Author’s response to reviews

Title: Disclosure to genetic relatives without consent – Australian genetic professionals’ awareness of the health privacy law

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Version: 1 Date: 27 Dec 2019

Author’s response to reviews:

28 December 2019

Editorial Office

BMC Medical Ethics

Dear Editor,

Re: Re-submission of revised manuscript entitled ‘Disclosure to genetic relatives without consent – Australian genetic professionals’ awareness of the health privacy law’

Please find attached a revised manuscript entitled ‘Disclosure to genetic relatives without consent – Australian genetic professionals’ awareness of the health privacy law’. We are very grateful for the reviewers’ many helpful suggestions and comments and have addressed each as follows. All text changes/inserts are underlined for clarity.

Naomi Hawkins (Reviewer 1)

1. Abstract and Introduction: Some further clarification in the abstract and introduction about the relationship between the legal and ethical duties here would be helpful.
This has been clarified in

- Lines 30-24 in the Abstract: “The ethical obligations to prevent harm to at-risk relatives and promote the duty of care by genetic health professionals (GHPs) is in conflict with Privacy laws and professional regulations that prohibits disclosure of information to a third party without the consent of the proband (duty of confidentiality). In New South Wales (NSW), Australia, amendments to Privacy legislation permits such disclosure to living genetic relatives with the process defined under guidelines although there is no legal duty to warn.”

- Lines 95-98 in the Introduction: The ethical obligation to prevent harm to at-risk relatives and promote the duty of care by GHPs is in conflict with Privacy laws and professional regulations that prohibits disclosure of information to a third party without the consent of the proband (duty of confidentiality).

2. In reference to the ABC v St George case, it may be helpful to consider and reference more of that academic commentary, including by legal commentators such as Victoria Chicco, Colin Mitchell, Michael Fay and others which has recently been published in relation to this case.

Lines 139-159: With thanks to Reviewer 2 (see below) the following text and references have been inserted a “There are both legal and ethical aspects of disclosure without consent, described by Dove et al (2019) ………….. matter was sent back to the High Court for trial which is currently in process.

3. Although this paper focuses on the situation in one Australian State, it has relevance beyond that particular context, and provides insight into a problem which is likely to become increasingly pressing in the clinical context internationally. It would be beneficial to consider and highlight more the broader international relevance of the findings in the discussion and conclusions.

This has been addressed by the following in

- Lines 160-165 “The findings have the potential to impact regulation in jurisdictions not only in the UK but more broadly as it will be important for GHPs to be clear of their roles, responsibilities and boundaries. Thus, exploration of NSW GHPs’ awareness of, or whether they act in accordance with, guidelines introduced to facilitate disclosure of genetic information without consent may inform any future support needed with the introduction of such legislation in other jurisdictions.”

- Lines 441-448: “The Australian health system is a mix of both private practice and government (public) services engendering complexity in the regulatory framework which may have added to the uncertainty and which may not be present in countries with a health service that is largely public. Nevertheless, these findings suggest that if legislation for disclosure to genetic relatives without consent is introduced, there is a need for education to increase awareness and support genetic health professionals in the application of the underpinning guidelines within their healthcare system.”

4. Active non-disclosure and passive non-disclosure are terms that are used throughout the manuscript. It would be worthwhile defining these terms for those less familiar with genetic counselling terminology. They are briefly defined in ln 64-66, but a clearer, and perhaps slightly expanded definition might be valuable.

To clarify genetic counselling terms and define passive and active non-disclosure, the following have been added to the Abstract and Introduction:

- Abstract: Lines 26-30: When a genetic mutation is identified in a family member (proband), internationally, it is usually the proband’s or another responsible family member’s role to disclose the information to at-risk relatives. However, both active and passive non-disclosure in families can occur: choosing not to communicate the information or failing to communicate the information despite intention to do so, respectively.
• Introduction: Lines 63-68: “However, some probands (that is, the first person in a family in whom the genetic nutation id identified) or another family member where there is incapacity in the proband choose not to communicate the information regarding their test results and their potential impact to at-risk relatives; others fail to despite their intention to do so and having opportunities where this may have occurred (3). Hereafter the former is referred to as active non-disclosure and the latter as passive non-disclosure.”

5. Ln 83-113 This section is somewhat convoluted and unnecessarily confusing, especially for international readers less familiar with the structure of the Australian healthcare system. It might be helpful to restructure to explain the relevance and focus of the paper upfront, then include the detail of the overlapping legal and policy regimes.

Inserted at Line 123 is a reference to (14) McWhirter R, Johnston C, Burke J. Disclosure of genetic results to at-risk relatives without consent: Issues for health care professionals in Australia. Journal of Law and Medicine. 2019;27(1):108-121.) which has been added to provide clarification of the health system and overlapping legal and policy regimes in Australia

6. Ln 114-120 In this paragraph, you reference studies from the USA and UK, but do not explore or question the applicability of these studies to the Australian healthcare system context. It may be worth considering how transferrable the conclusions of these studies are to the Australian context, or whether there are relevant differences in healthcare practice between these jurisdictions that might affect the applicability of the findings, and how they relate to your study. For example, later in the paper, you explore the difficulties in contacting at risk relatives. This is less an issue in the UK context, with a National Health Service, and more an issue in the USA. Such issues might be interesting to explore, space permitting.

In Line 114, the reference to McWhirter et al (2019) which examines the Australian context has been inserted to support the statement at Lines 160-162 that “The findings have the potential to impact regulation in jurisdictions not only in the UK but more broadly as it will be important for GHPs to be clear of their roles, responsibilities and boundaries (14).

7. Ln 213 See my comments on distinguishing the duty to warn from the duty of confidence above.

This has been addressed in Point 1 above
8. Ln 324 Typographical error 'NSW. Especially in circumstances' should read 'NSW, especially in circumstances'

This has been corrected – see Line 366.

9. Ln 329 This statement needs references.

This has been corrected with Reference to Clarke et al (2005) (now reference 1) at Lines 371-372: Research conducted by Clarke et al (2005) suggest that active non-disclosure is uncommon (1).

10. Ln 355-363 Again, the discussion of the case of ABC v St George conflates the questions of the duty to warn (the subject matter of the case) and the duty of confidence (which was not considered by the court). The issues are linked, but there needs to be greater clarity in the discussion in this paper about the relationship between the two duties.

The discussion of ABC vs St George has been expanded in the introduction with supporting references and detail (also see Reviewer 2 comments below) and is more briefly addressed in the discussion as follows:

• Introduction: Lines 144-159: “Illustrative of this is the ongoing UK legal case of ABC v St George NHS Trust where a father who had recently been diagnosed with Huntington disease refused consent for his neurology team to disclose this genetic information to his pregnant daughter. Disclosure was subsequently and unintentionally made to ABC that her father had Huntington disease (and therefore she was at 50% risk of also developing the condition) after she had given birth (20). The current appeal is ongoing. Initially the case that the Defendants (St George NHS Trust) had a relationship with the Claimant (ABC) leading to a duty of care: “to take reasonable steps to prevent the claimant from suffering injury” and that the Defendants should have provided information “in a timely manner when it was known, or ought to have been known, that the Claimant was pregnant” and that the Claimant should have been given the opportunity for “urgent diagnosis and testing” was struck out – see EWHC 1394 (QB) ([2015]) (22). The Claimant (ABC) appealed to the Court of Appeal, who allowed the appeal against the striking out, deciding that she did have an arguable case in negligence (and under the Human Rights Act 1998- see [2017] PIQR P15, [2017] EWCA Civ 336 (23). The matter was sent back to the High Court for trial which is currently in process.”

• Discussion: Lines 398-401: “The increasing need to balance the dual duties to maintain the confidentiality of the patient and limit the harms to at-risk genetic relatives brings in to focus both legal and ethical issues and cases such ABC vs St George may inform health professionals’ ongoing legal responsibilities but (13, 20, 22, 23).
Tracey Elliott (Reviewer 2)

(i) Line 122: The actual case citation should be provided here, but a secondary reference. The citation for the first High Court hearing is: [2015] EWHC 1394 (QB), and the Bailii webpage: https://www.bailii.org/ew/cases/EWHC/QB/2015/1394.html. The Court of Appeal citation is: [2017] EWCA Civ 336, and the Bailii webpage: https://www.bailii.org/ew/cases/EWCA/Civ/2017/336.html The authors should be aware that the trial of this case is currently taking place in the High Court.

We are grateful for these references which have been inserted appropriately as outlined in Point 10 of the response to Reviewer 1 above.

(ii) Line 329: A reference should be provided to these studies.

Addressed in Point 9 of the response to Reviewer 1 above.

(iii) Lines 358 -365: Your account of ABC is not wholly accurate. Disclosure was made to ABC, but by accident and only after she had given birth. There is no 'current appeal'. Initially the case was struck out as disclosing no reasonable cause of action (see [2015] EWHC 1394 (QB)). The Claimant appealed to the Court of Appeal, who allowed the appeal, deciding that she did have an arguable case in negligence (and under the Human Rights Act 1998- see [2017] EWCA Civ 336). Because this was an appeal against the striking out, the Court of Appeal did not determine whether she was likely to succeed- they sent the matter back to the High Court for trial. The trial is currently in process. Any discussion of this case should be accurate.

We are grateful not only for these references but for the detail of the case which we have inserted as described in Point 10 of the response to Reviewer 1 above.

(iv) Although it appears that necessary controls were followed, I do have a query in relation to the issue of consent. In relation to the consent of the participants, it is stated (Line 142) that consent was implied by submission of the questionnaire. I feel that this should be clarified. The information on the questionnaire does not make it clear that, by clicking 'submit' the participant consents to the data submitted being used. It may be this this information was available on the website elsewhere, or that this meets any requirements imposed with regard to ethical approval and consent, but I feel that this should be confirmed.
We have inserted in Supplementary File 1 the Participant Information Statement that was required to meet ethical approval by the University of Sydney’s Ethics Committee that participants had to have read in order to participate in the study and complete the survey. This has also been clarified in Lines 181-184: “Participants implied their consent through submitting their questionnaire after having acknowledged that they had read the Participant Information as approved by the University of Sydney’s Ethics Committee (see Supplementary file 1).”

Editor’s revision requested on revision RESUBMITTED 28th December 2019 (and please accept my apologies):

1. The Title has been corrected
2. The abstract now contains Background, Method, Results and Conclusion sections with headings.
3. Declarations have been completed as follows:
   • Ethics approval and consent to participate
   • Consent to publish
   • Availability of data and materials
   • Competing interests
   • Funding
   • Authors’ Contributions
   • Acknowledgements

Thank you for your consideration of this manuscript.

Yours faithfully,

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