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When law meets morality

PERSPECTIVES

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Who owns the information about potential illness – the person who takes the test or all those to whom this information applies?

If a genetic test has produced information about a treatable disease, it is illegal to inform any relatives against the patient's will. The Biotechnology Act regulates such 'provision of genetic information to persons other than the patient' (1). Health personnel can only inform the patient's relatives if the patient has given consent, or if consent cannot be obtained, such as in case of unconsciousness or death. The precondition is that the disease has been approved by the Directorate of Health (2), p. 57) and that the requirements in Section 5–9, fifth paragraph, of the Biotechnology Act ((1) have been met:

'1. [T]he disease in question has serious consequences for the individual's life or health;

2. there is a reasonable probability that the person's relatives are also genetically predisposed to the disease and may develop the disease later in life;

3. there is a documented link between genetic predisposition to the disease and the development of the disease;

4. the genetic tests used to determine whether a person carries a genetic predisposition to the disease are reliable; and

5. there are satisfactory methods of preventing or treating the disease.'

The history of the debate

The first Biotechnology Act from 1994 did not regulate provision of genetic information to persons other than the patient, even though the preparatory works appear to reject such activity. Because certain medical communities called for a clarification, a consultation paper was issued in 1997. Most of the consultative bodies were sceptical of the proposal, which entailed an opportunity to contact relatives if the patient was unwilling or unable to inform them ((3), p. 16–21). On the other hand, it was argued that provision of genetic information should be allowed, or even obligatory if the doctor is aware that the relative is at an increased risk of disease ((4), p. 18–26). The Storting nevertheless adopted an amendment to the Act in 2000 ((5), p. 106) with the same conditions as in the current legislation. The preparatory works for the current Act from 2003 describe how the new state of the law came to be of such short duration:

'Henceforth, health personnel will no longer be permitted to inform relatives when the patient does not *want* to consent to this. The Ministry assumes that this situation will rarely occur, but should it become relevant, the Ministry is of the opinion that the patient's privacy interests and the right not to know should prevail.' ((5), p. 108, italics in the original.)

In 2015, the majority of the Norwegian Biotechnology Advisory Board again called for provision of information to relatives to be permitted even when the patient did not consent (6), given that the requirements in Section 5–9, fifth paragraph, of the Act were met. The majority underscored that such situations were likely to occur rarely, and that this permission does not entail an obligation for health personnel to provide genetic information. Two of the board's 13 members voted against. The rationale was that such permission harms the relationship of trust between doctor and patient.

France changed its legislation in 2011 (7). The new dilemma for patients is whether they themselves should inform the relative concerned or whether health personnel should do it, and not whether the relative should be informed or not. The condition must be serious, and prevention or treatment must be available. A similar provision is applied in Australia (8), and clinical guidelines in the UK permit informing affected relatives if this is strictly necessary (9).

Individual or familial information?

A fundamental question is whether the information is the property of the person who chose to take the test or whether it belongs to all those to whom this information applies. Here, two extreme positions can be identified: one says that this information is individual in its nature, the other says that it is familial. The former can be designated as the 'personal account model' and the latter as the 'joint account model' (10).

In the personal account model, the question is whether the relatives should be informed or not. In the joint account model, the question concerns what is needed in order not to inform the relatives (10). There is, however, a line beyond which the duty of confidentiality can be breached to help relatives who are at risk, even in the personal account model (11). The Norwegian Act is therefore remarkably strict. The common principle of necessity (*jus necessitatis*) can be applied in very special cases ((2), p. 59), but regulation of the ignorant relative's fate through the principle of necessity seems to be too general as well as most likely too strict. Genetic information such as that referred to in Section 5–9, fifth paragraph, does not apply to the patient alone; it is of a familial nature. Accordingly, the joint account model is applicable.

> ***«The really paternalistic decision is made if the relative is not given a chance to know»***

A joint bank account can be used as an analogy to show that the family can share the benefit of the information, and that weighty reasons must be given for not granting access to a shared bank account (10). This analogy could be an argument for standardised storage of genetic information, which in turn can be retrieved (11). The latter raises the question of delimitation. If the joint account model is applied, it is difficult to argue against making all shared genetic information available. One possibility is that the information described in Section 5–9, fifth paragraph, triggers a duty to help because the disease is treatable, and therefore represents a special case. This does not solve the problem of where to draw the line, but it ensures the relatives access to this information. Although this is fraught with practical challenges, all concerned parties should have the right to know, within reason.

The right not to know

The preparatory works of the Act clearly state that the right not to know has been considered one of the decisive arguments against allowing provision of genetic information to persons other than the patient ((5), p. 106–108). The first issue that can be pointed out is that this is not necessarily less of a violation of the right not to know if the patient consents to it. Moreover, there is nothing to stop the patient from providing this information on their own initiative, irrespective of the conditions ((2), p. 58). What is far more important is that to be able to choose not to know, you need to know that there is something to know. The patient should not be able to make that choice on someone else's behalf. This, however, brings us into a controversial area of medical ethics.

One the one hand, we have those who totally disagree with the assertion that you need to know that there is something to know in order to fulfil the right not to know. If someone learns that there is something to know, this is equal to 'letting the cat out of the bag'. The loss of genetic innocence is a *fait accompli* (12), p. 25). Therefore, the decision that the relative needs to know that there is

something to know is a paternalistic decision. It comes close to 'paternalistic law' ((13), p. 131): You are rarely able to choose not to obtain information. To be sure, the rationale is that information is regarded as a necessary condition for making an autonomous decision ((14). Without information, there is no autonomy. Such a tenuous concept of autonomy is nevertheless misleading. At the deepest level, autonomy is about choosing the life you want. If someone else decides that you need to know, this decision is not of your making ((12), p. 35).

> ***«The patient is not the sole owner of the information, and accordingly cannot be the only one to decide over it»***

On the other hand, it is difficult to ignore that the really paternalistic decision is made if the relative is not given a chance to know. This decision deprives the ignorant relative of the opportunity to make vital decisions of his/her own. However, there is truth to the charge that the cat *ipso facto* has been let out of the bag. Because, even though the relative may decline to be told what there is to know, total ignorance is lost. But isn't this the brutality and true face of life? A reality from which there is no escape? Some even claim that we have a duty to know, and choosing something else is a contradiction in terms (15). What is invariably wrong, is to strip an adult of the opportunity to make a choice based on information that implies substantial consequences for life and health.

Privacy, trust and rarity

The second main objection focuses on the patient's privacy interests (5), p. 108). It is therefore of great importance that it appears possible to de-identify the information, so that it no longer needs to reveal who in the family had this genetic disposition confirmed ((16). If information can be de-identified, privacy concerns make for a less than persuasive argument. Sometimes it may still be impossible, but in such situations, with the exception of extraordinary cases (as, for example, is the case with the right to access your own medical records), the interests of the relative concerned should take precedence. The reason is that the patient is not the sole owner of this information, and should accordingly not be the only one to decide over it.

Trust, however, is closely associated with privacy concerns. A minority of the Norwegian Biotechnology Advisory Board believed that the opportunity to seek out relatives against the patient's will could undermine the relationship of trust between doctors and patients (6), and trust is an obvious argument for tipping the scales in the patient's favour. The duty of confidentiality is deeply embedded in professional ethics, for good reason. This notwithstanding, exceptions are permitted even today; the duty to notify the child welfare service is an example. Trust can also be regarded in the opposite way: relatives can lose their trust in the health services if information is deliberately withheld (9, 10). In response to this, it can be asserted that if it becomes known that information can be shared with relatives against the patient's explicit wishes, the use of private services is likely to increase (17). On the other hand, if the arguments in

favour of permitting this are accepted, a change in the law will result in more, not less, trust in the public services. The belief that permitting such access is contrary to the general consensus is an implicit premise in the counterargument.

In this context it is interesting to note that rarity is often emphasised. The quote from the preparatory works of the Act and the statement from the Norwegian Biotechnology Advisory Board above both refer to the probable rarity of a situation where the requirements in Section 5–9, fifth paragraph, of the Biotechnology Act have been met and the patient is unwilling to inform any relatives concerned. Apparently, this is used as a counterargument. It remains unclear why rarity should be an argument against changing the law. Quite the reverse, it is less intrusive to amend the Act if the situation is a rare occurrence. Both privacy concerns and trust thus seem to be less critical. Moreover, resource arguments become less credible, although the rate of occurrence has no impact on the legal principle.

An obligation?

The question of whether informing relatives should only be permitted or whether this should be an obligation for health personnel remains unanswered. The arguments would indicate that this *is* a moral obligation, and consequently that the Act should enable this moral obligation to be exercised. If the requirements in Section 5–9, fifth paragraph, of the Biotechnology Act are met, an omission seems more serious than what the law should permit. Accordingly, health personnel should be obligated to inform relatives, unless patients do so themselves.

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