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22 April 2026

Spencer Jones

By email: H2026080033
Ref: fyi-request-34050-20defe1a@requests.fyi.org.nz

Tēnā koe Spencer

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health – Manatū Hauora (the Ministry) on 12 March 2026 for information regarding informed consent in healthcare.

On 27 March 2026, parts 1 and 2 of your request were transferred to the Office of the Health and Disability Commissioner under section 14(b)(ii) of the Act. You can expect a response from their agency in due course: OIA@hdc.org.nz.

Turning to the remainder of your request (parts 3 to 5), the Ministry contacted you on 23 March 2026 in accordance with section 18B of the Act, to seek a refinement on the scope as it was for a very large volume of information and may be refused under section 18(f) of the Act. On the same day you agreed to refine to the scope below, which we have addressed in turn:

> *1. Priority timeframe*
> *Please prioritise the period 2018–present for all parts of the request.*
>
> *2. Earlier material (pre-2018) – targeted*
> *For the period 2000–2017, I request:*
> *any foundational policy papers, Cabinet papers, or regulatory analyses that:*
> *establish or describe the governance model for informed consent; or*
> *consider whether system-level monitoring or assurance should exist*
>
> *4. Key documents*
> *If full retrieval remains substantial, I am happy to receive:*
> *summaries of key documents; or*
> *a list of relevant documents (titles, dates, authors)*
> *to enable further refinement if required.*

The Ministry has identified 14 documents within scope of these parts of your request. All documents are itemised in Appendix 1 and copies of the documents are enclosed. Where information is withheld under section 9 of the Act, I have considered the countervailing public

interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

> *3. If no documents exist*
> *For any part of the request where no documents are held, please confirm:*
> *whether the issue has ever been formally considered by the Ministry*

The Ministry has not identified work towards a national governance model for informed consent since 2000. Informed consent forms one part of the Code of Health and Disability Services Consumers' Rights that all health workers and agencies are required to meet. This is along with the common law about informed consent and legislation such as the Protection of Personal and Property Rights Act 1988 and the Care of Children Act 2004.

The Health and Disability Services Safety Act 2003 provides a mechanism for audit of health services against national standards: www.health.govt.nz/regulation-legislation/certification-of-health-care-services/health-and-disability-services-safety-act.

Informed Consent is included in the national standards, which are publicly available here: www.health.govt.nz/publications/sector-guidance-for-nga-paerewa-health-and-disability-services-standard-nzs-81342021#introduction.

Complaints about informed consent can be investigated by the Health and Disability Commissioner (HDC) who can make recommendations for improvement of individual practitioners and health services: hdc@hdc.org.nz. Clinical governance is expected to be in place for health programmes and services.

In April 2024, Health New Zealand (HNZ) advised HDC that work is underway on a national policy on informed consent, with the goal of being able to achieve a nationally consistent approach. Four HNZ districts have undertaken significant work on their informed consent policies in the last two years, and this work is informing the this policy. The policy will be accompanied by a longer procedure document that expands on the principles and process of informed consent, including a section on research, teaching, and observers, as well as nationally consistent consent forms. HNZ confirmed that the informed consent policy is due to be published mid-2026. More information is available in a report by the Health and Disability Commissioner here, published in 2024: www.hdc.org.nz/media/f5wjw02x/19hdc01260.pdf.

> *Clarification of intent*
> *This request is focused on:*
> *system-level governance and oversight, not individual clinical practice*

The Ministry has not been able to locate any briefings or policy advice about the governance of informed consent across the system. In line with section 13 of the Act, we have provided documents where concerns about informed consent have been discussed with the Ministry of Health and other agencies or regulatory authorities.

The documents outlined in Appendix 1 indicate that while there is not a single system-level governance framework for informed consent, there has been ongoing policy considerations to how consent operates in practice across specific clinical contexts. Many of the documents released to you relate to the consideration or improvement of informed consent processes in targeted areas, such as the use of surgical mesh. These sit within the broader framework established by the Code of Health and Disability Services Consumers' Rights, with additional guidance provided through professional standards and ethical bodies like the National Ethics Advisory Committee.

If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Phil Knipe
Chief Legal Advisor
Corporate Services | Te Pou Tiaki

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	27 August 2010	Draft: Ethical and Social Considerations in Screening	Released in full.
2	27 August 2010	Draft: Improving Informed Consent in Screening	
3	27 August 2010	Health Report: Ethical and Social Considerations and Improving Informed Consent in Screening: Documents for Consultation	Some information withheld under section 9(2)(a) of the Act, to protect the privacy of natural persons.
4	23 September 2016	Health Committee Recommendations and Timeline for Implementation re Surgical Mesh	Section 18(d) of the Act applies, as this document is publicly available here: www.medsafe.govt.nz/devices/Surgical%20Mesh/Implementation.asp.
5	20 December 2019	Review of Health and Disability Commissioner Act and Code of Health and Disability Services Consumers Rights	Released in full.
6	22 July 2020	Official Information Act Response H202004940	Some information withheld under section 9(2)(a) of the Act.
6A	6 January 2020	Email: Letter to Director General of Health RE Informed Consent	
6B	23 December 2019	Attachment: Informed Consent in a training environment	Released in full.
6C	31 January 2020	Attachment: Meeting summary - Informed consent for Resident Medical Officers involved in surgical procedures	
7	20 September 2022	Informed Consent and Adverse Events Overseas	
8	1 August 2022	National Quality Forum Informed Consent Submission	
9	8 February 2023	Informed Consent in Aotearoa New Zealand Literature Review	
10	8 February 2023	Informed Consent Quality Forum Submission	
11	23 February 2023	Weekly Report Excerpt: Operational Issues	Some information withheld under section 9(2)(a) of the Act. Some information released under section 16(1)(e) of the Act by giving an excerpt or summary of the contents.

Document 1

National Screening Advisory Committee

Ethical and Social Considerations Working Group

Ethical and Social Considerations in Screening

Discussion Paper

June 2010

DRAFT

CITATION:

National Screening Advisory Committee, Ethical and Social Considerations Working Group. 2010. *Ethical and Social Considerations in Screening: Discussion paper*. Wellington: Ministry of Health.

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http://www.moh.govt.nz

A large print version is also available from our website

Contents

1 Introduction to this Paper

1.1 Purpose of this discussion paper

1 This discussion paper identifies the main issues or themes about ethical and social considerations in screening from the literature.

2 It seeks feedback on whether:

- the ethical and social considerations in the literature are relevant in the New Zealand context.
- there are other ethical and social considerations not mentioned in the literature that are important for screening in New Zealand.

3 This paper was written by the Ethical and Social Considerations Working Group, a subcommittee of the National Screening Advisory Committee.

1.2 Role of the National Screening Advisory Committee

4 The National Screening Advisory Committee (NSAC) provides independent advice to the Director-General of Health on "health and disability screening policy, practice and research, including cancer screening and genetic screening".[1]

5 NSAC is not part of the Ministry of Health's National Screening Unit (NSU). See section 5 for more information about NSAC.

1.3 Project on the ethical and social considerations of screening

6 NSAC is undertaking a project to provide guidance to policy decision-makers on the ethical and social considerations of screening in the health and disability sectors.

7 The project aims to develop a framework to help support decision-makers in identifying the ethical and social considerations they should take into account when making robust policy decisions about screening programmes. The framework will also help guide those responsible for implementing and delivering screening programmes. NSAC would also like this project to contribute to a review of the National Health Committee's *Criteria to assess screening programmes*. [3]

8 We recognise that the framework needs to be flexible, incorporate good practice, and provide guidance for problem-solving. It should be a living document that can take future developments into account.

1.4 Request for feedback on this discussion paper

9 We would like your help in this process. As a starting point for your feedback, throughout this document we ask questions about each of the issues and themes identified.

10 However, our overall aim is to hear your view about the considerations you think are relevant to New Zealand and that policy decision-makers need to take into account when assessing the ethical and social dimensions of a proposed screening programme or monitoring the ethical and social impact of a current programme.

11 Please use the submission form at the end of this discussion paper to record your feedback.

1.5 Supplementary discussion paper on informed consent

12 Informed consent is an important part of this project. The Informed Consent Working Group has developed a supplementary discussion paper *Improving Informed Consent in Screening*.[2] That paper contains more detailed discussion and information about informed consent, and also separately asks for your feedback.

1.6 Structure of this discussion paper

13 This discussion paper is divided into sections as follows.

- Section 1 introduces the purpose and context of the paper and provides a glossary.
- Section 2 introduces screening and the screening criteria.
- Section 3 details the key screening ethical and social considerations from the international literature.
- Section 4 identifies other considerations relevant to New Zealand.
- Section 5 describes the National Screening Advisory Committee and the Ethical and Social Considerations Working Group.
- A list of references follows section 5.
- The submission form for your feedback is at the end of the document.

1.7 Glossary

14 This paper uses specialised terms which are defined in this glossary. The symbol after each term shows the reference from which we adapted our definition:

a Code of Health and Disability Services Consumers' Rights 1996.

b *Merriam-Webster Online Medical Dictionary*. http://www.merriam-webster.com (accessed 1 April 2009).

c National Health Committee. *Screening to Improve Health in New Zealand: Criteria to assess screening programmes*. Wellington: National Health Committee; 2003.

d Health and Disability Commissioner Act 1994.

e A Barratt et al. Cancer screening. *Journal of Epidemiology and Community Health*, 2002;56(12);899–902.

f A. Raffle and J. Muir Gray. *Screening: Evidence and practice*. Oxford: Oxford University Press; 2005.

choice [a]

A decision to:

- receive services
- refuse services
- withdraw consent to services.

competence [b]

Having sufficient understanding and memory to comprehend a situation and the nature, purpose, and consequence of any screening activity that a person is considering undergoing.

confidentiality

Health information from or about a patient is divulged only with the permission of the patient. Exceptions may exist in unusual circumstances when it is clearly in the patient's best interests or there is an overriding public good.

false negative [c]

A negative or low-risk test result even though the person has the condition being screened for.

false positive [c]

A test result that incorrectly says a person has the condition being screened for, so the person is recalled for further testing before finally being given the all-clear.

health inequality

Differences in health between population groups.

health inequity

Differences in health between population groups that are unnecessary, avoidable, or unjust.

high risk [b]

A high level of susceptibility for a condition or disorder.

informed choice [a]

A choice that is made by a participant who has all the information that a reasonable participant, in that person's circumstances, needs to make such a choice. A person must be able to make an informed choice in order to give informed consent.

informed consent [d]

Consent to a procedure where consent is:

- freely given by the participant or, where applicable, by any person who is entitled to consent on that participant's behalf; and
- obtained in accordance with the requirements prescribed by the Code of Health and Disability Services Consumers' Rights 1996.

intention to screen [e]

In a trial of a screening intervention, patient outcomes are analysed according to the group into which subjects were randomised, regardless of whether those in the screening and control groups actually participated in screening

medicalisation

The phenomenon where health or behaviour becomes viewed and treated as a medical problem or disorder.

morbidity [b]

A synonym for illness.

mortality

The number of deaths in a population during a specific period as a result of a condition. Screening aims to reduce the number of deaths caused by the screened condition.

opportunistic screening [c]

Screening that occurs when a person who is presenting to the health system for another reason is also asked a question or offered a test to detect the presence or confirm the absence of a specific condition. Opportunistic screening may be organised to a degree, but lacks a quality assurance process, including routine monitoring and evaluation.

opt-off (or opt-out) screening programme

A screening programme where a participant is automatically enrolled in the programme after their first contact and must actively choose to be removed from the programme.

opt-on (or opt-in) screening programme

A screening programme that requires a participant to explicitly enrol in the programme.

over-diagnosis [f]

The phenomenon whereby screening diagnoses cases that would never have been clinically manifest in the person's lifetime.

over-treatment [f]

The phenomenon whereby screening leads to treatment of cases that would never have been clinically manifest in the person's lifetime.

participation rate [e]

The proportion of people eligible for screening who are actually screened.

population-based screening programme [c]

A programme in which screening is systematically offered by invitation to a defined, identifiable population.

quality assurance [c]

The detection of problems through external or internal inspection and their correction through systematic activity.

risk [c]

An assessment of the probability that an individual will develop the screened condition in future. A person is "at risk" if they have a high level of risk or susceptibility for a condition or disorder.

routinisation

Where a particular screening activity becomes routine or regarded as part of the standard (and expected) pathway of care.

screening [c]

A health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are affected by, a disease or its complications, are asked a question or offered a test to identify those individuals who are more likely to be helped than harmed by further tests or treatments to reduce the risk of disease or its complications.

screening pathway [c]

The screening process from a participant's perspective. The pathway includes:

- being invited to be screened
- being given information about the purpose of screening and other relevant information
- being questioned or offered a test
- having the test
- receiving the test results
- being assessed and diagnosed if the test is positive.
- undergoing possible treatment
- understanding there are activities to monitor and evaluate all the stages in the pathway.

ultrasound scan

A scan that is often used in pregnancy to obtain a visual image of the developing foetus or infant.

2 Introduction to Screening

2.1 Definition of screening

15 The National Health Committee defines screening as (at page 29):

> "a health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are already affected by, a disease or its complications, are asked a question or offered a test to identify those individuals who are more likely to be helped than harmed by further tests or treatments to reduce the risk of disease or its complications."[3]

16 Screening stems from the public health goal of improving the health of populations. Screening is not the same as testing during diagnosis or treatment. In screening, the individual tested usually has no symptoms and is undiagnosed.

17 Screening involves using information obtained through some process of questioning or testing to identify whether a person has a high or low likelihood (also known as "risk") of being affected by some condition, factor, or potential factor that could affect that person's health or, in the case of a pregnant woman, the health of the infant.

18 Screening places people in two groups - one containing those who are at more risk or are more likely to have the screened condition; and the other containing those who are at less risk or are less likely to have the screened condition.

19 Screening may occur opportunistically. Opportunistic screening occurs when someone presents to a health service for one reason and the opportunity is taken to initiate a relevant screening process. Opportunistic screening may also occur when a person presents to a health service on their own initiative with the specific aim of being screened. Because of the nature of opportunistic screening, it tends to occur outside a framework that allows for systematic quality assurance processes, including monitoring and evaluation. Examples of opportunistic screening in New Zealand include prostate cancer screening and chlamydia screening. Most screening that occurs during pregnancy (including the use of ultrasound scans) is also opportunistic.

20 Screening also occurs as part of organised population-based screening programmes. Screening programmes involve the co-ordinated planning of activities along the screening pathway, as well as formal monitoring, evaluation, and quality assurance.[3]

21 Population-based screening programmes are usually developed and run by the Government and are an organised attempt to ensure all members of a nominated population (for instance, newborn babies) are screened. Examples of organised population-based screening programmes include BreastScreen Aotearoa, the National Cervical Screening Programme, and the Newborn Metabolic Screening programme.

22 Screening is more than just the process of questioning or testing. Screening involves a set of organised activities, known as a 'screening pathway'. The screening pathway is designed to prepare people for screening including providing information for screening-related decision-making; setting in place options for further investigation, treatment, or other support in the event of a high-risk finding; and monitoring the screening programme's effectiveness.

23 Screening can reduce the morbidity (the health impact as measured by the incidence or rate of sickness of the disease or condition) or mortality (number of deaths) of the screened condition. Therefore, screening has the potential to prevent the development of disease and premature death and improve the quality of life.[3-5]

24 However, screening can also cause harm. Some harm from screening may be short term and relatively minor, such as the inconvenience of participating and discomfort or pain caused by that participation.

25 Longer-term and more serious harms can occur after screening, for example:

26 a false-negative result (false reassurance) – where a person has the condition being screened for but the test returns a negative or low risk result

27 a false-positive result (false alarm) – where the test result incorrectly says the person has the condition being screened for, so the person is recalled for further testing, before finally being given the all clear

28 over-diagnosis, over-treatment, and the possibility of over-aggressive treatment.

29 New Zealand's population is becoming increasingly diverse. Organised screening programmes are moving into realms that may involve broader social factors such as stigma around family violence, HIV or disability status. Consideration of ethical and social issues must therefore include contextual factors to ensure screening programmes meet the needs of consumers, practitioners, and the communities we live in.

30 Before decision-makers assess the ethical and social issues arising out of a proposed screening programme, they need to know what those ethical and social issues are. This project aims to help decision-makers to identify those considerations.

2.2 Screening criteria

31 In 2003, the National Health Committee developed criteria to assess screening programmes.[3] These criteria are to help decision-makers to decide whether a screening programme is likely to be of benefit to the population.

32 One criterion requires consideration of ethical and social issues. In its commentary on this criterion, the National Health Committee said (at page 26):

> "There should be evidence that the complete screening programme (identification and invitation, test, diagnostic procedures, treatment/intervention) is clinically, socially and ethically understood and acceptable to health professionals and the wider public."[3]

33 The criterion sets out a complex task requiring information, explanation and justification, and accessibility to both health professionals and the public.

34 In discussing the criterion, the National Health Committee considered the important ethical and social considerations were balancing harms and benefits, supporting informed choices in accepting an invitation for screening, enhancing equity in access to screening services, and reducing inequalities.

35 Since the development of the criteria, further questions have been raised about how to give a fuller account of different factors that need to be considered when thinking about ethical and social issues in screening. This is particularly important because screening activity has widened from a focus on disease, which was the subject of National Health Committee's concerns in 2003, to screening for disability and behavioural conditions.

2.3 Definition of a consideration

36 NSAC takes the view that considerations are matters that decision-makers and service providers must take into account when they are assessing potential screening programmes. The balance and weight to be given to each ethical and social consideration will vary depending on the circumstances and the screening activity under assessment.

37 This project aims to develop a framework to support decision-makers in identifying the ethical and social considerations to be taken into account when making robust policy decisions about screening. The framework needs to be flexible, incorporate good practice, and provide guidance for problem-solving. The framework will be a living document that can take future developments into account.

3 Ethical and Social Considerations from the Literature

38 This section introduces the ethical and social considerations identified from the literature on screening activity.

39 The literature review that was undertaken for this section was not exhaustive. The review was conducted to identify overarching themes about ethical and social considerations in screening.

40 The literature review undertaken for this section was not exhaustive. It involved searching three electronic databases (Medline, CINAHL, and PsycINFO) and the grey literature, employing the following search strategy nationally and internationally: 'communication and 'cultural diversity' or 'culture' or 'ethnic groups' or 'societal views' or 'social issues' or 'choice behaviour' and 'screening', limited to 2000 to 2007 and English language articles.

3.1 Summary of findings from the literature review

41 The key ethical and social considerations identified from the literature relate to:

- informed choice and informed consent
- balancing benefits and harms
- equality and equity
- maintaining trust and confidence
- technology and practice.

3.2 Request for feedback

42 Based on your experience and knowledge, we would like your feedback on whether the considerations listed in paragraph 41 are relevant to the New Zealand context and if there are other ethical and social considerations that policy decision-makers should take into account when making dec sions about a screening programme. We would also like to know whether you think specific aspects of any of the key ethical and social considerations should be prioritised in the New Zealand context. Please use the submission form at the end of the document to provide your feedback.

Relevance for New Zealand of ethical and social considerations in the literature

Q1 Are the ethical and social considerations identified from the literature and discussed in this discussion paper relevant to New Zealand? Please explain why or why not.

Q2 Are there other important ethical and social considerations relevant to New Zealand that are not covered or not covered adequately in this discussion paper? Why are these considerations important?

Q3 How should the different considerations be balanced against each other? Should some considerations be given more weight than other considerations? If so why?

3.3 Informed choice and informed consent

43 Screening is based in the public health goal of improving the health of populations. Evidence that screening programmes can improve health in populations comes from large-scale studies, usually randomised controlled trials. These trials usually invite large numbers of people (up to hundreds of thousands) to participate in studies that quantify how much benefit there is of screening for a particular condition.

44 There may be differences between people who choose to participate in screening trials and those who do not. Therefore, all analyses based on these trials are done on an 'intention to screen' basis– that is, according to the group into which trial participants were randomised, regardless of whether those in the screening and control arms actually participated in screening.

45 Because only a certain proportion of those invited to participate in a trial will do so, the risks, benefits, and costs calculated from these trials depend on the participation rate achieved. For example, 60 percent of people invited to participate in a study of bowel screening in the United Kingdom accepted the invitation.[4] This study found that mortality decreased about 15 percent after 10 years among those invited to screen. Had the participation rate been lower, the mortality benefit would have been less.[5]

46 If there are much lower levels of participation once screening is delivered in the community, then the balance of benefits and harms and the cost effectiveness of screening which were seen in the trial cannot be assured.

47 However, the emphasis on getting high participation levels has led to concern that consent processes have been aimed at persuading people to be screened rather than providing people with balanced information in order to make an informed choice about screening.[3, 6]

48 Screening programmes can take an opt-on or opt-off approach (also known as an opt-in or opt-out approach). An opt-off approach is when individuals are assumed to have agreed to be part of a population based screening programme when they consent to having a screening test, unless they actively request the contrary (that is, they actively opt-off the programme). This approach means the person's records are stored on a central register, so they can be recalled automatically and this information is used to monitor that the screening programme is achieving its aims.

49 An opt-off approach does not remove the requirement for informed choice relating to screening, but the default position is participation; an active effort is needed to opt out of participation.

50 An opt-on approach means people have to actively agree to be part of a screening programme. In New Zealand, the National Cervical Screening Programme was initially an opt-on programme. Participation under this system was very low, only 20–40 percent. By contrast, when the programme was changed to an opt-off approach in 1993, participation increased dramatically. The initial opt-on approach was one of the flaws of the initial screening programme design that the Ministerial Inquiry into Under-reporting of Cervical Smear Abnormalities in the Gisborne Region[7] noted,. The Inquiry noted that it was already clear in 1990, when the opt-on system commenced, that this was not best practice internationally.[8]

51 The literature also identifies issues and themes relating to informed consent in screening, including:

- information provided to consumers[10-31]
- communication and trust between practitioner and consumer[32-37]
- community or cultural values affecting informed choice[9-18]
- protecting people who are not fully autonomous decision-makers.[19-21]
- the routine nature of some screening leading to concern that some participants were not aware that screening was occurring or was optional[9, 11-16, 22-32]

52 These are detailed in NSAC's *Improving Informed Consent in Screening* discussion paper.[2]

53 Problems may also exist with the practical implementation of informed consent, for example time constraints, the availability of quality information, and the availability of appropriate translation services.[9, 16, 24, 25, 29, 33-35]

54 New Zealand has a legislative framework that creates a consumer-centred approach to informed consent and choice. The combined effect of the Health and Disability Commissioner Act 1994 and the Code of Health and Disability Services Consumers' Rights 1996 makes informed choice and informed consent required principles in any health-care setting in New Zealand. The Code of Health and Disability Services Consumers' Rights 1996 includes the right to:

- effective communication (right 5)
- be fully informed (right 6)
- make an informed choice and give informed consent – that is, to make voluntary decisions and give consent freely (right 7).

55 Right 7 of the Code of Health and Disability Services Consumers' Rights 1996 also sets out the requirements where a person is not competent to make an informed choice and give informed consent. There is little guidance in the Code about the key concept of competence or capacity, although the literature suggests that a person needs to be able to understand and weigh or balance the information provided.[19, 20]

56 For a person to be informed under the New Zealand legislative framework they need to know the facts about a particular condition and the risks and benefits associated with screening. This is not always easy to achieve because screening involves complex information that can be difficult and time-consuming to communicate; for example the risks associated with screening and the stages of the screening pathway.

57 Informed choice is linked to informed consent. Without the freedom to make a choice about whether to consent to a health-related activity, a person cannot give informed consent. The decision whether to participate in screening should be made by the individual, and this decision should represent an informed choice by that individual to participate or not.

58 Informed choice means a consumer can choose to participate, choose not to participate, or choose not to continue participating. However, there is evidence that consumers follow a recognised, prescribed, or normative pathway of care, particularly when their practitioner recommends it.[13, 32, 36, 37]

59 The routine nature of screening activities may obscure the fact that screening is optional and that a person can refuse to participate.[10, 34, 39, 50, 53, 54] The literature suggests that attempts by women to opt out of routine antenatal screening has lead to them being labelled difficult or uncooperative.[11-15, 31] This form of labelling and negative reaction may also occur in other areas of screening activity where that screening activity is widely supported or viewed as socially desirable.

60 An important part of informed consent is the aspect of being 'informed' or receiving information. The literature identifies issues about the quality of information available in screening, particularly its clarity, accuracy, usefulness, and recency,[28, 38-40] including information about the risks and limitations of screening and screening tests.[41, 42].

61 Receipt of information is not enough to ensure a person understands the consequences of screening.[42, 43] Information needs to be communicated in a user-friendly way. The literature suggests information provided may not always be appropriate to the consumer. It may be pitched at the wrong education level,[26, 44], be in a language the consumer does not understand or understand well[44-47], or use concepts that have little meaning to the consumer. Research indicates that the literacy level of health literature can be higher than that of the person for whom it is intended.[48] This may be an area of concern in New Zealand given that research indicates a significant percentage of New Zealanders have a relatively low level of literacy.[49]

62 Due to the importance of informed consent in screening, NSAC's Informed Consent Working Group has developed a supplementary discussion paper, *Improving Informed Consent in Screening*. [2] That paper contains a more detailed discussion about informed consent, and also separately asks for your feedback.

Questions about informed choice and informed consent	
Q4	What are the most effective ways of informing potential participants or the wider public about the advantages and disadvantages of a screening programme?
Q5	Under what circumstances should participation in a screening programme be on an opt-on (opt-in) basis? Under what circumstances should participation in a screening programme be on an opt-off (opt-out) basis?
Q6	What practical ways could be used to best meet the screening needs of individuals who are unable or only partially able to make informed choices and give informed consent for themselves?
Q7	When might the requirements for informed consent conflict with successful recruitment into a screening programme? What are the best ways to manage such conflict?

3.4 Balancing benefits and harms

63 Screening has the potential to prevent the development of disease and premature death and improve the quality of life. This means some people who participate in screening will receive significant benefit from participation.

64 However, some people who participate in screening will receive little personal benefit from it and may suffer some inconvenience. Others will experience more-significant harm. For instance, some people who participa e in screening will receive a positive result and elect to proceed to further, often more-invasive, testing even though it will eventually be discovered they are not affected by the condition being screened for (that is, they receive a false-positive result from the screening text).

65 The anxiety caused by a false-positive result is an obvious harm even if most of those people go on to receive a negative or clear result. However, the further testing may itself be the source of harm. For example, the usual follow-up test for bowel cancer is a colonoscopy. One of the procedure-related risks of a colonoscopy is perforation of the bowel, which can require emergency medical attention.

66 A false-negative result also has serious implications as people receive false reassurance that they do not have the condition being tested for, and this may lead them to ignore symptoms of that condition or may lead to that condition being ruled out as a 'possibility' because of the screening result.

67 The National Health Committee considered that the balancing of benefits and harms was an important consideration when assessing a screening programme. However, identifying benefits and harms is not always straightforward.

68 Each type of screening has different benefits and harms associated with it, and the acceptable balance of benefits and harms at a population level may differ with each screening activity. Some harm, for instance false positives and false negatives, will exist with all forms of screening activity. However, each screening activity may have different rates of each result, and there may be different levels of acceptability of these rates, depending on the condition being screened for, the subsequent screening pathway, and the broader social context. When the detection rate is high, there will probably be more false positives and more over–diagnosis than when the detection rate is low.

69 Some screening activity may have harms associated with it which are specific to the condition being screened for. For instance, screening for a communicable or infectious disease (such as HIV or Hepatitis B) or screening for a disability (such as Down syndrome) may result in social harm including stigma or discrimination. Screening for genetic conditions may affect a person's employment or ability to obtain insurance.[50]

70 The literature identifies various harms from participation in screening, including:

- anxiety, especially among people recalled for further testing
- psychosocial harms (for example, fear; poor self-perception, self-esteem or self-worth; a finding of sickness in those who consider themselves well; and implications of being labelled 'sick')[6, 26]
- economic harms (for example, the costs of treatment, medical insurance problems, and possible lost employment)[29, 51, 52]
- social harms (for example, possible stigma or discrimination associated with diagnosis)[53-55]
- physical harms (for example, the side effects of screening or treatment, over-treatment, over-diagnosis, and treatment that proves ineffective)[6, 56]
- morbidity and quality of life problems[57]
- harms resulting from false positives and false negatives[6, 27, 51, 53, 58, 59], including residual anxiety following a false positive[26]
- negative screening that reinforces unhealthy lifestyles[6]
- the medicalisation and over-medicalisation of conditions (for example, the medicalisation of pregnancy and the potential for negative labelling of people with certain disorders or conditions)[60, 61] and
- unmet expectations among participants arising from a lack of awareness about the limitations of screening.

71 When considering and balancing the benefits and harms associated with screening, different perspectives need to be considered. The balance of benefits and harms at a population level may be different to the balance at an individual level. In making a decision about whether there should be a screening programme, policy decision-makers must generally balance the benefits and harms at the population level, because a screening programme is initiated by the Government to improve the health of a population as a whole.

72 Special attention is needed to show benefits and harms are distributed among the population, and to ensure that vulnerable members of the population do not bear a disproportionate part of the burdens of a screening programme or forgo their share of the benefits.

73 Vulnerability can exist in several areas. It can arise out of personal or social barriers to screening, for instance, a person may be vulnerable because they are unable to understand the information supplied or to consider and make or express a decision. Vulnerability can also be caused by institutionalisation; for instance, when an individual is subject to the formal authority of others.

74 Children are particularly vulnerable in the screening context. Conflict may exist between what is in the best interest of the child and what is in the best interests of the child's family,[62, 63] or how the screening may affect the child's future rights 'not to know' (for instance, screening for late-onset conditions).[62, 64] Children can also be subject to screening that has the potential to label them as slow, bad, or mad,[14] and this may negatively affect their future. As with adults, many children screened may not benefit individually from their participation in the screening, but, unlike adults, they are more likely to have limited or no understanding of how their participation contributes to the public good.

75 The benefits of screening have generally been depicted at a population level as reducing morbidity and mortality of the condition being screened for, and at the individual level as identifying individuals early who have a condition and who can then access early treatment.

76 Other possible benefits of screening include those associated with having information. One of the criteria for evaluating a screening programme is the presence of appropriate treatment for the screened condition.[3] However, even when no treatment is available, information about health status could be regarded as an individual benefit because other choices may become possible or be better-informed.[14, 54] If this is the case, then this may change the health improvement premise on which screening is based.[63, 65]

77 There is a related issue of who benefits from having information from screening.[62, 66-69] This is pronounced in newborn screening.[62] For example, screening for a rare disorder that has no treatment (for instance, Duchenne muscular dystrophy) could help prevent the prolonged 'diagnostic odyssey' that some families experience seeking answers – a benefit to the both the screened child and their family. Screening might also provide information to help the parents in their future reproductive choices (a family or parental benefit). This second benefit does not accrue to the person who was screened.

78 If the benefit of screening can accrue to someone other than the person who was screened, then it also raises issues about the confidentiality of information and who has a right to know about someone else's health.[62, 66-69]

79 The benefits and harms of screening can be viewed as wider than just those affecting the individual being screened. Screening can affect families, communities, population sub-groups, and society as a whole. Therefore, individuals who are offered or take part in screening are not the only stakeholders of any screening programme.

Questions about balancing benefits and harms

Q8 What are the best ways to help individuals to balance the benefits and harms of screening?

Q9 What counts as a benefit of screening? Is information a benefit in itself? If so, what sort of information counts as a benefit?

Q10 Where information about the presence or absence of a condition is considered a significant benefit, should the value of that benefit be taken from the viewpoint of the person screened or is it enough for the information to be beneficial to someone else?

Q11 How (if at all) do the benefits and harms of screening change when the findings have implications for family members as well as for the person being screened?

Q12 Should screening be offered if a condition is not treatable or if there is no standard pathway of care?

3.5 Equality and equity

80 The National Health Committee considered that equity in screening required equity of access to the screening programme and to the screening pathway. In the National Health Committee's view, screening providers have a responsibility to minimise barriers to screening.

81 Health inequalities are differences in health between population groups. Health inequalities can arise for various reasons and are not inherently bad. For example, we would not expect a group of 10-year-olds to have the same health as a group of 80-year-olds.

82 Health inequities are differences in health that are unfair or unjust between population groups. Health inequities exist between different socioeconomic groups, ethnic groups, and people living in different geographical locations. Some inequities may be due to differences in the distribution of health determinants between population groups (for example, socioeconomic position and good quality housing) or differences in access to and the quality of health care.[70]

83 Health inequity often occurs when the constraints and barriers influence or reduce the choices available to some groups in the population. The distribution of the determinants of health between population groups may also unevenly affect the choices of some population groups.

84 Screening should not continue or increase health inequity. If some groups within society – for instance, cultural, ethnic, linguistic minorities or disabled people – are less likely to participate in screening, this may increase health inequalities. This increase in health inequalities risks increasing health inequity. Understanding and respecting people's reasons for not participating in screening while at the same time ensuring equitable opportunity to participate may be important considerations for New Zealand.

85 Differences in access to health services means that increased overall pressure on screening services (say from increased activity levels) may increase inequity for disadvantaged population groups. Delays in accessing publicly funded services may negatively affect those people and populations who are less likely to afford private health services.

86 The literature identifies barriers that operate to reduce access to screening. [6, 71-78] Barriers can be personal (for instance, geographical inaccessibility, lack of knowledge, lower socioeconomic status, inadequate transport, lack of available childcare, or poor communication, linguistic, or numeric ability). Barriers can be also be societal (for instance, stigma and discrimination arising out of screening or the perceived possible impact of screening on employment or insurance) and can particularly affect those who are already vulnerable.

87 Individuals cannot be considered separately from their environment. A person may come under societal or cultural pressure to participate in screening. People who do not participate may be regarded as irresponsible or difficult (and personally responsible for any negative result following their decision not to participate in screening).[22, 33, 34, 38-40] This societal or cultural (or religious) pressure may be more pronounced in cultural or religious groups where adherence to social norms is valued. Members of those groups may be more likely to engage in screening behaviour.[79]

88 Culture, religion, or spiritual beliefs may affect how ill health is perceived, and this perception may affect screening behaviour. Where ill health is viewed as a punishment, people may be less likely to engage in screening behaviour.[88-90] Other beliefs that may also discourage screening include the belief that cancer is caused by thinking about the disease or that ill health is destiny, fate, or otherwise preordained, so cannot be altered.[73, 77, 80-82] Some groups fatalistic views on cancer may be realistic assessments of their community's experiences of cancer.[81]

89 However, cultural beliefs may not be the only factor affecting screening decisions. Research in New Zealand found that cultural beliefs about the causes of cancer (including fate, unbalanced yin and yang, or poor qi) did not influence the uptake of cervical cancer screening.[83]

90 Cultural and societal norms and expectations may influence an individual's decision to participate or not participate in screening. Research looking into informed choice in the context of antenatal screening found differences among Northern European, Southern European, and Asian respondents in terms of the expected role of parental choice.[84, 85] This may reflect relationships being deemed more important than individualism.

91 Different cultural and religious groups may give different weight to the relative value and role of community, family, and individual.[17] A study looking at Turkish, Surinamese, and Dutch women's decisions to participate in antenatal screening for Down's Syndrome found that Turkish women tended to emphasise the importance of family in the decision-making process more than the other two cultural groups.[86]

92 Whether members of particular cultural or religious groups engage in screening may depend on the opinions or influence of family, community leaders, or the wider community – especially, where the physical or psychological health of communities are believed to be intertwined.[43, 99, 100] These points may be relevant to the New Zealand context given the known importance of whānau, aiga, and other extended family structures.

93 Differing cultural or religious values relating to gender and gender expectations may also influence screening behaviour, for example, where groups value the importance of machismo.[87] Machismo includes not showing or admitting to weakness, so ill health may be viewed as a weakness. Cultural beliefs of this nature make it unlikely that men in these groups will engage in screening behaviour.

94 Research into breast cancer and cervical cancer screening in New Zealand identified barriers to participation, some personal, some societal or cultural, and others reflecting structural or institutional barriers to screening.[83, 88, 89]

95 Structural or institutional barriers can prevent people from seeking health care. Institutional barriers include a poor cultural or service 'fit' with individuals or groups, inaccessible venues, institutional discrimination, and a 'one size for all' approach to the provision of health care.[90] The Task Force on Community Preventive Services found evidence that structural barriers negatively affected breast and colorectal cancer screening participation.[91]

96 New Zealand research suggests institutional constraints can result in disengagement with the system and health-care inequalities.[92] Research indicates that some minority groups consider there is discrimination in health-care delivery which they experience as a barrier to using services.[93]

97 Important operational barriers include the gate keepers to the health-care system.[72] Health professionals play an important role in providing information about screening and recommending or not recommending screening activity. A patient may proceed with screening because their doctor recommended it or not participate in screening because their doctor did not recommend it.[10, 13, 34] Certain groups, particularly ethnic minority groups, may receive less information about screening than other groups receive. This lack of information may account for some of the disparity in screening rates and the impact of screening programmes on ethnic minority health outcomes compared with those of other groups.

98 Barriers to screening may exist with any proposed screening programme. When assessing a screening programme, a policy decision-maker must consider what barriers might exist and how the programme could operate to reduce those barriers and reduce health inequalities, particularly for under-screened populations.

> Questions about equality
>
> Q13 When (if ever) is it acceptable or fair to use a screening programme that secures public health gains but risks increasing health inequalities? When (if ever) is it acceptable or fair to end a screening programme because it is increasing health inequalities?
>
> Q14 To what sort of harms (if any) is it acceptable to expose the majority of participants in a screening programme if doing so helps to secure health gains for the whole population?

3.6 Maintaining trust and confidence

99 An important part of any screening programme is ensuring the trust and confidence of participants, the public, and professionals in the screening programme and in the wider health system. The erosion of trust in the health system could have severe consequences. Research suggests that a person's trust in government institutions is an important part of their decision to participate in health-care activity, particularly screening.[94, 95]

100 Trust and confidence are important factors given that the people making the decision about a potential screening programme and the people offering screening are generally those with power, knowledge, and information.[96] The offer of screening or the existence of a screening programme may imply that it is well supported by best practice and evidence and is socially accepted.[12] Some screening activity may be supported by evidence or best practice, but other screening activity may not be so supported.

101 Ensuring trust and confidence in screening programmes can be difficult to quantify. However, two areas that can promote trust and confidence in a screening programme are quality assurance and privacy and confidentiality.

102 Quality assurance mechanisms make sure the screening programme achieves its goal of improving the health of the population, while at the same time deals with disparities in the impact of screening and treatment.[76]

103 Quality assurance begins before a programme is implemented and includes consideration of how the screening programme is or will be responsive to the needs of different eligible groups within the population. In particular, pre-implementation analysis should consider how under screened populations or populations that suffer disproportionately from the condition being screened for will be targeted.

104 A second aspect of quality assurance relates to how information is obtained, maintained, used, disclosed, and disposed of. When considering a screening programme, aspects that need to be considered are what information will be collected, how it will be used, and who will have access to it.

105 How information is collected, used, and disclosed are also important considerations relating to the privacy and confidentiality associated with a screening programme.[48, 54, 110, 111]

106 New Zealand has a legislative framework that requires health agencies to ensure that health information is collected, used, held, and disclosed in accordance with the Health Information Privacy Code 1994.[97]

107 The Health Information Privacy Code 1994 applies the 12 generic principles of the Privacy Act 1993 to the health and disability sector. The Code covers the collection (rules 3 and 4), storage and security (rule 5), accuracy (rule 8), and retention (rule 9) of information. The Code also limits the further use (rule 10) and disclosure (rule 11) of health information collected.

108 Privacy and confidentiality are important requirements of the health system. Privacy and confidentiality assumes greater importance in screening because health information and material (for instance, tissue and blood) is obtained from the screening pathway.[66, 98] Issues with privacy and confidentiality have been raised in New Zealand in relation to the Newborn Metabolic Screening Programme, particularly the storage of, secondary use of, and third-party access to samples obtained as part of the programme.[99] Secondary use and third-party access to the samples for research require formal approval from a Health Research Council accredited ethics committee.

109 Particularly complex issues may rise in relation to genetic screening, for instance, whether family members have a right to know of any genetic concerns that may affect them[16, 36, 75, 79, 113] or whether screening results may be disclosed to third parties such as insurance providers and employers.[66, 98]

Questions about maintaining trust and confidence

Q15 What are the best ways to maintain trust and confidence in screening programmes and in the people who staff those programmes?

Q16 What are the most obvious threats to maintaining trust and confidence in screening programmes and in the people who staff those programmes?

Q17 What are acceptable ways to communicate screening results to the person screened? What ways are unacceptable? Is it acceptable to communicate positive and negative results in the same way?

Q18 How will trust and confidence be affected if a patient's screening records or samples were to be used for purposes outside the screening programme, for instance, for research?

3.7 Technology and practice

110 Most screening practice is influenced by new technology. Likewise, the development of new treatment techniques, drugs or medical devices also influences screening activity and practice.

111 Advances in medical technology since the late 1980s have given health professionals the ability to test for more conditions than in the past. As new screening tests are developed, the number of potential screening programmes increases. There have been significant advances in the ability to test for genetic conditions, including for late-onset disorders.[51, 66, 98, 100]

112 Over time, medical screening technologies originally applied to one purpose are used for other applications, for example diagnostic ultrasound (originally used for detecting brain tumours).[9, 27] However, this wider range of technology and equipment use may not be evidence based and may not be cost-effective.

113 Health professionals play an important role in recommending and providing screening, and in providing information to participants. In doing so, they may be influenced by incentives other than the consumer's best interests. Funding may be based on screening participation rates, for example, creating an incentive to maximise participation rates regardless of actual benefit; private practitioners may be motivated to achieve a return on an investment on new equipment. [22, 50, 58] .

114 The British Medical Association has expressed concern that private clinics are offering screening tests without providing an appropriate screening pathway.[100] Related to this is the issue of direct marketing and self testing. Concerns have been raised about the lack of evidence of the quality of self tests, the lack of established pathways of care,[37, 51, 72, 100-104] and the harms that may be caused by self testing. [103, 105]

115 When private clinics offer screening tests or people use direct-to-public tests, the health system is left to deal with the results of the screening tests [100] This means that those who can afford to do so can pay to get their screening done, but will still end up in the public system once their condition is diagnosed.

116 In New Zealand, special consideration may be required of cultural values and practices when reviewing new technology and in particular the impact that new technology or practice may have on a Māori world view.[18]

117 The relationship between Māori and the wider world may need to be considered when reviewing new technologies.

Questions about technology and practice

Q19 How could stakeholders and the public usefully contribute to decisions about the application of new or developing technologies and practices as they relate to screening?

Q20 What evidence should be required before new screening technology is implemented? What evidence should be required before the use of technology is expanded beyond the use for which it was originally used?

4 Other Ethical and Social Considerations Relevant to New Zealand

118 Section 3 set out five key ethical and social considerations for policy decision-makers and those tasked with implementing and delivering screening programmes. These five key themes are:

- informed choice and informed consent
- balancing benefits and harms
- equality and equity
- maintaining trust and confidence
- technology and practice.

119 The literature largely comes from North America and the United Kingdom. This means considerations identified in the literature cannot be assumed to be relevant to New Zealand, which has a distinctive cultural and ethnic make-up and distinctive health system.

120 The history and context of screening in New Zealand (including the 1987 Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and into Other Related Matters (commonly called the Cartwright Inquiry)[7], the Ministerial Inquiry into Under-reporting of Cervical Smear Abnormalities in the Gisborne Region[8], and more recent publicity about the retention of samples obtained from the Newborn Metabolic Screening Programme[106] may influence how screening is perceived in New Zealand. This history may also affect the importance or primacy to be accorded to particular ethical and social considerations.

121 New Zealand's specific heritage, including the Treaty of Waitangi and its underlying principles of Partnership, Protection, and Participation, place an obligation on the New Zealand health and disability sector to identify and reduce health inequalities. This obligation is particularly important in the New Zealand context where Māori, Pacific, and non-Māori non-Pacific health needs may be different.[90]

122 Research shows that the implementation of the National Cervical Screening Programme has reduced the incidence of cervical cancer and cervical cancer deaths in New Zealand in both Māori and non-Māori women.[107, 108] .

123 However, research evaluating the National Cervical Screening Programme and BreastScreen Aotearoa identified barriers to cervical cancer and breast cancer screening in New Zealand, including lack of knowledge, fear, economic reasons, pain or discomfort, and linguistic issues.[88] Research also suggests that Māori women are less comfortable having cervical smears than Pākehā women are,[75] while both Māori and Pacific women experience higher levels anxiety than Pākehā women before undergoing mammography screening.[109]

124 Recent research looking at participation in cervical cancer screening by New Zealand Chinese women found that age, marital status, and place of birth were important factors influencing screening behaviour. The research identified barriers such as lack of knowledge, not knowing where to go, and language issues.[83, 89]

125 Finally, the need to consider the limited health dollar in New Zealand may also affect the ethical and social considerations relevant in New Zealand. Dilemmas can exist between the right of individuals to participate in the health system and the right of society to determine how limited resources are used.[110, 111] A focus on financial cost-effectiveness may result in other relevant factors – such as the considerations set out in this paper – being excluded from analysis.

Question about further comments or suggestions
Q21 Do you have any other comments or suggestions on ethical and social considerations in screening, or the considerations identified in this consultation document?

5 About the National Screening Advisory Committee

5.1 National Screening Advisory Committee

126 The Director-General of Health uses advisory committees to obtain independent, strategic advice on areas of particular interest.

127 Following recommendations that there be a specialist advisory committee to look at screening issues, the then Minister of Health and Director-General of Health agreed to set up the National Screening Advisory Committee (NSAC). NSAC came into existence in July 2004.

128 The Director-General of Health appoints NSAC members.

129 NSAC is not part of the National Screening Unit (NSU). However, the NSU is a stakeholder and the NSAC secretariat has previously been staffed by the NSU.

130 NSAC's work programme addresses key issues in screening. These issues have been identified in discussion with the Ministry of Health, the National Screening Unit, the National Health Committee, health practitioners, and consumer groups.

5.2 Ethical and Social Considerations Working Group

131 This discussion paper was developed by the Ethical and Social Considerations Working Group, a subcommittee of NSAC.

132 The NSAC sponsors for this project are Chris Parkin (until June 2009), Ross Lawrenson (since June 2009), and Orana Harris.

133 Working group members are Nicola Deveraux (National Screening Unit), Alec Ekeroma (University of Auckland, Auckland District Health Board, NSAC member), Barbara Holland (Consumer Advocate, NSAC member), Kara Hudson (National Screening Unit, NSAC Secretariat), William Michael (Ministry of Justice), Chris Parkin (Bioethicist, since July 2009), Cordelia Thomas (Office of the Health and Disability Commissioner), and Caroline Shaw (University of Otago, NSAC member).

5.3 Contacting Us

134 All communications about this project should be through NSAC's secretariat:

Secretariat, National Screening Advisory Committee
Ministry of Health
PO Box 5013
Wellington

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Your Submission

Please provide your contact details here.

Name	
If this submission is made on behalf of an organisation, name that organisation here	
If applicable, briefly describe the organisation including who you represent	
Postal address or email	
Interest in this topic	

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under the Act please make this clear in your submission, noting why you would like the information to be withheld.

If information from your submission is requested under the Official Information Act 1982., the Ministry of Health on behalf of the National Screening Advisory Committee, will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, and you check the following box, the Ministry will remove your personal details from the submission.

☐ I do not give permission for my personal details to be released to people under the Official Information Act 1982.

The National Screening Advisory Committee will acknowledge all submissions and will send a summary of submissions to people who request the summary. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission for the release of their personal details, the name of the organisation will be given if supplied.

Do you wish to receive the summary of submissions?

☐ Yes

☐ No

Relevance for New Zealand of ethical and social considerations in the literature

Question 1 – Are the ethical and social considerations identified from the literature and discussed in this discussion paper relevant to New Zealand? Please explain why or why not.

Question 2 – Are there other important ethical and social considerations relevant to New Zealand that are not covered or not covered adequately in this discussion paper? Why are these considerations important?

Question 3 – How should the different considerations be balanced against each other? Should some considerations be given more weight than other considerations? If so, why?

Informed Consent

Question 4 – What are the most effective ways of informing potential participants or the wider public at large about the advantages and disadvantages of a screening programme?

Question 5 – Under what circumstances should participation in a screening programme be on an opt-on (opt-in) basis? Under what circumstances should participation in a screening programme be on an opt-off (opt-out) basis?

Question 6 – What practical ways could be used to best meet the screening needs of individuals who are unable or only partially able to make informed choices and give informed consent for themselves?

Question 7 – When might the requirements for informed consent conflict with successful recruitment into a screening programme? What are the best ways to manage such conflict?

Balancing Benefits and benefits

Question 8 – What are the best ways to help individuals balance the benefits and harms of screening?

Question 9 – What counts as a benefit of screening? Is information a benefit in itself? If so, what sort of information counts as a benefit?

Question 10 – Where information about the presence or absence of a condition is considered a significant benefit, should the value of that benefit be taken from the viewpoint of the person screened or is it enough for the information to be beneficial to someone else?

Question 11 – How (if at all) do the benefits and harms of screening change when the findings have implications for family members as well as for the person being screened?

Question 12 – Should screening be offered if a condition is not treatable or if there is no standard pathway of care?

Equality and Equity

Question 13 – When (if ever) is it acceptable or fair to use a screening programme that secures public health gains but risks increasing health inequalities? When (if ever) is it acceptable or fair to end a screening programme because it is increasing health inequalities?

Commented [SD1]: Inequiti s?

Question 14 – To what sort of harms (if any) is it acceptable to expose the majority of participants in a screening programme if doing so helps to secure health gains for the whole population?

Maintaining Trust and Confidence

Question 15 – What are the best ways to maintain trust and confidence in screening programmes and the people who staff those programmes?

Question 16 – What are the most obvious threats to maintaining trust and confidence in screening programmes and the people who staff those programmes?

Question 17 – What are acceptable ways to communicate screening results to the person screened? What ways are unacceptable? Is it acceptable to communicate positive and negative results in the same ways?

Question 18 – How will trust and confidence be affected if a patient's screening records or samples were to be used for purposes outside the screening programme, for instance, for research?

Technology and Practice

Question 19 – How could stakeholders and the public usefully contribute to decisions about the application of new or developing technologies and practices as they relate to screening?

Question 20 – What evidence should be required before new screening technology is implemented? What evidence should be required before the use of technology is expanded beyond the use for which it was originally used?

Any other comments

Question 21 – Do you have any other comments or suggestions on ethical and social considerations in screening or the considerations identified in this discussion paper?

Please return your submission to

Secretariat, National Screening Advisory Committee
Ministry of Health
PO Box 5013
Wellington

Document 2

National Screening Advisory Committee

Informed Consent Working Group

Improving Informed Consent in Screening

Discussion Paper

June 2010

DRAFT

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Contents

1 Introduction to this Paper

1.1 Purpose of this discussion paper

1 This discussion paper introduces and seeks feedback on the key issues and themes about informed consent in screening.

2 This paper was written by the Informed Consent Working Group, a subcommittee of the National Screening Advisory Committee.

1.2 Role of the National Screening Advisory Committee

3 The National Screening Advisory Committee (NSAC) provides independent advice to the Director-General of Health on "health and disability screening policy, practice and research, including cancer screening and genetic screening".[1]

4 NSAC is not part of the Ministry of Health's National Screening Unit (NSU). See section 6 for more information about NSAC.

1.3 Project on the ethical and social considerations of screening

5 NSAC is undertaking a project to provide guidance to policy decision-makers about the ethical and social considerations of screening in the health and disability sectors. NSAC would also like this project to contribute to a review of the National Health Committee's *Criteria to assess screening programmes.*[2].

6 Informed consent is an important part of the project. Improving informed consent in New Zealand screening practice requires evidence to be gathered and a common understanding, useful guidance, tools, and relationships to be developed.

7 This discussion paper is a subsidiary paper to NSAC's consultation paper *Ethical and Social Considerations in Screening*.[3] This paper contains more detailed information about informed consent, drawing on a review of relevant literature. However, it is still only a summary of a larger body of knowledge.

1.4 Request for feedback on this discussion paper

8 After you have considered this discussion paper and the broader discussion paper *Ethical and Social Considerations in Screening*, we would like your feedback about any other informed consent issues that are important for screening in New Zealand.

9 We would also appreciate your feedback about good examples of informed consent processes and suggestions about what would most improve current practice.

10 Please use the submission form at the end of this discussion paper to record your feedback.

1.5 Structure of this paper

11 This paper is divided into sections as follows:

- Section 1 introduces the purpose and context of the paper and provides a glossary.
- Section 2 outlines salient factors of the current local context, then describes screening and informed consent and how they have been implemented in New Zealand. The section also notes the nature of available evidence about informed consent.
- Section 3 describes the New Zealand medico-legal context, and refers to the most relevant sections of our Code of Health and Disability Services Consumers' Rights 1996 and the Health and Disability Commissioner's findings that apply to informed consent and screening.
- Section 4 details key issues and themes from the international and local literature about informed consent in screening.
- Section 5 examines the practicalities of implementing informed consent in New Zealand.
- Section 6 describes the National Screening Advisory Committee and the Informed Consent Working Group.
- A list of references follows section 6.
- The submission form for your feedback ends the paper.

1.6 Glossary

12 This paper uses specialised terms which are defined in this glossary. The letter after each term shows the reference from which we adapted our definition:

a Code of Health and Disability Services Consumers' Rights 1996.

b *Merriam-Webster Online Medical Dictionary.* URL: http://www.merriam-webster.com (accessed 1 April 2009).

c National Health Committee. *Screening to Improve Health in New Zealand: Criteria to assess screening programmes*. Wellington: National Health Committee; 2003.

d Health and Disability Commissioner Act 1994.

e A. Raffle and J. Muir Gray. *Screening: Evidence and practice*. Oxford: Oxford University Press; 2005.[4]

f A Barratt et al. Cancer screening. *Journal of Epidemiology and Community Health*, 2002;56(12);899–902.

choice [a]

A decision to:

- receive services
- refuse services
- withdraw consent to services

competence [b]

Having sufficient understanding and memory to comprehend a situation and the nature, purpose, and consequence of any screening activity that a person is considering undergoing.

confidentiality

Health information from or about a patient is divulged only with the permission of the patient. Exceptions may exist in unusual circumstances when it is clearly in the patient's best interests or there is an overriding public good.

decision aid

A tool that helps a patient or health professional to reach a decision. A decision aid can improve a person's understanding of the options and increase their knowledge about potential outcomes (both positive and negative).

false negative [c]

A negative or low-risk test result even though the person has the condition being screened for.

false positive [c]

A test result that incorrectly says a person has the condition being screened for, so the person is recalled for further testing before finally being given the all-clear.

informed choice [a]

A choice that is made by a participant who has all the information that a reasonable participant, in that person's circumstances, needs to make such a choice. A person must be able to make an informed choice in order to give informed consent.

informed consent [d]

Consent to a procedure where consent is:

- freely given by the participant or, where applicable, by any person who is entitled to consent on that participant's behalf; and
- obtained in accordance with the requirements prescribed by the Code of Health and Disability Services Consumers' Rights 1996.

opportunistic screening [c]

Screening that occurs when a person who is presenting to the health system for another reason is also asked a question or offered a test to detect the presence or confirm the absence of a specific condition. Opportunistic screening may be organised to a degree, but lacks a quality assurance process, including routine monitoring and evaluation.

opt-off (or opt-out) screening programme

A screening programme where a participant is automatically enrolled in the programme after their first contact and must actively choose to be removed from the programme.

over-diagnosis [e]

The phenomenon whereby screening diagnoses cases that would never have been clinically manifest in the person's lifetime.

over-treatment [e]

The phenomenon whereby screening leads to treatment of cases that would never have been clinically manifest in the person's lifetime.

participation rate [f]

The proportion of people eligible for screening who are actually screened.

population-based screening programme [c]

A programme in which screening is systematically offered by invitation to a defined, identifiable population.

quality assurance [c]

The detection of problems through external or internal inspection and their correction through systematic activity.

risk [c]

An assessment of the probability that an individual will develop the screened condition in future. A person is "at risk" if they have a high level of risk or susceptibility for a condition or disorder.

routinisation

Where a particular screening activity becomes routine or regarded as part of the standard (and expected) pathway of care.

screening [c]

A health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are affected by, a disease or its complications, are asked a question or offered a test to identify those individuals who are more likely to be helped than harmed by further tests or treatments to reduce the risk of disease or its complications.

screening pathway [c]

The screening process from a participant's perspective. The pathway includes:

- being invited to be screened
- being given information about the purpose of screening and other relevant information
- being questioned or offered a test
- having the test
- receiving the test results
- being assessed and diagnosed if the test is positive.
- undergoing possible treatment
- understanding there are activities to monitor and evaluate all the stages in the pathway.

2 Introduction to Informed Consent

2.1 New Zealand context

13 In New Zealand, a need for the full provision of information to consumers and for informed consent was highlighted by the 1987 Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and into Other Related Matters (commonly called the Cartwright Inquiry).[5]

14 The well-publicised inquiry led to the establishment of the role of Health and Disability Commissioner and the associated medico-legal framework that largely governs consent in New Zealand. The Ministry of Health also set up the National Screening Unit to ensure screening programmes were appropriately managed and evaluated.

15 In 2003, New Zealand's National Health Committee (NHC) published criteria for effectively assessing screening programmes.[2] The NHC noted the increasing emphasis by individuals on informed choice, but that the 'success' of a screening programme was often measured by participation rates and not by the extent to which the programme enabled consumers to make an informed choice about participation.[2]

16 When discussing social and ethical considerations, the NHC observed (at page 26):

> "Potential participants in the screening programme should be given information that allows them to weigh up the probable benefit and harms, using their own values and preferences. Culturally appropriate, evidence-based information should be available for people offered screening to assist them in making an informed decision. This information should also explain the consequences of testing, the possibility and importance of false-negatives and false-positives, investigation and treatment." [2]

17 More recently, people have raised concerns about informed consent in the context of the Newborn Metabolic Screening Programme, as well as issues relating to privacy and the confidentiality of samples obtained as part of the programme.[6] The National Screening Unit is conducting work to ensure women are offered appropriate information to enable them to make an informed choice about screening and the storage and use of samples.

2.2 Definition of screening

18 The National Health Committee (at page 29) defines screening as:

> a "health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are already affected by, a disease or its complications, are asked a question or offered a test to identify those individuals who are more likely to be helped than harmed by further tests or treatments to reduce the risk of disease or its complications".[2]

19 Screening involves using information obtained through some process of questioning or testing to identify whether a person has a high or low likelihood (also known as a "risk") of being affected by a disease, condition, factor, or potential factor that could affect that person's health or, in the case of a pregnant woman, the health of the woman's baby.

20 Screening places people in two groups - one containing those who are at more risk or are more likely to have the screened condition; and the other containing those who are at less risk or are less likely to have the screened condition.

21 Screening is not the same as the testing that occurs during an individual's clinical care. In clinical care environments, individuals usually access care because they are experiencing symptoms and believe that they are unwell. In screening, the individual tested usually has no symptoms and is undiagnosed. Therefore, screening is offered to people who think they are healthy. Diagnostic testing follows a screening result of increased risk or 'positive test'.

22 Screening is more than just the process of questioning or testing. It involves what is known as the 'screening pathway'.

23 The screening pathway consists of providing:

- information about the screening test,
- the screening test,
- the results of the screening testing,
- diagnostic testing if the result is increased risk, and
- any further assessment or treatment if the diagnostic test result comes back positive.

24 Screening can provide reassurance and other benefits for the person who is screened. Depending on the condition being screened for, screening can reduce the health impact (or incidence rate) of the condition, and it can reduce the number of deaths from that condition.[7-9]

25 However, screening can cause participants anxiety, cost, and inconvenience, which can be described in ethical terms as "harms". Some harms from screening may be short term and relatively minor, such as the inconvenience of participating or discomfort and pain caused by that participation.

26 Longer-term and more serious harms can occur after screening, for instance:

- a false-negative result (false reassurance) – where a person has the condition being screened for but the test returns a negative or low-risk result
- a false-positive result (false alarm) – where the test result incorrectly says the person has the condition being screened for, so the person is recalled for further testing, before finally being given the 'all clear' or
- over-diagnosis, over-treatment, and the possibility of over-aggressive treatment.

27 Screening stems from the public health goal of improving the health of the population.

28 The harms and benefits of screening are wider than just for the individual being screened. Screening also affects families, communities, population sub-groups, and society as a whole. Therefore, individuals who are offered or take part in screening are not the only stakeholders of any screening programme.

29 New Zealand's population is becoming increasingly diverse. Organised screening programmes are also moving into realms that may involve broader social factors such as stigma around family violence, HIV or disability status. The informed consent process must therefore take contextual issues into account to ensure it meets the needs of consumers, practitioners, and the communities we live in.

2.3 Definition of informed consent

30 The Health and Disability Commissioner Act 1994 defines *informed consent*,

> "in relation to a health consumer on or in respect of whom there is carried out any health care procedure, means consent to that procedure where that consent—
> (a) Is freely given, by the health consumer or, where applicable, by any person who is entitled to consent on that health consumer's behalf; and
> (b) Is obtained in accordance with such requirements as are prescribed by the Code"[10]
> and where "the Code" refers to the Code of Health and Disability Services Consumers' Rights 1996.[11]

31 The New Zealand legal framework adopts an approach of correlativity; that is, every right has a corresponding duty. Thus, for every consumer right set out in the Code of Health and Disability Consumers' Rights 1996 (the HDC Code), there is a corresponding duty on the provider.

32 The Health and Disability Commissioner has approached the right of informed consent from a consumer-centred viewpoint, although the process involves both the rights and duties of consumers and providers.

33 The HDC Code defines *choice* to mean a decision to receive services, refuse services, or withdraw consent to services or treatment.

34 Therefore, informed choice implies the consumer has three basic options:

- to choose to participate
- to choose not to participate
- to choose not to continue participating.

35 NSAC and its Informed Consent Working Group have used a shared decision-making process as the framework for the informed consent decision-making process.

36 There is evidence that many consumers want more information from their health practitioner and want to participate in health-care decisions.[12] In shared decision-making, practitioners have an important role not only to convey information but to help the consumer feel able to express their views, values, and preferences. Health practitioners need to ensure the consumer feels able to ask questions.[13]

37 Shared decision-making allows consumers to participate in the decision-making process to the extent that they prefer.

- Some consumers will want the practitioner to take most of the responsibility for the decision.
- Others will want to make the decision completely by themselves after receiving information.
- Most consumers are likely to want a joint decision between themselves and the practitioner.[14, 15]

38 Shared decision-making recognises that health decisions are not always made solely by a health consumer, but may include family, friends, and, in some cases, the wider community. Shared decision-making empowers the consumer to have a central role in decision-making about their health care while also recognising that health care involves a partnership between the health provider, the health consumer, and any person the health consumer has to support them (for instance, family or whānau).[14, 16]

39 Informed consent is not a one-off event or the ticking of a box on a form. Decisions are required at various stages along the screening pathway, and information needs to be provided accordingly.

2.4 Informed consent in health and screening

40 Consumers have not always been informed of the risks and harms associated with screening,[17] and they may not have been given a real choice about participation in screening.[18]

41 Traditionally, screening programmes have prioritised population-wide benefits, so consent processes have tended towards persuading people to be screened. Maximising coverage has meant emphasising the benefits of screening while ignoring or downplaying the negatives or risks associated with screening.

42 A second approach is to ensure consumers are provided with detailed information about screening, including information about the benefits and risks associated with screening. This approach recognises that the provision of information may result in consumers deciding not to participate in screening.

43 However, consumers can be provided with a significant amount of complex information that is not tailored to their needs. This may result in miscommunication, misinterpretation, and information overload. These issues may prevent consumers making good decisions.

2.5 Consumer-centred approach to informed consent

44 The New Zealand medico-legal framework sets out the minimum standards that apply for informed consent. Under the HDC Code, consumers have the right to effective communication (right 5), to be fully informed (right 6), to make an informed choice and give informed consent (right 7).

45 The rights in the HDC Code underpin all decisions a person makes about their health care. These rights are especially important in the context of screening. The HDC Code is discussed in more detail in section 3.

46 To reach agreement about screening, the consumer and practitioner must work together to make decisions at different stages along the screening pathway. Reaching agreement involves recognising that the consent process in screening is not simple and that both the consumer and practitioner may require support for the process of agreement.

47 The Health and Disability Commissioner has approached the right of informed consent from a consumer-centred viewpoint, although the process involves both the rights and duties of consumers and providers. Accordingly, NSAC has focused on a consumer-centred and partnership-oriented approach that:

- enables consumers to make autonomous decisions that respect their needs and context
- provides information, education, and support to enable consumers to understand the benefits and risks associated with screening and make decisions about their participation
- requires consumer participation
- promotes choice, empowerment, and partnerships with practitioners and other stakeholders
- supports the needs and draws on the strengths of both practitioners and consumers.

2.6 International evidence about informed consent in screening

48 A significant body of literature internationally exists about informed consent in screening, but there is little New Zealand evidence or literature.

49 Some of the international research indicates that practitioners and consumers may report different experiences and memories of their interactions.[19, 20]

50 Three studies looked into what information consumers wanted to aid their decision-making process. The most recent study was conducted in the United Kingdom and involved focus groups and individual interviews with consumers.[21] The results suggest consumers were largely uninformed about the disease being screened for and the limitations of screening.

51 When respondents were asked about the information they wanted, they said they wanted information about the disease and not just information about the risks and limitations of screening. This result is consistent with the other two studies, both conducted in the United States.[22, 23]

52 Research into participation in screening in New Zealand has identified barriers to cervical cancer and breast cancer screening in New Zealand that may have an impact on informed consent. These barriers include lack of knowledge, fear, economic reasons, pain or discomfort, not knowing where to go, and language issues.[24-26]

53 Research into health promotion in screening has noted that the focus on recruitment may mean health promoters are compromising the informed consent process because they want to ensure enrolment in screening programmes.[24] The same research notes that other providers ensure women are fully informed, even though this may mean some women choose not to participate.

54 There has been little other research in New Zealand on informed consent in screening. None has focused on asking consumers their experiences of the informed consent process. The Informed Consent Working Group considers that more research is required about informed consent in screening in New Zealand, specifically from the consumer's perspective.

3 Medico-Legal Context

55 Health practitioners in New Zealand are bound by general duties of care under legislation as well as specific compliance requirements under occupational regulation and codes of conduct.

56 Most professional bodies have a position on informed consent. Some professional bodies have specific position statements on the informed consent requirements for screening. For instance, the Medical Council of New Zealand's statement on informed consent in screening states (at page 4):

> "Doctors have a special duty of care when enrolling an apparently healthy asymptomatic person in screening programmes, to make him or her aware of the limitations of screening and the uncertainties, in particular the chance of false positive and false negative results.
> Before obtaining consent the doctor should explain, or give information to the patient that explains:
>
> - the purpose of the screening
> - the uncertainties
> - any significant medical, social or financial implications of the condition for which the screening is done and
> - follow up plans, including the availability of counselling and support services."[27]

57 The starting point for considering informed consent in screening in New Zealand is the legal framework that sets out the right of consumers of health and disability services. This legal framework is provided by the Health and Disability Commissioner Act 1994 (the Act) and the Code of Health and Disability Services Consumers' Rights (the HDC Code).

58 The Act defines *informed consent* as above (see paragraph 30).

59 The requirements for informed consent are expanded in the HDC Code. The HDC Code sets out 10 consumer rights, many of which are relevant to informed consent. This analysis deals only with the three main rights: right 5 (right to effective communication), right 6 (right to be fully informed), and right 7 (right to make an informed choice and give informed consent, commonly referred to as voluntariness or free consent).

60 Other rights also have some relevance for informed consent, for instance, the right to support (right 8). However, these other rights are not discussed in this paper.

61 It is noted that under clause 3 of the HDC Code, providers will not breach the HDC Code if they have taken reasonable actions in the circumstances to give effect to a right and comply with the duties in the HDC Code. There is no case law specifically on this clause, and its effects on the interpretation of the rights within the HDC Code cannot be stated with any certainty.

62 The Health and Disability Commissioner has not had to issue many opinions relating to complaints about screening. The cases discussed below are the published findings and opinions of the Commissioner, and are aimed at providing key messages on informed consent that can be applied to screening. Where no screening cases have occurred, other cases have been used to illustrate points that may be relevant to the screening environment.

3.1 Effective communication (right 5)

63 Informed consent problems often start with poor communication. Right 5 of the HDC Code sets out that every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. This right requires health practitioners to do more than simply provide a form or brochure. It involves discussion, answering questions, and ensuring that the health consumer, patient, or screening participant understands.

64 Right 5 sets out that the right to effective communication includes the right to services of a competent interpreter (where reasonably practical) for people for whom English is not a first language or whose language function is not sufficiently high for the required complexity of conversation, for instance people with impaired learning or intellect.

65 Right 5 is also important in a country with a diverse population, and increasing numbers with English as their second or third language. In Opinion 02HDC04045, a non-screening situation, the Health and Disability Commissioner was of the view that health providers breached right 5 by failing to ensure reasonable support was available once they had identified the need for an interpreter. The Commissioner held that it was the responsibility of the provider to organise translation services if required, and that the medical centre had not provided staff with sufficient guidance when determining whether a competent interpreter was needed.

66 Right 5 also requires health practitioners to develop an environment that enables both the consumer and provider to communicate openly, honestly, and effectively. In Case 99HDC009973, a doctor spoke to parents of a new-born baby about the heel-prick test for the Newborn Metabolic Screening Programme. The parents refused consent to the test. In the course of the conversation, the doctor said he would contact child protection services because the parents' decision was not in the child's best interest. The Health and Disability Commissioner held that the doctor had breached right 5 because he had not created an environment that enabled the parents to communicate openly, honestly, and effectively.

67 Case 05HDC07699 considered a non-screening complaint where the informed consent discussion occurred in a reception area immediately before an operation. Although the case did not involve screening, it confirms that patients need to be given sufficient time to adequately explore options and recognises that the presence of other people may prevent a person from being able to communicate freely. These considerations may be important in the opportunistic screening context.

3.2 Fully informed (right 6)

68 Right 6 in the HDC Code sets out that the right to be fully informed includes the right to information that a reasonable consumer in the consumer's circumstances would expect to receive. This includes an assessment of the risks, side effects, benefits, and costs of each available option.

69 No specific case involving screening has been considered under this right. However, it is reasonable to assume that for a person to be fully informed about screening activity, they would need to know about the risks, benefits, side effects, and costs associated with being screened or not screened. They would also need information about the screening test, false positives and false negatives, and the screening pathway.

70 In two non–screening-related decisions, the Health and Disability Commissioner has made it clear that without information a health consumer cannot make an informed choice (Case 05HDC16711 and Case 98HDC19278). If a health consumer cannot make an informed choice, then they cannot give informed consent.

71 The links between effective communication and the right to be fully informed are seen in Opinion 02HDC10479 and Case 05/10730, although these were not considered under right 6. In Opinion 02HDC10479, a woman developed breast cancer despite having regular mammograms. She complained that three radiologists had failed to adequately report on her mammograms. Case 05/10730 involved cervical cancer screening. A woman underwent regular smear testing and was later diagnosed with glandular cell carcinoma.

72 Although the Health and Disability Commissioner found no breach of care or failure to provide information in either of Opinion 02HDC10479 or Case 05/10730, he did consider that the cases highlighted the need for consumers to know the limitations associated with screening. These two cases highlight the emotional harm that can occur when those participating in screening are not aware of the limits of screening and, in the Commissioner's view, the limitations of screening need to be made clear in publications.

73 Opinion 02HDC10479 and Case 05/10730 highlight the need for health practitioners and those providing screening activity to provide participants with information about screening the process, and its limits.

3.3 Voluntariness and free consent (right 7)

74 The concepts of informed choice and informed consent are intrinsically linked, because a person cannot give informed consent without being able to exercise an informed choice. Choice is defined in the Act as being able to make a decision to receive, refuse, or withdraw from a health care service. Services can be provided to a consumer only when the consumer has made an informed choice to receive those services.

75 The Act says that consent must be "freely given". The use of these words indicates that consent must be voluntary. The voluntary nature of informed choice and informed consent is set out in right 7 of the HDC Code.

76 The voluntary nature of consent is discussed in Case 99HDC009973 (discussed in paragraph 66) where a doctor pressured parents to agree to their newborn baby being screened as part of the Newborn Metabolic Screening Programme. In this case, the Health and Disability Commissioner considered that the doctor had breached right 7 because his statements were coercive, meaning the parents were unable to provide consent.

77 'Choice' requires the consumer to take an active role in the decision-making process, rather than passively acquiescing to the course of action proposed by the provider. This was confirmed in the non-screening case Opinion 97/9172 where an elderly man was placed in a retirement home without his consent. This case has implications for screening because the health practitioner needs to ensure the screening participant actively participates in the decision-making process.

78 Case 99/09011 highlights the importance of ensuring the informed consent process occurs. In this case, a mother had not been taken through the informed consent process for the Newborn Metabolic Screening Programme. As a result, she was not aware that a sample of her baby's blood had been stored. The Health and Disability Commissioner found that the informed consent process had not been followed and the mother had not given informed consent for the test.

3.4 Competence and capacity (right 7)

79 The Act requires that consent be given by a health consumer or by someone who is entitled to consent on the consumer's behalf.

80 Right 7 in the HDC Code states that consumers are presumed to be competent to make an informed choice and give informed consent unless reasonable grounds exist for believing otherwise. In Opinion 97/9172 (discussed in paragraph 77), the Health and Disability Commissioner considered that the consumer was competent, meaning that other people were not entitled to give consent on the consumer's behalf.

81 Competence and capacity can fluctuate. Incapacity may be permanent but it can also be temporary. This can be seen in Case 01/05619, where the Health and Disability Commissioner considered that the patient was stressed and not able to appreciate the information she was given. This meant the patient was not capable of making an informed choice. Emotions, such as fear, stress, and panic, can incapacitate or prevent a person from having the capacity to make a decision.

82 The Health and Disability Commissioner has considered only a few cases raising competence or capacity issues. In Opinion 01HDC02915, a case relating to the vaccination of a child, the Commissioner considered that the 14-year-old boy involved had the ability to understand the essential information given and was able to give consent to the vaccination. In Opinion 01HDC12269, the Commissioner noted that a general practitioner had reasonable grounds to believe that a 10-year-old girl was not competent to make an informed choice. Therefore, the general practitioner was obliged to seek consent from those people he believed were the girl's guardians.

3.5 Summary of the Health and Disability Commissioner's findings

83 Information about screening is complex. Explaining screening concepts and understanding the harms, risks, and benefits associated with screening can be difficult.

84 The right to be well informed relies on effective communication. Without effective communication, the participant cannot be said to be well informed. Likewise, the right to make an informed choice relies on being well informed. If the participant is not well informed, they are not able to make an informed choice or give informed consent.

85 The opinions of the Health and Disability Commissioner show that health practitioners need to ensure they communicate effectively; provide full, fair, and balanced information; and ensure that the consumer is able to make an informed choice and give informed consent before the consumer participates in any form of screening activity.

4 Informed Consent Issues from the Literature

86 This section summarises the informed consent concerns related to screening identified in the literature.

87 The literature review undertaken for this section was not exhaustive. It involved searching three electronic databases (Medline, CINAHL, and PsycINFO) and the grey literature, employing the following search strategy nationally and internationally: 'informed consent' and 'screening' or 'mass screening', limited to 2004 to 2007 and English language articles.

88 Most of the concerns identified below were raised in a North American or United Kingdom context. Therefore, they may not include specific concerns that arise within the New Zealand context and will not address local cultural factors.

4.1 Voluntariness and routine screening activity

89 One component of informed consent is voluntariness. Participation in screening must be voluntary.[28] To be voluntary, consent has to be given freely without pressure, coercion, or undue influence.[19, 28-30]

90 However, there is evidence that consumers simply follow a recognised, prescribed, or normative pathway of care; particularly where their practitioner recommends that course of action.[30-33]

91 The well-established and routine nature of many screening activities, particularly in the antenatal area, obscures the fact that participation in screening is voluntary. Consumers may not realise they are being screened, that the screening activity is optional, or that they have the opportunity to refuse.[30, 32, 34-37] The "routinisation" of screening can have the effect of negating choice and informed consent requirements.

92 Routinisation can make it harder for consumers to opt out of screening. The literature suggests that attempts by women to opt out of routine antenatal screening have lead to the women being labelled as "difficult" or "uncooperative".[28, 30, 34, 35, 38, 39]

93 The routinisation of screening also features in other contexts. For instance, it has been recommended that routine psychosocial assessments of older adults in New Zealand include screening for depression, anxiety, and substance abuse.[40]

94 Concerns have been raised in relation to opt-out or opt-off screening.[41] An opt-off approach assumes individuals have agreed to be part of a population-based screening programme unless they actively request to be removed from the programme (that is, to opt off). The National Cervical Screening Programme in New Zealand takes an opt-off approach. An opt-off approach does not remove the requirement for informed choice, but the default position is participation.

95 Although there are concerns about the routinisation of screening and opt-off approaches, these methods have the advantage of making it easier for people to participate in screening.[42]

4.2 Information provided to consumers

96 An important part of informed consent is the aspect of being 'informed' or receiving information. The literature identifies issues with the quality of information available in screening, particularly its clarity, accuracy, usefulness, or recency,[43-46] including information about risks and limitations of screening and screening tests.[47-49]

97 If a consumer does not have sufficient information, then they cannot give informed consent, because they will not know what they are consenting to. However, the literature suggests consumers are participating in screening programmes without adequate knowledge of the screening test, the evidence for and against the test or even the purpose of that test, especially in the area of antenatal screening.[50-52]

98 Miscommunication may occur due to the use of medical jargon and terminology or the use of common words (such as "protein") that have specialised meanings in some contexts.[20, 53, 54] Other common terms associated with screening can be confusing, for instance, the terms "risk" and "benefit".[20, 55-57]

99 Information provided may not be appropriate to the consumer. It may be pitched at the wrong education level,[58, 59] be in a different language[51, 53, 58, 60], or refer to concepts that have little meaning to the consumer

100 Research from overseas indicates that the literacy level of health literature can be higher than that of the patient for which it is intended.[61] Although research into health literacy has not been conducted in New Zealand, the New Zealand data from the International Adult Literacy Survey showed that 40 percent of adults in New Zealand did not have the necessary skills to participate in a knowledge society, and 18 percent were classified as having very low levels of literacy. Māori and Pacific adults were over-represented among those who had low levels of literacy.[62]

101 Levels of literacy have important implications for screening and the health literature provided to consumers. Informed choice requires consumers to have access to good quality information that they can read and understand.

102 Finally, because screening stems from a public health goal of improving the health of the population, it involves some consideration of population health and public good. Information provided to consumers may need to cover the benefits, harms and impacts of screening to certain populations or to the general public, as well as to individuals being screened.

4.3 Communication and trust between practitioner and consumer

103 The relationship between practitioner and consumer is based on trust. However, the literature identifies that the power and knowledge imbalance between the two parties can have three important implications in screening.

104 First, the practitioner will generally have the information and decide what the consumer needs to know.[20, 63] This can make it difficult for the consumer to question the advice of the practitioner or to refuse to follow that advice.[19, 38]

105 Secondly, most consumers accept their practitioner's recommendations for tests or screening without working through the benefits or harms of that recommendation.[30, 38, 63] Therefore, the offer of screening by a health provider may imply that the screening activity is well supported by best practice and evidence and has wide societal acceptance.[38] Some screening activity may be supported by evidence or best practice, but other screening activity may not be.

106 Thirdly, is the role the consumer should take in this process. Some commentators consider that consumers should take responsibility for being active in the process and seeking further information.[64, 65]

107 However, for consumers to take this responsibility, support mechanisms need to be put in place that are appropriate for all people, particularly vulnerable groups. One overseas commentator has suggested that to protect themselves, practitioners should assume that elderly people are incompetent and incapable of making decisions relating to screening.[66] If this view were followed, elderly people would be denied their right to make health care decisions that affect them. In New Zealand it would contravene the HDC Code's expectations about competence discussed in paragraphs 79–82 above.

4.4 Community or cultural values affecting individual choice

108 Informed consent is largely based on the ethical principle of respect for autonomy. However, social relationships inevitably have an impact on an individual's decision-making because individuals cannot be considered separately from their environment.

109 Individual autonomy and individual consent are not universal concepts and reflect particular cultural viewpoints. Different cultures give different weight to the relative value and role of community and individual.[67] Research has found that respondents from Northern Europe tend to value personal or parental choice in prenatal testing while respondents from Southern Europe, India, and Asia consider the views of others to be more important.[68, 69] A study looking at Turkish, Surinamese, and Dutch women's decisions to participate in antenatal screening for Down Syndrome found that Turkish women tended to emphasise the importance of family in the decision-making process more than the other two cultural groups.[70] In New Zealand, Māori communities may also value collective decision-making processes.[71]

110 Cultural and societal norms and expectations influence an individual's decisions. When there is societal pressure for a person to participate in screening, those who do not want to be screened may be viewed as irresponsible or difficult, and considered personally responsible for any negative result following the decision not to participate in screening.[20, 28, 30, 34, 38, 72] Alternatively, a consumer may have little experience in the choice-making process due to their community or cultural values.[20, 39, 73]

111 Consideration may need to be given to whether the decision is made by the individual (with or without family input) or whether the decision is made by a community or community leader and the individual abides by the decision.[67] This is relevant in New Zealand given the known importance of whānau, aiga, and other extended family structures.

4.5 Protecting people who lack capacity to consent to screening

112 The HDC Code states that consumers are assumed to have capacity or to be competent unless there are reasonable grounds for believing otherwise. The Informed Consent Working Group recognises that assessing a consumer's competence or capacity to consent can be difficult area for health practitioners and that there is scope for disagreement and conflict.

113 To have sufficient competence, a person is usually required to be able to make decisions, and this requires that they are able to understand and weigh or balance the information provided and communicate their decision (which could be by talking, Sign Language, or muscle movement).[74-76]

114 However, this formulation of competence means that people who are not fully autonomous decision-makers are excluded from screening activity, including its possible benefits (and its possible harms). This may mean certain groups like people experiencing disability or mental illness cannot access screening, even if screening would be in their best interest. Further, some people may lack competence on a temporary basis if their capacity fluctuates.

115 If a person permanently lacks mental capacity to consent, then decisions on health care, including screening, will generally be made on their behalf by a carer or someone who is authorised to make health-care decisions.[76] When making a "best interests decision", the following factors need to be considered:

- the degree of risk of the condition being screened for
- the nature of the tests and how the individual might respond to them
- the implications of an abnormal test result, including further investigations and treatment
- any previous opinions regarding screening held by the individual before they lost their capacity, particularly previously expressed support for or refusal of screening

- the opinions of people who know the individual well (for instance, family, friends, and other carers) as to what they feel the individual would do.[76]

5 Practicalities of Informed Consent in New Zealand

116 The people responsible for providing population-based screening programmes in New Zealand have recognised that informed consent issues can arise. Quality and policy standards have been developed to inform professional practice and service provision. These quality and policy standards are also supported by consumer and practitioner resources. The intent is for screening participants to receive information that enables them to make an informed choice.

117 However, practical difficulties exist when informed consent in screening is implemented. This section discusses some of those difficulties.

5.1 Time and other resource constraints

118 Screening poses a serious challenge for practitioners, particularly those in a busy practice. The conversation about screening and the condition and the other aspects of information exchange required for informed consent all take time – which may not be available in a busy practice with limited time funded for each appointment.[77] Informed consent in this context has been called little more than a "rushed chat".[20]

119 Although it may be possible to separately resource different aspects of the informed consent process (for example, by using nurse practitioners or health educators at some stages), staff with the right skills and knowledge may not always be available when needed.

5.2 Relevant, up-to-date, and accurate information

120 Research suggests that quality information relating to cancer treatment and care may not be available in New Zealand.[78] Although this research did not include analysis of cancer screening information, there is no New Zealand–based information that clearly and accurately explains the concept of screening and screening pathways.

121 Overseas research suggests that consumer resources may not always include all of the information that a consumer needs to know before making a screening decision.[79] Not having all of the required information may affect a consumer's ability to provide informed consent to screening activity.

122 Even when relevant, up-to-date, and accurate information exists, it may not be readily available to those participating in screening. In Case 99/09011, the Health and Disability Commissioner noted that it was not clear whether the available information resources were distributed to the women participating in screening.

5.3 Cultural context

123 The literature on informed consent and screening largely comes from North America and the United Kingdom. This means the issues with informed consent discussed in that literature may not be relevant to New Zealand, which has a distinctive cultural and ethnic make-up and distinctive health system.

124 New Zealand's specific heritage, including the Treaty of Waitangi and its underlying principles of Partnership, Protection, and Participation, place an obligation on the New Zealand health and disability sectors to identify and reduce health inequalities. This is particularly important in the New Zealand context where Māori, Pacific, and non-Māori non-Pacific health needs may be different.[80]

125 The history and context of screening in New Zealand, including the Cartwright Inquiry[5], the Ministerial Inquiry into Under-reporting of Cervical Smear Abnormalities in the Gisborne Region[81], and more recent publicity about the retention of samples obtained from the Newborn Metabolic Screening Programme[82], may influence how screening and informed consent in screening is perceived in New Zealand.

5.4 Translation services

126 New Zealand research has identified that one of the barriers to screening is language.[24-26] New Zealand is a diverse country with increasing numbers who have English as their second or third language.

127 Unfortunately, funding for interpreters and translation services is not readily available in primary care (including maternity care), and translators may not always be readily available to those who need them when engaging with the health sector.

128 Even where funding for a translator is available, an appropriate translator may not be available when needed.

129 Issues of confidentiality may arise in small communities where the translator knows the health consumer (perhaps because they are a family member).

5.5 Availability of consequent options

130 A final practical issue with informed consent relates to the availability of options. At times, a variety of choices may theoretically be available to a consumer. However, not all of these options will be practically available due to costs, location, or non-existence.

131 Sometimes funding decisions may affect the options available to a consumer.[55] Some health options may be resourced to a higher level than others, which may imply the health system considers them the preferred or best option(s).[55] That may influence the perceived acceptability of those options for consumers.

5.6 Self-screening without health practitioners

132 Screening activity can occur without the presence of a health practitioner. For instance, health-related screening can occur outside the health sector such as in schools, workplaces, or prisons, and screening tests may be performed by non-health practitioners.

133 There is also a move to self-testing and self-screening activity to reduce some of the barriers to screening activity that people face.[83, 84] Information is still an important part of the self-screening process, including information about the condition, the test, and how to do the test.

134 One form of self-screening is screening for bowel cancer. The way this screening is practised in the United Kingdom, it is assumed that an individual has consented to the screening test merely by returning the completed bowel cancer screening kit.[85] This can be compared with Opinion 97/9172, where the Health and Disability Commissioner held that a health consumer must be actively involved in health decisions.

135 Since screening consists of a pathway of actions and is not simply the screening test itself, self-testing or self-screening has consequences. It is no less important that the individual is fully informed, is able to make an informed choice about whether to participate, and understands the implications of participating or not participating. The act of returning a testing kit may imply consent at some level,[85] but to ensure the consumer genuinely understands the implications of participation, more must be required.

5.7 Advances in genetic knowledge

136 Advances in medical technology since the late 1980s have given health practitioners the ability to test for more conditions than in the past. As new screening tests are developed, the number of potential screening programmes increases. There have been significant advances in the ability to test for genetic conditions, including for late-onset disorders.[64, 65, 86, 87]

137 Direct-to-market tests are now available, many of which lack evidence of quality or an established pathway of care.[33, 65, 87-93] Consumers who use these tests may lack an appropriate level of information or understanding, and this may affect their ability to fully consent to undertaking these screening tests.

138 The implications of genetic screening are not well known but may result in stigma and discrimination in employment, insurance and health care.[64, 86, 94] The implications of genetic screening for the wider family are also not known,[64, 86, 88, 95] including whether unscreened family members have the right to know of any genetic concerns that may affect them.[46, 64, 88, 96, 97]

139 Children are vulnerable, and conflict may exist between what is in the best interest of the child and what is in the wider interests of the child's family.[98, 99] The impact of genetic screening on a child's future right not to know (for instance, screening for late-onset conditions) may not always be considered.[98, 100, 101]

140 Research has been carried out in New Zealand seeking to obtain consumer views on genetics and genetic testing. The Bioethics Council's project on pre-birth testing,[102] and the Constructive Conversations project into genetic testing and biobanking sought to investigate the ethical and social issues associated with genetic developments and technology.[103] These studies provide an ideal starting point for research in New Zealand aimed at investigating informed consent in the genetic context.

5.8 Decision aids: tools to improve informed consent

141 Decision aids can improve a consumer's understanding about the options and increase their knowledge about potential outcomes (both positive and negative).[104]

142 Evidence from clinical trials of shared decision-making, where consumers have been helped with decision aids show that when it comes to choosing options, practitioner choices and consumer preferences are not well correlated.[105]

143 Decision aids can help both the health consumer and health practitioner. By helping consumers become more aware of their values and how these values relate to and affect the possible options and potential outcomes, consumers are able to better engage in the decision-making process with practitioners.[106]

144 Decision aids also help practitioners by providing a validated format for presenting facts in terms of balance, accuracy, and consistency.[107] However, it is possible for decision aids to be unbalanced, inaccurate, or incomplete.[108] They may have been developed without consultation or without properly addressing the information needs of all target consumer populations.[104] How information is presented is known to influence screening decisions.[109]

145 There are no universally accepted quality standards for the development or evaluation of decision aids. Decision aids can sometimes be used to promote screening activity rather than aid the decision-making process.[110-112]

146 Internationally, work is being conducted to establish an internationally approved set of criteria for determining the quality of patient decision aids. The International Patient Decision Aid Standards (IPDAS) Collaboration consists of researchers, practitioners, and stakeholders from several countries.[110, 113]

147 The IPDAS Collaboration has identified criteria and questions for decision aids and their development. Research is now needed in a New Zealand context to identify whether these criteria and questions are relevant to New Zealand and whether additional criteria or questions would help take into account New Zealand's cultural and ethnic heritage and distinctive health system (for instance, components relating to cultural relevance or cultural sensitivity).

6 About the National Screening Advisory Committee

6.1 National Screening Advisory Committee

148 The Director-General of Health uses advisory committees to obtain independent, strategic advice on areas of particular interest.

149 Following recommendations that there be a specialist advisory committee for screening issues, the then Minister of Health and Director-General of Health agreed to set up the National Screening Advisory Committee (NSAC). NSAC came into existence in July 2004.

150 The Director-General of Health appoints NSAC members.

151 NSAC is not part of the National Screening Unit (NSU). However, the NSU is a stakeholder and the NSAC Secretariat has previously been staffed by the NSU.

152 NSAC's work programme addresses key issues in screening. These issues have been identified in discussion with its stakeholders including: the Ministry of Health, the National Screening Unit, the National Health Committee, health practitioners, and consumer groups.

6.2 Informed Consent Working Group members

153 This discussion paper was developed by the Informed Consent Working Group, a subcommittee of NSAC. The working group brings together a variety of perspectives.

154 The NSAC sponsors for this project are Sacha Dylan and Stephanie Erick-Peleti.

155 Working group members are Kara Hudson (National Screening Unit; NSAC Secretariat) until December 2009, Owen Hughes (Office for Disability Issues), Sarah Perry (Cancer Society of New Zealand), Debb Pittam (National Screening Unit), Julian Sakarai (Office of the Health and Disability Commissioner) from December 2008,Tina Mitchell (Office of the Health and Disability Commissioner) until December 2008, and Norma Campbell (New Zealand College of Midwives, NSAC member).

6.3 Contacting Us

156 All contact about this project should be with NSAC's secretariat:

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Your Submission

Please provide your contact details here.

Name	
If this submission is made on behalf of an organisation, name that organisation here	
If applicable, briefly describe the organisation including who you represent	
Postal address or email	
Interest in this topic	

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under the Act, make this clear in your submission, noting why you would like the information to be withheld.

If information from your submission is requested under the Official Information Act 1982, the Ministry of Health on behalf of the National Screening Advisory Committee will release your submission to the person who requested it. If you are an individual, rather than an organisation, and you check the following box, the Ministry of Health will remove your personal details from the submission.

☐ I do not give permission for my personal details to be released to people under the Official Information Act 1982.

The National Screening Advisory Committee will acknowledge all submissions and will send a summary of submissions to people who request the summary. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission for the release of their personal details, the name of the organisation will be given if supplied.

Do you wish to receive the summary of submissions?

☐ Yes

☐ No

Question 1 – Are there important informed consent issues that are not covered or are not covered adequately in this discussion paper? Why are these issues important?

Question 2 – What would a good informed consent process look like and what might it involve?

Question 3 – What would most improve informed consent in screening in New Zealand?

Question 4 – What information should be provided to potential screening participants? How should that information be provided?

Question 5 – Do you have any other comments or suggestions on informed consent in screening?

Please return your submission to:

Secretariat, National Screening Advisory Committee
Ministry of Health
PO Box 5013
Wellington

Document 3

MINISTRY OF HEALTH
MANATŪ HAUORA

Health Report number: 20101353

Action required by: routine

Date sent to Minister: [Date]

Minister's reference: not applicable

File number: NS01-02-7-8

To: Hon Tony Ryall, Minister of Health

Ethical and Social Considerations and Improving Informed Consent in Screening: Documents for Consultation

Executive summary

i. This Health Report seeks your agreement to release two discussion papers for consultation and feedback.

ii. The National Screening Advisory Committee (NSAC), which advises the Director General of Health on screening policy, practice and research, has produced two documents, *Ethical and Social Considerations in Screening* and *Improving Informed Consent in Screening* (attached as Appendices I and 2). These documents will be used to help decision makers to implement and deliver quality screening services in accordance with the Code of Health and Disability Services Consumer's Rights, and ethical principles.

iii. NSAC wishes to circulate these documents to appropriate stakeholders in New Zealand for consultation and feedback. A list of these stakeholders is attached (Appendix 3).

The Ministry recommends that you:

a) **Agree:** that the National Screening Advisory Committee releases the two discussion documents *Ethical and Social Considerations in Screening* and *Improving Informed Consent in Screening,* for stakeholder consultation. Yes / No

Janice Wilson (Dr)

Deputy Director-General

Population Health Directorate

Minister's Signature

Date:

Ministry of Health Contacts:

Graeme Gillespie Group Manager, Population Health Protection Group		Dr Geoffrey Roche Analyst, Screening Strategy and Policy Team, Population Health Protection Group	
Phone:	s 9(2)(a)	Phone:	s 9(2)(a)
Cellphone:		Cellphone:	

Advice

Summary of the Discussion Documents

1. The document *Ethical and Social Considerations in Screening* sets out central issues in the ethics and social aspects of screening discussed in the international literature, and considers whether there are other considerations relevant to the New Zealand context. It covers informed consent, equality and equity, the balancing of harms and benefits, the maintenance of trust and confidence, and issues relating to screening technology and practice.
2. The document *Improving Informed Consent in Screening* sets out legal and ethical issues focusing on informed consent. Key issues outlined are the need for adequate information, the issue of communication and trust between consumer and practitioner, various community and cultural attitudes towards informed consent, and the need to protect those who lack the capacity to make an informed choice. Practical issues are also addressed, such as the creation and implementation of decision aids, and the need for information provided to be sound. To achieve this, information must present screening harms and benefits in a balanced and accurate manner.

Background

3. The attached discussion documents have arisen out of NSAC's role in providing guidance to policy makers on the ethical and social considerations of screening in the health and disability sector.
4. They also respond to the National Health Committee's 2003 *Criteria to assess screening programmes*,[1] which require that ethical and social considerations are considered in the planning stages of screening programmes.
5. Informed consent, an issue which applies to all screening modalities, is a central concern for NSAC. While a general requirement of all medical interventions, the uncertain and complex nature of screening makes it even more important that consumers are able to decide for themselves the balance of potential benefits and harms. Informed consent to receive health services is also a requirement of The Code of Health and Disability Services Consumer's Rights (The Code).
6. The Code sets out rights of the health consumer which are required to be followed by providers of health and disability services. It also requires that participants have the right to effective communication, to be fully informed, and to be able to make informed decisions regarding treatment.
7. Further, informed consent must be obtained from health consumers at each stage of the screening pathway, requiring that it is built into the design of screening programmes at the outset.

[1] National Health Committee, 2003. *Screening to Improve Health in New Zealand: Criteria to assess screening programmes.* Wellington: National Advisory Committee on Health and Disability (National Health Committee).

8. The objectives of the discussion documents are to seek feedback on key issues identified in the international literature, to evaluate whether these considerations are directly relevant to the New Zealand context, and whether there are any other considerations important for screening activities within New Zealand.
9. The feedback received will inform future work including screening analyses, research by NSAC, and a review of the New Zealand screening criteria. NSAC will also be able to use feedback to inform the development of decision aids for various screening modalities.
10. Decision aids improve patient-decision making, through reducing uncertainty; increasing knowledge of the illness, options and outcomes; creating realistic expectations; and increasing participation in decision making without increasing anxiety.

Risks

11. While it is unlikely that there would be any adverse reaction to work aimed at improving the transparency and clarity regarding screening programmes, there is a risk that the release of the discussion documents may lead to public questioning of current processes. There is also a possibility that scrutiny of screening processes and practices may negatively impact on the public's perception of the value of screening.

Minister's feedback

	Very poor	Poor	Neutral	Good	Very Good
Quality of advice	1	2	3	4	5
Writing style	1	2	3	4	5
Quality of analysis	1	2	3	4	5
Completeness of information	1	2	3	4	5

Comments:

Document 5

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

20 December 2019

Hon Dr David Clark
Minister of Health
Parliament Buildings
WELLINGTON 6160

Dear Minister David

Review of Health and Disability Commissioner Act and Code of Health and Disability Services Consumers' Rights

I am writing to inform you about my review of the Health and Disability Commissioner Act (the Act) and Code of Health and Disability Services Consumers' Rights (the Code), and to seek your support to progress legislative amendments from earlier reviews.

Background

The Act requires the Health and Disability Commissioner to regularly review the Act and Code, and report the findings to the Minister of Health. In practice, the Act and Code reviews have been carried out together every 5 years. The last combined review was completed in 2014.

The reviews in 2009 and 2014 made several recommendations for amending the Act. There were some recommendations that were supported by the then Minister of Health and the Ministry at the time but have never been actioned. I discuss these earlier recommendations further below.

My focus on process improvements

I am currently focused on a strategic development work programme that is looking at how this office can achieve best impact within existing legislation. Against the backdrop of a significant growth in complaint volumes in recent years, this work programme is designed to, among other things, increase the efficiency and effectiveness of the HDC complaints resolution process. I believe that focusing on improvements that can be made within existing legislation is the most effective way to ensure this office continues to meet the needs of health and disability service consumers.

Act and Code review

Alongside the strategic work programme, we have been working on a review of the Act and Code. In my view, the Act and Code are generally working well. I have, however, identified some issues where change could be considered.

PO Box 11934, Wellington 6142; Level 11, TechnologyOne House, 86 Victoria Street, Wellington 6011, New Zealand
Ph: +64 4 494 7900; Fax: +64 4 494 7901; Toll Free Ph: 0800 11 22 33; www.hdc.org.nz

The most significant issue in recent times has been the question of whether some health and disability research should be permitted to take place in relation to those who cannot provide consent. As you know, following extensive consultation, I have recently published the report *Health and disability research involving adult participants who are unable to provide informed consent* (Right 7(4) report). The report recommends changes to rules in the Code that govern when research involving participants who are unable to provide informed consent can occur. We propose to carry out further consultation regarding these proposed changes in due course.

We will continue to monitor issues relevant to other matters that may warrant changes to the Act and Code. We plan to consult once on both the proposed changes coming out of the Right 7(4) report and any other proposed changes to the Act and Code. This will be the most efficient use of resources and avoid unnecessary duplication of process.

Seeking support to progress legislative amendments from earlier review

As part of my Act and Code review, I have also considered past recommendations from the 2009 and 2014 Commissioner reviews. I confirm my continued support for four earlier recommendations for amendments to the Act. These recommendations were supported by the then Minister of Health and the Ministry at the time, but have never been actioned. I seek your support for including these amendments in any appropriate upcoming legislative vehicle.

The four amendments are:

1. Extending the timeframe for reviewing the Act and Code
   The Act requires the Commissioner to review the Act at least every five years, and the Code at least every three years. Since the early days of the Act and Code, the reviews have not resulted in any substantive changes to the Act and Code, and they continue to be time consuming and resource intensive. The recommendation is for 10 yearly reviews, with the option of earlier reviews where necessary.

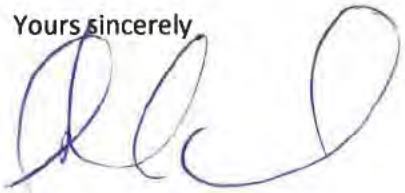
2. Increasing the maximum fine for an offence under the Act from $3,000 to $10,000
   The penalty for offences against the Act is a fine not exceeding $3,000. Offences include obstruction, failing to provide information, or providing false or misleading information to the Commissioner. Increasing the maximum fine to $10,000 would bring it into line with comparable offences under the Health Practitioners Competence Assurance Act 2003. The large majority of submitters in 2014 supported this proposal.

3. Giving the Director of Proceedings the power to require information
   The Act does not provide the Director of Proceedings with the power to collect information to inform decisions about whether to issue proceedings. The Director often needs to seek information from providers, consumers or third parties (for example, ACC) and relies on their cooperation to freely give information. The majority of submissions on this issue supported an amendment to enable the Director of Proceedings to require any person to provide information, up until the Director decides to issue proceedings.

4. Introducing a definition for "aggrieved person"
   The Act allows an "aggrieved person" to bring proceedings against a health or disability service provider in the Human Rights Review Tribunal. The term "aggrieved person" is not defined and has resulted in litigation. High Court and Court of Appeal decisions have interpreted "aggrieved person" narrowly, making access to the Tribunal overly restrictive.

Staff from my office are available to work with Ministry of Health officials to help progress these amendments.

Yours sincerely



Anthony Hill
Health and Disability Commissioner

Official Information Act Response

Response to s 9(2)(a) (H202004940)

Date due to MO:	22 July 2020	**Due to requestor by:**	29 July 2020
Security level:	IN CONFIDENCE	**Health Report number:**	20201162
To:	Hon Chris Hipkins, Minister of Health		
Proactive release:	Release response		

Contact for Telephone Discussion

Name	Position	Telephone
Clare Possenniskie	Manager, Office of The Chief Clinical Officers, Chief Medical Officer	s 9(2)(a)
Nick Allan	Manager, OIA Services, Office of the Director-General	

Action for Private Secretaries

Note the enclosed response to the requestor by 29 July 2020

Date dispatched to MO:

Response to s 9(2)(a) (H202004940)

About the request

1. On 1 July 2020 the Ministry of Health (the Ministry) received an Official Information Act 1982 (the Act) request for:

> *"A list that records all and any actions, meetings or reports generated or requested or received in relation to this request from WDHB*
>
> *A list of any of the above that relate to DHBs OTHER than WDHB*
>
> *Release of any minutes of any related meetings noted in the list above*
>
> *The latest 3 substantive communications (in any form) (not including administrative emails) between the MOH and WDHB on this matter*
>
> *Details of any decisions made re this*
>
> *Any emails between MOH and WDHB from Dece 2019 on till now, that have in the subject line the words 'informed consent' or variations thereof."*

s 9(2)(a)

Proposed response

4. Four sets of documents have been identified within scope of this request. These documents are itemised in Appendix 1.

5. Document 1 is a copy of a summary drafted by the Ministry of a meeting held in January 2020 to discuss the issues raised in the letter from Waitematā DHB.

6. Document 1A has been provided by the Health and Disability Commissioner (HDC) as their version of the January 2020 meeting summary. Upon compiling the response, the Ministry was advised by HDC that they held a version of this document with changes they had made. The HDC requested that this version also be released.

7. Document 2 is email correspondence between Waitematā DHB, the Ministry and the Health and Disability Commissioner in regard to informed consent. The Ministry

proposes some information is withheld under section 9(2)(a) of the Act, to protect the privacy of natural persons and section 9(2)(h) of the Act, to maintain legal professional privilege.

8. Document 2 also contains feedback and changes from Waitemata DHB on the draft summary provided as Document 1.

9. Document 2A is the letter from Waitematā DHB to the Director-General of Health, Dr Ashley Bloomfield raising concerns about lack of consistent national guidance on informed consent in the training environment of public hospitals. This letter is publicly available, and therefore refused under section 18(d) of the Act. The weblink has been provided to the requester.

Other information

10. Approximately seven years ago, concerns were raised under the Protected Disclosures Act 2000, by a senior nurse in Child, Women and Family services at Waitematā DHB regarding consent. This prompted a quality improvement service for consent which in turn lead to changes in consent policy and documentation over the next year. These policies have not been revised since.

11. In the past 18 months, the focus of consent discussions has shifted from medical students involved in surgical procedures (subject to the 2015 national consensus statement) to RMOs. RMOs are fully registered and qualified medical practitioners, however they are also progressing in their training under the oversight of educational bodies.

12. The specific request for changes to Waitematā DHB's consent process was made by the NZNO, who had supported the senior nurse in the incident mentioned above. The NZNO's position is that there needs to be 'explicit consent for any teaching to be occurring' separate from the existing consent process and documentation.

13. On 5 December 2019, RNZ published the following article titled *'Nurses say gynaecology patients' rights were breached.'* This can be found at: https://www.rnz.co.nz/news/national/404883/nurses-say-gynaecology-patients-rights-were-breached. This article was prompted by an Official Information Act request by RNZ to Waitematā DHB.

14. On 23 December 2019, Waitematā DHB wrote to the Director-General of Health, Dr Ashley Bloomfield, raising concerns around a lack of national guidance on informed consent that covers training aspects of clinical work for RMOs in the context of the training environment of public hospitals. The letter asked the Ministry to provide, as a matter of urgency, national guidance on this issue that aligns with the Code of Health and Disability Services Consumers' Rights, including the right be fully informed, to make an informed choice, and to give informed consent.

15. Following the letter of 23 December 2019, there has been communication between the Ministry, Waitematā DHB, the Health and Disability Commissioner in regard to informed consent. This is captured in Document 3.

16. On 31 January 2020 there was a meeting to discuss informed consent for RMOs involved in surgical procedures. The meeting minutes for this are captured in Document 1. This was chaired by Ministry Chief Medical Officer (CMO), Dr Andrew

Simpson. Those in attendance included Health and Disability Commissioner (HDC), Mr Anthony Hill; Associate HDC, Dr Cordelia Thomas; CMO of Waitematā DHB, Dr Johnathan Christiansen; Chief Executive Officer (CEO), Medical Council of New Zealand, Joan Simeon; Deputy CEO, Medical Council of New Zealand, Aleyna Hall; and Ministry Chief Legal Advisor, Mr Phil Knipe.

17. A proposed solution and next steps of this meeting are discussed on pages 3 and 4 of Document 1. Follow up from this meeting was disrupted by Covid-19, but the Ministry continues work with stakeholders and consider ways to support sector consistency and clarify expectations on informed consent.

18. These documents have been released in a previous request for information (H202003845 refers). They will also be captured in another request for information (H202005056 refers) due to the requester on or before 3 August 2020. These requests were made by Rebecca Scott, a barrister for Harbour Chambers. Ms Scott has been instructed by the NZNO to represent a registered nurse who raised a number of serious allegations of systemic breaches by the Waitematā DHB of the Code of Health and Disability Services Consumers' Rights; in particular, the right of health consumers to be fully informed, to make an informed choice, and to give informed consent.

Internal consultation

Health Legal

19. Health Legal has been consulted on the proposed response.

Communications

20. The Ministry's Communications team has been consulted on the proposed response. It is expected that this response may generate further media attention.

External consultation

21. Please refer to Appendix 2 for a full list of external agencies consulted on information proposed for release and feedback received.

PP J Rumbal-Smith

Dr Andrew Simpson
Chief Medical Officer

Appendix 1: List of documents proposed for release

#	Date	Title	Decision on release	Previous release
1	31 January 2020	Meeting Summary: Informed consent for Resident Medical Officers involved in surgical procedures	Release in full	Previously released under the Act
1A	31 January 2020	Meeting Summary: Informed consent for Resident Medical Officers involved in surgical procedures (HDC version)	Release in full	Not previously released under the Act
2	6 January to 2 February 2020	Email correspondence	Release with information deemed out of scope withheld and some information withheld pursuant to: • section 9(2)(a) of the Act, to protect the privacy of natural persons	Previously released under the Act
2A	6 January 2020	Email attachment: Letter to Director-General of Health RE Informed Consent	Refuse under section 18(d) of the Act as the information is publicly available at: https://assets.documentcloud.org/documents/6672314/Letter-to-DG-Re-National-Guidance-19199-No-7.pdf	Previously released under the Act by Waitematā DHB

Appendix 2: External agencies consulted on documents proposed for release

#	Agency	Contact	Documents consulted on	Feedback received
1	Waitematā District Health Board	Denise Poole	1, 2, 3, 3A	No concerns
2	Health and Disability Commissioner (HDC)	Craig Goodwillie	1, 3	Requested that the HDC version of Document 1 is released (Document 1A refers)
3	Medical Council of New Zealand	Aleyna Hall	1	No concerns

Document 6A

Letter from Waitematā DHB on Informed Consent
Deanne Manuel (WDHB)
to:
'andrew.simpson@health.govt.nz'
06/01/2020 09:46 a.m.
Hide Details
From: "Deanne Manuel (WDHB)" <Deanne.Manuel@waitematadhb.govt.nz>
To: "'andrew.simpson@health.govt.nz'" <andrew.simpson@health.govt.nz>,
History: This message has been forwarded.

1 Attachment

Letter to Director General of Health RE Informed Consent.pdf

'Refer to Document 6B'

Dear Dr. Simpson,

Kia Ora.

Please find attached a copy of the letter from the Board Chair, Judy McGregor and CEO, Dr Dale Bramley of Waitematā DHB related to Informed Consent.

Ngā mihi,

Deanne Manuel
Committee Secretary
Corporate Services | Waitemata DHB
Level 2 Shea Terrace, Private Bag 93-503, Takapuna 0622
p: 4846116 s 9(2)(a)
www.waitematadhb.govt.nz

Legal Disclaimer

Document 6A

Fw: Letter from Waitematā DHB on Informed Consent

Ashley Bloomfield to: Andrew Simpson, Margareth Broodkoorn 07/01/2020 08:44 a.m.

FYI

Kind regards
Ashley

Dr Ashley Bloomfield
Director-General
Ministry of Health
email: ashley.bloomfield@health.govt.nz
s 9(2)(a)
www.health.govt.nz

----- Forwarded by Jo Waugh/MOH on 07/01/2020 08:44 a.m. -----

From: "Deanne Manuel (WDHB)" <Deanne.Manuel@waitematadhb.govt.nz>
To: "'ashley.bloomfield@health.govt.nz'" <ashley.bloomfield@health.govt.nz>,
Cc: "Board Chair (WDHB)" <BoardChair.WDHB@waitematadhb.govt.nz>, "Dale Bramley (WDHB)" <Dale.Bramley@waitematadhb.govt.nz>, "'d.clark@ministers.govt.nz'" <d.clark@ministers.govt.nz>
Date: 24/12/2019 09:38 a.m.
Subject: Letter from Waitematā DHB on Informed Consent

Dear Dr. Ashley,

Kia Ora.

Please find attached a letter from the Board Chair, Judy McGregor and CEO, Dr Dale Bramley of Waitematā DHB related to Informed Consent.

Ngā mihi,

Deanne Manuel
Committee Secretary
Corporate Services | Waitemata DHB
Level 2 Shea Terrace, Private Bag 93-503, Takapuna 0622
p: 4846116 s 9(2)(a)
www.waitematadhb.govt.nz

Legal Disclaimer Letter to Director General of Health RE Informed Consent.pdf

Document 6A

RE: Catch up
Jonathan Christiansen (WDHB)
to:
'Andrew.Simpson@health.govt.nz'
15/01/2020 07:27 p.m.
Hide Details
From: "Jonathan Christiansen (WDHB)"
<Jonathan.Christiansen@waitematadhb.govt.nz>
To: "'Andrew.Simpson@health.govt.nz'" <Andrew.Simpson@health.govt.nz>,
History: This message has been replied to.

1 Attachment

Letter to Director General of Health RE Informed Consent.pdf

Hi Andy,

Happy New Year.

I do have some time tomorrow afternoon (Thursday) between 1-2 and 3-4.30, and failing that Monday afternoon next week is good. Hope one of those works.

Would also be good to pick up a discussion on issues around consent – as in the letter from our Board to the DG, attached, which hopefully you received a copy of.

Cheers

Jonathan

Jonathan Christiansen I Chief Medical Officer
Waitemata District Health Board
s 9(2)(a)

FRACP ADULT MEDICINE RACP

There is only one day left, always starting over: it is given to us at dawn, and taken away from us at dusk. Jean-Paul Sartre

From: Andrew.Simpson@health.govt.nz [mailto:Andrew.Simpson@health.govt.nz]
Sent: Wednesday, 15 January 2020 4:00 p.m.
To: Jonathan Christiansen (WDHB)
Subject: Catch up

Hi Jonathan

Happy New Year
Are you free to catch up by phone sometime next couple of days?
Be good to touch base on things Mesh

Regards
Andy

Andrew Simpson | Chief Medical Officer
Office of the Chief Medical Officer

Document 6A

s 9(2)(a)

s 9(2)(a)

Document 6A

s 9(2)(a)

s 9(2)(a)

s 9(2)(a)

Document 6A

s 9(2)(a)

Document 6A

s 9(2)(a)

Document 6A

RE: Informed consent for Resident Medical Officers involved in surgical procedures minutes - 31 January 2020
Jonathan Christiansen (WDHB)
to:
'Andrew.Simpson@health.govt.nz'
20/02/2020 05:41 p.m.
Hide Details
From: "Jonathan Christiansen (WDHB)" <Jonathan.Christiansen@waitematadhb.govt.nz>
To: "'Andrew.Simpson@health.govt.nz'" <Andrew.Simpson@health.govt.nz>,

2 Attachments

Consent Form Feb 2020 version.docx 31 1 20 consent meeting summary.docx

Thanks Andy. A couple of small changes to the minutes for clarity.

Waitemata is in the process of making relatively minor modifications to its consent form in response to this issue.

We have sought advice from Prof Ron Patterson, and his proposal for the wording changes around students and RMOs is in the "mock-up" draft form attached.
This wording has the endorsement of our steering group for consent, and is going to our Consumer Council for their consideration also.

If you have thoughts about that I would welcome them.

Cheers

Jonathan

Jonathan Christiansen I **Chief Medical Officer**
Waitemata District Health Board
s 9(2)(a)

FRACP ADULT MEDICINE RACP

There is only one day left, always starting over: it is given to us at dawn, and taken away from us at dusk. Jean-Paul Sartre

From: Katrina.McLaren@health.govt.nz [mailto:Katrina.McLaren@health.govt.nz] **On Behalf Of** Andrew.Simpson@health.govt.nz
Sent: Thursday, 20 February 2020 11:19 a.m.
To: anthony.hill@hdc.org.nz; cordelia.thomas@hdc.org.nz; jsimeon@mcnz.org.nz; Phil.Knipe@health.govt.nz; Jonathan Christiansen (WDHB)
Subject: Informed consent for Resident Medical Officers involved in surgical procedures minutes - 31 January 2020

Dear All,

Here are the draft notes from the informed consent meeting on 31 January 2020. Any corrections or comments are welcome.

If you could feed back by Friday 6 March 2020, that would be great.

Document 6A

s 9(2)(a)

Waitemata District Health Board

Best Care for Everyone

Document 6A

Waitemata DHB Wide

[*PLACE PATIENT LABEL HERE*]

First Name: _____ Gender: _____

Surname: _____ Ph: _____

Address: _____

Date of Birth: _____ NHI#: _____

Ward/Clinic: _____ Consultant: _____

Agreement to Treatment / Consent

INTERPRETER REQUIRED: Yes ☐ No ☐ LANGUAGE: _____

SURGERY / OTHER PROCEDURE(S)

I, _____ (name of patient / parent or guardian / welfare guardian or attorney under enduring power of attorney)

Agree that the following procedure be performed for me / my child / person in respect of whom I am welfare guardian or attorney under an enduring power of attorney

_____

_____

_____

_____ If relevant specify side (***circle one***): **Right / Left**

I have discussed this with:

Name _____ **Designation** _____ **Signature** _____

They have explained to me the reason for this procedure, the alternatives, and the possible risks.

Risks of the procedure include (but are not limited to):_____

_____

_____

_____

_____

I agree that: *[Cross out anything you don't agree with]*

- I have had adequate opportunity to ask questions and I have received all the information that I need.
- In the event of an emergency, and as determined by my / the patient's medical team at the time, there may be other procedures undertaken to save my / the patient's life or prevent harm.
- My / the patient's care is occurring in a teaching hospital and healthcare students (medical, nursing) and clinicians in training may be present to observe and learn. I understand they will be appropriately supervised but at any time I can ask for them not to be present.
- My / the patient's health care will be delivered by a team, which may include registered doctors and nurses in training. On the day, so far as reasonably practicable, I / the patient will be introduced to the clinicians who will be performing my / the patient's procedure. They will be suitably qualified and, if in training, will be appropriately supervised by a senior clinician.

Blood accidents

- If a healthcare worker is accidentally exposed to my / the patient's blood or other body fluids, I agree to a sample of my / the patient's blood being taken and tested for transmissible diseases such as Hepatitis and HIV
- I understand I will be informed if this happens and test results will be discussed with me and if required treatment will be given.

Return of Body Parts

- I wish to have any body part / tissue removed during this procedure that is not required for diagnosis returned to me: Yes / No (***circle one***) if *yes ensure this is documented on the Laboratory form and Theatre staff have been informed.*

Patient / Welfare Guardian / Attorney's signature:_____ **Date:**_____/_____/_____

Interpreter's signature:_____ **Interpreter's name:**_____

Review Date: mmm yyyy

AGREEMENT TO TREATMENT / CONSENT

Waitemata District Health Board
Te Wai Awhina

Waitemata DHB Wide

[PLACE PATIENT LABEL HERE]

First Name: _____ Gender: _____
Surname: _____ Ph: _____
Address: _____
Date of Birth: _____ NHI#: _____
Ward/Clinic: _____ Consultant: _____

Agreement to Treatment / Consent

ANAESTHETIA

I, _____(name of patient / parent or guardian / welfare guardian or attorney under enduring power of attorney)

Agree that the Anaesthetic for me / my child / person in respect of whom I am welfare guardian or attorney under an enduring power of attorney has been explained to me for the procedure discussed overleaf

- I agree to the following Anaesthetic as discussed: _____
  _____
- The possible benefits and risks of the Anaesthetic have been explained to me relating to my / the patient's clinical history and condition.

The risks include, but are not limited to: _____
_____
_____
_____

I / the patient have been advised NOT to drive a motor vehicle, operate machinery or potentially dangerous appliances, drink alcoholic beverages or make important decisions for 24 hours after having a general anaesthetic or sedation agents administered.

Patient / Welfare Guardian / Attorney's signature: _____ **Date:** ____/____/____

Interpreter's signature: _____ **Interpreter's name:** _____

Anaesthetist's signature: _____ **Anaesthetist Designation:** _____

Name of Anaesthetist: _____ **Date:** ____/____/____

BLOOD COMPONENTS AND PRODUCTS

☐ I have been advised that I / the patient may require blood, or blood product transfusion. I have been advised of the possible risks, benefits and alternatives to blood transfusion. I understand the risks of blood transfusion refusal.

☐ I have had the opportunity to ask questions and discuss this with the Clinician whose signature appears below.

☐ I agree to receive blood or blood products if these are considered necessary by the Doctors looking after me / the patient. I understand I / the patient may need to receive repeated transfusions.

OR

☐ I **DO NOT** agree to receive blood components and / or products under any circumstance and I understand the risks of this decision.

Patient / Welfare Guardian / Attorney's signature: _____ **Date:** ____/____/____

Interpreter's signature: _____ **Interpreter's name:** _____

Clinician's signature: _____ **Clinician's Designation:** _____

Name of Clinician: _____ **Date:** ____/____/____

Review Date: mmm yyyy

AGREEMENT TO TREATMENT / CONSENT

Meeting summary

Informed consent for Resident Medical Officers involved in surgical procedures

Date:	31 January, 2020
Time:	11.00am – 12.00am
Location:	1S.5, 133 Molesworth St and via teleconference
Chair:	Andrew Simpson
Attendees:	Anthony Hill, Dr Cordelia Thomas, Aleyna Hall, Isobel Freeman, Dr Jonathan Christiansen, Joan Simeon, Phil Knipe

Purpose

The purpose of the meeting was to discuss ways to respond to an issue raised by the New Zealand Nurses Organisation (NZNO) with Waitemata District Health Board (DHB) regarding the consent process when a Registered Medical Officer (RMO) is involved in a surgical procedure.

Background

Background information was provided to attendees by Dr Jonathan Christiansen, Chief Medical Officer, Waitemata DHB.

Approximately seven years ago, concerns were raised by a senior nurse in Child, Women and Family Services regarding consent. This prompted a quality improvement service for consent, which in turn lead to changes in consent policy and documentation over the next year. These policies have not been revised since. The policy has been reviewed by the Health and Disability Sector Standards audit , most recently in 2019, and found to be appropriate.

In the past 18 months, the focus of consent discussions has shifted from medical students involved in surgical procedures (subject to the 2015 national consensus statement) to RMOs.

RMOs are fully registered and qualified medical practitioners, however they are also progressing in their training under the oversight of educational bodies.

The specific request for changes to Waitemata DHB's consent process was made by the New Zealand Nurses' Organisation (NZNO), who had supported the senior nurse in the incident mentioned above. The NZNO's position is that there needs to be 'explicit consent for any teaching to be occurring', separate from the existing consent process and documentation.

Dr Christiansen noted that this most recent request is led by the NZNO independently of any patient or practitioner complaint, of which none have been received in regard to the incidents in question.

Key discussion points

Waitemata DHB current process

Waitemata DHB's current consent form includes a statement that if there is someone in training in the procedure then they will be appropriately supervised.

Waitemata DHB's view is that there is generally no need for specific informed consent in the involvement of an RMO when providing clinical care in the context of the DHB for which they are employed. However when an RMO is undertaking a procedure that they are not credentialled to do as part of their training programme the patients should be made aware and specific reasons given for the RMO's involvement.

Deleted: support

Waitemata DHB's current process allows for the information to be provided at the discretion of the leading clinician, with the expectation that patients are informed if someone in training is participating. It is the responsibility of the clinician to judge whether the RMO is considered, in the specific context, to be in training.

Definition of training

The inseparability of service and training has been identified by Waitemata DHB as a complicating factor to the NZNO's request. Waitemata DHB's approach to consent reflects their acknowledgement of the difficulties associated with separating training and service in the context of consent.

The concerns that have been raised by the NZNO are in regard to when teaching is a component of the clinical care, rather than explicit training contexts such as exams or assessments, and when an RMO and a clinician are performing a procedure together and training is occurring, rather than if the RMO were performing the procedure alone.

Contextual differences

One issue identified in the meeting was the large variety of situations that are included within NZNO's request, and the difficulties associated with creating one rule for all situations.

One example is that some of the concerns raised have conflated credentialled registrars with non-credentialled registrars. Similarly, the level of training the RMO has received in relation to the procedure they will be involved in varies significantly. Waitemata DHB's approach can be seen to allow such differences to be accounted for in the consent process.

Waitemata's view is that NZNO's request is substantially beyond that provided for in the Code of Health and Disability Services Consumers' Rights (the Code) or the MCNZ's statement of informed consent.

The Code states that "Every consumer has the right to honest and accurate answers to questions relating to services, including questions about... the identity and qualifications of the provider", and that "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".

Point 23(c) of the MCNZ's statement of informed consent states "Sometimes, it could be practical to delegate a patient's care to another doctor or health practitioner. When deciding whether to delegate, you should consider whether your patient or anyone else involved in the decision to delegate has been given enough information and time to think it over and to express their views."

The absence of an explicit statement in these two documents around informed consent in relation to the presence of trainees has led to disagreement around whether Waitemata DHB's current standards align with legal requirements.

This discussion raises broader questions of consent in regard to training situations outside of RMOs. Examples include credentialled clinicians who have vocationally trained in one area and are then undertaking training in a further specialty area, or if other trainee practitioners are present such as an anaesthetic registrar.

The attendees agreed that the lead clinician is accountable for all aspects the procedure, including being responsible for an RMO who is present and for any potential risks that their presence may bring.

Consistency of processes across New Zealand

The concerns raised by the NZNO are specific to Waitemata DHB. However, the attendees acknowledged that this must also be considered at a national level.

There was general agreement that there is inconsistency across DHBs in regard to consent documentation. It was also recognised that a large component of the consent process is undocumented, which contributes to difficulties in regulating and enforcing processes both across and within DHBS.

Proposed solution

The meeting attendees agreed that patients have the right to be told who is operating on them, and should therefore be informed if someone in the room is in training as part of the consent process.

In response to the NZNO's request for a separate consent form, the attendees proposed instead that the current consent form be expanded upon to include an acknowledgement that relevant information has been provided to the patient, including whether there will be a trainee assisting in the delivery of care. It would become part of the standard written consent requirements for clinicians, ensuring that the patient is giving their consent on a fully informed basis.

Next steps

The following next steps were agreed upon:

- The Medical Council of New Zealand will review their statement on informed consent.

- The Medical Council of New Zealand and the Health and Disability Commissioner will clarify their view around the key consent issues revealed by this request.
- The Ministry of Health will consider ways to support sector consistency and clarify expectations.
- The issue and proposed solution will be submitted for discussion at the Chief Medical Officers national meeting in March.
- Waitemata DHB will continue to manage their relationship with the NZNO, and manage media enquiries and Official Information Act requests.

Document 6B

Waitematā
District Health Board

Best Care for Everyone

Waitematā DHB
Board Office
Level 2, 15 Shea Terrace, Takapuna, Auckland
Private Bag 93-503, Takapuna, Auckland 1332
Telephone: 09 441 8938
Facsimile: 09 486 8924

23 December 2019

Dr Ashley Bloomfield
Director General of Health

Cc: Hon Dr David Clark, Minister of Health
Dr Andrew Simpson, CMO
Dr Curtis Walker, Chair, Medical Council of New Zealand
Mr Anthony Hill, Health and Disability Commissioner

Dear Ashley,

RE: Informed Consent in a training environment

The Waitematā District Health Board is concerned about the lack of consistent national guidance on informed consent in the context of the training environment of public hospitals. We are asking the Ministry of Health to lead a process to achieve a consistent national consensus on the issue which aligns with the Code of Consumers' Rights and meets the team-based approach to delivery of health care in training hospitals.

The right of our patients to make an informed choice about the care they receive is fundamental to the work we do, and underpins the Code of Consumers' Rights. The DHB environment brings inherent challenges to the application of the Code. Healthcare is delivered by teams of clinicians, typically including registered medical, nursing and allied health practitioners in different stages of training and career progression. Questions have recently been raised about the requirements of informed consent in a modern hospital when members of the clinical team may commonly be participating in supervised learning.

The issue of informed consent in the context of training is particularly relevant to Resident Medical Officers (RMOs) who are employed as registered practitioners for the provision of clinical care, but are in most cases, pursuing further vocational training. The MCNZ has recently released its updated guidance on Informed Consent (September 2019) but this document does not provide specific guidance on consent for the training aspects of the clinical work our RMOs carry out.

Waitematā DHB has taken the view that there is generally no requirement to obtain consent to the participation of an RMO, who is employed as a member of the clinical team providing care. However, if an RMO is to undertake a procedure (under the supervision of an SMO), which the RMO is not yet qualified to do on their own, so far as reasonably practicable, the patient's consent to the RMO's participation should be obtained.

It is unclear whether Waitematā DHB's view of informed consent in relation to RMOs is consistent with that at other DHBs, or supported by regulatory and consumer bodies. Nor is it clear whether this view should extend to all healthcare professionals working and upskilling in training settings. We

are also mindful of the mobility of the healthcare workforce who may be in training pathways, and inconsistency of standards for informed consent between providers would raise concerns.

The Waitematā District Health Board, at its December meeting, discussed an external report on the informed consent issue undertaken by Professor Ron Paterson. The Board resolved to urgently request the Ministry of Health to provide national guidance on informed consent that covers training aspects of clinical work.

Yours sincerely,

Professor Judy McGregor
Chair WDHB

Dr Dale Bramley
CEO WDHB

MINISTRY OF HEALTH
MANATŪ HAUORA

Meeting summary

Informed consent for Resident Medical Officers involved in surgical procedures

Date:	31 January, 2020
Time:	11.00am – 12.00am
Location:	1S.5, 133 Molesworth St and via teleconference
Chair:	Andrew Simpson
Attendees:	Anthony Hill, Dr Cordelia Thomas, Aleyna Hall, Isobel Freeman, Dr Jonathan Christiansen, Joan Simeon, Phil Knipe

Purpose

The purpose of the meeting was to discuss ways to respond to an issue raised by the New Zealand Nurses Organisation (NZNO) with Waitemata District Health Board (DHB) regarding the consent process when a Registered Medical Officer (RMO) is involved in a surgical procedure.

Background

Background information was provided to attendees by Dr Jonathan Christiansen, Chief Medical Officer, Waitemata DHB.

Approximately seven years ago, concerns were raised by a senior nurse in Child, Women and Family Services regarding consent. This prompted a quality improvement service for consent, which in turn lead to changes in consent policy and documentation over the next year. These policies have not been revised since.

In the past 18 months, the focus of consent discussions has shifted from medical students involved in surgical procedures (subject to the 2015 national consensus statement) to RMOs.

RMOs are fully registered and qualified medical practitioners, however they are also progressing in their training under the oversight of educational bodies.

The specific request for changes to Waitemata DHB's consent process was made by the New Zealand Nurses' Organisation (NZNO), who had supported the senior nurse in the incident mentioned above. The NZNO's position is that there needs to be 'explicit consent for any teaching to be occurring', separate from the existing consent process and documentation.

Dr Christiansen noted that this most recent request is led by the NZNO independently of any patient or practitioner complaint, of which none have been received in regard to the incidents in question.

MINISTRY OF HEALTH
MANATŪ HAUORA

Key discussion points

Waitemata DHB current process

Waitemata DHB's current consent form includes a statement that if there is someone in training in the procedure then they will be appropriately supervised.

Waitemata DHB's view is that there is generally no need for specific informed consent in the involvement of an RMO when providing clinical support in the context of the DHB for which they are employed. However when an RMO is undertaking a procedure that they are not credentialled to do as part of their training programme the patients should be made aware and specific reasons given for the RMO's involvement.

Waitemata DHB's current process allows for the information to be provided at the discretion of the leading clinician, with the expectation that patients are informed if someone in training is participating. It is the responsibility of the clinician to judge whether the RMO is considered, in the specific context, to be in training.

Definition of training

The inseparability of service and training has been identified by Waitemata DHB as a complicating factor to the NZNO's request. Waitemata DHB's approach to consent reflects their acknowledgement of the difficulties associated with separating training and service in the context of consent.

The concerns that have been raised by the NZNO are in regard to when teaching is a component of the clinical care, rather than explicit training contexts such as exams or assessments, and when an RMO and a clinician are performing a procedure together and training is occurring, rather than if the RMO were performing the procedure alone.

Contextual differences

One issue identified in the meeting was the large variety of situations that are included within NZNO's request, and the difficulties associated with creating one rule for all situations.

One example is that some of the concerns raised have conflated credentialled registrars with non-credentialled registrars. Similarly, the level of training the RMO has received in relation to the procedure they will be involved in varies significantly. Waitemata DHB's approach can be seen to allow such differences to be accounted for in the consent process.

Waitemata's view is that NZNO's request is substantially beyond that provided for in the Code of Health and Disability Services Consumers' Rights (the Code) or the MCNZ's statement of informed consent.

The Code states that "Every consumer has the right to honest and accurate answers to questions relating to services, including questions about... the identity and qualifications of the provider", and that "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".

Point 23(c) of the MCNZ's statement of informed consent states "Sometimes, it could be practical to delegate a patient's care to another doctor or health practitioner. When deciding whether to delegate, you should consider whether your patient or anyone else involved in the decision to delegate has been given enough information and time to think it over and to express their views."

The absence of an explicit statement in these two documents around informed consent in relation to the presence of trainees has led to disagreement around whether Waitemata DHB's current standards align with legal requirements.

This discussion raises broader questions of consent in regard to training situations outside of RMOs. Examples include credentialled clinicians who have vocationally trained in one area and are then undertaking training in a further specialty area, or if other trainee practitioners are present such as an anaesthetic registrar.

The attendees agreed that the lead clinician is accountable for all aspects the procedure, including being responsible for an RMO who is present and for any potential risks that their presence may bring.

Consistency of processes across New Zealand

The concerns raised by the NZNO are specific to Waitemata DHB. However, the attendees acknowledged that this must also be considered at a national level.

There was general agreement that there is inconsistency across DHBs in regard to consent documentation. It was also recognised that a large component of the consent process is undocumented, which contributes to difficulties in regulating and enforcing processes both across and within DHBS.

Proposed solution

The meeting attendees agreed that patients have the right to be told who is operating on them, and should therefore be informed if someone in the room is in training as part of the consent process.

In response to the NZNO's request for a separate consent form, the attendees proposed instead that the current consent form be expanded upon to include an acknowledgement that relevant information has been provided to the patient, including whether there will be a trainee assisting in the delivery of care. It would become part of the standard written consent requirements for clinicians, ensuring that the patient is giving their consent on a fully informed basis.

Next steps

The following next steps were agreed upon:

- The Medical Council of New Zealand will review their statement on informed consent.
- The Medical Council of New Zealand and the Health and Disability Commissioner will clarify their view around the key consent issues revealed by this request.

- The Ministry of Health will consider ways to support sector consistency and clarify expectations.
- The issue and proposed solution will be submitted for discussion at the Chief Medical Officers national meeting in March.
- Waitemata DHB will continue to manage their relationship with the NZNO, and manage media enquiries and Official Information Act requests.

Document 7

Informed Consent – Literature Search Results

Informed Consent and Adverse Events Overseas

Austin, L. V. (2018). "Grimstone v Epsom and St Helier University Hospitals NHS Trust: (It's Not) H p to Be Square." Med Law Rev 26(4): 665-674 DOI: 10.1093/medlaw/fwx053 ***Nov 1.***

In Montgomery v Lanarkshire Health Board [2015] UKSC 11 the Supreme Court redefined the standard of disclosure in informed consent to medical treatment, rejecting the application of the doctor-focused Bolam standard in favour of one focused on what was significant to patients. In Grimstone v Epsom and St Helier University Hospitals NHS Tru t [2015] EWHC 3756 (QB), despite acknowledging a new standard now applied, McGowan J nevertheless used the Bolam test to determine liability for non-disclosure. This il ustrates ongoing judicial deference to the medical profession and this case commentary explores that decision and its implications.

Austin, L. V. (2019). "Hii Chii Kok v (1) Ooi Peng Jin London Lucien (2) National Cancer Centre: Modifying Montgomery." Med Law Rev 27(2): 339-351 DOI: 10.1093/medlaw/fwy044 ***May 1.***

In Hii Chii Kok v (1) Ooi Peng Jin London Lucien; (2) National Cancer Centre, the Singapore Court of Appeal followed the approach of other Commonwealth jurisdictions by rejecting the application of Bolam as the standard of disclosure in claims concerning informed consent to medical treatment. Instead the court employed a modified version of the standard of disclosure adopted in Montgomery v Lanarkshire Health Board. While broadly welcomed, Montgomery has been criticised for its lack of clarity on the application of some elements of its disclosure standard. In particular, questions remain as to: what factors should be taken into account within the reasonable and particular patient limbs of the test of materiality; how will the 'reasonableness' of alternative treatments be determined; and what is the scope of the therapeutic exception. This case commentary explores how Hii's analysis of the modified standard offers insights into how those elements of Montgomery could be interpreted in the future.

Birch, N. and N. V Todd (2020). "The cost of consent: why healthcare providers must be compliant with the Montgomery principles." The bone & joint journal 102-B(5): 550-555 DOI: https://dx.doi.org/10.1302/0301-620X.102B5.BJJ-2019-1759

The cost of clinical negligence in the UK has continued to rise despite no increase in claims numbers from 2016 to 2019. In the US, medical malpractice claim rates have fallen each year since 2001 and the payout rate has stabilized. In Germany, malpractice claim rates for spinal surgery fell yearly from 2012 to 2017, despite the number of spinal operations increasing. In Australia, public healthcare claim rates were largely static from 2008 to 2013, but private claims rose marginally. The cost of claims rose during the period. UK and Australian trends are therefore out of alignment with other international comparisons. Many of the claims in orthopaedics occur as a result of "failure to warn", i.e. lack of adequately documented and appropriate consent. The UK and USA have similar rates (26% and 24% respectively), but in Germany the rate is 14% and in Australia only 2%. This paper considers the drivers for the increased cost of clinical negligence claims in the UK compared to the USA, Germany and Australia, from a spinal and orthopaedic point of view, with a focus on "failure to warn" and

lack of compliance with the principles established in February 2015 in the Supreme Court in the case of Montgomery v Lanarkshire Health Board. The article provides a description of the prevailing medicolegal situation in the UK and also calculates, from publicly available data, the cost to the public purse of the failure to comply with the principles established. It shows that compliance with the Montgomery principles would have an immediate and lasting positive impact on the sums paid by NHS Resolution to settle negligence cases in a way that has already been established in the USA. Cite this article: Bone Joint J 2020;102-B(5):550-555.

Breen, D. T., et al. (2014). "Implications for Australian anaesthetists and proceduralists of a recent court decision regarding informed consent and patient positioning." Anaesth Intensive Care 42(1): 11-14 DOI: 10.1177/0310057x1404200104 ***Jan.***

This article discusses the medicolegal implications of a recent judgment in relation to a patient who suffered significant morbidity as a result of patient positioning during an operative procedure. The patient developed an unexpected serious complication following surgery, in the context of a preoperative consent that did not cover every potential complication or contingency. The court held that the failure to warn of a particular risk that would have prevented the patient from undergoing a procedure but did not occur will not necessarily result in a finding of negligence in relation to another risk where the harm did occur. This finding is well aligned to current clinical practice and at the same time does not abrogate the practitioner's duty to provide a comprehensive list of possible complications during the consent process for any proceduralist. In the context of a procedure requiring anaesthesia, the importance of communication and understanding between the anaesthetist and proceduralist as to which aspects of the consent process are undertaken by whom, and to ensure the process is done comprehensively, is of great importance and is indirectly highlighted by this recent judgment.

Burningham, S., et al. (2013). "Informed consent and patient comprehension: The law and the evidence." McGill Journal of Law and Health 7: 123-128 ***01/01.***

Few areas of health law attract as much attention as informed consent. In Canada, several well-known Supreme Court cases,1 and, in some provinces, health care consent laws,2 provide that physicians must obtain the informed consent of patients prior to providing medical treatment. While the basic parameters of informed consent law are clear, confusion remains about the extent of the duty of physicians to ensure that patients understand the information provided. The need for patient comprehension is self-evident: providing patients with information facilitates decision making and promotes autonomy only if patients are able to understand that information. However, it may be challenging for physicians in practice to meet legal or ethical obliga-

Carver, T. (2020). "Informed consent, Montgomery and the duty to discuss alternative treatments in England and Australia." Journal of Patient Safety and Risk Management 25(5): 187-193 DOI: 10.1177/2516043520941330

The UK Supreme Court in Montgomery v Lanarkshire Health Board imposes a duty on healthcare professionals in relation to information disclosure. The obligation is to take reasonable care to ensure that patients are aware, not just of material risks inherent in any recommended treatment, but of any reasonable alternative treatments. While liability for information non-provision was previously decided according to whether the profession would deem disclosure appropriate, the law now judges the sufficiency of information from a patient's perspective. In doing so, it adopts the approach advocated for Australia in Rogers v Whitaker. However, commentators, in this journal and elsewhere, have expressed concern that the disclosure obligation is unclear. Although Montgomery defines what is 'material' for

the purpose of identifying notifiable treatment risks, it offers less guidance as to when alternative treatments will be sufficiently 'reasonable' to warrant disclosure. Through an analysis of Australian and UK case law and examples, this article considers the ambit of a practitioner's duty to discuss alternatives. It concludes that although likely subject to further litigation, the identification of reasonable treatment options requiring disclosure will be influenced by the patient's clinical condition, their prognosis and viable options from a medical perspective, and various non-clinical matters influenced by the test of materiality. © The Author(s) 2020.

Cave, E. (2017). "The ill-informed: Consent to medical treatment and the therapeutic exception." Common Law World Review 46(2): 140-168 DOI: 10.1177/1473779517709452 ***2017/06/01.***

Affirming the doctrine of informed consent, the UK Supreme Court in Montgomery v Lanarkshire HB belatedly followed the Australian decision of Rogers v Whitaker, decoupling the duty to inform patients about the material risks of medical treatment from Bolam. The underlying commitment to patient autonomy coincides with a wider body of medical law that protects the right of capacitous adult patients to make treatment decisions, even if others consider those decisions bizarre and even if they will cause the patient serious harm. It is seemingly anomalous, therefore, that the Supreme Court in Montgomery referred to a ?therapeutic exception? (TE), as this suggests an underlying paternalistic approach. Contrary to this view, international examples suggest that a TE does not necessarily conflict with commitment to patient autonomy. In some countries, the exception mitigates the effects of a broadly objective test of materiality by enabling clinicians in exceptional circumstances to protect the autonomy interests of the particular patient. In others, it protects those incapable of an autonomous decision from harm. In England and Wales, however, alternative mechanisms can be interpreted to protect such patients from harm. On this basis, it is argued that the TE is obfuscatory, unnecessary and unjustified.

Chan, S. W., et al. (2017). "Montgomery and informed consent: where are we now?" BMJ 357: j2224 DOI: 10.1136/bmj.j2224

Dunn, M., et al. (2019). "Between the Reasonable and the Particular: Deflating Autonomy in the Legal Regulation of Informed Consent to Medical Treatment." Health Care Analysis 27(2): 110-127 DOI: 10.1007/s10728-018-0358-x ***2019/06/01.***

The law of informed consent to medical treatment has recently been extensively overhauled in England. The 2015 Montgomery judgment has done away with the long-held position that the information to be disclosed by doctors when obtaining valid consent from patients should be determined on the basis of what a reasonable body of medical opinion agree ought to be disclosed in the circumstances. The UK Supreme Court concluded that the information that is material to a patient's decision should instead be judged by reference to a new two-limbed test founded on the notions of the 'reasonable person' and the 'particular patient'. The rationale outlined in Montgomery for this new test of materiality, and academic comment on the ruling's significance, has focused on the central ethical importance that the law now (rightfully) accords to respect for patient autonomy in the process of obtaining consent from patients. In this paper, we dispute the claim that the new test of materiality articulated in Montgomery equates with respect for autonomy being given primacy in re-shaping the development of the law in this area. We also defend this position, arguing that our revised interpretation of Montgomery's significance does not equate with a failure by the courts to give due legal consideration to what is owed to patients as autonomous decision-makers in the consent process. Instead, Montgomery correctly implies that doctors are ethically (and legally) obliged to attend to a number of relevant ethical considerations in framing decisions about consent to treatment, which

include subtle interpretations of the values of autonomy and well-being. Doctors should give appropriate consideration to how these values are fleshed out and balanced in context in order to specify precisely what information ought to be disclosed to a patient as a requirement of obtaining consent, and as a core component of shared decision-making within medical encounters more generally.

Edozien, L. C. (2015). UK law on consent finally embraces the prudent patient standard, British Medical Journal Publishing Group. **350**.

Farrell, A. M. and M. Brazier (2016). "Not so new directions in the law of consent? Examining Montgomery v Lanarkshire Health Board." Journal of Medical Ethics 42(2): 85-88 DOI: 10.1136/medethics-2015-102861

This paper examines the UK Supreme Court decision in Montgomery v Lanarkshire Health Board, which deals with consent and information disclosure in medical treatment and care. It signaled a move away from a 'doctor knows best' approach to one that focuses on disclosing information to which particular patients would attach significance. Notwithstanding concerns about increased litigation and loss of professional autonomy, the reality is that the decision will make little difference to healthcare practice and consent in the UK. The Supreme Court has endorsed a view that most lawyers and doctors thought already prevailed, and it reflects the General Medical Council's guidance on the issue of consent in any case. Given recent healthcare scandals in the National Health Service (NHS), the Supreme Court's legal recognition of the importance of recognizing patient autonomy in disclosing risks about medical treatment and care is a welcome development.

Grauberger, J., et al. (2017). "Allegations of Failure to Obtain Informed Consent in Spinal Surgery Medical Malpractice Claims." JAMA surgery 152(6): e170544 DOI: https://dx.doi.org/10.1001/jamasurg.2017.0544

Importance: Predictive factors associated with increased risk of medical malpractice litigation have been identified, including severity of injury, physician sex, and error in diagnosis. However, there is a paucity of literature investigating informed consent in spinal surgery malpractice., Objective: To investigate the failure to obtain informed consent as an allegation in medical malpractice claims for patients undergoing a spinal procedure., Design, Setting, and Participants: In this retrospective cohort study, a national medicolegal database was searched for malpractice claim cases related to spinal surgery for all years available (ie, January 1, 1980 through December 31, 2015)., Main Outcomes and Measures: Failure to obtain informed consent and associated medical malpractice case verdict., Results: A total of 233 patients (117 [50.4%] male and 116 [49.8%] female; 80 with no informed consent allegation and 153 who cited lack of informed consent) who underwent spinal surgery and filed a malpractice claim were studied (mean [SD] age, 47.1 [13.1] years in the total group, 45.8 [12.9] years in the control group, and 47.9 [13.3] years in the informed consent group). Median interval between year of surgery and year of verdict was 5.4 years (interquartile range, 4-7 years). The most common informed consent allegations were failure to explain risks and adverse effects of surgery (52 [30.4%]) and failure to explain alternative treatment options (17 [9.9%]). In bivariate analysis, patients in the control group were more likely to require additional surgery (45 [56.3%] vs 53 [34.6%], P = .002) and have more permanent injuries compared with the informed consent group (46 [57.5%] vs 63 [42.0%], P = .03). On multivariable regression analysis, permanent injuries were more often associated with indemnity payment after a plaintiff verdict (odds ratio [OR], 3.12; 95% CI, 1.46-6.65; P = .003) or a settlement (OR, 6.26; 95% CI, 1.06-36.70; P = .04). Informed consent allegations were significantly associated with less severe (temporary or emotional) injury (OR, 0.52; 95% CI, 0.28-0.97; P = .04). In addition, allegations of informed consent were found to be

predictive of a defense verdict vs a plaintiff ruling (OR, 0.41; 95% CI, 0.17-0.98; P = .046) or settlement (OR, 0.01; 95% CI, 0.001-0.15; P < .001)., Conclusions and Relevance: Lack of informed consent is an important cause of medical malpractice litigation. Although associated with a lower rate of indemnity payments, malpractice lawsuits, including informed consent allegations, still present a time, money, and reputation toll for physicians. The findings of this study can therefore help to improve preoperative discussions to protect spinal surgeons from malpractice claims and ensure that patients are better informed.

Haskell, H. (2020). "Cumberlege review exposes stubborn and dangerous flaws in healthcare." BMJ 370: m3099 DOI: 10.1136/bmj.m3099 ***Aug 6.***

Herring, J., et al. (2017). "Elbow Room for Best Practice? Montgomery, Patients' values, and Balanced Decision-Making in Person-Centred Clinical Care." Medical Law Review 25(4): 582-603 DOI: https://dx.doi.org/10.1093/medlaw/fwx029

The UK Supreme Court Montgomery judgment marks a decisive shift in the legal test of duty of care in the context of consent to treatment, from the perspective of the clinician (as represented by Bolam rules) to that of the patient. A majority of commentators on Montgomery have focused on the implications of the judgment for disclosure of risk. In this article, we set risk disclosure in context with three further elements of the judgment: benefits, options, and dialogue. These elements, we argue, taken together with risk disclosure, reflect the origins of the Montgomery ruling in a model of consent based on autonomy of patient choice through shared decision-making with their doctor. This model reflects recent developments in both law and medicine and is widely regarded (by the General Medical Council and others) as representing best practice in contemporary person-centred medicine. So understood, we suggest, the shift marked by Montgomery in the basis of duty of care is a shift in underpinning values: it is a shift from the clinician's interpretation about what would be best for patients to the values of (to what is significant or matters from the perspective of) the particular patient concerned in the decision in question. But the values of the particular patient do not thereby become paramount. The Montgomery test of duty of care requires the values of the particular patient to be balanced alongside the values of a reasonable person in the patient's position. We illustrate some of the practical challenges arising from the balance of considerations required by Montgomery with examples from surgical care. These examples show the extent to which Montgomery, in mirroring the realities of clinical decision-making, provides elbowroom for best practice in person-centred clinical care.

Huxtable, R. (2020). Informed Consent and the Law. The Wiley Handbook of Healthcare Treatment Engagement**:** 75-91.

Summary This chapter traces the development of English law in relation to informed consent, before reflecting on how the law in this area might help or hinder patient engagement. For many decades, English law essentially favored a paternalistic approach to consent. In a 2015 ruling, however, the Supreme Court favored an approach much more in line with the ethical ideal of respect for patient autonomy. This approach seems capable of supporting patient engagement, although we should continue to monitor how the law in this area might develop.

Knight, S. R., et al. (2019). "Patient consent in the post-Montgomery era: A national multi-speciality prospective study." The Surgeon 17(5): 277-283 DOI: https://doi.org/10.1016/j.surge.2018.08.009 ***2019/10/01/.***

Background The Montgomery ruling has had a wide-ranging impact on the consent process and has been the subject of new guidelines by bodies, including the Royal College of Surgeons (RCSEng). This is the first study to examine the current standard of consent for surgical procedures at a national level. Method A national collaborative research model was used, with prospective data collection performed across hospitals in Scotland. Variables associated with the consent process were audited across three surgical specialities (general surgery, urology and orthopaedics) and measured against standards set by RCSEng, the Scottish Public Services Ombudsman and medical defence organisations. Results A total of 289 cases were identified from 12 hospitals. The majority of patients were reviewed by a consultant surgeon in clinic (79.9%) or on the day of surgery (55.4%). The clinic consent rate was 27.0%, while a copy of the documented discussion was only provided to 4.2% of patients. On the day of surgery, the benefits, risks and alternatives to the planned procedure were discussed in less than half of cases. This rate was similar across different clinician grades, while marked variation was seen across hospitals. Conclusion In this prospective multi-centre study we have demonstrated wide variation in the consent processes in many surgical specialities across Scotland. Following the Montgomery ruling, we have demonstrated the current consent process in elective surgery is likely to be substandard, and may require additional steps to be taken by clinicians to ensure patients are fully informed to make decisions regarding their treatment.

Leclercq, W. K. G., et al. (2013). "A survey of the current practice of the informed consent process in general surgery in the Netherlands." Patient Safety in Surgery 7(1): 4 DOI: 10.1186/1754-9493-7-4 ***2013/01/21.***

A properly conducted surgical informed consent process (SIC) allows patients to authorize an invasive procedure with full comprehension of relevant information including involved risks. Current practice of SIC may differ from the ideal situation. The aim of this study is to evaluate whether SIC practiced by Dutch general surgeons and residents is adequate with involvement of all required elements.

Lee, A. (2017). "'Bolam' to 'Montgomery' is result of evolutionary change of medical practice towards 'patient-centred care'." Postgrad Med J 93(1095): 46-50 DOI: 10.1136/postgradmedj-2016-134236 ***Jan.***

The Supreme Court judgement in 'Montgomery v Lanarkshire Health Board' has caused a change in the law concerning the duty of doctors on disclosure of information to patients regarding risks. The law now requires a doctor to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. Are doctors totally removed from the protective shield even if the practice is accepted by a reasonable body of medical opinion previously laid down by 'Bolam' with the recent Supreme Court decision in the 'Montgomery' case? This paper questions whether the 'Bolam' principle needs to be discarded or re-interpreted in the modern context of health care. Adopting 'patient-centred' care to unfold the 'significant risks' attached to patients would align with the evolving changes in medical law. It should be the changing context of health care driving the evolving change of law.

Lewis, C. (2015). "Editorial: Consent to treatment: Supreme Court discards Bolam principle." The Medico-legal journal 83(2): 59-61 DOI: https://dx.doi.org/10.1177/0025817215582167

McCormack, D. J., et al. (2018). "Informed consent: a global perspective." The bone & joint journal 100-B(6): 687-692 DOI: https://dx.doi.org/10.1302/0301-620X.100B6.BJJ-2017-1542.R1

Our aim in this paper was to investigate the guidelines and laws governing informed consent in the English-speaking world. We noted a recent divergence from medical paternalism within the United Kingdom, highlighted by the Montgomery v Lanarkshire Health Board ruling of 2015. We investigated the situation in the United Kingdom, Australia, New Zealand, Canada, and the United States of America. We read the national guidance regarding obtaining consent for surgical intervention for each country. We used the references from this guidance to identify the laws that helped inform the guidance, and reviewed the court documents for each case. There has been a trend towards a more patient-focused approach in consent in each country. Surgeons should be aware of the guidance and legal cases so that they can inform patients fully, and prevent legal problems if outdated practices are followed. Cite this article: Bone Joint J 2018;100-B:687-92.

McFadden, B. L., et al. (2013). "Patient recall 6 weeks after surgical consent for midureth al sling using mesh." International urogynecology journal 24(12): 2099-2104 DOI: https://dx.doi.org/10.1007/s00192-013-2136-5

INTRODUCTION AND HYPOTHESIS: We aimed to determine patient recall of specific surgical risks and benefits discussed during consent for midurethral sling (MUS) surgery immediately after consent and at 6 weeks follow-up. Specifically we sought to determine whether or not women recalled specific risks related to the placement of mesh., METHODS: Surgeons consented patients for MUS in their usual fashion during audio recorded consent sessions. After consent and again at 6 weeks postoperatively, women completed a checklist of risks, benefits, alternatives, and general procedural items covered during consent. In addition, women completed the Decision Regret Scale for Pelvic Floor Disorders (DRS-PFD). Audio files were used to verify specific risks, benefits, alternatives, and procedural items discussed at consent. Recall of specific risks, benefits, and alternatives were correlated with DRS-PFD scores., RESULTS: Sixty-three women completed checklists immediately post consent and at 6 weeks postoperatively. Six-week recall of benefits, alternatives, and description of the operation did not change. Surgical risk recall as measured by the patient checklist deteriorated from 92 % immediately post consent to 72 % at 6 weeks postoperatively ($p < .001$). Recall of the risk for mesh erosion declined from 91 to 64 % ($p < .001$). Recall that mesh was placed during the MUS procedure declined from 98 to 84 % ($p = .01$). DRS-PFD scores were correlated with poorer surgical risk recall and surgical complications ($r = .31$, $p = .02$)., CONCLUSIONS: Recall of MUS surgery risks deteriorated over time. Specifically, women forgot that mesh was placed or might erode. Further investigations into methods and measures of adequate consent that promote recall of long-term surgical risks are needed.

McKinnon, C., et al. (2018). "Surgical consent practice in the UK following the Montgomery ruling: A national cross-sectional questionnaire study." International journal of surgery (London, England) 55: 66-72 DOI: https://dx.doi.org/10.1016/j.ijsu.2018.05.016

BACKGROUND: The Supreme Court case of Montgomery vs Lanarkshire Health Board in 2015 was a landmark case for consent practice in the UK which shifted focus from a traditional paternalistic model of consent towards a more patient-centered approach. Widely recognised as the most significant legal judgment on informed consent in the last 30 years, the case was predicted to have a major impact on the everyday practice of surgeons working in the UK National Health Service (NHS). Two years after the legal definition of informed consent was redefined, we carried out an audit of surgical consent practice across the UK to establish the impact of the Montgomery ruling on clinical practice., MATERIALS & METHODS: Data was collected by distribution of an electronic questionnaire to NHS doctors working in surgical specialities with a total of 550 respondents., RESULTS: 81% of surgical doctors were aware of the recent change in consent law, yet only 35% reported a noticeable change in the local consent process. Important barriers to modernisation included limited consent

training, a lack of protected time for discussions with patients and minimal uptake of technology to aid decision-making/documentation., CONCLUSIONS: On the basis of these findings, we identify a need to develop strategies to improve the consent process across the NHS and limit the predicted rise in litigation claims. Copyright © 2018 IJS Publishing Group Ltd. Published by Elsevier Ltd. All rights reserved.

Miller, D., et al. (2012). "Informed surgical consent for a mesh/graft-augmented vaginal repair of pelvic organ prolapse. Consensus of the 2nd IUGA Grafts Roundtable: optimizing safety and appropriateness of graft use in transvaginal pelvic reconstructive surgery." Int Urogynecol J 23 Suppl 1: S33-42 DOI: 10.1007/s00192-012-1680-8 ***Apr.***

INTRODUCTION AND HYPOTHESIS: Complex issues surround informed surgical consent for pelvic reconstructive surgery. METHODS: Vaginally placed mesh/grafts are used with the intent to increase durability of the repair but potentially introduce unique compl cations, offering new challenges in informed surgical consent counseling. RESULTS: Informed consent is a process that takes place throughout the entire consultation with the patient. A written document often accompanies that process. This paper outlines necessary components of informed surgical consent and the theory behind each component. CONCLUSIONS: We explore elements that should be included in the consent process with regard to expected benefits, alternatives, and material risks that are specific to the use of a mesh/graft-augmented vaginal repair of prolapse. Included is an appendix that may serve as a template for the creation of a surgeon's own written informed consent document.

Omilabu, T. (2019). "Shwab v. Ravindra and the Legal Implications of Informed Consent." American journal of law & medicine 45(4): 453-457 DOI: https://dx.doi.org/10.1177/0098858819892748

Prashar, A., et al. (2021). "Informed consent in interventional radiology – are we doing enough?" The British Journal of Radiology 94(1122): 20201368 DOI: 10.1259/bjr.20201368

Objectives:Obtaining informed consent is a mandatory part of modern clinical practice. The aim of this study was to identify how often complications relating to Interventional Radiology (IR) procedures were discussed with the patient prior to the procedure.Methods:A retrospective analysis of 100 patients who experienced a complication related to an IR procedure was performed. The patient's procedure consent form was examined to identify whether the complication they experienced had been discussed as a possible risk. Other parts of the consent form relating to need for blood transfusion and the need for further procedures were also examined.Results:39% of patients who experienced a complication did not have the complication documented as a potential risk on the consent form. 14% of patients required a blood transfusion but were not consented for this. 42% of patients required a further procedure or operation but were not warned of this.Conclusion:The model of gaining informed consent on the day of procedure is no longer valid. Better education and the use of clinics, patient information sheets and other resources is essential.Advances in knowledge:The paper highlights the inadequacies of the current model in gaining consent for IR procedures. A more comprehensive consent process making use of all available resources is essential.

Rayess, H. M., et al. (2018). "Adverse events in facial implant surgery and associated malpractice litigation." JAMA Facial Plastic Surgery 20(3): 244-248 DOI: 10.1001/jamafacial.2017.2242

IMPORTANCE Facial implants represent an important strategy for providing instant and long-lasting volume enhancement to address both aging and posttraumatic defects. OBJECTIVE To better understand risks of facial implants by examining national resources encompassing adverse events and considerations facilitating associated litigation. DESIGN, SETTING, AND PARTICIPANTS A cross-sectional study reviewed complications following facial implants. The

procedures reviewed were performed on patients at locations throughout the United States from January 2006 to December 2016. Data collection was completed in March 2017. The Manufacturer and User Facility Device Experience database, which contains medical device reports submitted to the US Food and Drug Administration (FDA), was searched for complications that occurred from January 2006 to December 2016 involving facial implants made by Implantech, MEDPOR, Stryker, KLS Martin, and Synthes. Furthermore, the Thomson Reuters Westlaw legal database was searched for relevant litigation. MAIN OUTCOMES AND MEASURES The complications of facial implants were analyzed in relation to the location of implant and severity of complication. Litigation was analyzed to determine which factors determine outcome. RESULTS Thirty-nine instances of adverse events reported to the FDA were identified. Sixteen (41%) involved malar implants, followed by 12 chin implants (31%). The most common complications included infection (18 [46%]), implant migration (9 [23%]), swelling (7 [18%]), and extrusion (4 [10%]). Thirty-two patients (83%) had to have their implants removed. Infection occurred at a mean (SD) of 83.3 (68.8) days following the surgery. One-third of complications involved either migration or extrusion. The mean (range) time to migration or extrusion was 381.1 (10-2400) days. In 12 malpractice cases identified in publicly available court proceedings, alleged inadequate informed consent and requiring additional surgical intervention (ie, removal) were the most commonly cited factors. CONCLUSIONS AND RELEVANCE Infection and implant migration or extrusion are the most common complications of facial implants. Most of these complications necessitate removal. These considerations need to be discussed with patients preoperatively as part of the informed consent process, as allegedly inadequate informed consent was cited in a significant proportion of resultant litigation, and there were overlapping considerations among adverse events reported to the FDA and factors brought up in relevant litigation. Cases resolved with settlements and jury-awarded damages encompassed considerable award totals.

Rix, K. J. B. (2017). "After a prolonged gestation and difficult labour, informed consent is safely delivered into English and Scots law." BJPsych Advances 23(1): 63-72 DOI: 10.1192/apt.bp.116.015990

It is over 40 years since the principle of informed consent was accepted in the USA and it has been long established in other common law jurisdictions. But for decades English law has been constrained by the Sidaway case, which effectively perpetuated a form of medical paternalism. Nevertheless, a patient-centred approach can be traced to one of the judgments in that case, and in the case of Montgomery the Supreme Court has now adopted an approach to consent which is based on self-determination and autonomy and is more closely aligned to professional practice. It calls for a dialogue between doctor and patient, recognition of the patient's right to make a choice and recognition by the doctor of their duty to provide the comprehensible information necessary for the patient to exercise choice, having regard to what a prudent patient, in that patient's circumstances and with that patient's characteristics, would want to know.Learning Objectives• Understand how the principle of informed consent has emerged in UK law• Understand the principle of informed consent• Know how to apply the principle of informed consent to the practice of psychiatry

Sivarajah, V., et al. (2021). "Chronic groin pain following open inguinal hernia repair: has consenting practice improved?" Ann R Coll Surg Engl 103(1): 5-9 DOI: 10.1308/rcsann.2020.0184 ***Jan.***

INTRODUCTION: Chronic groin pain following inguinal hernia surgery is a common and potentially debilitating complication, and yet patients are infrequently informed of this risk. This leaves surgeons open to negligence claims, especially given recent changes to case law, which for the first time highlighted the need for a more patient-centred approach to risk disclosure. We investigated how these changes have influenced our consenting practice with

respect to the disclosure of this risk. METHODS: We compared how often surgeons discussed the risk of chronic groin pain with adults undergoing elective open unilateral inguinal hernia mesh repairs in 2019 and 2009. The first 50 patients in each of these two years were retrospectively compared. Discussions during the initial consultation and on the day of surgery were assessed by reviewing clinic letters, medical notes and consent forms. FINDINGS: The risk of chronic pain was discussed with significantly more patients in 2019 than in 2009 (96% v 54%, p<0.0001). Most of these discussions occurred on the day of surgery (92% v 54%, p<0.0001). Only a few patients had these discussions during their initial consultation (18% v 4%, p<0.025). CONCLUSIONS: Discussing the risk of chronic groin pain has improved significantly over the past 10 years. However, these discussions occur mostly on the day of surgery, which gives patients very little time to weigh up the risk. This potentially invalidates the consent they give for surgery. Patients should be given an opportunity to discuss their operative risks in advance of their operation.

Skiba, R., et al. (2021). "Doctors' understanding of consent law." Internal Medicine Journal 51(7): 1068-1073 DOI: https://doi.org/10.1111/imj.14873 ***2021/07/01.***

Abstract Background: Obtaining informed consent is an important responsibility of all doctors and is a major component of their day-to-day practice. However, little is known regarding practising doctors' understanding of consent in relation to medical law. Aims: To gain insights into current doctors' understanding of the legal requisites that underpin the consent of patients to medical procedures in Australia. Methods: A cross-sectional survey of Western Australian medical practitioners was conducted. A 15-question online questionnaire (SurveyMonkey, USA) was developed and distributed to Western Australia medical practitioners via social media, hospital-based Junior doctor society pages and through the email accounts of practitioners registered with MDA National - a large medical defence organisation. Doctors were questioned on their understanding of medicolegal responsibilities, informed consent practice and knowledge of a historically significant Australian medicolegal case (Rogers v Whitaker, 1992). Results: A total of 172 responses was received during the survey period. The respondents came from various levels of seniority and from a variety of subspecialist areas. The survey demonstrated that among the respondents, the understanding of their medicolegal responsibilities around the issues of informed consent was deficient. Only 31% of respondents were aware that it is a court of law that defines the reasonable standard of care in relation to obtaining informed consent. Less than half of the respondents (48%) were aware of the High Court of Australia's definition by which the standard of reasonable care is defined. Conclusion: The results from our survey suggest that there is a requirement to enhance the education of medical practitioners to meet the medicolegal requirements and optimise consent.

Smith, M. K. and T. Carver (2018). "Montgomery, informed consent and causation of harm: lessons from Australia or a uniquely English approach to patient autonomy?" J Med Ethics 44(6): 384-388 DOI: 10.1136/medethics-2017-104273 ***Jun.***

The UK Supreme Court in Montgomery v Lanarkshire Health Board adopts an approach to information disclosure in connection with clinical treatment that moves away from medical paternalism towards a more patient-centred approach. In doing so, it reinforces the protection afforded to informed consent and autonomous patient decision making under the law of negligence. However, some commentators have expressed a concern that the widening of the healthcare providers' duty of disclosure may provide impetus, in future cases, for courts to adopt a more rigorous approach to the application of causation principles. The aim would be to limit liability but, in turn, it would also limit autonomy protection. Such a restrictive approach has recently been adopted in Australia as a result of the High Court decision in Wallace v Kam This paper considers whether such an approach is

likely under English negligence law and discusses case law from both jurisdictions in order to provide a point of comparison from which to scope the post-Montgomery future.

Turton, G. (2019). "Informed Consent to Medical Treatment Post-Montgomery: Causation and Coincidence." Medical Law Review 27(1): 108-134 DOI: 10.1093/medlaw/fwy026

If a patient suffers physical harm during medical treatment when a risk materialises which the doctor failed to warn the patient about, there are two key issues when a negligence claim is brought by the patient. First, it must be shown that the doctor was negligent in failing to warn the patient about the particular risk. Secondly, it must normally be shown that this failure to warn was a cause of the damage suffered, although courts also allow claims to succeed when a patient may still have undergone treatment even if adequately warned. The recent decision in Montgomery v Lanarkshire HA [2015] UKSC 11 changes the test for the first of these steps, by moving away from asking what a reasonable doctor would warn about and asking instead what a reasonable patient, or indeed the actual patient, would want to know. This article considers how that change ought to impact on the second step, causation. The first part of this article traces the development of the law on the standard of disclosure of risks, from Sidaway to Montgomery in order to expose the place that patient autonomy now occupies and the conception of autonomy that underlies the decisions. The second section addresses the causation issues arising in cases of medical non-disclosure of risk, and includes but is not limited to discussion of Chester. It first considers the modified objective approach to proof of causation adopted in Canada and argues that English law would be wise to reject such a development. The Chester problem is then addressed, and the analysis will focus primarily on what is actually meant by 'coincidence' since this term is often used but rarely explained. Finally, considering the situation that arises when the risk that materialises is different from the risk about which the doctor failed to warn the patient, it argues for a closer delineation of the relevant risks in English law.

Urtasun, L. E. (2012). "Content of medical information and unpredictable results in Spanish law." Medicine and law 31(4): 553-565

In this study we consider the problem of content of medical information the patient must receive before a medical treatment. Specifically, Spanish law doesn't clarify if doctors must inform patients about every known risk or consequence inherent to an operation, or only about the most probable ones. There have been several contradictory judicial decisions of the Supreme Court about this, and in some cases it's been affirmed that the duty of information is not absolute, while in other decisions it's been affirmed just the opposite.

Veerman, M. M. et al. (2019). "A decade of litigation regarding surgical informed consent in the Netherlands." Patient Education and Counseling 102(2): 340-345 DOI: https://doi.org/10.1016/j.pec.2018.08.031 ***2019/02/01/.***

Objective An inadequate surgical informed consent process (SIC) may result in a medical malpractice claim or medical disciplinary board (MDB) complaint. Aim of this study was to analyse characteristics of a decade of malpractice claims and MDB decisions regarding SIC in the Netherlands. Methods A retrospective analysis of malpractice claims and MDB decisions concerning SIC disputes in four major surgical specialties was conducted based on company data from the largest medical malpractice insurance company and two public available online MDB databases. Results A total of 11376 malpractice claims and 661 MDB complaints were filed between 2004–2013 and 676(6%) of these claims and 69(10%) of these complaints involved an alleged deficient SIC process. A random sample of 245(37%) claims and all MDB decisions were analysed. Reasons for filing a claim or complaint were insufficient counselling or recording of SIC elements. In 20% of lawsuits and 25% of claims the case resulted in favour of the complainant. Conclusion A substantial portion of

malpractice claims and MDB decisions is related to a deficient SIC process. Practice implications Focusing on crucial SIC elements for patients may improve satisfaction and expectations and result in a lower risk for malpractice claims and MDB complaints.

Wheeler, R. (2017). "The evolution of informed consent." British Journal of Surgery 104(9): 1119-1120 DOI: 10.1002/bjs.10520

The common law links continents. A recurring clinical legal question across the original British Commonwealth territories relates to the information that must be disclosed before operation, so that a patient can decide whether to agree to treatment. The judgments that have influenced modern attitudes have evolved over many years. As surgical standards become increasingly globalized, many countries will need to adapt existing practices surrounding the process historically covered by the term 'informed consent'.In 1930s Canada1, a woman with Dupuytren's contracture was advised that immediate su gery would restore function within 3 weeks. Instead, permanent injury resulted. She claimed that if she had known the risk she would have refused surgery. The appeal court held that the surgeon's duty of disclosure did not extend to warnings '…calculated to frighten or distress the patient'. In England 20 years later2, a woman with goitre chose surgery. Left with a vocal cord palsy, her surgeon admitted that he had asserted that there was no risk to her voice. Encouraged by the judge, the jury dismissed the case. These cases begged the question of whether the standard for disclosure should be set not by the reasonable doctor, but by the reasonable patient.

Best Strategies for Improving Informed Consent

Bagnall, N. M., et al. (2017). "Informing the process of consent for surgery: identification of key constructs and quality factors." Journal of Surgical Research 209: 86-92 DOI: https://doi.org/10.1016/j.jss.2016.09.051 ***2017/03/01/.***

Background Informed consent is a fundamental requirement of any invasive procedure. Failure to obtain appropriate and informed consent may result in unwanted or unnecessary procedures, as well as financial penalty in case of litigation. The aim of this study was to identify key constructs of the consent process which might be used to determine the performance of clinicians taking informed consent in surgery. Methods A multimodal methodology was used. A systematic review was conducted in accordance with PRISMA guidelines to identify evidence-based components of the consent process. Results were supplemented by semistructured interviews with senior trainees and attending surgeons which were transcribed and subjected to emergent theme analysis with repeated sampling until thematic saturation was reached. Results A total of 710 search results were returned, with 26 articles included in the final qualitative synthesis of the systematic review. Significant variation existed between articles in the description of the consent procedure. Sixteen semistructured interviews were conducted before saturation was reached. Key components of the consent process were identified with broad consensus for the most common elements. Trainers felt that experiential learning and targeted skills training courses should be used to improve practice in this area. Conclusions Key components for obtaining informed consent in surgery have been identified. These should be used to influence curricular design, possible assessment methods, and focus points to improve clinical practice and patient experience in future.

Bethune, A., et al. (2018). "e-Consent: approaching surgical consent with mobile technology." Canadian journal of surgery. Journal canadien de chirurgie 61(5): 339-344 DOI: https://dx.doi.org/10.1503/cjs.016017

Background: Patient recall of information about procedures, including risks and benefits and potential outcomes, is often insufficient. We sought to determine whether a multimedia educational tool enhances the informed consent discussion for elective neurosurgical procedures by increasing patient knowledge of the procedure., Methods: Adult patients from a single neurosurgical site eligible for 4 neurosurgical procedures (lumbar spine or cervical spine decompression for degenerative disease, craniotomy for brain tumour or trigeminal neuralgia treatment) were offered enrolment. Patients were randomly assigned to either the control arm (standard consent discussion) or the intervention arm (review of an e-book containing information tailored to their disease/injury plus standard consent discussion). Participants completed a 14-item questionnaire before and after the consent discussion., Results: Questionnaires were completed by 38 participants, 18 in the control group and 20 in the intervention group. The mean age was 62.2 (standard deviation [SD] 13.6) years and did not differ significantly between the 2 groups. The mean baseline questionnaire scores were similar for the control and intervention groups (20.4 [SD 7.3] v. 20.6 [SD 6.7]). However, the mean scores on the follow-up questionnaire were significantly different between the 2 groups (20.2 [SD 4.0] v. 23.2 [SD 4.9], p = 0.02). There was no change in the scores on the 2 questionnaires in the control group, whereas, in the intervention group, the mean score was significantly higher after the intervention (p = 0.03)., Conclusion: The use of an electronic booklet appears to improve patients' knowledge of their surgical procedure. The use of multimedia booklets in clinical practice could help standardize and optimize the consent process, ensuring that patients receive the relevant information to make a truly informed decision.

Gabay, G. and Y. Bokek-Cohen (2020). "What do patients want? Surgical informed-consent and patient-centered care - An augmented model of information disclosure." Bioethics 34(5): 467-477 DOI: https://dx.doi.org/10.1111/bioe.12703

The ideal moral standard for surgical informed-consent calls upon surgeons to carry out a disclosure dialogue with patients so they have as full as possible an understanding of the procedure before they sign the informed-consent form. This study is the first to empirically explore patient preferences regarding disclosure dialogue. Twelve Israelis who underwent life-saving surgeries participated in a narrative study. Three themes emerged from the analysis: objectification of patients, anxiety provoking processes and information, and lack of information that was essential for patients. Findings contribute to existing debates among surgeons regarding the scope and importance of some disclosure components. Analysis led to our formulation of an augmented subjective model of information disclosure that participants prefer, which extends beyond the immediate present of the surgery to the period after discharge, and until return to routine. Surgeons should be aware of patient preferences in disclosure, and gaps between perceptions of surgeons, and preferences and needs of patients. Copyright © 2019 John Wiley & Sons Ltd.

Gillett G. and S. Walker (2012). "The evolution of informed consent." Journal of law and medicine 19(4): 673-677

Informed consent and the changes in what is expected over the 21st century provide an instructive case study of the mutual influence on one another of medical law and medical ethics. Over the years we have moved from a doctor-centred standard to a patient-centred standard and from a one-size-fits-all patient-centred standard to a more individual requirement that engages with the needs of a particular patient It is unreasonable to expect those changes to be reflected in anything less than an extended conversation in which the health care professional gives out some version of what a reasonable patient would expect to hear from an informed health care professional and then responds to the patient's questions as informatively and helpfully as he or she can. It is therefore convenient to refer

to spontaneous and responsive disclosure as a very concrete implementation of the health care professional-patient partnership that is contemporary health care and at the heart of health care ethics.

Golembiewski, E. H., et al. (2021). "An Electronic Tool to Support Patient-Centered Broad Consent: A Multi-Arm Randomized Clinical Trial in Family Medicine." Annals of family medicine 19(1): 16-23 DOI: https://dx.doi.org/10.1370/afm.2610

PURPOSE: Patients are frequently asked to share their personal health information. The objective of this study was to compare the effects on patient experiences of 3 electronic consent (e-consent) versions asking patients to share their health records for research., METHODS: A multi-arm randomized controlled trial was conducted from November 2017 through November 2018. Adult patients (n = 734) were recruited from 4 family medicine clinics in Florida. Using a tablet computer, participants were randomized to (1) a standard e-consent (standard), (2) an e-consent containing standard information plus hyperlinks to additional interactive details (interactive), or (3) an e-consent containing standard information, interactive hyperlinks, and factual messages about data protections and researcher training (trust-enhanced). Satisfaction (1 to 5), subjective understanding (0 to 100), and other outcomes were measured immediately, at 1 week, and at 6 months., RESULTS: A majority of participants (94%) consented to future uses of their health record information for research. No differences in study outcomes between versions were observed at immediate or 1-week follow-up. At 6-month follow-up, compared with the standard e-consent, participants who used the interactive e-consent reported greater satisfaction (B = 0.43; SE = 0.09; P <.001) and subjective understanding (B = 18.04; SE = 2.58; P <.001). At 6-month follow-up, compared with the interactive e-consent, participants who used the trust-enhanced e-consent reported greater satisfaction (B = 0.9; SE = 1.0; P <.001) and subjective understanding (B = 32.2; SE = 2.6, P <.001)., CONCLUSIONS: Patients who used e-consents with interactive research details and trust-enhancing messages reported higher satisfaction and understanding at 6-month follow-up. Research institutions should consider developing and further validating e-consents that interactively deliver information beyond that required by federal regulations, including facts that may enhance patient trust in research. Copyright © 2021 Annals of Family Medicine, Inc.

Hall, D. E., et al. (2012). "Informed consent for clinical treatment." Canadian Medical Association Journal 184(5): 533-540 DO : 10.1503/cmaj.112120

Although informed consent for clinical treatment has become a vital part of contemporary medical practice, it means different things in different contexts , is variably practised and rarely achieves the theoretical ideal. In this review, we focus on the clinical practice of informed consent. We first describe what we know about informed consent: what it is, where it came from and what purposes it serves. We then describe several limitations that complicate the practice of informed consent. Finally, we make several practical suggestions as to how clinicians might optimally approach the informed consent process.

Khan, S. U., et al. (2018). "Patient's views of the consent process for groin hernia repair: Use of consent template improves compliance with best practice (Original research)." Ann Med Surg (Lond) 35: 67-72 DOI: 10.1016/j.amsu.2018.09.033 ***Nov.***

BACKGROUND: Informed consent obtained for day case surgery has been historically incomplete. An assessment of consenting practice for groin hernia was performed relative to existing gold standards and patient's perception of the consent process was evaluated with a questionnaire. The aim of the study was to identify areas of improvement to comply with best practice. METHODS: A retrospective audit of adult patients undergoing groin hernia repair (June-November 2016) at a tertiary care centre was performed. The same cohort of

patients was surveyed with a self-administered questionnaire to identify their view on consenting practice. RESULTS: 113 patients were identified who underwent groin hernia repair during the study period. Pre-printed consent templates-stickers (as opposed to hand-written) were used in 53(47%) cases. In 75(66%) cases, there was complete documentation of the risks and benefits of surgery. 81(72%) patients received information about the full benefits of surgery. 27(23%) patients received partial information and 7(6%) patients had no mention of benefit recorded. Postoperative recovery was fully explained to 85(75%) patients. Use of pre-printed templates ensured 100% documentation compared to handwritten consent forms (risks 37%, benefits 47%, and recovery 53%). Preference for the timing of consent was in clinic (64%), day of surgery (25%). 34(56%) felt the choice for the technique and 22(36%) felt the choice for anaesthesia. Satisfaction was non-significantly better in those consented in clinic (87% versus 76% p = 0.74). 49(80%) felt happy with the overall consent process. 57(93%) felt that they received support and advice. 60(98%) responders felt confidence in the National Health Service and 59(97%) would recommend treatment to family and friends. CONCLUSIONS: The use of pre-printed consent and discharge summary templates improve compliance with best practice. Whilst patient preference favours consent in the outpatient clinic, satisfaction levels were high wherever consent was obtained. Patients should have more choice.

Kinnersley, P., et al. (2013). "Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures." Cochrane Database Syst Rev(7): Cd009445 DOI: 10.1002/14651858.CD009445.pub2 ***Jul 6.***

BACKGROUND: Achieving informed consent is a core clinical procedure and is required before any surgical or invasive procedure is undertaken. However, it is a complex process which requires patients be provided with information which they can understand and retain, opportunity to consider their options, and to be able to express their opinions and ask questions. There is evidence that at present some patients undergo procedures without informed consent being achieved. OBJECTIVES: To assess the effects on patients, clinicians and the healthcare system of interventions to promote informed consent for patients undergoing surgical and other invasive healthcare treatments and procedures. SEARCH METHODS: We searched the following databases using keywords and medical subject headings: Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library, Issue 5, 2012), MEDLINE (OvidSP) (1950 to July 2011), EMBASE (OvidSP) (1980 to July 2011) and PsycINFO (OvidSP) (1806 to July 2011). We applied no language or date restrictions within the search. We also searched reference lists of included studies. SELECTION CRITERIA: Randomised controlled trials and cluster randomised trials of interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures. We considered an intervention to be intended to promote informed consent when information delivery about the procedure was enhanced (either by providing more information or through, for example, using new written materials), or if more opportunity to consider or deliberate on the information was provided. DATA COLLECTION AND ANALYSIS: Two authors assessed the search output independently to identify potentially-relevant studies, selected studies for inclusion, and extracted data. We conducted a narrative synthesis of the included trials, and meta-analyses of outcomes where there were sufficient data. MAIN RESULTS: We included 65 randomised controlled trials from 12 countries involving patients undergoing a variety of procedures in hospitals. Nine thousand and twenty one patients were randomised and entered into these studies. Interventions used various designs and formats but the main data for results were from studies using written materials, audio-visual materials and decision aids. Some interventions were delivered before admission to hospital for the procedure while others were delivered on admission.Only one study attempted to measure the primary outcome, which was informed

consent as a unified concept, but this study was at high risk of bias. More commonly, studies measured secondary outcomes which were individual components of informed consent such as knowledge, anxiety, and satisfaction with the consent process. Important but less commonly-measured outcomes were deliberation, decisional conflict, uptake of procedures and length of consultation.Meta-analyses showed statistically-significant improvements in knowledge when measured immediately after interventions (SMD 0.53 (95% CI 0.37 to 0.69) I(2) 73%), shortly afterwards (between 24 hours and 14 days) (SMD 0.68 (95% CI 0.42 to 0.93) I(2) 85%) and at a later date (15 days or more) (SMD 0.78 (95% CI 0.50 to 1.06) I(2) 82%). Satisfaction with decision making was also increased (SMD 2.25 (95% CI 1.36 to 3.15) I(2) 99%) and decisional conflict was reduced (SMD -1.80 (95% CI -3.46 to -0.14) I(2) 99%). No statistically-significant differences were found for generalised anxiety (SMD -0.11 (95% CI -0.35 to 0.13) I(2) 82%), anxiety with the consent process (SMD 0 01 (95% CI -0.21 to 0.23) I(2) 70%) and satisfaction with the consent process (SMD 0 12 (95% CI -0.09 to 0.32) I(2) 76%). Consultation length was increased in those studies with continuous data (mean increase 1.66 minutes (95% CI 0.82 to 2.50) I(2) 0%) and in the one study with non-parametric data (control 8.0 minutes versus intervention 11.9 minutes, interquartile range (IQR) of 4 to 11.9 and 7.2 to 15.0 respectively). There were limited data for other outcomes.In general, sensitivity analyses removing studies at high risk of bias made little difference to the overall results. AUTHORS' CONCLUSIONS: Informed consent is an important ethical and practical part of patient care. We have identified efforts by researchers to investigate interventions which seek to improve information delivery and consideration of information to enhance informed consent. The interventions used consistently improve patient knowledge, an important prerequisite for informed consent. This is encouraging and these measures could be widely employed although we are not able to say with confidence which types of interventions are preferable. Our results should be interpreted with caution due to the high levels of heterogeneity associated with many of the main analyses although we believe there is broad evidence of beneficial outcomes for patients with the pragmatic application of interventions. Only one study attempted to measure informed consent as a unified concept.

Lindsley, K. A. (2019). "Improving quality of the informed consent process: Developing an easy-to-read, multimodal, patient-centered format in a real-world setting." Patient Education and Counseling 102(5): 944-951 DOI: https://dx.doi.org/10.1016/j.pec.2018.12.022

OBJECTIVE: To develop a patient-centered informed consent and assessment tool written at a 6th grade-level that is multimodal, affordable, transportable, and readily modifiable for protocol updates., METHODS: This quality improvement initiative was performed in two phases on an actively-recruiting study at a pediatric diabetes clinic. In phase I, 38 volunteers underwent the standard-paper consent process, a comprehension assessment and provided feedback. Using feedback and the structure of the Plan-Do-Study-Act cycle a multimodal consent and assessment were developed. In phase II, volunteers were randomized to the standard (n = 25) or the multimodal consent (n = 25) and all completed the same comprehension assessment via touch-screen tablet. Primary outcomes were comparison of the individual and total comprehension assessment scores., RESULTS: Total comprehension scores were higher in the multimodal versus the standard consent group ($p < 0.001$) and on the elements of benefits ($p < 0.001$), risks ($p < 0.001$), volunteerism ($p < 0.012$), results ($p < 0.001$), confidentiality ($p < 0.004$) and privacy ($p < 0.001$)., CONCLUSION: A multimodal consent and assessment presented sequentially on a touch-screen tablet were patient-centered enhancements to standard consent., PRACTICE IMPLICATIONS: Multimodal standardization of delivery with improved readability may strengthen the informed consent process.

Main, B. G., et al. (2017). "Core information sets for informed consent to surgical interventions: baseline information of importance to patients and clinicians." BMC medical ethics 18(1): 29 DOI: https://dx.doi.org/10.1186/s12910-017-0188-7

BACKGROUND: Consent remains a crucial, yet challenging, cornerstone of clinical practice. The ethical, legal and professional understandings of this construct have evolved away from a doctor-centred act to a patient-centred process that encompasses the patient's values, beliefs and goals. This alignment of consent with the philosophy of shared decision-making was affirmed in a recent high-profile Supreme Court ruling in England. The communication of information is central to this model of health care delivery but it can be difficult for doctors to gauge the information needs of the individual patient. The aim of this paper is to describe 'core information sets' which are defined as a minimum set of consensus-derived information about a given procedure to be discussed with all patients. Importantly they are intended to catalyse discussion of subjective importance to individuals., MAIN BODY: The model described in this paper applies health services research and Delphi consensus-building methods to an idea orginally proposed 30 years ago. The hypothesis is that, first, large amounts of potentially-important information are distilled down to discrete information domains. These are then, secondly, rated by key stakeholders in multiple iterations, so that core information of agreed importance can be defined. We argue that this scientific approach is key to identifying information important to all stakeholders, which may otherwise be communicated poorly or omitted from discussions entirely. Our methods apply systematic review, qualitative, survey and consensus-building techniques to define this 'core information'. We propose that such information addresses the 'reasonable patient' standard for information disclosure but, more importantly, can serve as a spring board for high-value discussion of importance to the individual patient., CONCLUSION: The application of established research methods can define information of core importance to informed consent. Further work will establish how best to incorporate this model in routine practice.

Mawhinney, G., et al. (2019). "Oxford Video Informed Consent Tool (OxVIC): a pilot study of informed video consent in spinal surgery and preoperative patient satisfaction." BMJ open 9(7): e027712 DOI: https://dx.doi.org/10.1136/bmjopen-2018-027712

OBJECTIVES: The British Association of Spinal Surgeons recently called for updates in consenting practice. This study investigates the utility and acceptability of a personalised video consent tool to enhance patient satisfaction in the preoperative consent giving process., DESIGN: A single-centre, prospective pilot study using questionnaires to assess acceptability of video consent and its impacts on preoperative patient satisfaction., SETTING: A single National Health Service centre with individuals undergoing surgery at a regional spinal centre in the UK., OUTCOME MEASURE: As part of preoperative planning, study participants completed a self-administered questionnaire (CSQ-8), which measured their satisfaction with the use of a video consent tool as an adjunct to traditional consenting methods., PARTICIPANTS: 20 participants with a mean age of 56 years (SD=16.26) undergoing spinal surgery., RESULTS: Mean patient satisfaction (CSQ-8) score was 30.2/32. Median number of video views were 2-3 times. Eighty-five per cent of patients watched the video with family and friends. Eighty per cent of participants reported that the video consent tool helped to their address preoperative concerns. All participants stated they would use the video consent service again. All would recommend the service to others requiring surgery. Implementing the video consent tool did not endure any significant time or costs., CONCLUSIONS: Introduction of a video consent tool was found to be a positive adjunct to traditional consenting methods. Patient-clinician consent dialogue can now be documented. A randomised controlled study to further evaluate the effects of video consent on patients' retention of information, preoperative and postoperative anxiety, patient reported outcome measures as well as length of stay may be beneficial. Copyright © Author(s) (or their

employer(s)) 2019. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

McWhirter, R. E. and L. Eckstein (2018). "Moving Forward on Consent Practices in Australia." Journal of bioethical inquiry 15(2): 243-257 DOI: https://dx.doi.org/10.1007/s11673-018-9843-z

Allowing persons to make an informed choice about their participation in research is a pre-eminent ethical and legal requirement. Almost universally, this requirement has been addressed through the provision of written patient information sheets and consent forms. Researchers and others have raised concerns about the extent to which such forms-particularly given their frequent lengthiness and complexity-provide participants with the tools and knowledge necessary for autonomous decision-making. Concerns are especially pronounced for certain participant groups, such as persons with low literacy and Indigenous persons. Multimedia strategies have the potential to usefully supplement current consent practices in Australia; however, information is needed about the need for supplementary consent practices, along with drivers for and barriers against adoption. This study initiates the required evidence base through an audit of informed consent practices for medical research in the Australian state of Tasmania to assess the need for, and current uptake of, supplementary consent strategies. Drivers for and barriers against adoption of multimedia consent practices were explored in detail through interviews with key stakeholders, including researchers, HREC chairs and members, and research participants, including Indigenous participants.

Michalski, A., et al. (2016). "Use of Multimedia Technology in the Doctor-Patient Relationship for Obtaining Patient Informed Consent." Medical science monitor : international medical journal of experimental and clinical research 22: 3994-3999 DOI: 10.12659/msm.894147

Patient informed consent for surgery or for high-risk methods of treatment or diagnosis means that unlawful breach of the patient's personal interests is avoided and the patient accepts the risk of surgery and takes the brunt of it. Patient awareness - their knowledge of the condition and circumstances of continued therapeutic procedure, including offered and available methods of treatment and their possible complications - constitutes a particular aspect of the informed-consent process. The rapid development of technologies and methods of treatment may cause communication problems between the doctor and the patient regarding the scope and method of patient education prior to surgery. The use of multimedia technology (e.g., videos of surgical procedures, computer animation, and graphics), in addition to media used in preoperative patient education, may be a factor in improving the quality of the informed consent process. Studies conducted in clinical centers show that with use of multimedia technology, patients remember more of the information presented. The use of new technology also makes it possible to reduce the difference in the amount of information assimilated by patients with different levels of education. The use of media is a way to improve the quality of preoperative patient education and, at the same time, a step towards their further empowerment in the healing process.

Normahani, P., et al. (2020). "Achieving good-quality consent: review of literature, case law and guidance." BJS open 4(5): 757-763 DOI: https://dx.doi.org/10.1002/bjs5.50306

BACKGROUND: Informed consent is an integral part of clinical practice. There is widespread agreement amongst health professionals that obtaining procedural consent needs to move away from a unidirectional transfer of information to a process of supporting patients in making informed, self-determined decisions. This review aimed to identify processes and measures that warrant consideration when engaging in consent-based discussions with competent patients undergoing elective procedures., METHODS: Formal written guidance from the General Medical Council and Royal College of Surgeons of England, in addition to

peer-reviewed literature and case law, was considered in the formulation of this review., RESULTS: A framework for obtaining consent is presented that is informed by the key tenets of shared decision-making (SDM), a model that advocates the contribution of both the clinician and patient to the decision-making process through emphasis on patient participation, analysis of empirical evidence, and effective information exchange. Moreover, areas of contention are highlighted in which further guidance and research are necessary for improved enhancement of the consent process., CONCLUSION: This SDM-centric framework provides structure, detail and suggestions for achieving meaningful consent. Copyright © 2020 The Authors. BJS Open published by John Wiley & Sons Ltd on behalf of British Journal of Surgery Society.

O'Neill, J. (2021). "Lessons from the vaginal mesh scandal: enhancing the patient-centric approach to informed consent for medical device implantation." International journal of technology assessment in health care 37(1): e53 DOI: https://dx.doi.org/10.1017/S0266462321000258

The vaginal mesh scandal, in which thousands of women were irreversibly maimed by polypropylene mesh, revealed multilevel failures in medical device regulation and implantation, demonstrating that patient-centric care has not yet fully transcended from policy into practice. In law, informed consent is considered by a two-stage test: reasonable treatment and patient information disclosure. The standard of reasonable treatment is determined according to what is deemed acceptable in accordance with a body of medical opinion. However, such bodies of medical opinion were vulnerable to external influence from device manufactures. Vaginal mesh manufacturers were found to have had financial links to research, royal colleges, and influential clinicians, which then influenced the basis of the evidence-based practice that often guides such bodies of medical opinion. According to the Independent Medicines and Medical Device Safety Report, patients' mesh complications were also frequently under-reported and patient-based evidence of harm disregarded. Patients were also not sufficiently informed of the material risks or reasonable alternatives to mesh, which is required of the second stage of informed consent pertaining to information disclosure. This paper makes the following recommendations: that conflict of interest disclosure be mandated, that greater value be afforded to patient-based evidence to improve evaluation of treatments, and that information disclosure for informed consent should relate to the risks, benefits, and alternatives to the surgical procedure and medical device. This will ensure that patients can evaluate whether surgeons are offering unbiased treatment options and are also informed of the potential long-term risks associated with device implantation.

Rawlings, A., et al. (2020). "Informed consent: a shared decision-making process that creates a new professional obligation for care." Surgical endoscopy 34(11): 4713-4716 DOI: https://dx.doi org/10.1007/s00464-020-07970-1

This statement on informed consent, developed by the SAGES Ethics Committee, has been reviewed and approved by the Board of Governors of SAGES. This statement is provided to offer guidance about the purpose and process of obtaining informed consent, and it is intended for practicing surgeons as well as patients seeking surgical intervention. It is an expression of well-established principles and extensive literature. Excluded from this document are discussions of informed consent for research and informed consent for introduction of new technology, as that has been addressed in previous publications (Strong in Surg Endosc 28:2272, 2014; Stefanidis in Surg Endosc 28:2257, 2014; as reported by Sillin (in: Stain (ed) The SAGES Manual Ethics of Surgical Innovation, Springer, Switzerland, 2016)).

Ripley, B. A., et al. (2015). "Improving the Informed Consent Conversation: A Standardized Checklist that Is Patient Centered, Quality Driven, and Legally Sound." Journal of vascular and interventional radiology : JVIR 26(11): 1639-1646 DOI: https://dx.doi.org/10.1016/j.jvir.2015.06.007

The informed consent conversation is a key component of patient-centered medicine, a concept that emphasizes the importance of patients actively participating in their care. Studies reveal that many informed consent conversations throughout medical practice lack essential elements and leave patients' needs unmet. This review addresses these deficiencies, discusses solutions, and introduces a standardized checklist that values the patient's role in shared decision making during the informed consent conversation. The checklist could be particularly helpful to interventional radiologists and other consulting physicians who usually obtain informed consent early in their encounters with patients.

Schauer, C., et al. (2019). "Video or verbal? A randomised trial of the informed consent process prior to endoscopy." The New Zealand medical journal 132(1489): 57-68

AIM: Informed consent (IC) prior to endoscopy is often inconsistently and poorly performed. We compared use of video-assisted consent to standard verbal consent for enhancing patients' recollection of procedural risks, understanding and fulfilment of expectation., METHOD: Two hundred patients attending for gastroscopy or colonoscopy were randomised to either video-assisted consent (n=100) or verbal consent (n=100). The primary outcomes measured via a questionnaire were the recollection of procedural risks (sum of all correct answers for risk recall items) and patient experience compared to information provided in the consent process. Secondary outcomes included reported patient understanding and staff satisfaction between groups., RESULTS: There was no difference between video or verbal groups in terms of risk recall scores (p=0.46), with less than half the patients able to recall more than two risks. There was a signal towards improved recall of bleeding as a potential risk in the video as compared to the verbal arm but it did not reach statistical significance (p=0.059). Patients' perceived understanding and fulfilment of expectation was high (>96%) in both groups. Seventy-one percent of the staff preferred using the video over the verbal IC., CONCLUSION: Video-assisted consent made no significant difference to the IC process in terms of patient recollection or experience compared to usual verbal IC. Despite very poor recollection of procedural risks, patients in both the video and verbal groups reported understanding of the procedure and satisfaction with the IC process. Reasons for this mismatch are unclear. Further action to prioritise information delivery during IC is required. Future studies in this field should include patient-centred outcomes as a measure of success.

Siegal, G., et al. (2012). "Personalized disclosure by information-on-demand: attending to patients' needs in the informed consent process." The Journal of law, medicine & ethics : a journal of the American Society of Law, Medicine & Ethics 40(2): 359-367 DOI: https://dx.doi.org/10.1111/j.1748-720X.2012.00669.x

Obtaining informed consent has typically become a stylized ritual of presenting and signing a form, in which physicians are acting defensively and patients lack control over the content and flow of information. This leaves patients at risk both for being under-informed relative to their decisional needs and of receiving more information than they need or desire. By personalizing the process of seeking and receiving information and allowing patients to specify their desire for information in a prospective manner, we aim to shift genuine control over the informational process to patients. A new paradigm of Information on Demand, such as we suggest, would also enhance legal certainty, achieve greater congruence between the information patients want and the information they receive, and promote more meaningful patient-physician interactions, a desirable outcome that has been difficult to achieve by other means.

Spatz, E. S., et al. (2016). "The New Era of Informed Consent: Getting to a Reasonable-Patient Standard Through Shared Decision Making." JAMA 315(19): 2063-2064 DOI: 10.1001/jama.2016.3070

Ward, J., et al. (2020). "Shared decision making and consent post-Montgomery, UK Supreme Court judgement supporting best practice." Patient Education and Counseling 103(12): 2609-2612 DOI: https://doi.org/10.1016/j.pec.2020.05.017 ***2020/12/01/.***

The UK Supreme Court Montgomery judgement marks a decisive shift in the legal test of duty of care in the context of consent to treatment from the perspective of the clinician (as represented by Bolam rules) to that of the patient. This has important implications in the surgical field worldwide, where informed consent is critical. This paper aims to explain the ruling and how it impacts the consent process. The case and ruling are outlined and summarised as pertaining to consent and requirements for validity; a shift from the clinician's interpretation about what would be best for patients to the values of the particular patient concerned in the decision in question. A sample of recent commentaries is reviewed. Four examples illustrate some of the practical applications of the Montgomery ruling on consent and how the ruling can empower doctors and patients to make mutually beneficial shared decisions. Future consent should be obtained using a Montgomery compliant strategy in accordance with the principles of shared decision making.

Wells, R. E. and T. J. Kaptchuk (2012). "To Tell the Truth, the Whole Truth, May Do Patients Harm: The Problem of the Nocebo Effect for Informed Consent." The American Journal of Bioethics 12(3): 22-29 DOI: 10.1080/15265161.2011.652798 ***2012/03/01.***

The principle of informed consent obligates physicians to explain possible side effects when prescribing medications. This disclosure may itself induce adverse effects through expectancy mechanisms known as nocebo effects, contradicting the principle of nonmaleficence. Rigorous research suggests that providing patients with a detailed enumeration of every possible adverse event?especially subjective self-appraised symptoms?can actually increase side effects. Describing one version of what might happen (clinical ?facts?) may actually create outcomes that are different from what would have happened without this information (another version of ?facts?). This essay argues that the perceived tension between balancing informed consent with nonmaleficence might be resolved by recognizing that adverse effects have no clear black or white ?truth.? This essay suggests a pragmatic approach for providers to minimize nocebo responses while still maintaining patient autonomy through ?contextualized informed consent,? which takes into account possible side effects, the patient being treated, and the particular diagnosis involved.

West, L. et al. (2020). "Multimedia Technology Used to Supplement Patient Consent for Mohs Micrographic Surgery." Dermatologic Surgery 46(5)

BACKGROUND The patient consent process traditionally relies on conversations between the physician and the patient and rarely utilizes supplemental multimedia aids. OBJECTIVE To determine whether the addition of an educational video on Mohs micrographic surgery (MMS) can improve patient satisfaction with the consent process. MATERIALS AND METHODS This prospective observational quality improvement study compared the outcomes of traditional patient consent alone versus standard consent plus an educational video among patients undergoing their first MMS for a primary skin cancer. End points were patient satisfaction and preferences measured by postprocedure questionnaires. RESULTS The addition of a supplemental video to the consent process did not affect overall patient satisfaction, which was very high in both video and control groups. However, specific

components of patient satisfaction were improved such as patient perception of the opportunity to ask questions and understand the procedure. CONCLUSION Multimedia aids can be effective tools in the patient consent process.

Zhang, M. H., et al. (2019). "A randomized, controlled trial of video supplementation on the cataract surgery informed consent process." Graefe's archive for clinical and experimental ophthalmology = Albrecht von Graefes Archiv fur klinische und experimentelle Ophthalmologie 257(8): 1719-1728 DOI: https://dx.doi.org/10.1007/s00417-019-04372-5

PURPOSE: To assess the effects of the American Academy of Ophthalmology's 2015 patient education video on patient information retention and anxiety preoperatively, on the day of surgery and postoperatively., METHODS: This is a prospective, surgeon-blinded randomized controlled trial at the University of Chicago Medical Center. Ninety-one patients with a diagnosis of first-eye cataract were randomized into either a video or control group. Subjects in both groups received face-to-face discussion with the surgeon and an informational brochure at the preoperative evaluation. Participants in the video group then viewed a four-minute educational video at the preoperative evaluation and on the day of surgery. Both groups completed an information retention quiz and a state anxiety assessment at the preoperative visit, on the day of surgery, and on the postoperative week one visit. Subject understanding of cataract surgery was measured using a twelve-question multiple choice quiz. State anxiety was measured by State Trait Anxiety Inventory-Y1 survey score., RESULTS: Participants in the video group did not score significantly higher on the information retention quiz compared with the control group at the preoperative evaluation (8.7 +/- 2.4 vs 7.7 +/- 2.5, P = 0.07), but did so on the day of surgery (11.2 +/- 0.8 vs 8.4 +/- 1.7, P < 0.001) and postoperative week 1 visit (10.8 +/- 1.5 vs 9.0 +/- 2.0, P < 0.001). Subjects in the video group were significantly less anxious on the day of surgery (26.4 +/- 5.1 vs 41.1 +/- 10.3, P < 0.001)., CONCLUSIONS: Video supplementation to the traditional informed consent process demonstrated an improvement in patient understanding of cataract surgery at multiple timepoints and decreased anxiety on the day of surgery.

Search Strategy

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions <1946 to May 25, 2022>, adapted for Cochrane, Scholar, Scopus

Search Strategy:

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1 informed consent/lj, es or (informed adj3 consent).ti. or (informed adj3 decision*).mp. or duty to warn/lj, es [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

2 exp *Postoperative Complications/

3 (adverse adj3 event*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

4 malpractice/

5 Practice Guideline/ or Guideline/

6 patient education as topic/

7 exp Process Assessment, Health Care/

8 Patient Satisfaction/ or Patient-Centered Care/

9 Decision Making, Shared/

10 ("repeat back" or "multimod*" or "multimod*" or video* or multimedia).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

11 surgical mesh/

12 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11

13 (*informed consent/lj, es or (*informed/ adj3 *consent/) or (*informed/ adj3 *decision*/) or *duty to warn/lj, es) and 12

14 limit 13 to (english language and yr="2012 -Current")

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Document 8

National Quality Forum
Informed Consent Submission

Quality problem submission template

PROBLEM TITLE	AGENCY SUBMITTING
Inconsistent informed consent practices	Ministry of Health & Health and Disability Commissioner

PROBLEM DESCRIPTION	
Briefly describe the problem. How was it identified? Why is it a cross sector issue? (see definition in instructions) How is this problem relevant for Māori?	**Problem** Recently the Ministry of Health has noticed an increasing number of issues due to lack of or inadequate informed consent practices for patients Complaints to HDC about inadequate informed consent practices have remained at around 15% of all complaints for many years, and informed consent continues to be a prominent theme in HDC investigations (see below for a ist of some recent investigations). These complaints and issues have been raised through formal channels such as the HDC complaints process, through processes such as the restorative process for addressing harm caused by surgical mesh, through survey data for medical schools and as part of the COVID-19 vaccination programme. The patient experience surveys completed by HQSC may also contain further examples. There is currently no national policy on informed consent, and informed consent policies/practices are inconsistent across DHBs/districts. However the Code of Health and Disability Services Consumers' Rights (the Code) & The Health and Disability Services Standards cover the requirements for informed consent discussions. Informed consent is the responsibility of all health care professionals and there have been examples across all groups of where the standards haven't been met. **Informed Consent Standards and Background** Informed consent under the Code is a process with three essential elements: effective communication between the parties (Right 5); the provision of all necessary information to the consumer (Right 6); and the consumer's freely given and competent consent (Right7). Right 5: Right to effective communication • Every consumer has the right to effective communication in a form, language, and manner the enables the consumer to understand the information provided • Every consumer has the right to an environment that allows the consumer and provider to communicate openly, honestly and effectively Right 6: Right to be fully informed: ▪ 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.

- This includes information such as: an explanation of their condition, the options available and an assessment of the risks and benefits of each option; notification of any proposed participation in teaching or research; and the results of tests and procedures

Right 7: Right to informed consent

- Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent (unless there are other provisions in the Code of common law that provides otherwise)

The Health and Disability Services Standards outline NZs 8134.1.1.10 Consumer R ghts: Informed Consent

- Consumers and where appropriate their family/whanau of choice are provided with the information they need to make informed choices and give informed consent.

The Medical Council of New Zealand has outlined key points about informed consent:

- The patient has the right to make an informed choice about their care and, in most instances, must give permission to proceed with treatment. That permission is called informed consent.
- It is an interactive process between the doctor, the patient and sometimes those close to the patient, such as their family or whānau.
- As the doctor, it is your responsibility to ensure informed consent is obtained, and to communicate and work with your patient to help them make the best decision for themselves (Code of Health and Disability Services Consumers' Rights 1996).
- The doctor undertaking the treatment is responsible for the overall informed consent process.

The Nursing Council of New Zealand outlines information about informed consent within their Code of Conduct.

- Principle 3 states: Work in Partnership with health consumers to promote and protect their well-being. Specifically Standard 3.1 states 'Explain and share information with health consumers that they want and/or need. Give health consumers information that is honest and accurate in a way they can understand and invite questions.'

Background information:

In 1988 The Report of the Cervical Cancer Inquiry in 1988 lead by Dame Sylvia Cartwright (otherwise known as the Cartwright Inquiry) – resulted in sweeping changes in law and practice around health and disability consumers' rights in New Zealand. It established the Office of the Health and Disability Commissioner.

This Inquiry focused on 'the Unfortunate Experiment' at National Women's Hospital where from 1966, Dr Herbert Green withheld conventional treatment from some patients with carcinoma in situ of the cervix (CIS). The women were not told of the study, nor of their participation in it. Many went on to develop invasive cancers, and some died. During the course of the inquiry other unethical practices were uncovered: there was a concurrent neonatal study where vaginal smears were taken from newborn female infants without parental consent; and vaginal examinations were undertaken on anesthetised women by multiple undergraduate medical students, without the women's knowledge or consent.

Ultimately Judge Cartwright concluded that the study was unethical where the potential risks to the patients outweighed the potential benefits of avoiding radical treatment, and where despite concerns being expressed internationally and within the hospital itself – no special efforts were made to ensure that patients did not suffer harm.

In her report Judge Cartwright advocated for a system that shifted the focus from health provider to patient and set the direction for informed consent in New Zealand stating:

"I have come to consider that the patient is entitled to all relevant information concerning her treatment, the options for treatment, and all information concerning her possible inclusion in a research trial. The focus should be centred on the patient, and not the doctor. It is a principle designed to protect and preserve the patients' rights, not to protect the doctor from liability…an informed patient is better equipped to participate in treatment".

Judge Cartwright recommended the appointment of a Health Commissioner, with provision for a statement of patients' rights (including that such rights should apply to research, and that a patient's right to informed consent should be included). This ultimately led to the establishment of the Health and Disability Commissioner in 1994, and the Code coming into force in 1996.

Examples of recent evidence below:

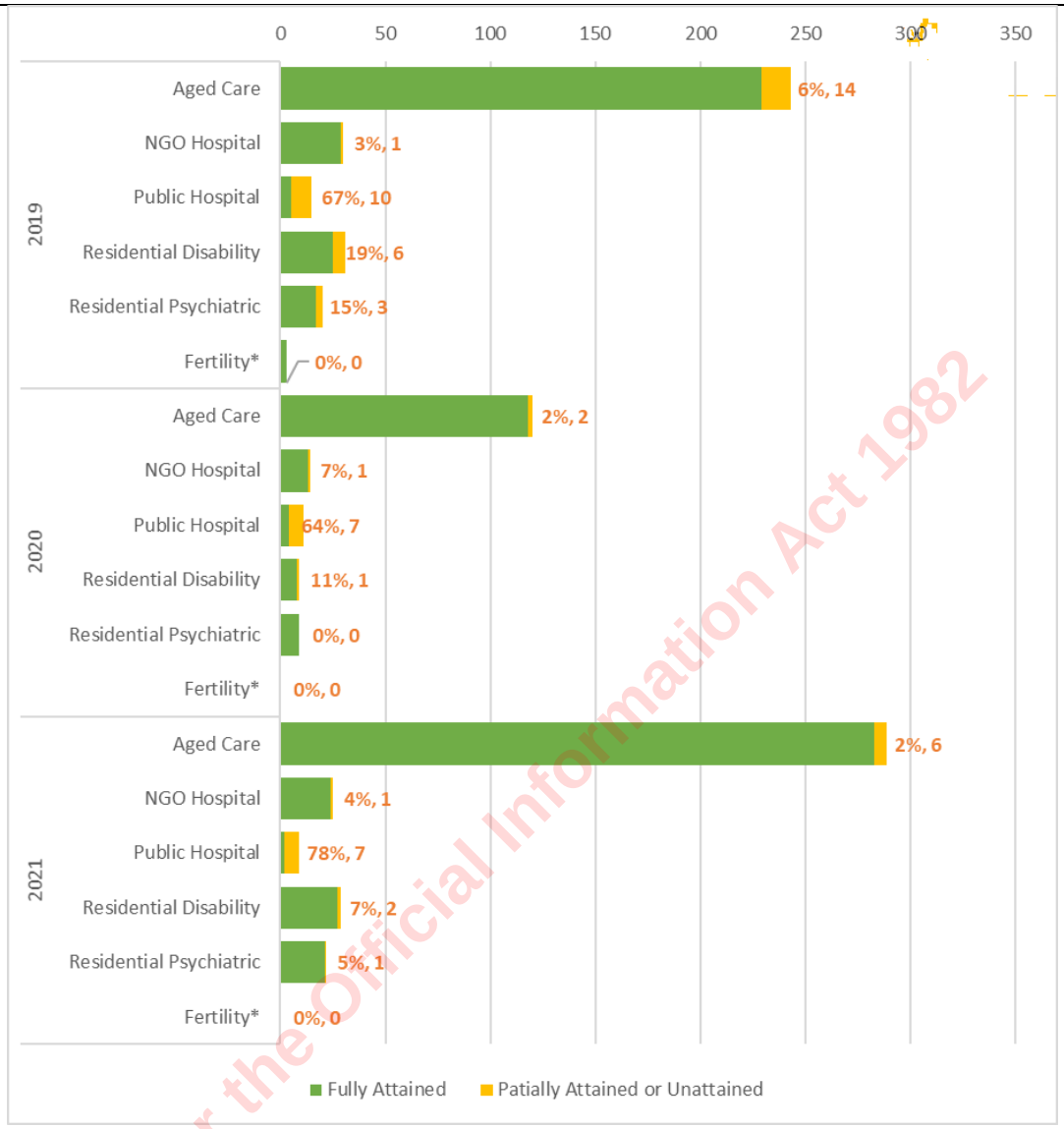
Recent HDC cases where it was found that informed consent practices were inadequate:

- 19HDC00773: A psychiatrist failed to share important information with a woman about the risks of taking Epilim while pregnant. Highlights the importance of prescribing clinicians sharing clear information with women of child-bearing age about the risks of Epilim to enable them to make an informed choice and give informed consent.
- 20HDC00511: GP undertook an endometrial pipelle biopsy during IUD insertion without the woman's consent.
- 19HDC00666: A contraceptive implant was removed from a patient whose competence was at issue. The device was removed even though the patient's legal guardian had provided information from a specialist regarding competence concerns. The provider did not have in place adequate protocols to deal with the situation of assessing capacity in a young person with intellectual impairment.
- 19HDC01583: A GP failed to inform a man of four test results which showed that the man's PSA levels were abnormal
- 19HDC00455: Orthopaedic surgeon failed to inform women that her ulna bone would be cut in half during wrist surgery or that her surgery would involve a plate and screws
- 18HDC01268: Midwife failed to advise woman that risk factors during her pregnancy met the criteria for referral and/or transfer of care to obstetrics under the Referral Guidelines
- 18HDC01697: GP carried out breast examination on woman without her informed consent
- 18HDC00131: Gynaecologist used ablation to treat a women's endometriosis, despite the women having specifically refused consent for this. Staff at the DHB lacked clarity and guidance on the relevance of consent discussions and the escalation of pertinent information about consent.

	Ministry of Health COVID-19 Vaccination Survey results outline: ▪ Vaccination centres could provide more/better/consistent information o "Give more info to the person who is getting the vaccination about adverse reactions" o 'While waiting for my vaccination I would've liked to have spoken to somebody knowledgeable about whether or not I should take it, given my unique circumstances" o "Honesty about side effects, and being consistent as my partner got told a lot different things than I." COVID-19 Vaccination Survey for providers (1300 responses): ▪ 73% of respondents advised that they always verbally convey the very rare but serious risks of myocarditis and pericarditis to consumers ▪ 55% said they always provide physical brochures and factsheets about myocarditis and pericarditis Addressing the past, present and future for people of childbearing potential on anti-seizure medicines report April 2021: ▪ Addressing present needs – People currently on anti-seizure medicines deserve informed consent, informed choice, and a whole of system approach ▪ Require healthcare professionals to adhere to the Code of health and disability services consumers' rights and fully inform consumers regarding the risks of anti-seizure medicines in pregnancy. ▪ Issue of ongoing consent - especially where they were started on anti-seizure medicines pre puberty and reach childbearing age. Auckland University Medical Students Survey: • Adherence by University of Auckland medical students to the national consensus statement on obtaining informed consent for sensitive examinations was "unsatisfactory", a survey has found. (93/265 responded to the survey). • The survey identified a number of factors contributing to a lack of compliance, including a lack of awareness. • Pressure from supervisors was also common. One student "was forced to perform an unconsented digital rectal examination (where a finger is inserted into the rectum) in theatre while a patient was under general anaesthetic. • "I objected to this, but was coerced into performing it anyway by the urologist." • Supervisors were also portrayed as indifferent and unsupportive about informed consent at times, and students found it challenging to stand up to authority. • One often felt unable or unwilling to question seniors "even though I was aware the consent process was not being followed", due to "hierarchy". • Most reported they were "not always compliant" with the consensus statement for obtaining informed consent for almost all sensitive exams.
A. IMPACT & RISK	
High level information to show extent of this problem, e.g., number of people this impacts; how serious this problem is; what	The graph below outlines the attainment results against the informed consent standard by provider over the past 3 years. This data is provided by Healthcert, who oversees the certification process against the Health and Disability Service Standards.

risks this problem exposes. *What proportion and how many Māori are affected by this issue?* *How will this problem be impacted by/or impact the health sector reforms?*	Partially attained or unattained suggests a corrective action is required. The corrective actions vary depending on the service and policies in place – further analysis of the corrective actions could be done to understand the problem. Note there were less audits completed in 2020 due to COVID-19. Public Hospitals appear to have the highest number of partially and/or unattained standards for informed consents. Residential Disability facilities have the next highest % of partially and/or unattained standards for informed consents – although this has improved from 19% in 2019 to 7% in 2021.

	Public Hospital % Partially Attained or Unattained	Number of audits completed
2019	67%	10
2020	64%	7
2021	78%	7



Issues around information provision and the consent process are raised by complainants in around 15% of complaints to HDC each year

Impact of lack of informed consent:

Complaints to HDC highlight the physical and psychological harm that can occur when a person's right to make an informed choice and give their consent are undermined. This can also result in a significant loss of trust in the health system, reluctance to seek further care and a disengagement from treatment.

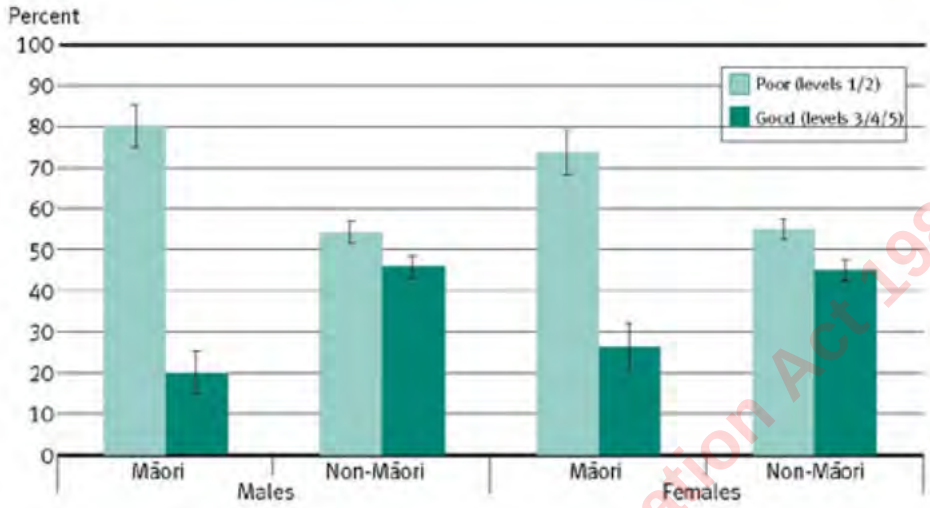
Surgical Mesh

The report *Hearing and Responding to the Stories of Survivors of Surgical Mesh* was commissioned by the Ministry of Health to summarise the themes that emerged from a restorative process to hear from New Zealand men and women affected by surgical mesh.

A significant number of stories were heard through this process which cantered on informed consent. A widely held view was that consent practices did not meet the

	standard expected in the Code of Consumers' Rights. Many claimed mesh had been implanted without their consent, saying they only became aware of *"this foreign toxic plastic in my body"* when complications arose. The consent process for initial surgery was frequently described as a sales pitch: *"This is a quick and easy fix", "I've done thousands of these with no problems"* and *"You will be back on your feet in no time".* In many elective cases, no information was given about the other options available, such as a native tissue repair or pelvic floor physiotherapy, nor any assessment of the expected risks, side effects, benefits and costs of each option. Many participants commented, *"I would never have had mesh put in me if the risks were fully explained"*. Some indicated feeling pressured into surgery with mesh. One said, *"He held open the door and said come back when you agree to have mesh"*. Only later did she learn that alternatives were possible. Others noted that their concerns were dismissed: *"I went to my surgeon; I mentioned the risk around mesh as I had heard it in the news and was shown a brochure and told, 'you will be sweet mate' " (Mesh injured man/LC)* FACS: 3737 people of childbearing age were dispensed sodium valproate in 2020. Up to 40% of babies exposed to more than 800mg of sodium valproate exposure per day during pregnancy will have developmental delays.
B. EQUITY	
What inequity exist in relation to this problem? *How do you know inequity exists?* *What do you think will reduce the incidences of inequity?*	**What inequity exists:** In this section we talk about health literacy as it is one component of informed consent, however we would like to acknowledge that this does not mean that improvements in health literacy will solve all the problems of informed consent. Health professionals have a large role to play in improving informed consent practices. Informed consent is linked with health literacy in that Health literacy is defined as the ability to obtain, process, and understand basic health information and services in order to make informed and appropriate health decisions. International research shows there is a relationship between a person's level of literacy and their health status (Canadian Council of Learning 2008, Kickbusch et all 2005, Kinght 2006: Korhonen 2006: Institute of Medicine 2004: Nutbeam 2008). The Kōrero Mārama: Health Literacy and Māori report, 2010 found that Māori have poorer health literacy skills compared to non-Māori across all of the measured variables. 80% of Māori males (4 out of 5) and 75% (3 out of 4) of Māori females were found to have poor health literacy. Māori who live in a rural location have on average the poorest health literacy skills, closely followed by Māori who live in an urban location. Māori in the 50-65, 16-18, and 19-24 year age groups have the poorest health literacy compared to the rest of the population. Māori across all income quintiles have poorer health literacy skills compared to non-Māori. Almost 90% of Pacific men and women have poor health literacy.

Figure 1: The distribution of health literacy, for Māori and non-Māori, by sex



How do you know inequity exists?

Foetal Anti-Convulsant Syndrome:

The Addressing the past, present and future for people of childbearing potential on anti-seizure medicines report April 2021 found that approximately 338 babies would have been harmed due to sodium valproate exposure during pregnancy between 2007-2019. Of this approximate, 123 babies (36%) will be Māori.

Lilo et. Al 2015 Health Literacy, culture and Pacific Peoples in Aoearoa, New Zealand: A Review found that inadequate health literacy was consistent among adult females, particularly older adults of low socioeconomic status, lower level of education, non-English speakers and adults with compromised health status. Further, culture may play a role in attainment of adequate health literacy. These individuals were more likely to report worse chronic physical conditions, such as diabetes, including lack of knowledge of their condition such as the inability to identify normal blood sugar levels, the range of a normal blood pressure or how to self-manage hypoglycaemia

Kidd J, Black S, Blundell R, Peni T. Cultural health literacy: the experiences of Māori in palliative care. Glob Health Promot. 2018 Dec;25(4):15-23. doi: 10.1177/1757975918764111. Epub 2018 May 3. PMID: 29722596.

Found that poor cultural health literacy on the part of organisations has likely impacted on late access to or avoidance of palliative care for Māori.

What will reduce the incidences of inequity?

Improvement in Health practitioners understanding of informed consent and the importance of it will help to reduce the incidences of inequity.

	Improvement in Health literacy for all Māori combined with improved informed consent discussions from health professionals will help to reduce incidences of inequity. Kaitakawaenga (Māori Liasion Advisors) work with Whānau to assist with making sure patients and whānau understand what the doctor or nurse is telling them about their health problems. Kaitakawaenga can help to improve health literacy for Māori (and other populations) and therefore help to improve informed consent discussions. Lilo et. Al 2015 Health Literacy, culture and Pacific Peoples in Aoearoa, New Zealand: A Review states: Public Health practitioner should apply effective communication using a culturally and ethnically tailored apporach to support Pacific peoples to undrestand Health messages, improve behaviours and Health status. Equity focussed training and information about informed consent for Health professionals will help to improve the inequities. HQSC three-step model for better Health literacy: 
C. TE TIRITI	
What contribution to Māori health advancement and reducing inequity would resolving this problem make? *What input have you had from Māori that this is a priority?* *What potential does resolving this problem provide to demonstrate: Kāwanatanga (partnering and shared decision making; Tino rangatiratanga*	As above, involving Kaitakawanga (Māori Liasion advisors) and whanau in the informed consent process would help to reduce the inequitable outcomes for Māori and improve health literacy. Kāwanatanga – partnering and shared decision making – speaks to the essence of the informed consent process. Working together as patients and Health professionals to understand and make shared decisions.

(recognising Māori authority); Ōritetanga (equity); Wairuatanga (upholding values, belief systems and worldviews)?	
D. STRATEGIC ALIGNMENT	
How resolving this problem contribute to the New Zealand Health Strategy and Whakamaua, Māori Action Plan, and other relevant government, sector, or community strategies?	Strategically aligns with Whakamaua: Māori Health Action Plan 2020 – 2025 – Priority Area 6: Te whai kouga me te noho haumaru (Quality and Safety): ▪ Purpose: To improve the quality, safety and experience of health and disability services received by Māori individuals and their whanau Strategically aligns with the iGPS specifically: Priority 1: Embedding Te Tiriti o Waitangi across the health system 1.6 Te whai kounga me tenohohaumaru Quality and Safety: Agencies will take action to be genuinely accountable to Māori for tackling inequities of access and health outcomes, and to lift their capability to achieve change for Māori. This includes building the knowledge of all staff in Te Tiriti o Waitangi and mātauranga Māori and taking steps to address bias in decision making. Priority 4: Achieving equity in health outcomes 4.1, 4.2 and 4.3 - which speak to outcomes for Māori, Pacific and Disabled people
E. FEASIBILITY	
To what degree can this problem be resolved? *Are there examples of progress to resolving this problem in NZ and overseas?*	Given the amount of information and evidence (as above) outlining the issue of inconsistent practices around informed consent, we propose that the Quality forum recommend that an action plan is developed to address these issues at a national level. This could involve some quick wins as well as outline some longer-term projects. Measures of success for the action plan would be a combination of monitoring HDC complaints, HQSC consumer experience data, health and disability standards attaintment, consumer & health professional survey's etc. There are international examples of how other countries have tried to improve informed consent – these can be used to inform the action plan
F. SUSTAINABILITY	
How will resolving this problem impact system change? *What long term benefits can be achieved by fixing this immediate problem?*	Informed consent is the foundation of consumer-centred care and of the partnership between patients and providers. It helps to ensure that people are empowered in their care, their needs are met and harm is reduced. A well informed consumer is better able to participate and engage in their care, and good informed consent practices can assist to improve health literacy and maintain or improve people's trust in the health system. Ultimately it may also result in an improved experience of care for both providers and consumers, higher patient satisfaction and well-being and fewer complaints to HDC and providers.

	Informed choice for patients. Involving patients in their care. Ensuring that the standards for informed consent are met consistently. Although we have discussed the impact of health literacy in this submission, it will take improvements from health professionals to improve the overall informed consent process. Adherence to current informed consent principles and policies needs to improve from all health professionals. There is an opportunity to use patient experience feedback in real time to enhance quality improvement of the informed consent process. Both short term and long-term benefits are ensuring patients are involved in deci ions about their care, improving health literacy for all, which leads to improved outcomes.

MINISTRY OF HEALTH
MANATŪ HAUORA

Informed consent in Aotearoa New Zealand

Literature Review

Samantha Samaniego

Intern – Office of the Chief Clinical Officers

Context

- The Code and professional guidelines outline expectations of informed consent
- What are the dynamics around informed consent?
  - Enablers, barriers and associated implications, solutions
- New Zealand academic literature from range of settings
  - Lack of evidence from vaccination and unregulated settings
- 29 relevant articles from the past 10 years
- Findings - Confirming and reaffirming what we know anecdotally

Enablers

- Culturally safe, whānau-based care
- Collaboration between health professionals
- Positive learning environment for medical students
- Relationships of trust between health professionals and whanau
- Whānau are empowered to know their rights under the Code

Enablers

Culturally safe, whānau-based care

Collaboration between health professionals

Positive learning environment for medical students

"Perioperative nurses are in a prime position to reinforce informed consent. They should actively support the consenting process and be proactive in collaborating with patients and physicians to ultimately ensure that the patient has every opportunity to make an informed decision."

Agnew & Jorgensen (2012)

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Whānau being empowered to know their rights under the Code

Enablers

Culturally safe, whānau-based care

Collaboration between health professionals

Positive learning environment for medical students

Relationships of trust between health professionals and whanau

Whānau are empowered to know their rights under the Code

"In my opinion, it was done particularly well by [de-identified], a general and colorectal surgeon at [de-identified]. When he consents patients at their last clinic appointment before surgery, he always informs them there may be 1. students present, 2. that they may be assisting in the operation and 3. that they may also examine the patient under anaesthetic, then he gains and documents consent (for however much of it they are comfortable with)." (PIN 16; 26 years; female)

Bhoopatkar *et al* (2022)

Enablers

- Culturally safe, whānau-based care
- Collaboration between health professionals
- Positive learning environment for medical students
- Relationships of trust between health professionals and whanau
- Whānau are empowered to know their rights under the Code

Barriers

- Power dynamics
- Time constraints
- Communication challenges
- Poor health literacy
- Limited availability of good resources
- Poor patient recall of information
- Lack of knowledge/support of student informed consent policies
- Inconsistency in patient understanding of informed consent

Barriers

- Power dynamics
- Time constraints
- Communication challenges
- Poor health literacy
- Limited availability of good resources
- Poor patient recall of information
- Lack of knowledge/support of student informed consent policies
- Inconsistency in patient understanding of informed consent

Powell (2015) found significant variation in expectations for information in informed consent related to breech birth

Barriers

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- Lack of knowledge/support of student informed consent policies
- Inconsistency in patient understanding of informed consent

Amarasekera & Lander found that understanding of fundamental concepts of informed consent and its medico-legal implications by patients and public is poor

Barriers

- Power dynamics
- Time constraints
- Communication challenges
- Poor health literacy
- Limited availability of good resources
- Poor patient recall of information
- Lack of knowledge/support of student informed consent policies
- Inconsistency in patient understanding of informed consent

Implications – what are the consequences of these barriers?

- Individuals/whānau do not feel comfortable asking questions or for further clarification
- Individuals/whānau are unaware that they can have a support person with them at their appointments
- Individuals/whānau do not fully understand the provided information and are thus not fully informed
- Medical students feel reluctant to stand up to their supervisors and say no
- Clinicians cannot build relationships and ensure that whanau understands the necessary information
- Losing trust in the Individuals/whānau -health professional relationship

Potential Solutions

Improving access to quality resources e.g info sheets, visual aids	Implementing dynamic consent more widely and using digital platforms to support this	Supporting culturally safe, whānau-based care	Ensuring informed consent across all professionals who whanau interact with	Improving knowledge of the Code (for patients) and medical student policies for informed consent	Better access to advocacy groups
Kearns *et al* (2020) found that visual materials were useful to all patients when giving consent for moderate or complex operations	Lunt et al (2019), Wee et al (2013) – allowing individuals to express and change their consent virtually immediately	Cargo et al (2016) – Tiriti principles must be applied to informed consent	Agnew & Joergensen (2012) – perioperative nurses, as patient advocates, should work closely with providers to ensure informed consent	Bhoopatkar (2022) – need to ensure policies are understood by supervisors	
Batuyong et al (2012) – multimedia tools used after verbal consent improved patient understanding of information	Leitch et al (2021) – proposed electronic prescribing, decision-support and communication tool to provide tailored information for patients	Agnew & Joergensen (2012) – involving family members in decision making (e.g typical for Māori and Pacific people)		Bagg et al (2015)- there are different ways that health professionals responsible can support informed consent of medical students	

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Health & Disability Commissioner
Te Toihau Hauora, Hauātanga

MINISTRY OF HEALTH
MANATŪ HAUORA

Informed Consent

Quality Forum Submission

Robyn Carey & Morag McDowell

Informed Consent – what does good look like?

- Informed consent is the foundation of consumer-centred care and of the partnership between patients and providers.
- It helps to ensure that people are empowered in their care, their needs are met and harm is reduced.
- A well informed consumer is better able to participate and engage in their care, and good informed consent practices can assist to improve health literacy and maintain or improve people's trust in the health system.
- Ultimately it may also result in an improved experience of care for both providers and consumers, higher patient satisfaction and well-being and fewer complaints to HDC and providers.

Problem Statement

- Recently the Ministry of Health has noticed an increasing number of issues due to lack of or inadequate informed consent practices for patients.

- Complaints to HDC about inadequate informed consent practices have remained at around 15% of all complaints for many years, and informed consent continues to be a prominent theme in HDC investigations

- These complaints and issues have been raised through formal channels such as
  - the HDC complaints process
  - the restorative process for addressing harm caused by surgical mesh,
  - survey data for medical schools and as part of the COVID-19 vaccination programme

- There is currently no national policy on informed consent, and informed consent policies/practices are inconsistent across DHBs/districts. However the Code of Health and Disability Services Consumers' Rights (the Code) & The Health and Disability Services Standards cover the requirements for informed consent discussions.

- Informed consent is the responsibility of all health care professionals and there have been examples across all groups of where the standards haven't been met.

Clear Informed Consent Standards

- Informed consent under the Code is a process with three essential elements:
  - effective communication between the parties (Right 5);
  - the provision of all necessary information to the consumer (Right 6);
  - and the consumer's freely given and competent consent (Right7)

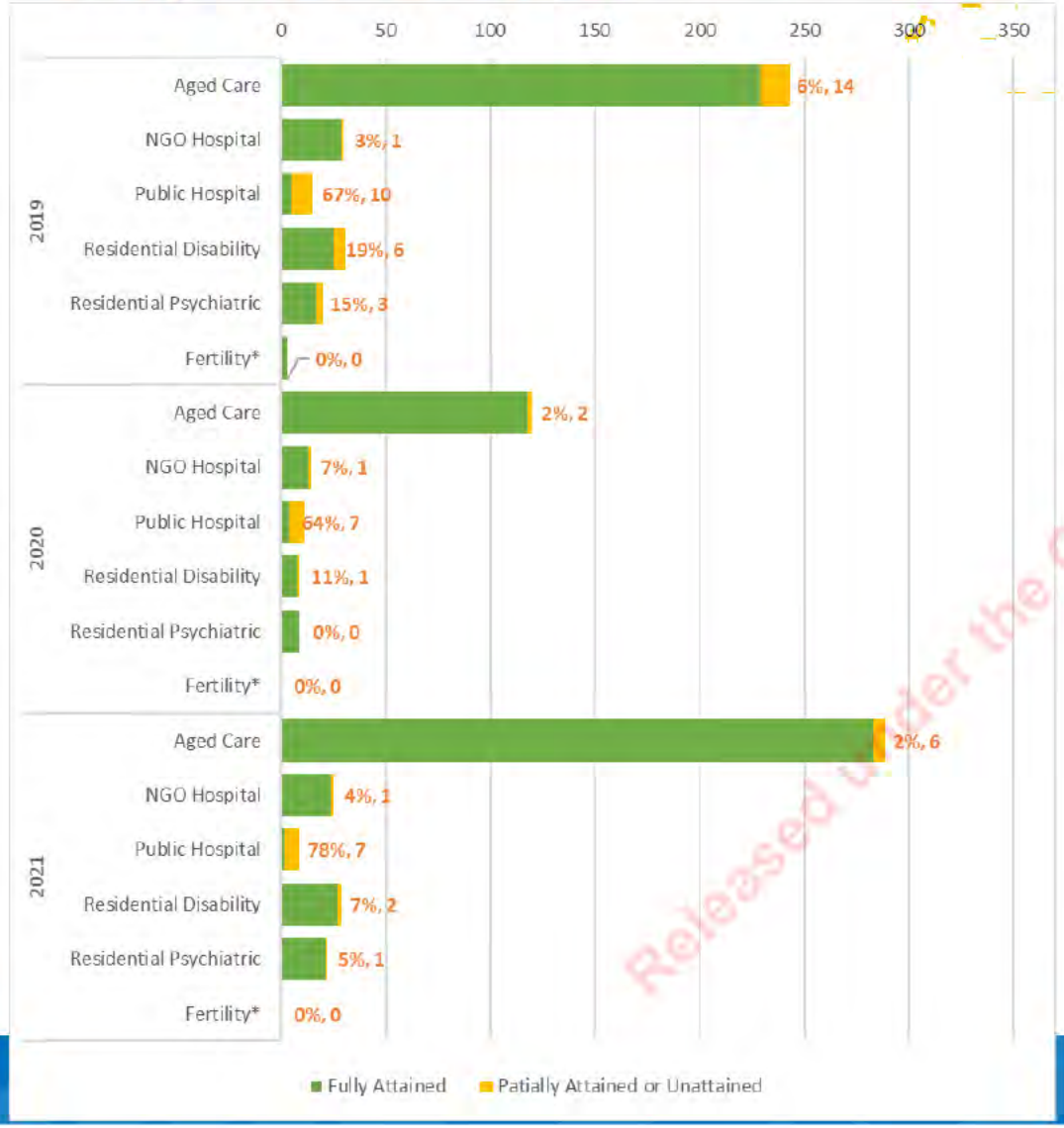
- *The Health and Disability Services Standards* outline NZs 8134.1.1.10 Consumer Rights: Informed Consent
  - Consumers and where appropriate their family/whanau of choice are provided with the information they need to make informed choices and give informed consent.

Recent Evidence of Inadequate Informed Consent Practice

- 8 recent HDC cases outlined in the submission highlighting inadequate informed consent practice occuring across all health professions
- Ministry of Health COVID-19 Vaccination Survey results outline vaccination centres could provide more, better, and consistent information
- COVID-19 Vaccination Survey for providers (1300 responses) highlighted that 55% said they always provide physical brochures and factsheets about myocarditis and pericarditis
- Addressing the past, present and future for people of childbearing potential on anti-seizure medicines report April 2021 highlighted the need to address present needs – People currently on anti-seizure medicines deserve informed consent, informed choice, and a whole of system approach
- Auckland University Medical Students Survey: Adherence by University of Auckland medical students to the national consensus statement on obtaining informed consent for sensitive examinations was “unsatisfactory”, a survey has found. (93/265 responded to the survey).

Document 10

Impact and Risk



- This data is provided by Healthcert, who oversees the certification process against the Health and Disability Service Standards.
- The graph outlines the attainment results against the informed consent standard by provider over the past 3 years.
- Partially attained or unattained suggests a corrective action is required.
- The corrective actions vary depending on the service and policies in place – further analysis of the corrective actions could be done to understand the problem.
- Note there were less audits completed in 2020 due to COVID-19.
- Public Hospitals appear to have the highest number of partially and/or unattained standards for informed consents.

	Public Hospital % Partially Attained or Unattained	Number of audits completed
2019	67%	10
2020	64%	7
2021	78%	7

Impact and Risk

- **HDC complaints**: Complaints to HDC highlight the physical and psychological harm that can occur when a person's right to make an informed choice and give their consent are undermined. This can also result in a significant loss of trust in the health system, reluctance to seek further care and a disengagement from treatment.

- **Surgical mesh report:** A significant number of stories were heard through this process which cantered on informed consent. A widely held view was that consent practices did not meet the standard expected in the Code of Consumers' Rights. Many claimed mesh had been implanted without their consent, saying they only became aware of *"this foreign toxic plastic in my body"* when complications arose.

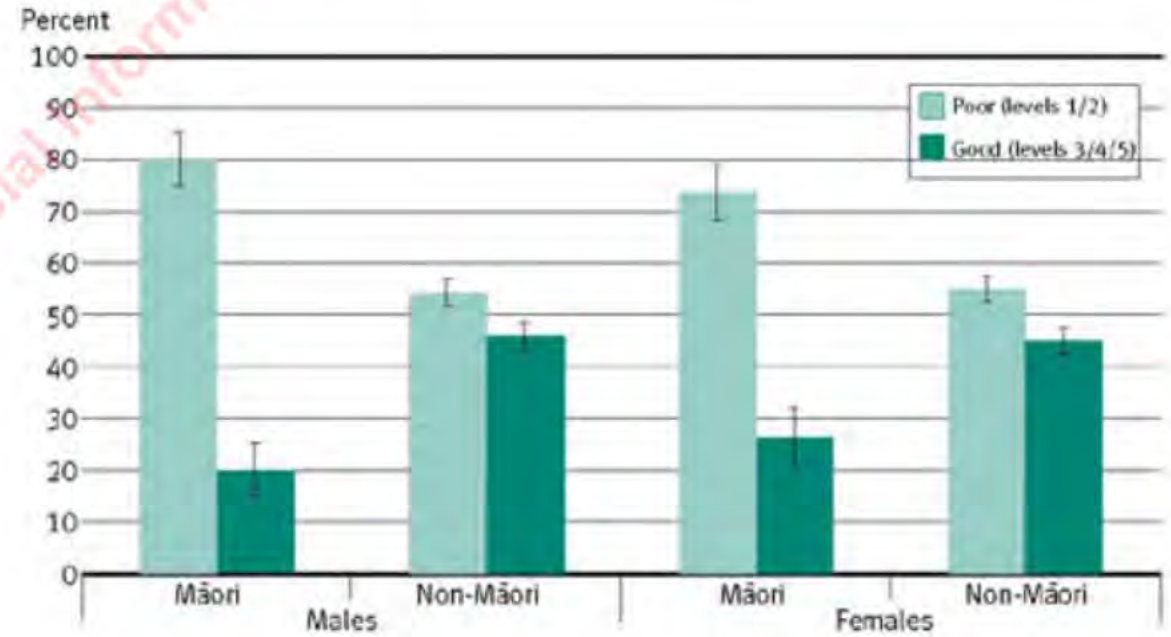
- **FACS**: 3737 people of childbearing age were dispensed sodium valproate in 2020. Up to 40% of babies exposed to more than 800mg of sodium valproate exposure per day during pregnancy will have developmental delays.

Equity

- Informed consent is linked with health literacy in that Health literacy is defined as the ability to obtain, process, and understand basic health information and services in order to make informed and appropriate health decisions.

- Health literacy is one component of informed consent, however we would like to acknowledge that this does not mean that improvements in health literacy will solve all the problems of informed consent. Health professionals have a large role to play in improving informed consent practices.

Figure 1: The distribution of health literacy, for Māori and non-Māori, by sex



How do we know inequity exists?

- **Foetal Anti-Convulsant Syndrome:** The Addressing the past, present and future for people of childbearing potential on anti-seizure medicines report April 2021 found that approximately 338 babies would have been harmed due to sodium valproate exposure during pregnancy between 2007-2019. Of this approximate, **123 babies (36%) will be Māori.**

- Lilo et. Al 2015 **Health Literacy, culture and Pacific Peoples in Aoearoa, New Zealand: A Review** found that inadequate health literacy was consistent among adult females, particularly older adults of low socioeconomic status, lower level of education, non-English speakers and adults with compromised health status.

- Kidd J, Black S, Blundell R, Peni T. **Cultural health literacy: the experiences of Māori in palliative care** found that poor cultural health literacy on the part of organisations has likely impacted on late access to or avoidance of palliative care for Māori.

Te Tiriti

The principle of Kāwanatanga – partnering and shared decision making – speaks to the essence of the informed consent process. Working together as patients and Health professionals to understand and make shared decisions.

Strategic Alignment

- Whakamaua: Māori Health Action Plan 2020 – 2025 – Priority Area 6:
  - Te whai kouga me te noho haumaru (Quality and Safety):
  - Purpose: To improve the quality, safety and experience of health and disability services received by Māori individuals and their whanau

- iGPS
  - Priority 1: Embedding Te Tiriti o Waitangi across the health system
    - 1.6 Te whai kounga me tenohohaumaru Quality and Safety: Agencies will take action to be genuinely accountable to Māori for tackling inequities of access and health outcomes, and to lift their capability to achieve change for Māori. This includes building the knowledge of all staff in Te Tiriti o Waitangi and mātauranga Māori and taking steps to address bias in decision making.
  - Priority 4: Achieving equity in health outcomes
    - 4.1, 4.2 and 4.3 - which speak to outcomes for Māori, Pacific and Disabled people

Recommended Next Steps (for discussion)

- We propose that the Quality forum recommend that an action plan is developed to address these issues at a national level.
- This could involve some quick wins as well as outline some longer-term projects.
- Measures of success for the action plan would be a combination of monitoring HDC complaints, HQSC consumer experience data, health and disability standards attaintment, consumer & health professional survey's etc.
- There are international examples of how other countries have tried to improve informed consent – these can be used to inform the action plan

4 Operational issues / Ngā take whakahaere

4.1 Manatū Hauora

4.1.1 Addressing inconsistencies with informed consent practices

Background

Informed consent is an important component of Aotearoa New Zealand's health system and is the responsibility of all health care professionals.

The reformed health system provides an opportunity to develop nationally consistent advice and practices in this critical area. Approximately 15% of complaints to the Health and Disability Commissioner relate to informed consent, and the lack of informed consent is regularly raised in the media.

The Code of Health and Disability Services Consumers' Rights and the Health and Disability Services Standards include requirements for consumers to provide informed consent before any treatment.

Work to date

In July 2022 the National Quality Forum (the group convened by the Health Quality and Safety Commission to provide overall governance for the quality and safety system) agreed that we would work with the Health and Disability Commissioner to convene a group to review this issue in more detail. It was proposed that the group would determine what action is required and by whom to improve the consistency of informed consent practices in Aotearoa New Zealand.

Informed consent workshop

We led a system-wide workshop on informed con ent on 8 February 2023. Representatives from the Health and Disability Commission, the Health Quality and Safety Commission (HSQC), the Medical Council of New Zealand, the College of Midwives, ACC, the University of Otago, Te Whatu Ora, and Te Aka Whai Ora attended. Individuals shared their experiences of inconsistent informed consent practices across different care settings, which led them to be confused and unsure about what they had consented to.

The core outcome of the workshop was an agreement to work together across the system to continue to improve the consistency of informed consent practices. Manatū Hauora will complete a stocktake of current initiatives to address inconsistent informed consent practices. We expect to complete this by the end of March 2023.

In addition, there was a strong consensus we should undertake broader but focused engagement to better understand individual stories. These experiences will be utilised to identify actions reflective of what matters to individuals and their whānau. HQSC are determining what resource is available to lead engagement processes.

Next steps

Our role continues focused on convening the group in partnership with the Health and Disability Commission. We will also monitor overall progress in improving informed consent practices across the health system.

Deputy Director-General	Dr Joe Bourne, Chief Medical Officer, Office of the Chief Clinical Officers – Ngā Āpiha Hauora, s 9(2)(a)