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# What Does the Duty to Warn Require?

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We all have a duty to warn others when we can easily provide information to protect them from significant harm. In the medical context, a duty to warn patients and research subjects who are at risk of a disease is widely recognized. More recently, a similar duty to warn relatives of patients or research subjects has been discussed in the literature (Offit et al. 2004).

Several prominent organizations have provided guidance on the disclosure of genetic information to family members in the clinical context (American Society of Clinical Oncology 2003; American Society of Human Genetics [ASHG] 1998; Green et al. 2013; Institute of Medicine 1994; President's Commission 1998). These groups agree that health care professionals have an obligation to inform patients about the potential for genetic risks to relatives (ASHG 1998). McGuire and colleagues have proposed that this duty expands to include individuals participating in research when the relevant information or tests have been validated (McGuire, Caulfield, and Cho 2008). Most commentators and organizations argue

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that this duty has to be balanced against the obligation to maintain the confidentiality of genetic information and to respect the desires of those who wish not to know certain information.

In the case presented, there is a strong ethical justification to inform subjects' relatives about the mutation and the availability of genetic testing and counseling. The research team is in the unique position of having information that is clinically actionable and could prevent serious harm in some people with the genetic mutations. There are several interventions, including treatment with preventive antibiotics, vaccination, and bone-marrow transplant, that could prevent or possibly cure disease. Without knowledge of this syndrome, therapeutic interventions may be delayed, overlooked, or mismanaged. For example, prior to discovery of the mutation in question, a patient could receive a bone-marrow transplant from a sibling who unknowingly carried the same mutation. This could contribute to a patient's subsequent relapse and death after transplant. For this reason, it is critically important to screen related donors for the relevant mutations. Additionally, this genetic information can be relevant when making reproductive decisions. In many respects, therefore, failure to disclose this information could lead to significant harm.

Although there is a strong justification for disclosing this information, how the information should be disclosed is not straightforward. First, it is important to consider the value of respecting the confidentiality of subjects who may not want their health information disclosed to family members. Some of the subjects who were involved in the study are now deceased. With respect to deceased subjects, in the absence of a prospective conversation about disclosure after death, the researchers would not know whether the deceased subjects had preferences to keep their information confidential that would be violated by contacting their relatives. Even if deceased subjects had previously expressed a desire to maintain confidentiality, however, it is difficult to see how they would be harmed by disclosure after their death, and these desires likely would be outweighed by the potential to prevent serious harm to their relatives (Chan et al. 2012).

With regard to living subjects, family-mediated contact may be the best approach. Ideally, the subject would share information with the research team about family members who may be at risk and would facilitate contact with those family members. Family members may sometimes neglect to, or choose not to, disclose health information within their family (Gaff et al. 2007), however, which raises the question of what the research team should do if some living subjects do not wish to reveal their health information.

In some cases, parents may decide that they would not like to have their children tested for the genetic mutation. Acknowledging that parents are given considerable discretion over medical decision making for their children and that the syndrome may not affect some individuals until they are adults, the wishes of a parent with regard to genetic testing generally should be respected if the child is a minor. Nevertheless, given that there are medical interventions that can help prevent or cure disease, it would be reasonable for researchers to urge reluctant parents to have their children tested for the mutation. For parents who continue to decline testing for their children, it will be important to try to foster an ongoing conversation with the point of contact so that even if the information is not

shared with an at-risk individual immediately, there is still some possibility of sharing the information at a later date.

When a subject does not want the team to contact relatives who are adults, however, the team should weigh the ethical duty to warn against the duty to maintain confidentiality in each case, and there will likely be cases in which the duty to warn trumps confidentiality.

The American Society of Human Genetics permits unauthorized disclosure when:

> attempts to encourage disclosure on the part of the patient have failed;
>
> the harm is highly likely to occur and is serious, imminent, and foreseeable;
>
> the at-risk relative(s) is identifiable; and the disease is preventable, treatable,
>
> or medically accepted standards indicate that early monitoring will reduce the
>
> genetic risk. (ASHG 1998, 474)

These conditions appear to be met in this case, given the potential for serious harm, the options for treatment and prevention, and the fact that early monitoring and intervention could reduce the risks of serious complications in the future. Thus, unauthorized disclosure may be permissible if attempts to encourage disclosure fail, but should be considered an option of last resort.

Finally, the approach to disclosure should not merely be a way to increase recruitment for the research, and would ideally include genetic counseling to convey the information appropriately. For this reason, it is important to explain to individuals how they can obtain testing and treatment even if they decline study participation, and to provide genetic counseling to all individuals about the test and their results.

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