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3 September 2021

9(2)(a)



RE Official Information Act request CDHB 10672

I refer to your email dated 27 July 2021 requesting the following information under the Official Information Act from Canterbury DHB regarding the CanRisk questionnaire written by the Canterbury Initiative and adapted by HealthInfo clinical advisers. Specifically:

- 1. The CanRisk questionnaire written by the Canterbury Initiative and adapted by HealthInfo clinical advisers (<https://www.healthinfo.org.nz/patientinfo/CanRisk-assessment-questionnaire.pdf>) ("the Canterbury DHB CanRisk questionnaire"):**
 - (a) How does the Canterbury DHB CanRisk questionnaire differ from CanRisk developed by the University of Cambridge (described in: (1) Lee et al. (Genet Med, 2019) and Carver et al. (Cancer Epidemiol Biomarkers Prev, 2020); (2) <https://canrisk.org/about/> ; and (3) <https://ccge.medschl.cam.ac.uk/canrisk/>) ("The UK CanRisk tool").**

The HealthInfo questionnaire is an optional step in the process of a clinician completing a University of Cambridge online CanRisk assessment.

- (b) If related to the UK CanRisk tool, who were the Clinical Advisers who adapted the questionnaire?**

The HealthInfo questionnaire was created by Janine Close (GP Clinical Leader) with advice from Suzannah Bawden (Genetic Counsellor) and Josie Todd (Oncoplastic Breast and General Surgeon)

- 2. In relation to the CanRisk tool described on the HealthInfo Canterbury website <https://www.healthinfo.org.nz/index.htm?Disability-aids-for-home-mobility.htm> (accessed 21 July 2021) (the Canterbury DHB's CanRisk tool"):**

- (a) Details of the model**

The details of the Canterbury DHB's CanRisk tool including, without limitation:

- (i.) What variables are used in the model;**
- (ii.) What statistical analyses are used;**

(iii.) What probability thresholds are used.

The CanRisk tool on HealthInfo is the Cambridge University CanRisk tool. The CanRisk Tool uses the latest version of the BOADICEA model to compute breast cancer risks, described in the following paper:

Lee A, Mavaddat N, Cunningham AP, Carver T, Harley S, Babb de Villiers C, Izquierdo A, Wilcox AN, Chatterjee N, Schmidt M, Simard J, Walter FM, Gardia-Closas M, Tischkowitz M, Pharoah P, Easton DF, Antoniou AC. 2019. BOADICEA: a comprehensive breast cancer risk prediction model incorporating genetic and non-genetic risk factors: <https://www.nature.com/articles/s41436-018-0406-9>;

(b) NZ Cancer incidence rates

- i. What New Zealand cancer incidence rates does the Canterbury DHB's CanRisk tool use?**
- ii. Are the NZ Cancer incidence rates updated in the Canterbury DHB's CanRisk tool?**

There is not a Canterbury DHB CanRisk tool. When using the University of Cambridge CanRisk tool the NZ breast cancer rates are included in the assessment.

(c) Inclusion of Māori and other non-Europeans.

- i. An update to the UK CanRisk tool includes NZ data but specifically notes that it is based on a non-Māori population (Lee, British J Cancer, 2014). Does the Canterbury CanRisk tool include Māori wāhine? If not, why not?**

As above, there is no Canterbury DHB CanRisk tool.

The University of Cambridge CanRisk tool does have the limitation of only being validated for European populations but is reported as a reasonable tool for use in other Western populations. Good datasets and/or appropriate alternatives are currently not available to rectify this situation. The CanRisk tool is recommended by the eviQ reference committee and used by the Genetic Health Service NZ to assess risk across the Māori and non-Māori population. Currently, there is no evidence to suggest it is significantly inaccurate.

Ministry of health statistics around breast cancer incidence over the last 15 years reports the incidence of breast cancer is equivalent for Maori women compared to Pakeha women.

- ii. The UK CanRisk tool also has a general exclusion or under-representation of non-Europeans. Does the Canterbury CanRisk tool under-represent non-Europeans? If so, why?**

See above answer.

There are no/ limited datasets for non-Europeans to inform the University of Cambridge CanRisk tool.

(d) Adaptation/modification

- i. Is the Canterbury DHB's CanRisk tool an adaptation/modification of the UK CanRisk tool?**
- ii If the answer to (i) is yes, in what way(s) does the Canterbury DHB's CanRisk tool adapt/modify the UK CanRisk tool?**

No. The University of Cambridge CanRisk tool is being used for the Canterbury DHB at-risk programme

iii. If the answer to (i) is yes, do the adaptation(s)/modification(s) made to the UK CanRisk tool impact on the safety and effectiveness of the Canterbury DHB's CanRisk tool? If so, how?

Not applicable

(e) Authors

i. Who were the HealthInfo clinical advisers who wrote the web page:

<https://www.healthinfo.org.nz/index.htm?Disability-aids-for-home-mobility.htm>

Janine Close (GP Clinical Leader)

ii. Who was the oncoplastic breast and general surgeon, Canterbury DHB, who endorsed the web page:

<https://www.healthinfo.org.nz/index.htm?Disability-aids-for-home-mobility.htm>

Josie Todd (Oncoplastic Breast and General Surgeon)

(f) Risk-benefit analysis

i Was a risk-benefit analysis undertaken regarding the use of the Canterbury DHB's CanRisk tool ?

ii If the answer to (i) is yes, may I have a copy of that risk-benefit analysis?

No

(g) Implementation

i. Why was the Canterbury DHB's CanRisk tool implemented? For example, and non-exhaustively, is it being used to:

- gather baseline data? If so, to what end?
- actively screen for prioritization to a service – e.g. mammography or genetic testing? If so, what are the applicable thresholds and how have they been set?

Canterbury DHB provides funded screening mammograms to women at increased risk of breast cancer based on their family history of breast cancer.

Previously women were assigned to moderate risk status by their GP based on the age and number of their relatives who had previously been diagnosed with breast cancer. This method of risk stratification does not take account of the number of unaffected relatives a woman has and is a traditional non-validated approach to determining risk level.

[EviQ guidance](#) provides recommendations for assessment and screening for moderate risk women and was recommended by the Genetic Health Service (Caroline Lintott and Suzannah Bawden Genetic Counsellors).

- EviQ advises annual screening from age 40 to 49 years of age in women who are at moderate risk of breast cancer based on their family history of breast cancer. Moderate risk women have a 10-year risk of breast cancer of between 3% and 8%.
- EviQ guidance recommends the use of a validated risk model such as CanRisk, IBIS or iPrevent to determine moderate risk status.

ii. When was the Canterbury DHB's CanRisk tool implemented?

Canterbury DHB's CanRisk tool was implemented on April 7, 2021

iii. Where has the Canterbury DHB's CanRisk tool been implemented?

The CanRisk tool has been implemented for both Canterbury DHB and West Coast DHB.

- iv. In determining whether to implement the Canterbury DHB's CanRisk tool, was regard had to the conclusions reached by Archer S, Babb de Villiers C, Scheibl F, Carver T, Hartley S, Lee A, et al. (2020) "Evaluating clinician acceptability of the prototype CanRisk tool for predicting risk of breast and ovarian cancer: A multi-methods study." PLoS ONE 15(3): e0229999, in particular, that CanRisk may not have been versatile enough for clinical use in both primary care and specialist genetics clinics where the needs of clinicians are different, emphasising the importance of understanding the clinical context when developing cancer risk assessment tools?**

No. The conclusions of this article were not included in the implementation of the Canterbury DHB's at-risk programme changes.

The University of Cambridge CanRisk tool was trialled by a GP clinical adviser. It is recognised that the tool requires time both to learn to use and for each assessment. It is envisaged that a proportion of clinicians (practice nurses, nurse practitioners and general practitioners) will upskill in the use of the tool and will provide assessments for women who would have been considered moderate risk under the previous criteria.

In the light of the additional time and skill needed to perform this assessment the CDHB has funded a transitional programme that employs a nurse to complete CanRisk assessments with patients. She is supervised by the GP clinical advisor and has access to advice from a genetic counsellor and an oncoplastic breast and general surgeon. Her role includes assisting upskilling of interested clinicians in completing CanRisk assessments.

The authors of the above paper have made modifications to the CanRisk tool based on the results of the paper to make it more accessible for primary care use. They have committed to an ongoing process to make the tool more accessible to primary care clinicians.

- v. In determining whether to implement the Canterbury DHB's CanRisk tool, was regard had to the conclusions reached by French et al. "What are the benefits and harms of risk stratified screening as part of the NHS breast screening Programme? Study protocol for a multi-site non-randomised comparison of BC-predict versus usual screening (NCT04359420)" BMC Cancer (2020) 20:570 <https://doi.org/10.1186/s12885-020-07054-2?>**

No. This paper is a study protocol. There are no conclusions as the study is in progress.

Access to CDHB funded at-risk screening has always required risk stratification by the referring clinician. The use of the University of Cambridge CanRisk tool which includes both relatives with cancer and non-affected relatives improves the risk assessment.

(h) Validation

- i. Has the Canterbury DHB's CanRisk tool been validated, either retrospectively or prospectively?)**

Canterbury DHB is using the University of Cambridge CanRisk tool

- 3. In relation to both the Canterbury DHB CanRisk questionnaire and the Canterbury DHB CanRisk tool:**
 - i. Do women provide explicit consent to their use?**

Women consent to the CanRisk assessment. The completion of the HealthInfo CanRisk Questionnaire is encouraged but is optional. Please find attached as **Appendix 1** a copy of the CanRisk Questionnaire.

- ii. If so, how is that consent obtained? Please may I have a copy of the information sheet which accompanies the consent form.**

Verbal consent is obtained by the CanRisk nurse for completion of a CanRisk assessment. Information is provided in the email/ letter sent to the women. The CanRisk nurse proceeds with a CanRisk assessment when a woman has had the opportunity to ask any questions about the assessment and agrees to proceed.

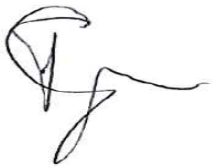
iii. If not, why not?

Not applicable.

I trust that this satisfies your interest in this matter.

Please note that this response, or an edited version of this response, may be published on the Canterbury DHB website after your receipt of this response.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Tracey Maisey', with a long horizontal flourish extending to the right.

Tracey Maisey
Executive Director
Planning, Funding & Decision Support

CanRisk Questionnaire

Name:

NHI:

Please complete this form as fully as you are able to. There may be some questions you do not have the answer to, it is ok to leave these blank. This family information helps when completing the CanRisk assessment. If you cannot complete the form a CanRisk assessment can still be done.

After you have completed this form:

- Photo or scan and email the form to the CanRisk Nurse at CIAdmin@cdhb.health.nz
- Confirmation and details of your CanRisk assessment appointment will be sent to you by email
- At the appointment the Nurse will discuss the responses you have provided on this form.
- There will be time at the appointment to discuss any items you are unsure of.

Genetic testing:

1. Have any of your whānau members had genetic testing to see if they carry a cancer gene?

Yes

No

2. If **yes**, what are their names and the result of this genetic testing?

Name(s):

Mutation found

No mutation found

Unsure

Family diagnosis of cancer:

At the CanRisk assessment appointment the Nurse will talk to you about all your close family members. On the following page please, list all family members from these groups

- Mother, mother's mother, mother's father, mother's sisters, mother's brothers
- Father, father's mother, father's father, father's sisters, father's brothers
- Your sisters, your brothers
- Your daughters, your sons

It's important to include all your close family members, whether or not they've been diagnosed with cancer. It will be helpful if you record your family members' first names.

The details will be entered into the CanRisk tool to create a family tree diagram and will appear on the CanRisk report.

CanRisk Questionnaire

First Name	Relation to me	Current age or year or birth	Type of Cancer (Only include Breast, ovary, prostate, pancreas)	Age when cancer(s) diagnosed	Still living (Y/N)	Age at death
Mary (Example)	Mother's mother	1932	Breast	52	N	69
Angela (Example)	Sister	34yo	None	--	Y	--
	Daughters					
	Sons					
	Sisters					
	Brothers					
	Mother					
	Father					
	Mother's Mother					
	Mothers Father					
	Mothers Sisters					
	Mothers Brothers					
	Mothers Brothers					
	Father's Mother					
	Father's Father					
	Father's Sisters					
	Father's Brothers					