration often fails to consider how the health of individuals and communities is protected and improved through research. This case is based on the fact that many standards of care do not have adequate evidence to support them. Two examples of important lifesaving research are below.

Among patients who are hospitalised with severe traumatic brain injury, 60 percent either die or survive with severe disability.

One treatment - a decompressive craniectomy - showed promise in reducing deaths caused by traumatic brain injuries. To see whether this treatment that had started to become commonplace was the best approach, a study was conducted.

The Decompressive Craniectomy in Diffuse Traumatic Brain Injury study was published in 2011. This study showed that what appeared to be a treatment with good outcomes, in fact ended up being worse for patients. The study's results, by changing standard practice, also saved an estimated 20 million dollars a year for New Zealand.

Another study conducted in New Zealand is the CHEST trial. This trial was a National Health and Medical Research funded study conducted in New Zealand and Australia. It was the largest double-blind randomised controlled trial ever performed in critically ill patients. It showed that resuscitation with starch containing colloid fluid, which is the most common artificial colloidal solution in the world with sales of millions of litres worldwide, led to an increased risk of severe acute kidney injury requiring renal replacement therapy.

This study had an immediate worldwide impact with black box alerts issued by the Food and Drug Administration, suspension of marketing by the Emergency Nurses Association and National Health Service and more than a 70 percent decrease in use in Australia and New Zealand. This led to millions of dollars saved and many instances of acute dialysis treatment prevented.

By conducting research, we are changing the way we treat patients by making evidence-based decisions. The current legal environment is not designed for research, and clarity is needed for the health sector, researchers and ethics committees in order to ensure important ethical research may proceed.

Matters of justice

People have the right to participate in research, and there are mechanisms to ensure research is safe and ethical, including ethical review and scientific review. Many new treatments are delivered through research, and while some are experimental, they may offer the only chance at an improvement in health outcomes. Other countries have developed robust research-based regulation for this complex area of research that balances the right to participate in research with protecting participants.

Lack of evidence to support treatment for future people

Research is primarily conducted for the benefit of future people. This is particularly important as New Zealand has an aging population. NEAC has provided the previous Associate Minister of Health, Minister Dunne, advice on dementia. Their advice referred to Australian research that indicates that people with dementia are more likely to be admitted to hospital and experience worse clinical outcomes including longer stays in hospital and higher mortality¹. UK research found that 47 percent of people with dementia who went into hospital experienced a deterioration in their physical health (eg, weight loss, malnutrition, dehydration) and 54 percent had an increase in dementia symptoms (eg, becoming more confused, less independent and more distressed)².

NEAC are concerned that without a clear legal frame work for research with adults who cannot consent for themselves, our future generation will experience the same health issues. New Zealand must have a safe, ethical, equitable and robust legal framework so that we are able to begin to generate evidence now, to support current and future standards of care.

¹ Alzheimer's Australia. 2014. *Dementia Care in the Acute Hospital Setting: Issues and Strategies*. Australia: Alzheimer's Australia.

² Alzheimer's Society. 2009. *Counting the cost: Caring for people with dementia on hospital wards*. London: Alzheimer's Society.

NEAC have agreed to work with the HDC and the Ministry of Health to continue to improve the ethics system in New Zealand. What is required to continue this work, and to improve the outcomes of individuals and communities experiencing real vulnerability, is a change in the legal environment.

Yours sincerely



Neil Pickering

Chair, National Ethics Advisory Committee

cc: Hon Dr David Clark, Minister of Health