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Guidelines for disclosing genetic information to family members: From development to use

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Abstract

This paper presents the existing legal frameworks, professional guidelines and other documents related to the conditions and extent of the disclosure of genetic information by physicians to at-risk family members. Although the duty of a physician regarding disclosure of genetic information to a patient's relatives has only been addressed by few legal cases, courts have found such a duty under some circumstances. Generally, disclosure should not be permitted without the patient's consent. Yet, due to the nature of genetic information, exceptions are foreseen, where treatment and prevention are available. This duty to warn a patient's relative is also supported by some professional and policy organizations that have addressed the issue. Practice guidelines with a communication and intervention plan are emerging, providing physicians with tools that allow them to assist patients in their communication with relatives without jeopardizing their professional liability. Since guidelines aim to improve the appropriateness of medical practice and consequently to better serve the interests of patients, it is important to determine to what degree they document the 'best practice' standards. Such an analysis is an essential step to evaluate the different approaches permitting the disclosure of genetic information to family members.

Introduction

The use of genetic tests to identify individuals with an increased risk of hereditary diseases has generated legal and ethical controversies in relation to the duty of physicians to warn family members of their genetic risks. Indeed, when it comes to potentially preventable or treatable hereditary diseases, it can be very important for individuals to be informed of a family member's genetic test result and thus of their own genetic risk [1]. However, in certain circumstances, the tested person might want to withhold this diagnosis from his spouse, children and other blood relatives [3]. In this case, there arises the problem of how patients and their doctors should mediate the patients' 'right to keep their genetic information secret' with family members' 'right to know about their genetic risks'. This issue is particularly problematic for physicians who hold such information and are aware of the individuals' refusal to share information with at-risk family members.

In the United States, three claims for negligence alleging the failure to disclose genetic information to the patients' relatives have been brought against physicians [4, 5, 6]. A duty to warn family members of their

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potential risk of suffering from hereditary syndromes was recognized by the courts. In parallel, an increasing number of professional organizations and government agencies have identified disclosure of genetic information to at-risk family members as an important issue. In certain cases, however, they adopted different viewpoints and recommended whether to disclose to family members without or with the patient's consent, whether not to disclose at all, whether special consideration be made for informing family members.

This paper presents the existing legal frameworks, professional guidelines and other documents related to the conditions and extent of the disclosure of genetic information by physicians to at-risk family members. This paper examines the commonality and differences between the positions taken in order to discern general trends. Practical frameworks to guide physicians for resolving 'difficult' situations are proposed. Since guidelines aim to improve the appropriateness of medical practice and consequently to better serve the interests of patients, it is important to determine to what degree they document the 'best practice' standards. Such an analysis is an essential step to evaluate the different approaches permitting the disclosure of genetic information to family members.

Methods

We made a structured review of guidelines published from 1987 through April 2004 identified by a PUBMED, HUMGEN as well as global Internet search using the following terms: duty, warn, disclosure, notification, guidelines, statement, position paper, protocol, recommendations, opinion, policy, genetic, testing, confidentiality, family members and relatives. Names of professional organizations and government agencies involved in practice guideline activity were also included as search terms. Articles about guidelines were searched for additional published guidelines. In addition, we searched citations of key papers and recent reviews of the subject. We reviewed legal decisions pertaining to a physician's duty to warn in the United States and Canada.

Retrieved documents were considered guidelines if they made specific recommendations for practice. Since few guidelines were published prior to 1987, we evaluated only guidelines published in odd-numbered years from 1987 through April 2004. We analyzed 62 guidelines produced by 42 different developers. Of the guidelines examined, seven were produced by international organizations (HUGO, UNESCO, WHO, WMA), eight by regional bodies (Council of Europe, European Parliament, GAEIB, HGSA), and 47 by national instances (Australia, Austria, Canada, Denmark, France, Germany, Japan, Switzerland, The Netherlands, UK, USA).

Results

The duty to warn a patient's relative raises conflicting ethical obligations. Physicians must weigh their duty to preserve their patient's privacy and autonomy against their obligation to prevent harm and promote the beneficence of family members [7, 8]. In this process, a second, related dilemma is that physicians' duty to promote others' beneficence may be outweighed by family members' autonomy and their own right not to know about their genetic conditions.

Respect for patient's privacy

Since the Hippocratic Oath, physicians have been bound by a duty to protect the privacy of their patients. This duty rests on three premises: (1) individual autonomy, (2) shared respect for confidentiality, (3) benefits to both individuals and the society [9]. Ethical guidelines and recommendations issued by professional and governmental agencies in the medical field have emphasized the fundamental value of confidentiality in the patient–doctor relationship. This ethical duty has evolved to a legal duty in most jurisdictions and most countries have enacted legislation to protect confidentiality of personal and/or medical information. However, with a few exceptions, such as Austria,[1] Israël,[2] the United States,[3] Denmark,[4] the province of Manitoba in Canada,[5] and Switzerland,[6] no enacted[7] legislation relates specifically to the protection of personal *genetic* data. Therefore, it is general data protection legislation that may apply to the protection of confidentiality of genetic information.

Nevertheless, medical confidentiality is not an absolute principle and has never been so, even in the traditional physician–patient relationship [10]. First, physicians may disclose information to a third party when specifically authorized by the patient. Second, the law may mandate physicians to disclose patients' medical information without their consent for use in judicial proceedings or in cases of transmissible diseases, child abuses, domestic violence or conditions that could constitute a danger for the safety of the public. It is in this last exception that the roots of a duty to warn third parties in the context of the physician–patient relationship were found.

Right not to know

A further complication resulting from the duty to warn is that some family members may wish not to be informed of their genetic risks. The ethical principle of non-maleficence stipulates that one should refrain from taking actions that will result in a harmful outcome. According to this principle, the decision to inform family members of their genetic risks should be weighed against all the possible harm that may result from such a disclosure. Potential for harm incurred from such disclosure may include psychological, social or financial damages. There are positive aspects to ignorance, particularly in a disease where there is no prospect of prevention or treatment.

On the other hand, when a prevention or treatment is available, is it possible to objectively consider the relatives' wish to remain ignorant of that information? There

are two contexts in which the right not to know can be discussed. The first is where an individual knows that he has an increased prior risk but reserves the right not to seek extra information; the second is where an individual has no knowledge of prior risk [11]. In the first case, few would seriously question the individual's right not to know and an unsolicited disclosure would be rarely justified. It would also be rare for close relatives not to know anything about each other's serious medical conditions, and often they have heard something when the disease is hereditary. That explains why in Denmark, relatives who underwent a genetic test for $_1$-antitrypsin deficiency supported the disclosure of familial information; because of the condition's hereditary nature, they were also more likely to endorse communication with relatives without the patient's consent [12].

In the second case, an unsolicited disclosure to someone ignorant of its risk status might be justified; it should be based on the principle of maximizing benefit and minimizing harm [13, 14]. It has been argued that people cannot be expected to make autonomous choices about their future without having all the relevant information at their disposal and that declining to give them this information is indefensibly paternalistic [15]. In this view, there is a presumption that knowledge is to be preferred to ignorance, particularly when matters of reproductive choice are involved or if prevention and treatment are available. Consequently, limits may occur where there are harmful effects on the patient or for the protection of another person's life [16, 17, 18].

Promotion of patient's beneficence

The duty to warn family members of their genetic risks: legal aspects

A duty to warn third parties in the context of the physician–patient relationship has been recognized in a leading case in the United States [19], creating a cause of action when physicians fail to inform at-risk third parties of information gathered during a therapeutic relationship.[8] The duty to warn has been interpreted as a duty to act to prevent foreseeable harm.[9]

In regard to genetic diseases, the jurisdictions that have considered genetic cases (Florida [4], New Jersey [5] and Minnesota [6]) have recognized a legal duty of a physician to warn the relatives of his patients.[10] The courts balanced the patient's right to confidentiality and the benefits this brings against the right of the unaware. The *Pate* court recognized the need for confidentiality and determined that a physician can fulfill his duty by notifying the patient of any genetic ramifications of the disease to his family members, while the *Safer* court held that a physician has a duty to directly warn those third parties known to be at risk of avoidable harm from a genetically transmissible condition. The three-judge panel in the *Safer* case concluded that 'there is no essential difference between the type of genetic threat at issue here and the menace of infection, contagion, or a threat of physical harm' [5]. The *Molloy* court held that 'a physician who undertakes to test for and diagnose a genetic disorder in an existing child owes a duty of care to the biological parents of the child when it is reasonably foreseeable that the parents would be injured if the testing and diagnosis are negligently performed' [6]. However, these decisions do not provide American physicians with a clear statutory ruling on this issue and to date, they have not been followed in other jurisdictions of the United States.

In other countries, with a few notable exceptions such as Austria[11] and France,[12] the legal system does not provide more guidance on the responsibilities of physicians towards at-risk relatives in the context of genetic testing. Most European jurisdictions, evoking professional secrecy, require the free consent of the individual before relevant personal information is passed on to relatives [20]. Yet, general personal data protection legislation usually specifies the exceptional circumstances in which personal information may be disclosed without the individual's consent. These exceptions include the cases where disclosure is required to prevent or lessen a serious and imminent threat to the health and safety of third parties.[13] Nevertheless, how this legal exception may apply in cases of risks resulting from genetic diseases remains highly controversial and unclear in Europe as well as in North America and Australia.

The duty to warn family members of their genetic risks: guidelines

Guidelines issued by professional organizations and governmental advisory agencies on this issue are of primordial importance. They constitute an important part of the regulatory context within which clinical genetics is practiced. Although such guidelines, codes of ethics and recommendations have no legal standing in most countries, they may be used as evidence of the accepted standards of professional practice [21].

The duty of a physician regarding disclosure of a genetic disease to a patient's relative has been considered by several professional organizations as well as by government agencies (Table 1). However, their recommendations vary and often leave room for different and somehow subjective interpretations for the health care providers faced with this issue.

Some organizations authorize the disclosure of genetic information to family members with the patient's consent only and do not explicitly address any exception to the traditional principle of confidentiality in this respect. Others specifically address the circumstances in which such a disclosure may occur without the patient's consent. Conversely, a few organizations advise against any direct communication between a physician and his patients' relatives.

Direct communication between physician and patient's relatives not supported

Some instances advise against any direct communication between physicians and patients' relatives. Consequently,

Table 1. Disclosure of genetic information to family members by physicians.

	s	With patient's consent only	Without patient's consent, under exceptional circumstances	Special considerations
International			WMA, 1992[1] WHO, 1998[2]	UNESCO, 1997,[3] 2004 [4] HUGO, 1996 [5]
Regional		European Parliament, 1990 [6] GAIEB (EGE), 1996 [7] HGSA, 1999 [8]		European Parliament, 2001 [9] Council of Europe, 1992,[10] 1997[11] European Commission, 2004 [12]
National				
Australia		NHMRC, 1999 [13] AMA, 1998 (2000, 2002) [14]	AMA, 2004[15] CCV, 1997 & NHMRC, 1999 [16]	NHMRC, 2000 [17]
Canada		TCPS, 1998 [18]	CCOHTA, 1999 [20]	Ontario Provincial Advisory Committee, 2001[25]
		CCFF, 2002 [19]	SCC, 1991 [21] RMGA, 2000 [22] CMA, 1996,[23] 2000[24]	CMA, 1998 [26] CBAC, 2001 [27]
Denmark	DCE, 1993 [28]			DCE, 2001 [29]
France	CCNE, 1991, 2001, 2003[30]	GGC & FNCLCC, 2002 [31]		
Germany			GSHG, 1996, 2001 [32]	
Greece				GNBC, 2002 [33]
Italy		CNB, 1999 [34]		
Japan			JSHG, 1994 [35] JSHG, 1995 [36]	
Switzerland		SAMS, 1993[37]		
United Kingdom		HCSTC, 1995[38] GIG, 2001[39]	BSHG, RCP & RCP, 2003[40] HGC, 2002[41] BMA, 1998[42] GMC, 1996[43] GIG, 1998[44] NCB, 2000[45]	
United States	ASCO, 2003 [46]	NSGC, 1991, rev. 2002[48]	American President's Commission, 1983[50]	
	AMA, 2003[47]	GLRGG, 1993[49]	IOM, 1994[51] ASHG/ACMG, 1995[52] ASHG, 1998[53] NHGRI, 1997[54]	

Notes: Refer section on Notes for Table 1.

they do not support disclosure of genetic information by the physician to family members, and this, to a certain extent, even with the patient's consent. This position is grounded on two main ideas. First, the confidentiality of the results of genetic tests is an absolute ethical imperative and no exception should ever occur. Second, the duty to inform relatives of their genetic risks is a moral obligation that is owed by the patient him/herself and not by physicians. Therefore, physicians should not deal with family members.

Such a position prevails in France, where, as mentioned above, legislation considerably limits any direct communication between physicians and third parties. French law even mandates physicians not to intrude into their patients' 'family business', unless they have professional reasons to do so.[14] Thus, accordingly, the CCNE (1991, 2001, 2003) supports a strict observance of medical confidentiality and explicitly states that it is up to the person tested, and to this person only, to inform his/her family members of their genetic risks, while physicians should content themselves with advising their patients (CCNE, 2003). In the same vein, the Danish Council of Ethics believes that the disclosure of genetic information to a relative is best done by having the decision made by the patient: when dealing with personal sensitive information, 'no unsolicited approach may be made by the health authorities in the case of an examination that may show any hereditary disease in the family. This should also be the case in situations where it can have serious consequences' (DCE, 1993). Meanwhile, the Greek National Bioethics Commission stresses that all patients who know about their genetic risk 'must assume responsibility for informing any third persons involved' (GNBC, 2002).[15] However, in cases where the patient has decided not to know about his/her own results, a physician could disclose information to the patient's relatives when 'absolutely necessary' (GNBC, 2002). Finally, the American Society of Clinical Oncology and the American Medical Association do not seem to support any direct contact between physicians and

their patients' relatives either. ASCO strongly believes that a 'cancer care provider's obligations (if any) to at-risk relatives are best fulfilled by communication of familial risk to the person undergoing testing (...)' (ASCO, 2003). AMA only states that 'physicians should identify circumstances under which they would expect patients to notify biological relatives of the availability of information related to risk of disease'. However, AMA believes that physicians should 'make themselves available to assist patients in communicating with relatives to discuss opportunities for counseling and testing (...)' (AMA, 2003).

Disclosure with the patient's consent only

Most guidelines do not preclude direct communication between a physician and her/his patient's relatives. However, some of them limit such communication and the disclosure of genetic information to family members in cases where the consent of the patient has been obtained. Such positions emphasize the idea that confidentiality can never be infringed without the patient's consent, whatever the circumstances. That is the position of the European Parliament (1990) and the former Group of Advisers to the European Commission on the Ethical Implications of Biotechnology[16] (1996), as well as the Human Genetics Society of Australasia (1999). At the national level, this viewpoint is clearly supported by the British House of Common Science and Technology Committee which states that 'if counseling cannot persuade someone to consent sharing information with their relatives, the individual's decision to withhold information should be paramount' (HCSTC, 1995). In other national recommendations, disclosure of genetic information within families is described as a moral obligation owed by the patient and disclosure is permitted with the consent of the data subject only (Canada: CCFF (2002); Australia: NHRMC (National Statement..., 1999); Switzerland: SAMS (1993); UK: GIG (2001); USA: GLRGG (1993), NSGC (1991, 2002); Italy: CNB (1999)).

Disclosure without the patient's consent

Most guidelines also allow the disclosure of genetic information to family members without the patient's consent. However, certain conditions should be respected. Already, in 1983, the American President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research defined four conditions that must be met before patient genetic information is disclosed without consent: '(1) reasonable efforts to elicit voluntary consent to disclosure have failed; (2) there is a high probability both that harm will occur if the information is withheld and that the disclosed information will actually be used to avert harm; (3) the harm that identifiable individuals would suffer is serious; and (4) appropriate precautions are taken to ensure that only the genetic information needed for diagnosis and/or treatment of the disease in question is disclosed'. Ten years latter, the Committee on Assessing Genetic Risks of the Institute of Medicine [24] added another condition: 'there is no other reasonable way to avert the harm'.[17] However, neither group supported a legal duty to inform relatives, but they argued for an ethical duty and legal permission (*vs* legal obligation) to inform in certain cases.

In balancing the duty to inform against the right to confidentiality, the serious nature of the threat has been considered in most documents that authorize disclosure without patients' consent. The WMA's position in its Declaration on the Human Genome Project [1992], is that 'even if family members of the patient may be at risk, medical secrecy has to be kept unless there is a serious harm and this harm could be avoided by disclosing the information; the confidentiality can be breached only as a last resort when all trials to convince the patient to pass on the information by himself, have failed'. Similarly, WHO (1998) considers that, 'especially when a serious burden can be avoided', '(...) counselors should inform people that genetic information may be useful to their relatives and may invite individuals to ask the relatives to seek genetic counseling. If the individual refuses, particularly in cases where effective and affordable treatment or preventative measures are available, the counselor may ethically make direct contact with the relatives, bearing in mind that the information provided should concern only their own genetic risk, not the genetic status nor the identity of the relative who refused to inform them.'

At the national level, numerous guidelines support the disclosure of genetic information to family members without the patient's consent under similar exceptional circumstances: Australia: CCV & NHMRC (1997, 1999), AMA (2004); Canada: SCC (1991), CMA (1996), CCHOTA (1999), CMA (2000), RMGA (2000); Germany: GSHG (1996, 2001); Japan: JSHG (1994, 1995); Netherlands (1989); the United Kingdom: BMA (1998), GIG (1998), NCB (2000), HGC (2002), Joint Committee on Medical Genetics (2003) and the United States of America: ASHG/ACMG (1995), NHGRI (1997) ASHG (1998).

Disclosure without patient's consent under special considerations

Several guidelines have addressed the issue of disclosure of genetic information to family members without patient's consent under particular perspectives, or have added special considerations and conditions to the exceptional circumstances described above.

In first place, several organizations do not preclude the disclosure of genetic information to family members without the patient's consent but ultimately refer to national laws. UNESCO (1997, 2004) clearly states that 'limitations to the principles of consent and confidentiality may only be prescribed by law' and that any disclosure of genetic information without the individ-

ual's consent could only occur for 'an important public interest reason in cases restrictively provided for by domestic law consistent with the international law of human rights'. Similarly, the Council of Europe (1992 and [25]) recognizes that consideration should be given to informing family members of their genetic risks, in particular to avoid any prejudice to their health. However, such a communication could only take place if it is provided for by national law or 'in accordance with national legislation'. Such positions are also supported by some national bodies such as, for example, the Canadian Medical Association in its *Information Privacy Code* (1998) and the Australian National Health and Medical Research Council (2000) which allows disclosure of genetic information to family members without the patient's consent in exceptional circumstances but ultimately stress that there is no such obligation in Australian legislation and that before breaching confidentiality, health providers should consider the potential for professional censure or legal action.

Other instances did not choose to take an explicit position on this issue. HUGO (1996), for instance, states that 'special consideration should be given to the actual or potential interests of family members'. Consequently, the need for practical guidance, further research, more specific regulations or legislation is often stressed by other organizations. In 2001, the Temporary Committee on Human Genetics and Other New Technologies of Human Medicine of the European Parliament recommended the creation of an appropriate legislation to sort out such issues. The European Commission (2004) recently concluded that 'there is a need for clear guidance acceptable to all parties involved (...) on how to handle professional secrecy and the protection of privacy'. Such a position is also shared by some national bodies such as the Canadian Biotechnology Advisory Committee (2001) or the Ontario Provincial Advisory Committee on the New Predictive Genetic Technologies (2001) which states that 'further research should be undertaken to determine whether disclosing genetic information to high-risk relatives against an individual's wishes should be allowed'. More explicitly, the Danish Council of Ethics (2001) recently recommended that 'for groups of diseases presenting the same hereditary succession and ethical problems, descriptions be formulated of the practice considered to be the good, professional standard in force, and that these overall guidelines accommodate a stance on the question of the conditions governing the disclosure of genetic information to another person'.

Certain recommendations (HUGO (1996, 1998), WMA (1995), HGSA (1999), JSHG (2001)) have mainly focused on the potential right of family members to have *access* to the genetic information of their relatives and not on the potential obligation of physicians to disclose information without the patient's consent. The right to access genetic information of one's relatives must be clearly distinguished from a duty to warn. Indeed, a duty to warn does not involve an actual request of a family member to know about his genetic risks. Therefore, recommendations on the right to access genetic information of one's relatives do not provide us with practical guidance for the disclosure of genetic information to family members who have not expressed their will to know about their risks.

Discussion

Most of the guidelines issued by professional organizations and governmental advisory agencies are also directed to this end. When the penalty for ignorance has had serious damage, courts have leaned toward the right to know and away from the right to confidentiality. This indicates that a duty to warn by physicians to family members of the presence of a genetic disease in a patient might evolve as a reasonable behaviour to prevent a serious and foreseeable harm. For Lemmens and Austin [26], finding a duty to warn the family members on the physician means that we recognize an indirect harm caused to potentially affected family members. The breach of the duty to warn may result in a subsequent injury, such as impairment of the right to decide whether to benefit a medical surveillance, to modify life habits, or to have offspring.

Nevertheless, commentators differ on whether a duty to warn when genetics information is involved is a negative or positive development. Generally, the view is that the confidentiality of genetic information should be given absolute protection and should never be breached without the consent of the patient, even if the passing on of the information would enable others to protect themselves from the risk of harm. A study conducted by Falk et al. [8] reveals that although 69% of medical geneticists believe they bear responsibility to warn their patients' relatives when found to be at-risk for genetic disease and 25% who faced the dilemma of a patient refusing to notify their at-risk relatives seriously considered disclosure without patient consent, only four respondents proceeded to warn at-risk relatives of their status. In another study, 46% of genetic counselors have had a patient refuse to notify an at-risk relative: 21% seriously considered warning at-risk relatives without patient consent but only one genetic counselor did go on to disclose [7].

According to Mertz et al. [27], control of information about oneself is a fundamental embodiment of privacy, and confidentiality is the backbone of the provider–patient trust relationship. Also, there may be significant numbers of individuals who do not want to know that they are at risk [28; 29; 30]. Other commentators have argued that the imposition of a duty to warn is unwise since the patient has not deliberately 'created' a genetic risk and a harm for the relatives. Lemmens and Austin [26] explain that it is a 'preexisting' risk that is suddenly identified because of newly acquired knowledge of genetic information. The risk is not so much related to something external to the other persons. Moreover,

with rare exception, asymptomatic genetic conditions do not hold the prospect of imminent harm; while the course of infectious disease exhibits relative uniformity and predictability, genetic conditions, most of which are multifactorial, are marked by substantial variability, burdening genetic prediction with considerable uncertainty. Another argument is that the physician cannot presume to have complete and accurate information about the patient's family history and interpersonal dynamics, about how information may be received by his relatives. In some cases, providing genetic information to family members could do more harm than good.

Yet an emerging view is that it may be permissible to breach medical confidentiality in order to protect another from serious harm (Table 1). Such an approach is based on the notion that a family member owes a moral duty of care to the family members of the patient and when that duty is not exercised, the physician may breach confidentiality and warn at-risk relatives [31]. Physicians are expected to seek to do good for their patients; this is described as the principle of beneficence. Beauchamp and Childress [32] have stated that this principle can apply for warning at-risk relatives in the following circumstances: (1) that the person to be helped is at significant risk of harm; (2) that help from the person faced with the choice is needed to prevent that risk materializing; (3) that there is a high probability that their help will prevent the harm; (4) that helping would not present significant risks, costs or burdens to the person asked to help; (5) that the benefit for the person to be helped outweighs the costs or burdens to the person asked to help. Studies have shown that most patients do consent to disclosure after considering these arguments [3,33,1,2,12,34]. In a study conducted by Clarke et al. [3] on the attitudes towards disclosure, only 65 patients out of nearly 40 000 surveyed over a period of 12 months refused to warn their relatives. Thus, 39 parents refused to inform their adult children of a potential genetic risk; 32 children or relations were not informed, as well as 4 spouses. A fear that the information might cause anxiety for relatives was the reason most frequently cited in justifying non-disclosure. In contrast, concerns for confidentiality and privacy were rarely invoked. In another study relative to genetic testing for hereditary colon cancer, 78% of relatives thought it acceptable to have the genetic information brought to their attention, the remaining 22% did not mind being approached with the information and 91% decided to take the genetic test [2].

The tendency towards a family and community-oriented approach, supported by the Human Genome Research Project encourages a shift from 'individual therapy' to a 'family-and-future-generation oriented' one [66]. It is necessary however, that this shift does not overstep the principles of individual will, responsibility and self-determination. A duty of physicians to disclose the presence of a genetic disease to relatives of their affected patients has been recognized when the disease is fatal if diagnosed late but curable if diagnosed early. This was the case in *Pate*. By contrast, if the disease is incurable and even untreatable, the duty would be tenuous, except for reproductive decisions. For instance, the International Huntington Association [35] was not in favour of such a duty. Some diseases would fit in-between, such as hereditary breast cancer, which is treatable by prophylactic surgery. Thus, policies for disclosure should be developed with caution and in considering the following facts: (1) the patient; (2) the accuracy of the genetic test; (3) the disease and (4) the relative [36]. If the genetic test is not accurate and the disease is not fatal, or treatable and with a high degree of genetic penetrance, disclosure serves little purpose, other than to aid the relative in making informed reproductive decisions [36]. Consequently, it has been recommended that individual cases should be based on specific facts and that the disclosure should be limited to the minimum extent needed to prevent harm [37].

Regarding the patient, some authors recommend asking the patient's consent in advance of the genetic testing for permission to disclose genetic information to relatives [36, 11; 24]. Seeking the consent of the patient preserves his autonomy and allows physicians to explain to him why they think that disclosure might be important in some circumstances. For instance, in Denmark, the law does not authorize physicians to directly transmit genetic information to relatives but accepts such a physician's disclosure on a patient's request. Patients may be asked to disclose the identities of family members to a physician to ensure diffusion of genetic risk information within affected families. The identity of the patient is disclosed to relatives on request if consent has been given by the patient [12]. Wilcke et al. [12] have shown a strong consensus on the position that the patient ought to disclose the identity of relatives to enable the physician to offer them genetic testing. The authors explain the lack of concern about one's own right to privacy by the need of sick persons for family support and to achieve such family support, it seems crucial to maintain openness about the disease in the family.

Regarding the relative, there still remain the risks of harming those who do not want to know. It has been stated that 'the harm caused by disclosure should not outweigh the harm for which the family members would be exposed to by non-disclosure [38]. Or, disclosure 'could perhaps be justified if the potential harm to the relative of not being informed, and the benefits of being informed, outweigh the potential harm to the index case of confidentiality being broken' [11]. Legal cases indicate that it is unlikely to see a jury awarding great damages to a patient because the doctor warned a relative about a genetic condition that the patient did not want them to know about.

A reasonable approach calls for a case-by-case determination of whether the benefits and harms of disclosure outweigh the benefits and harms of protecting confidentiality. Such an approach is advocated by the American Society of Human Genetics (ASHG) Social Issues Subcommittee on Familial Disclosure [39]. The ASHG stated that when a patient refuses to inform

relatives, rather than imposing a firm duty to warn at-risk relatives or an absolute duty of confidentiality, policy should make room for the exercise of sound professional judgment to weight and measure the interests and values at stake. More recently, more detailed advice concerning the duty to warn relatives has been established, urging physicians to assist patients in their communication with relatives. In its policy update on genetic testing for cancer susceptibility, the American Society of Clinical Oncology states that 'the cancer care provider's obligations (if any) to at-risk relatives are best fulfilled by communication of familial risk to the person undergoing testing, emphasizing the importance of sharing this information with family members so that they may also benefit' (2003). This view is reaffirmed by the American Medical Association Code of Medical Ethics (2004): physicians 'should make themselves available to assist patients in communicating with relatives to discuss opportunities for counseling and testing, as appropriate.'

As the availability of tests to identify hereditary predispositions continues to grow, some authors propose that a plan should be formulated to initiate contact with family members and to provide a framework for counseling and guidance [31; 40; 41]. Delay et al. [33] have developed a communication skills-building intervention for providing the patients with skills for communicating genetic test results to their relatives. The six-step communication counseling intervention addresses the important questions of whom to tell, what to tell, and how to tell, whereas a Genetic Resource Handbook offers the proband reference materials and flexibility in tailoring her/his messages to the emotional needs and educational and interest levels of her family. Two other models have been imagined in which the patient is the primary provider of information within the family but has the assistance of health care practitioners in presenting and explaining information as the patient and his or her family deem appropriate; such a model might alleviate the potential conflict between the wishes of the patient and the physician's obligation to third parties [40; 41]. These models can be found in the ASCO [42] and [43] recommendations. Finally, in the joint account model elaborated by Parker and Lucassen [44], it is assumed that genetic information should be available to all account holders (health professionals, relatives) unless there are good reasons to do otherwise. The justifications in favour of a joint account must adhere to the ethical principles of justice and reciprocity; there must also be benefits to be gained by sharing genetic information. Seeing as geneticists work with families, the chosen approach must be consistent with the very nature of practice in genetics.

Conclusion

Although the duty of a physician regarding disclosure of genetic information to a patient's relatives has only been addressed by a few legal cases, courts have found such a duty under some circumstances. Generally, disclosure should not be permitted without the patient's consent. Yet, due to the nature of genetic information, exceptions are foreseen, where treatment and prevention are available. This duty to warn a patient's relative is also supported by some professional and policy organizations that have addressed the issue. Moreover, practice guidelines with a communication and intervention plan are emerging, providing physicians with tools that allow them to assist patients in their communication with relatives without jeopardizing their professional liability.

Medical advances will result in an increasing number of individuals who know that they have a genetic disease that they can transmit to offspring, and a related number of physicians who know of the existence of such a disease in their patients and thus in their patients' relatives. There is no doubt that genetic information will lead to the recognition of new duties of health care professionals in the future. This could also lead to a social change within families where there would be a greater openness towards sharing medical information.

The current socio-cultural context and pressures of the 'promise' of genetic information cannot be ignored. However, it would be fair if there was transparency about the grounds of the decision to warn a patient's relatives. Appealing to rationales that all can accept as relevant to meet health needs fairly, it would allow procedures for revising decisions in the light of challenges to them.

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Notes for Table1

1. World Medical Association, *Declaration on the Human Genome Project* (September 1992, doc. 17.S/1): 'The disclosure of information to a third party or the accessibility to personal genetic data should be allowed only with the patient's informed consent. Even if family members of the patient may be at risk, medical secrecy has to be kept unless there is a serious harm and this harm could be avoided by disclosing the information; the confidentiality can be breached only as a last resort when all trials to convince the patient to pass on the information by himself, have failed; even in this case, the relevant genetic information only should be disclosed.'
2. World Health Organization (WHO), *Proposed international guidelines on ethical issues in medical genetics and genetics*, 1998, http://whqlibdoc.who.int/hq/1998/WHO_HGN_-GL_ETH_98.1.pdf: '...if genetic test results indicate genetic risks to the individual's relatives, the genetic service provider should encourage the individual to ask the relatives to seek genetic counselling. If the individual refuses, particularly in cases where effective and affordable treatment or preventative measures are

available, the counsellor may ethically make direct contact with the relatives, bearing in mind that the information provided should concern only their own genetic risk, not the genetic status nor the identity of the relative who refused to inform them.' 'The provision of genetic information to relatives about the family so as to learn their own genetic risks should be possible, especially when a serious burden can be avoided.'

3. UNESCO, *Universal Declaration on the Human Genome and Human Rights*, 1997: 'In order to protect human rights and fundamental freedoms, limitations to the principles of consent and confidentiality may only be prescribed by law, for compelling reasons within the bounds of public international law and the international law of human rights'.
4. UNESCO, *International Declaration on Human Genetic Data, Publ: 2004; 11 p.; SHS.2004/DECLAR.BIOETHIQUE CIB/4.*, http://unesdoc.unesco.org/images/0013/001342/134217e.pdf: 'Human genetic data, human proteomic data and biological samples linked to an identifiable person should not be disclosed or made accessible to third parties, in particular, employers, insurance companies, educational institutions and the family, except for an important public interest reason in cases restrictively provided for by domestic law consistent with the international law of human rights or where the prior, free, informed and express consent of the person concerned has been obtained provided that such consent is in accordance with domestic law and the international law of human rights.'
5. HUGO, *Statement on the Principled Conduct of Genetic Research*, 1996: 'Special consideration should be given to the actual or potential interests of family members'.
6. European Parliament, Resolution on the Ethical and Legal Problem of Genetic Engineering, 1990.
7. Group of Advisers to the European Commission on the Ethical Implications of Biotechnology (European Group on Ethics in Science and New Technologies (EGE), *Ethical aspects of prenatal diagnosis*, opinion no 6, February 1996.
8. Human Genetics Society of Australasia, *Guidelines for the Practice of Genetic Counselling*, September 1999.
9. European Parliament, Temporary Committee on Human Genetics and Other New Technologies of Human Medicine, Report on the ethical, legal, economic, and social implications of human genetics, A5-0391/2001, 2001: http://www.europarl.eu.int/comparl/tempcom/genetics/rapfin/rapfin_en.doc; http://www.europarl.eu.int/comparl/tempcom/genetics/rapfin/rejet_rapport_en.pdf
10. Council of Europe, *Recommendation on genetic testing and screening for health-care purposes of the European Committee of Ministers* (1992, n. R92, 3), http://www.coe.fr/cm/ta/rec/1992/92r3.htm: 'In the case of a severe genetic risk for other family members, considerations should be given, in accordance with national legislation and professional rules of conduct, to informing family members about matters relevant to their health or that of their future children.'
11. Council of Europe, Recommendation on the Protection of Medical Data of the*European Committee of Ministers* (1997, n. 97, 5), www.coe.fr/cm/ta/rec/1997/97r5.html: 'Article 4.7 states that 'Genetic data collected and processed for preventive treatment, diagnosis or treatment of the data subject or for scientific research should only be used for these purposes or to allow the data subject to take a free and informed decision on these matters'. According to Article 4.8, 'Processing of genetic data for the purpose of a judicial procedure or a criminal investigation should be the subject of a specific law offering appropriate safeguards. The data should only be used to establish whether there is a genetic link in the framework of adducing evidence, to prevent a real danger or to suppress a specific criminal offence. In no case should they be used to determine other characteristics which may be linked genetically'. Article 4.9 stipulates that for purposes other than those provided for in Principles 4.7 and 4.8, the collection and processing of genetic data should, in principle, only be permitted for health reasons and in particular to avoid any serious prejudice to the health of the data subject or third parties. However, the collection and processing of genetic data in order to predict illness may be allowed for in cases of overriding interest and subject to appropriate safeguards defined by law.'
12. Groupe d'experts de la Commission européenne, Direction générale de la recherche, *25 recommandations sur les implications éthiques, juridiques et sociales des tests génétiques*, Bruxelles, 2004: http://europa.eu.int/comm/research/conferences/2004/genetic/pdf/recommendations_en.pdf: Recommandation 10: '(a) les données génétiques importantes dans un contexte clinique et/ou familial devraient recevoir le même niveau de protection que d'autres données médicales d'une sensibilité comparable; (b) la pertinence pour d'autres membres de la famille doit être abordée; (c) l'importance du droit d'un patient à savoir ou à ne pas savoir devrait être reconnue et des mécanismes respectant ce droit devraient être intégrés dans la pratique professionnelle. Dans le contexte des tests génétiques, qui englobent la fourniture d'informations, de conseils, les procédures du consentement éclairé et la communication des résultats du test, des pratiques devraient être établies pour répondre à ce besoin; (d) ces questions sont particulièrement pertinentes pour les populations vulnérables, que ce soit dans l'UE ou ailleurs dans le monde.'http://europa.eu.int/comm/research/conferences/2004/genetic/pdf/report_en.pdf: 'With the increase in genetic testing possibilities, there is a need for clear guidance acceptable to all parties involved, on how to deal in practice with competing rights about knowing and not knowing, and how to handle professional secrecy and the protection of privacy.'
13. National Health and Medical Research Council: *National Statement on Ethical Conduct in Research Involving Humans*, 1999: 'A researcher must not disclose identifying genetic information to third parties, including family members, without the written consent of the individual to whom the information relates, or the written consent of a person or institution which may legally consent on the participant's behalf' (art 16.7).
14. Australian Medical Association, *Position Statement on Human Genetic Issues*, 1998, revised 2000, 2002: Para. 5.7: 'Genetic information acquired in the context of the doctor–patient relationship should not be disclosed to a third party without the patient's specific, and where possible, written consent.'
15. Australian Medical Association, Code of Ethics, 2004: 'Exceptions to this [i.e. confidentiality] must be taken very seriously. They may include where there is a serious risk to the patient or another person, where required by law, where part of approved research, or where there are overwhelming societal interests' (Para 1.1.l).
16. Cancer Council of Victoria (former Anti-Cancer Council of Victoria), *Ethics and Familial Cancers*, 1997, endorsed by the NHRMC in *Familial Aspects of Cancer: A Guide to Clinical Practice*, 1999, http://www.nhmrc.gov.au/publications/pdf/cp67.pdf, see also Bell and Bennett 65: 'In the exceptional situation where a patient or other inquirer objects to information on his or her genetic risk becoming known to relatives, it could still be possible for relatives to be advised that they may be at risk from a family cancer susceptibility, but without identifying the reluctant inquirer. For the purpose of their own genetic testing, the aim should also be to acquaint relatives with the specification of the gene mutation carried in their family. Objection by inquirers to knowledge of their risk status being used for the benefit of their relatives and descendants should not in itself be regarded as sufficient reason for the information not to be used in de-identified form. This remains the case even if the inquirer's identity and even risk status may be inferred.'
17. National Health and Medical Research Council (NHMRC), *Ethical Aspects of Human Genetic Testing – an Information Paper*, 2000, http://www.nhmrc.gov.au/publications/pdf/e39.pdf: '...there may be rare circumstances in which a health professional considers that the risk to the health of relatives is sufficiently large,

serious, imminent and potentially preventable that consideration should be given to breaching the individual's confidentiality. Before doing so, the health professional should consider the potential for professional censure or legal action if confidentiality is breached.' (However, it is also stated that 'It is generally accepted that an individual has responsibilities to his/her family as well as a right to the privacy and confidentiality of his/her genetic information. In family relationships, there is, in Australia, no established legal duty to warn. Most individuals can refuse to pass on information to relatives without breach of law. In deciding not to disclose such information to relatives, an individual will need to balance carefully their right to privacy with the fact that disclosure could lead to the avoidance of a substantial chance of harm to a relative.' And: 'Health professionals can only recommend that information is shared with relatives and are not in a position to ensure that information transfer occurs. They must rely on their patient to carry out the task if he/she has agreed to do so.Health professionals should be aware that in Australia, there is no established legal requirement to warn their patient's relatives of a genetic risk. Their duty of care is to the patient, not to the relatives. Clearly though, health professionals will wish information to be passed on to relatives if it is of potential significance to their health. This is most appropriately done by asking the patient to inform his/her relatives, and recording the request in the patient's medical record. The health professional may be able to facilitate the process by providing written information or agreeing to phone contact from the relatives.'

18. Tri-Council Policy Statement*: Ethical Conduct for Research Involving Humans*, 1998.
19. Canadian Cystic Fibrosis Foundation, *Cystic Fibrosis: Confidentiality and Genetic Information*, 2002: 'However, it is up to the individual tested to decide whether he/she wants to disclose any information, and to whom such disclosure can be made. In the absence of expressed consent from the individual tested, no information contained in an individual's genetic record should be revealed to anyone.'
20. Canadian Coordinating Office For Health Technology Assessment (CCOHTA), *Predictive Genetic Testing for Breast and Prostate Cancer*, 1999: 'For breast cancer, notification would allow at-risk family members to adopt early monitoring, prophylactic treatment, and informed reproductive choices. The possibility must be considered that within a family, knowledge of genetic information may constitute greater harm than nondisclosure, particularly for those family members who may not wish to know. Potential for harm incurred from disclosure may include psychological, social, financial, and discriminatory harm, stigmatization and labelling, and the potential to lose or encounter difficulty in obtaining employment or insurance. Likewise, failure to disclose such genetic information to at-risk individuals may incur harm by limiting opportunities for prevention and treatment, as well as denying one the opportunity of making reproductive choices.'
21. Science Council of Canada, *Genetics in Canadian Health Care*, 1991 *Canadian Biotechnology Advisory Committee*: The Science Council of Canada has adopted the same guidelines for physician disclosure to third parties as the President's Commission for the Study of the Ethical Problems in Medicine and Biomedical and Behavioral Research: 1. reasonable efforts to elicit voluntary consent to disclosure have failed; 2. there is a high probability both that harm will occur if the information is withheld and that the disclosed information will actually be used to avert harm; 3. the harm that identifiable individuals would suffer would be serious; 4. appropriate precautions are taken to ensure that only genetic information needed for diagnosis and/or treatment of the disease in question is disclosed.
22. Réseau de Médecine Génétique Appliquée (RMGA), *Statement of principles Human Genome Research*, Version 2000.
23. Canadian Medical Association, *Code of Ethics*, 1996 (and similar provision in revision draft of 2003): '22. Disclose your patients' health information to third parties only with their consent, or as required by law, or when the maintenance of confidentiality would result in a significant risk of substantial harm to others or to the patient if the patient is incompetent; in such cases, take all reasonable steps to inform the patient that confidentiality will be breached'.
24. Canadian Medical Association, *The Medical Record: Confidentiality, Access and Disclosure*, 2000: 'Unless the law requires otherwise, or if the maintenance of confidentiality would result in a significant risk of substantial harm to others or to the patient if the patient is incompetent, patient authorization is necessary for the disclosure of information contained in medical records to third parties.'
25. Ontario Provincial Advisory Committee on the New Predictive Genetic Technologies, 2001: 'Further research should be undertaken to determine whether disclosing genetic information to high-risk relatives against an individual's wishes should be allowed.'
26. Canadian Medical Association, *Information Privacy Code*, 1998: 'Health information collection, use, disclosure or access without patient consent shall only occur in the limited circumstances provided by this clause. Non consensual health information collection, use, disclosure or access, including the conversion of health information from one information format to another, is a violation of a patient's right of privacy, may compromise the physician's duty of confidentiality, and is potentially disruptive of the trust and integrity of the therapeutic relationship. Therefore, it must only occur under strict conditions and in these very limited circumstances: (a) when permitted or required by legislation or regulation that meets the requirements of this Code; or (b) when ordered or decided by a court of law.'
27. Canadian Biotechnology Advisory Committee, Of Volume, Depth and Speed: The Challenges of Genetic Information, 2001.
28. Danish Council of Ethics (DCE), Ethics and mapping of the human genome, Protection of personal sensitive information, Copenhagen, 1993: 'no unsolicited approach may be made by the health authorities in the case of an examination that may show any hereditary disease in the family. This should also be the case in situations where it can have serious consequences'.
29. Danish Council of Ethics (DCE), *Genetic Investigation of Healthy Subjects: Report on Presymptomatic Gene Diagnosis*, 2001: 'The Danish Council of Ethics believes that the disclosure of genetic information to another person is best done by having the decision about the approach made by the testee...'.
30. Comité Consultatif National d'Éthique pour les sciences de la vie et de la santé (CCNE), *Opinion No 25*, Opinion regarding the application of genetic testing to individual studies, family studies and population studies. (Problems related to DNA 'banks', cell 'banks' and computerisation), June 1991; CCNE, *Opinion No 70, Consent for the benefit of another person*, December 2001; CCNE, *Avis No 76, Regarding the obligation to disclose genetic information of concern to the family in the event of medical necessity*, April 2003.
31. Groupe Génétique et Cancer et Fédération Nationale des Centres de Lutte Contre le Cancer, *Le risque familial de cancer du sein et/ou de l'ovaire*, 2002: http://www.fnclcc.com/fr/sor/pdf/patient/ssp_familial_integral.pdf
32. German Society of Human Genetics, Committee for Public Relations and Ethical Issues of the German Society of Human Genetics, *Position paper of the German Society of Human Genetics*, 1996; GSHG, *Position paper of the German Society of Human Genetics*, 2001 (http://www.medgenetik.de/sonderdruck/2000-376d.PDF).
33. Greek National Bioethics Commission, *Recommendation on the collection and use of genetic data*, 16/09/02, http://www.bioethics.gr/mod/userpage/images/opinion%20in%20english.pdf.
34. Comitato Nazionale per la Bioetica, Orientamenti bioetici per i test genetici: Sintesi e raccomandazioni, 19 Novembre 1999.
35. Japan Society of Human Genetics, *Guidelines for Genetic Counseling and Prenatal Diagnosis*, (September 1996) 6:5 Eubios Jour-

nal of Asian and International Bioethics, 138, http://www.biol.tsukuba.ac.jp/~macer/EJ64/EJ64I.html (date accessed: March 8, 2000). (Guidelines issued in December 1994): 'However, in case that consent of the subject to reveal that information is obtained *[sic... shouldn't it be .in case that consent of the subject to reveal that information is not obtained'?]*, if the disclosure of information to a third party will avoid risk to that person, and the reason is judged to be serious enough, the obligation of confidentiality can be broken. Such an exception must be following the judgment of the responsible ethics committee, not of only one person.'

36. Japan Society of Human Genetics, *Guidelines for Genetic Testing, Using DNA Analysis*, September 1996, 6 Eubios Journal of Asian and International Bioethics, 137, http://www.biol.tsukuba.ac.jp/~macer/EJ64/EJ64I.html (date accessed: February 1, 2000). Guidelines issued in September 1995: 'However, if the sharing of information to another specific person (family member at present or in the future) will avoid serious injury to that person, it is necessary to seek the consent of the subject to reveal that information, and even if agreement can not be obtained, if it is judged necessary the obligation of confidentiality can be broken. Such an exception must be following the judgment of the responsible ethics committee, not by the counselor.'
37. Swiss Academy of Medical Sciences (SAMS), Medical-ethical guidelines for genetic investigations in humans, 1993.
38. House of Common Science and Technology Committee (HCSTC), *Human Genetics: The Science and its Consequences*, London, 1995.
39. Genetic Interest Group (GIG), Genetics and Human Behaviour: the ethical context–GIG submission, July 2001, http://www.gig.org.uk/docs/gig_nuffieldbg.pdf: Are there any circumstances when such information should be available to third parties either with or without the consent of the individual? Informed consent to disclosure is an essential pre-requisite to the communication of genetic information. Genetic information relating to human behaviour is no different.
40. British Society of Human Genetics (BSHG), Royal College of Physicians, Royal College of Pathologists, Joint Committee on Medical Genetics, *Consent and Confidentiality in Medical Genetic Practice*: Guidance on genetic testing and sharing genetic information – a consultation paper (Draft document), October 2003: 'In special circumstances it may be justified to break confidence where a person declines to inform relatives of a genetic risk of which they may be unaware, or to allow the release of information to allow specific genetic testing to be undertaken. Such disclosure in these circumstances should be on the proviso that an attempt has been made to persuade the patient in question to consent to disclosure; the benefit to those at risk is so considerable as to outweigh any distress which disclosure would cause the patient; and the information is, as far as possible, anonymised and restricted to that which is strictly necessary for the communication of risk. We recommend that before disclosure is made when consent has been withheld, the situation should be discussed carefully with professional colleagues and the reasons for disclosure documented. Current GMC guidance states that the individual should generally be informed before disclosing the information' (p. 19).
41. Human Genetics Commission: *Inside Information: Balancing interests in the use of personal genetic data*, 2002; http://www.hgc.gov.uk/insideinformation/index.htm; 'Bearing in mind the principle of genetic solidarity and altruism, we take the view that disclosure of sensitive personal genetic information for the benefit of family members in certain circumstances may occasionally be justified. This would arise where a patient refuses to consent to such disclosure and the benefit of disclosure substantially outweighs the patient's claim to confidentiality. Such disclosure should be on the proviso that (1) an attempt has been made to persuade the patient in question to consent to disclosure; (2) the benefit to those at risk is so considerable as to outweigh any distress which disclosure would cause the patient; and (3) the information is, as far as possible, anonymised and restricted to that which is strictly necessary for the communication of risk'.
42. British Medical Association, *Human Genetics: Choice and Responsibility*, Oxford University Press, Oxford 1998: http://www.hgc.gov.uk/whoygconsultation_responses/bma.htm#chp6. 'The BMA believes that, as a general rule, genetic information should not be disclosed without the consent of the individual concerned. People seeking testing should be informed of the implications for other family members before they consent to testing and should be strongly encouraged to share the information with those affected. Experience has shown that the vast majority of individuals are happy to share the information with their relatives. If they refuse, however, this should be respected unless there are sufficient grounds to justify a breach of confidentiality. The type of factors that should be taken into account in reaching that decision are: – the severity of the disorder; – the level of predictability of the information provided by testing; – what, if any, action the relatives could take to protect themselves or to make informed reproductive decisions, if they were told of the risk; – the level of harm or benefit of giving and withholding the information; and – the reason given for refusing to share the information. In some, exceptional, cases a breach of confidentiality may be justified. Health professionals may find it helpful, in such cases, to discuss the situation, on an anonymous basis, with other senior colleagues or with their professional association. Before any disclosure is made, the patient should be informed of the doctors' intention to disclose information, and the reasons for that decision.'
43. General Medical Council (GMC), *The protection and use of Patient Information*, 1996: 'Disclosure to other family members should be subject to the same requirements as any other form of disclosure, that is, that consent to disclosure must always be sought but that in cases where serious harm to third parties could arise, non-consensual disclosure may be justified.'
44. Genetic Interest Group (GIG), *Confidentiality Guidelines*, London, 1998 http://www.gig.org.uk/docs/gig_confidentiality.pdf: 'Professionals should have the discretion to breach confidentiality according to the following principles: The right to confidentiality of the index case should be protected when the potential harm caused to the index case by breaching confidentiality outweighs the potential benefits to the relative of being informed. Conversely, disclosure without the index case's permission could perhaps be justified if the potential harm to the relative of not being informed (and the benefits of being informed), outweighs the potential harm to the index case of confidentiality being broken.'
45. Nuffield Council on Bioethics (NCB), *Genetic Screening: Ethical Issues*, 2000: 'When genetic screening reveals information that may have serious implications for relatives of those who have been screened, health professionals should explain why the information should be communicated to other family members. The Council recommends that in such circumstances health professionals should seek to persuade individuals, if persuasion should be necessary, to allow the disclosure of relevant information to other family members. They should also seek to ensure that treatment, counselling and other appropriate support are made available to those to whom such unsought information is disclosed. Both the law and professional guidelines provide for exceptional circumstances, when an individual cannot be persuaded to inform family members with a legitimate right to know. In such exceptional circumstances the individual's desire for confidentiality may be overridden. The decision can only be made case by case.'
46. American Society of Clinical Oncology (ASCO), *Policy Statement Update: Genetic Testing for Cancer Susceptibility*, Journal of Cinical Oncology, Vol. 21, No 12 (June 15), 2003.
47. American Medical Association (AMA), Report of the Council on Ethical and Judicial Affairs, Disclosure of Familial Risk in Genetic Testing, CEJA Report 9-A-03, 2003.

48. National Society of Genetic Counselors, *National Society of Genetic Counselors' Statement: Confidentiality of test results*, Adopted 1991, revised 2002: 'It is the right and responsibility of the individual to determine who shall have access to his/her own medical information, including genetic information'.
49. Great Lakes Regional Genetic Group (GLRGG), The Evaluation of Clinical Services Subcommittee, *Minimum Guidelines for the Delivery of Clinical Genetic Services*, 1993.
50. American President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research, 1983.
51. Institute of Medicine, Committee on Assessing Genetic Risks, *Assessing Genetic Risks - Implications for Health and Social Policy*, 1994.
52. American College of Medical Genetics & American Society of Human Genetics, *Ethical, Legal and Psychosocial Implications of Genetic Testing in Children and Adolescents*, 1995, http://genetics.faseb.org/genetics/acmg/pol-13.htm: 'Although the provider might presume an obligation to inform other family members at risk, some patients may prefer not to inform other family members. Current recommendations [22] and practices [23] suggest that the patient's wishes for confidentiality should be respected as long as the failure to disclose genetic information is not likely to result in immediate serious physical harm to the relative.'
53. American Society of Human Genetics, Social Issues Subcommittee on Familial Disclosure, *Statement: Professional disclosure of familial genetic information*, 1998.
54. National Human Genome Research Institute, ELSI, *Promoting Safe and Effective Genetic Testing in the United States – Final Report of the Task Force on Genetic Testing*, 1997: http://www.genome.gov/10002405: 'Health care providers have an obligation to the person being tested not to inform other family members without the permission of the person tested, except in extreme circumstances.'

Notes

1. Gentechnikgesetz (GTG; Gene Technology Act), BGBl. Nr. 510/1994, amended in 1998 (BGBl. I Nr. 73/1998), and in 2002 (BGBl. I Nr. 94/2002.
2. Genetic Information Law, 5761–2000 (13 December 2000).
3. Many states in America have enacted legislation restricting the use of genetic information by health insurers and in employment. Some states even prohibit communication of genetic information to anyone without the permission of the person tested [43]. However, there is currently no comprehensive federal legislation that protects the right to privacy of individually identifiable health care information in the United States of America [16].
4. The *Personal Data Protection Act*, 2000, also deals specifically with genetic information.
5. The *Manitoba Personal Health Information Act*, 1997, explicitly states that the definition of 'health information' includes genetic information.
6. The Amendment of the Federal Constitution [45] states that, in regard to genetics and assisted procreation, the genetic heritage of a person may only be analysed, recorded, and disclosed with that person's consent, or on the basis of a legal provision.
7. Some countries are currently considering legal reforms and new laws in this field. For instance: Switzerland (Bill regarding Genetic Testing on Humans, 1998, approved by the Federal Council in September 2002, FF 02.065, 6841), United States (Genetic Information Nondiscrimination Act of 2003, S. 1053, approved by the Senate in November 2003), Australia (see ALRC 96, 2003),
8. *Tarasoff* v. *The Regents of the University of California*, 131 Cal. Rptr. 14 (Sup. Ct. 1976) [hereinafter *Tarasoff*]. In this case, the California Supreme Court ruled against a psychiatrist who did not warn a third party of his patient's harmful intent.
9. Other examples include a physician's duty to warn a third party who may be at foreseeable risk for contracting a sexually transmitted or communicable disease, and a case of a physician's duty to a third party who was injured by the physician's epileptic patient who had a seizure while driving.
10. In the *Pate* case, the plaintiff was receiving treatment for medullary thyroid carcinoma and sued the physician who had previously treated her mother for the same condition, but with whom the plaintiff had no patient–physician relationship. The plaintiff alleged that the physician failed to warn the mother that her condition could be genetically transmitted and that her children should be tested [4]. The *Safer* case involved a suit by a plaintiff against the estate of a physician who had treated the plaintiff's father for multiple polyposis with adenocarcinoma of the colon 30 years earlier. At the time of the father's death caused by metastatic cancer, the plaintiff was 10 years old. At age 36, the plaintiff was diagnosed with cancerous blockage because of multiple polyposis of the colon with evidence of metastatic disease. The cause of action against the physician was for professional negligence, alleging that multiple polyposis is a hereditary condition that, if undiscovered or untreated, invariably leads to metastatic colorectal cancer [5]. In the *Molloy* case, the plaintiff proceeded with a lawsuit against the physicians who had treated her daughter more than 10 years earlier. In this case, Kimberly Molloy claimed that the physicians failed to inform her and her second husband about future risks due to a hereditary form of mental retardation, fragile X syndrome, present in her first daughter. In this case, which stems more from an alleged failure to perform a diagnostic test than from a failure to breach confidentiality to warn of a genetic disease, the mother and her second husband stated they would not have conceived another child if they had known of the diagnosis of fragile X syndrome in the mother's first child [46].
11. In Austria, the Gene Technology Act (1994) explicitly states that 'the physician responsible for genetic testing shall (...) recommend to the person undergoing testing that he advises those members of his family likely to be affected to undergo genetic testing and counseling'. Thus, in this respect, the Austrian physician may fulfill his duty to warn by notifying his patients of the genetic risks to his blood relatives and it belongs to the patient only to disseminate the information within his family.
12. French legislation – which does not specifically deals with genetic information – seems to prohibit any direct disclosure of genetic information to a third party, including patient's family members in any circumstance [47].
13. Australia [48], Switzerland, Canada (Manitoba), Israël.
14. Décret no 95–1000 du 6 septembre 1995 portant code de déontologie médicale, art. 51.
15. National Bioethics Commission, *Recommendation on the collection and use of genetic data*, Greece, September 2002. http://www.bioethics.gr/mod/userpage/images/opinion%20in%20english.pdf
16. The GAIEB has become the European Group on Ethics in Science and New Technologies (EGE) since 1997.
17. The committee gave the example of malignant hypothermia, a genetic disease that can cause a fatal reaction to common anaesthetics.

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4. Pate v, Threlkel. 661 So.2d 278 (Fla. 1995).
5. Safer v. Estate of Pack, 677 A.2d (N.J. Super. Ct. App' Div. 1996).
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