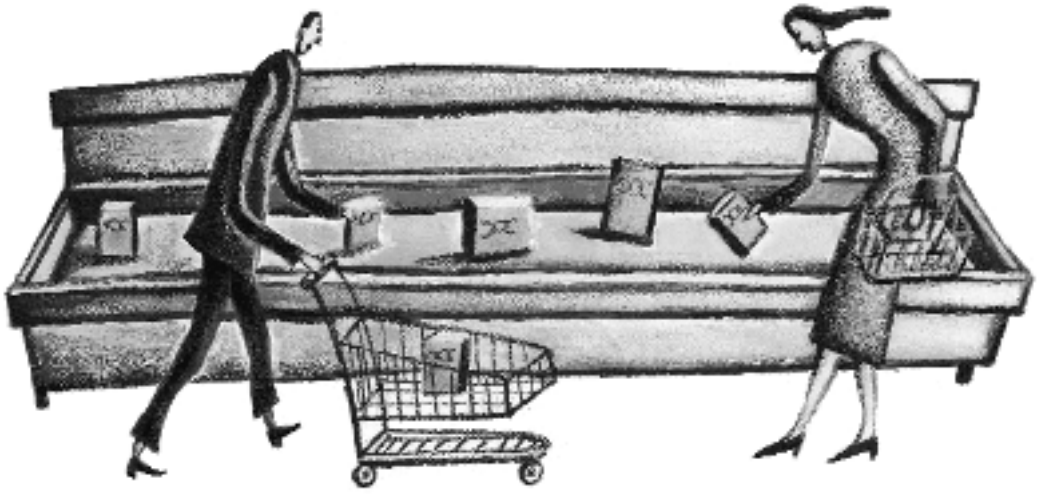
PROVIDING GENETIC TESTING THROUGH THE PRIVATE SECTOR

A View From Canada



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RÉSUMÉ ► De plus en plus, les techniques de dépistage génétique quittent les laboratoires de recherche pour faire leur entrée sur le marché. Pourtant, très peu de bourses sont consacrées à la recherche sur les conséquences du dépistage génétique privé sur un système public de soins de santé comme celui du Canada. Il est crucial de déterminer si, et comment, ces tests devraient être offerts au public et si les individus auraient à débourser pour bénéficier de ces services, et en quelle proportion. De plus, il est impératif d'évaluer jusqu'à quel point les tests génétiques sont, ou devraient être, inclus dans le système de soins de santé, et l'impact qu'aurait un système à deux régimes. C'est en tenant compte de ce contexte difficile que nous avons proposé cette série de seuils de validité qui visent à déterminer si, d'un point de vue moral, un test génétique se justifie, s'il est efficace et sans danger, s'il est rentable et opportun de le financer avec les fonds publics et si son accès dans le domaine privé pose des problèmes particuliers et nécessite une réglementation approfondie. Ces seuils de validité permettent aussi d'identifier les questions autour desquelles les débats professionnel, public et moral doivent être orchestrés : Qu'est-ce qu'un objectif moralement acceptable en ce qui a trait aux services génétiques ? Quels sont les bienfaits appropriés ? Quels sont les risques ? Dans quelles circonstances est-il acceptable qu'un service ne soit pas couvert par l'assurance-maladie ? Finalement, comment est-il possible de gérer les effets négatifs qu'entraîne l'accès privé au dépistage génétique ? (Traduction : **www.isuma.net**)

ABSTRACT ► Genetic testing technologies are rapidly moving from the research laboratory to the market place. Very little scholarship considers the implications of private genetic testing for a public health care system such as Canada's. It is critical to consider how and if these tests should be marketed to, and purchased by, the public. It is also imperative to evaluate the extent to which genetic tests are or should be included in Canada's public health care system, and the impact of allowing a two-tiered system for genetic testing. A series of threshold tests are presented as ways of clarifying whether a genetic test is morally appropriate, effective and safe, efficient and appropriate for public funding and whether private purchase poses special problems and requires further regulation. These thresholds also identify the research questions around which professional, public and policy debate must be sustained: What is a morally acceptable goal for genetic services? What are the appropriate benefits? What are the risks? When is it acceptable that services are not funded under health care? And how can the harms of private access be managed?

ILLUSTRATIONS : YAYO

THE PRACTICE OF MEDICINE will be revolutionized by a vast array of new genetic testing technologies as they become available to the public, through health care providers or privately.[1] Testing will provide prospective parents with more information about their own genetic makeup (carrier testing) as well as about their potential or developing child (preimplantation or prenatal testing). People may be able simultaneously to learn about their individual risk for a host of conditions or illnesses (predictive and pre-symptomatic testing), and thus be given the opportunity or responsibility to change certain lifestyle behaviours to reduce risk, make career planning decisions, or take prophylactic measures (e.g., surgery). Testing of people who have already developed a disease may also allow for the development of individualized therapies and pharmaceuticals (pharmacogenomics) that more accurately target treatments and reduce unwanted side-effects.[2]

While these advances undoubtedly hold much promise, concerns have been raised in relation to the provision of commercial testing services. For example, it has been argued that commercial pressure may cause testing services to be offered prematurely, in circumstances in which the benefit has not been established, or to an inappropriately broad population. Moreover, for the purposes of marketing, the uncertainties associated with private testing may be minimized.[3] It has been speculated that this market pressure may further "geneticize" society's view of disease and disability, as well as of normal variation, such as athletic ability, intelligence or criminal behaviour.[4] There is also concern that industry—and researcher—generated interest in testing may cause unnecessary anxiety in individuals who may not, but for the "genohype," be interested in testing.[5] These are some of the reasons that some policy groups, such as the U.S. Task Force on Genetic Testing, have concluded that "advertising or marketing of predictive genetic tests to the public" should be discouraged.[6] It has also been argued that physicians, health professionals and institutional attitudes and practices may stimulate the premature or inappropriate use of genetic tests by inflating public interest.[7]

In the context of a publicly funded system like Canada's, any use of resources for genetic testing may mean fewer resources for other health needs. Even if privately financed, genetic testing will have an impact on the public sector. For example, after receiving the test results, concerned patients may flow back to the public sector for advice and treatment or make lifestyle choices that over the long run may impose further costs on the public system.

> Testing services may be offered to an inappropriately broad population before the benefit has not been established.

Commentators have raised concerns about the potential for inappropriate counselling and consent processes,[8] a lack of effective confidentiality guidelines within the private sphere,[9] and the need for ensuring quality control.[10] It has also been noted that many health care providers, such as family physicians, know little about genetic testing, a lack of professional knowledge that is worrisome.[11] However, until the research necessary to establish appropriate testing guidelines is conducted, health care providers cannot be expected to know how, when or for whom a particular genetic test is appropriate.

Regulatory challenges

Currently no Canadian jurisdiction has regulations to address the information and economic concerns related to the adoption of genetic tests in the public health care system or private market. Neither the federal nor provincial governments have formal mechanisms to monitor the marketing of genetic services. Yet there are good economic and social policy arguments for avoiding—or, at least, tightly regulating—a private market in any type of health care service that is judged to be necessary.[12] Primarily, health care services are not commodities that are subject to the usual actions of the market (i.e., competitiveness and consumer ability to assess). Moreover, the existence of a private market reduces the economic efficiency of the public system because, for example, private companies profit from these overhead services (e.g., access to trained research staff) without contributing to their funding and development. Finally, there is some controversy whether the NAFTA regulations will require that once a private market is opened, it cannot subsequently be regulated in any way that might results in impediments to American trade.[13]

There are, nevertheless, examples of private markets for health care services that are not or only partially covered under Canada's provincial health insurance schemes (e.g., pharmaceuticals, some cosmetic surgery, fertility treatments, corrective eye surgery, alternative or complementary medicines). It is beyond the scope of this paper to determine whether such treatments should, in fact, receive public funding, or how NAFTA requirements affect these and other health care services. Since these examples already exist, a specific regulation of private genetic tests should be based on explicit justification. In addition, given the current disarray of regulatory mechanisms, a novel regulatory framework may be required in implement a prohibition or regulatory policy effectively.

A number of factors may make it difficult for any one jurisdiction

(provincial or federal) to address the noted policy issues. These factors include the promotion of biotechnology by industry, universities, researchers, government,[14] health care professionals and institutions;[15] the global nature of the genetic revolution and the potential for "cross-border shopping;"[16] and the possible regulatory implications of monopoly control resulting from a patent on a genetic sequence.[17] A variety of the technological advances still on the horizon have the potential to alter both the scope and nature of the policy issues in this area. For example, multiplex tests that use emerging genomic technology such as DNA chips to test hundreds or thousands of genes for a number of diseases simultaneously, may create unique consent and patent law issues while, at the same time, make genetic testing seem more routine.[18]

Finally, the nature of Canada's health care system needs to be considered. As will be discussed more fully below, there are no clear criteria for determining what services will receive full or partial public funding and what services will be left totally to private financing. Compounding this ambiguity over regulatory and funding policy are the federal-provincial tensions over the legal jurisdiction to govern in the area of health care and the legislative framework delineating the public system's funding obligations (e.g., the *Canada Health Act* refers to the funding of "medically necessary" physician and hospital services but gives provinces considerable latitude to define the scope, level and nature of service coverage). In short, the reality is that there is uncertainty and poor justification for what services are or are not partially or fully insured, and for the level of funding.

There is no doubt that the complex context in which genetic testing is emerging creates unique challenges to the development of effective policies. These difficulties, however, should not be an excuse for inaction on the part of governments. Instead, the regulatory challenges should be a spur to solve these problems, not only to ensure the health and well-being of Canadians and their treasured social health care system, but also for the long-term health of genetic testing industries. This paper is meant to serve as a step toward identifying the pieces to the puzzle that Canadian policy makers must solve.

Analytic framework

The following analysis is organized around a modified version of Deber et. al.'s proposal for determining what services deserve public funding.[19] Their staged analysis illustrates a clear analytic framework for assessing some of the issues, as well as for structuring arguments for or against public funding. The following analysis proposes four thresholds that deal with whether anyone should receive a service, and two final thresholds that consider whether this service should be fully or partially financed with public money or be available for patient-paid purchase. We recognize that the logical ordering does not always correspond to the chronology of how knowledge and technology are developed so some of the analysis for a specific test will necessarily be retrospective (e.g., moral concerns may be raised after the use of a test identifies harms).

Threshold 1: Is the test morally acceptable?

Some tests or interventions may be found objectionable because their goals or consequences are viewed as simply unacceptable. At any point in the development of a genetic test, a society may decide that a test should not be made available and/or that certain procedures should be required if a test were conducted. For example, in Canada, the 1993 Royal Commission on New Reproductive Technologies recommended, and the federal government concurred in Bill C-47, that sex selection should be prohibited.[20] Similarly, in some countries "non-medical" uses of genetic tests are prohibited; a number of European countries have enacted prohibitions on a variety of reproductive and genetic technologies.[21]

In practice, the adverse implications of such prohibitions should also be considered in policy development. For example, they may have an unintended impact on potentially useful research, and economic development opportunities may be lost.[22] This is not a simple trade-off of health benefits for economic loss, since wealth, health and welfare are recognized to be inextricably bound together at the level of both individuals and populations.

Because this threshold reflects values, it evokes questions of how, and by whom, these values will be expressed. In this context it is worth noting that there is a growing body of literature that critiques the manner in which economic, technology and public policies are developed and influenced by industry and intellectual elites. For example, the tendency to value public input only if it is "educated" with respect to technical aspects of an issue such as genetic testing has been criticized as a "deficit model" of public participation.[23] It is particularly important in areas of moral ambiguity and vested interests that improved public participation mechanisms be developed. Danish public consensus conferences and sci-

ence shops in the Netherlands, Austria and Germany provide some examples of innovative approaches to involving the public in policy development.[24]

In any event, an outright prohibition of genetic testing or certain genetic tests may not be completely effective as some people may still order tests from other jurisdictions. Nonetheless, a government regulation prohibiting specific tests stands as a statement of national values and may feed into what preferences consumers have with regard to the private purchase of testing. It may also reduce the visibility of such tests, and exposure of the general public to advertising for these tests, thus helping to reduce the "genohype" pressure.

Threshold 2: Does the test actually identify a genetic factor?

No test should be offered without passing some minimum standard of efficacy. Currently, there is no formal, generally accepted, standard for determining threshold validity in this context. But as we contemplate policy, it seems axiomatic that a test must at least detect what it claims to detect. Such a threshold criterion would ensure that tests that have no efficacy are not marketed or sold to health care professionals and patients (i.e., genetic tests might be held to a standard of proof similar to that in the pharmaceutical industry). Thus, for example, a test should reliably identify the specific genetic variation(s) in question, both in the laboratory and in the marketplace.[25]

Neither the federal nor provincial governments have specific policies or regulatory mechanisms to deal with this criterion. Laboratories are generally regulated via provincial accreditation schemes to ensure sufficient staff training, quality of laboratory techniques, etc.[26] For example, in British Columbia, this service is undertaken by the Diagnostic Accreditation Program (DAP),[27] which is jointly funded and administered by the B.C. Medical Association and the B.C. College of Physicians and Surgeons. In Ontario, accreditation is assumed by the Laboratory Proficiency Testing Program (LPTP),[28] which is also involved in laboratory licensing. British Columbia does not yet have laboratory licensing. The federal government, through the Health Protection Branch (HPB) and its Therapeutic Products Program (TPP), monitors the development and marketing of genetic test kits (e.g., for cystic fibrosis or paternity). However, the majority of genetic tests are offered as in-house laboratory services and, as such, their validity and quality are not formally evaluated;[29] this situation is similar to that in the United States where the Clinical Laboratory Improvement Amendments (CLIA) regulate laboratories and the Food and Drug Administration (FDA) controls test kits, but there is currently no oversight of laboratory-based genetic tests.[30]

A regulatory hole exists which could and must be filled by existing federal or provincial structures. For example, in the United States, it has been recommended that the FDA pick up this quality control responsibility.[31] Part of a complete regulatory scheme would also involve oversight of personnel and laboratories—indeed, regulation of laboratory quality has been identified as a critical issue for this emerging industry.[32] However, the fact that patent law permits the establishment of single source providers, often with a laboratory in another country, may undermine the ability for any one jurisdiction to comprehensively regulate quality. For example, if one U.S. company has monopoly control of the use of a given test, it may be more difficult for a Canadian regulatory body to address issues of quality control.

Threshold 3: Is the test useful?

Once it has been determined that a test can actually identify a given mutation, the usefulness of the information it provides must be evaluated. In other words, is there an established and well-understood association between the genetic variation and a given phenotype for a given population? For example, the BRCA1/2 test more dependably predicts disease frequency in the Ashkenazi Jewish populations than for the general population. Though the test is also available for people with a significant family history, its usefulness in some populations is still being debated.[33] Assessment of usefulness must weigh benefits against possible harms. Benefits of genetics tests may include directing treatment, avoiding unnecessary harms caused by more frequent screening (e.g., mammography, colonoscopy), possible preventative strategies for asymptomatic individuals (e.g., prophylactic surgery), anxiety reduction, and even the provision of information that individuals may use for personal and/or reproductive planning. The emphasis on promoting autonomy in medical genetics and counselling is often cited to support the provision of any accurate information about genetic risk that can be provided without undue risk or cost.[34]

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Threshold 4: Is the test harmful?

Harms are also complex and may be justified by benefits. Some people will experience as harmful the knowledge of genetic risk in the absence of clear preventative or therapeutic strategies. Commentators have identified harms caused to the individual by the test and to his/her response to the test results (e.g., anxiety and depression,

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suicide and inappropriate lifestyle changes or seeking prophylactic surgery).[35] There are also identified harms caused by the responses of third parties and social systems to genetic testing (e.g., stigmatization, insurance and employment discrimination, and altered family relations).[36] It could be argued that the broad social concern (e.g., geneticization) weighed against individual benefits should also be considered at this level.

Some of the harms identified above might be eliminated or reduced, at least for some genetic tests, through regulatory initiatives. Tests that have passed the thresholds to this point may vary in the amount of regulation to which they should be subject. For example, some tests may warrant categorical prohibition through professional self-regulation or, in the extreme, direct regulation to avoid misuse (e.g., testing of young children for an untreatable, late adult onset disorder or for "adoptability"). Some regulatory mechanisms are generally relevant to patients and health care providers who may seek genetic testing, i.e., public education, gatekeeping, and support for gatekeepers through education and regulation.

Given the amount of information available, and given the various sources of information (e.g., the Internet[37]), a crucial regulatory response will be to improve the quality and accessibility of information that consumers receive about the harms, benefits and quality of genetic testing (e.g., through the Internet, public education, in physicians' offices, etc.). Further, since it is essential that accurate information is provided to both the public and test providers (i.e., physicians, counsellors), it seems reasonable to regulate the marketing and advertising of genetic services to require truth in advertising, so that scientific claims are substantiated and the wording of information (benefits, harms, etc.) provided to consumers is monitored.[38] Such regulation would be not unlike current demands placed on the pharmaceutical industry, which ensure that detailed, accurate product information is available for all medications. Thresholds one to four presume that a governance mechanism similar to drug and device regulatory agencies is required.

Threshold 5: Should the test be publicly funded?

The tests that have passed the previous thresholds must next be evaluated as to whether they merit public financing. Public funding will of course increase utilization and may facilitate private profit through the purchase of licences or provision of services by private laboratories. Considerations at this level include cost minimization (is this the least expensive option?), but the key ethical issue is whether it is acceptable that people who want and can benefit from testing (but who cannot afford it) are denied access. Ideally, tests that provide genuine net health benefit at reasonable cost should be included in the public health insurance system. This is in keeping with the spirit, as reflected in health care legislation, of that amorphous concept of "medical necessity." Equal access to effective health care independent of economic status is a central tenet of public health insurance schemes worldwide. Ethical justification for this claim has been based on equal opportunity, as well as economic efficiency. These ethical arguments and assumptions would support public funding of any test that passes the thresholds to this point, provided it is the least expensive option to achieve the health benefit.

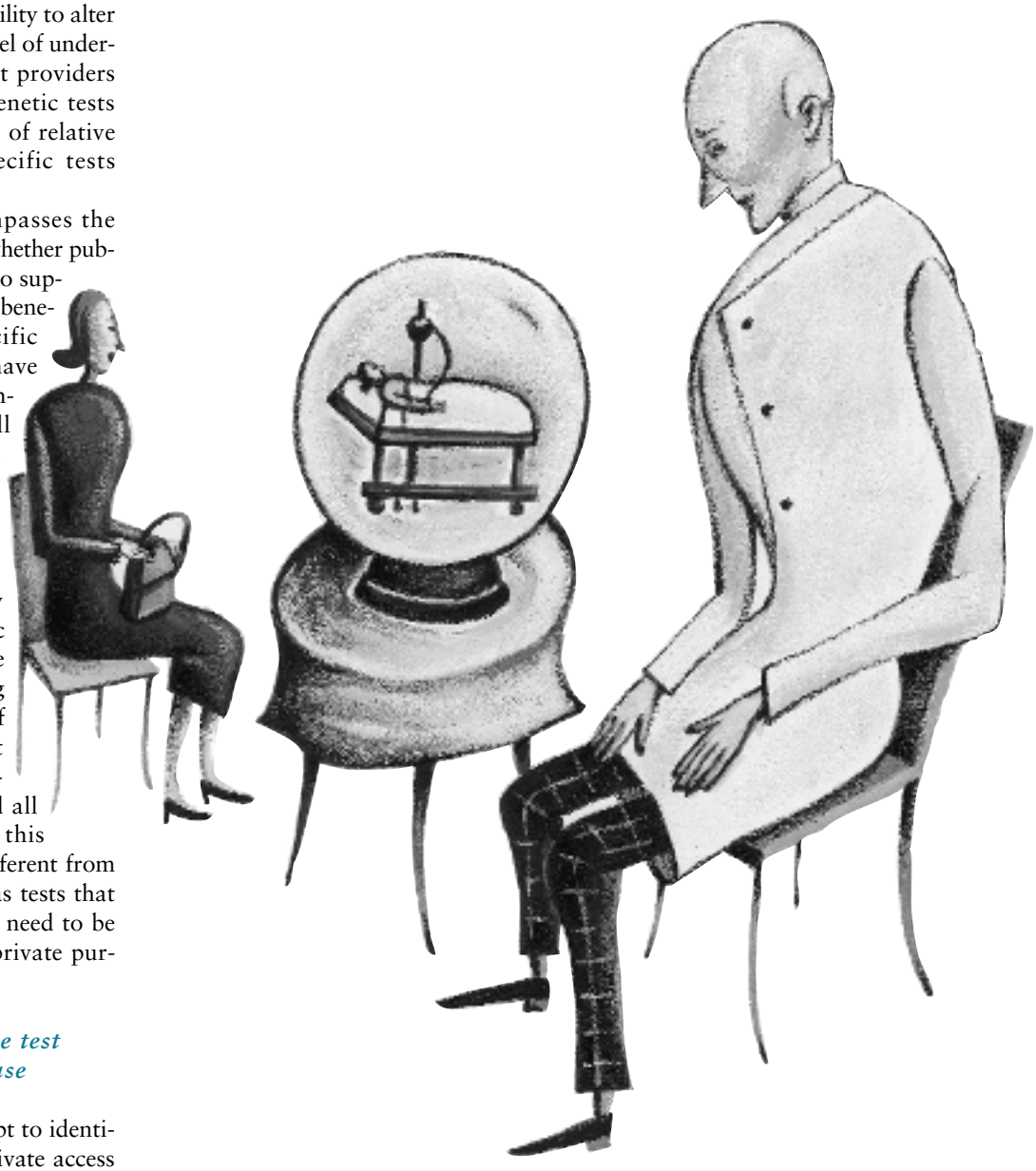
Unfortunately, whether particular services are included in public health insurance is not the result of a rational assessment.[39] Rather, health care budgets are restricted without consideration of what services should be covered. Some services are insured because they are historically associated with professional or institutional practices. Some services are insured without adequate demonstration of benefit and some that are beneficial are not universally insured (e.g., pharmaceuticals, wheelchairs). Pressure for public financing comes from a variety of sources including the media, interest groups, liability concerns, marketing pressure, researcher interest and clinician enthusiasm. Levels of funding and waiting lists are also influenced by these factors. Inevitably and regrettably, decisions about genetic testing will be made in this ad hoc decision-making environment.

The general issue of rationalized provision of health services is unlikely to be resolved in the near future, but evaluating the issue of public insurance coverage and private availability of genetic testing services in an internally consistent and justified manner might be exemplary for health care insurance in general. As such, after determining that a genetic test is ethical, useful and relatively safe, consideration needs to be given to the worth of the service relative to other health care goods. For example, it may be determined by provincial ministries of health that other health care needs constitute more urgent demands for limited public health care funds.

Public and provider consultation, and an evaluation of the wider social and structural impacts of providing these services will also be an essential but not sufficient component in the determination of the relative value of funding genetic tests. Since specific tests will engage provider and public groups most affected by the specific tests, consultations about relative worth will need to be more general, aimed at assessing the relative merit of

being able to predict or assess risk of illness, and whether the value of the test is dependent on the ability to alter risk or onset. Even this level of understanding of the value that providers and the public give to genetic tests should assist assessments of relative worth and whether specific tests should be insured.

Threshold five encompasses the range of issues related to whether public funds should be spent to support access to the kind of benefits provided by specific genetic tests. Tests that have passed the first four thresholds but not the fifth will require re-evaluation as understanding about their accuracy or benefits in particular populations develop. Nonetheless, in the current ad hoc policy environment, some genetic tests at this stage will be rejected for public funding not because of lack of accuracy or benefits, but because health care funding is inadequate to fund all cost-worthy services. In this sense, threshold five is different from the first four thresholds as tests that fail to be publicly funded need to be evaluated in relation to private purchase.



Threshold 6: Should the test be available for purchase with private funds?

Threshold six is an attempt to identify the issues related to private access to tests that are accurate and beneficial but not publicly funded, to consider the possible regulatory responses to reducing the risks, and to suggest what effects of private testing should be studied. On the assumption that there are genetic tests that will meet the considerations of the thresholds up to but not including support under public health care insurance, some useful and safe genetic tests may be available only through private arrangements. It is also probable that some publicly funded tests will be under-funded, with the effect that a lengthy waiting list will establish a

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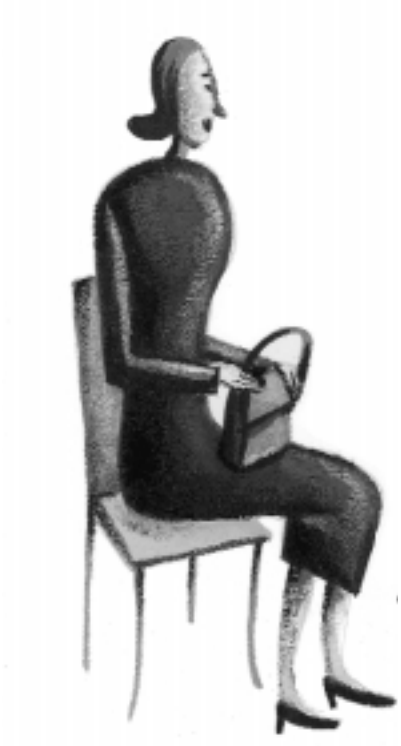
further market for genetic tests that are covered under public health insurance, or some people may prefer private purchase to facilitate privacy or other values.

There are significant economic and ethical problems associated with the co-existence of public and private genetic testing. Privately purchased tests and the related profits are publicly subsidized through education, research and supportive services.[40] The quality of the publicly funded system may not be maintained if resources, such as health professionals, are pulled toward the privately funded system. Indeed, there are strong reasons to believe that private testing may actually lengthen the waiting lists in the public system for those who do not pay for more rapid access by, for example, reducing pressure to increase access in the public system. The ideal solution is more adequate health care funding of the public system and more rigorous evaluation of services for inclusion with better control over the private market. It is, however, unlikely that there will be significantly increased health care funding or a rationalized system of controlling supply and access to private health care services in the near future. How then can the harms of private genetic testing be appraised and minimized?

In Canada, the equitable distribution of health care resources is high on the social agenda. Indeed, recent debates about the introduction of more private health care delivery have highlighted Canadians' continued commitment to a public system.[41] However, Canada is also a country that puts great emphasis, particularly in health care jurisprudence, on the ethical principle of autonomy and the notion of consumer choice. The tension created by these two social norms is emphasized in the context of genetic testing.

Gatekeepers to genetic testing

One possible mechanism for regulating many genetic tests is to require that they be accessed only through an appropriate gatekeeper (e.g., BRCA1/2 testing might only be provided through a genetics or oncology program). The level of expertise needed in a given gatekeeper will vary between tests. For example, for some tests it may be sufficient to go through a family physician or genetic counsellor, while others may require a medical specialist. Finally, some tests may be available (privately) with the assurance of accurate information (e.g., carrier CF screening in the United Kingdom). Whether the genetic gatekeeper is a family physician, counsellor or medical specialist, the emerging norms around non-directive counselling and informed consent would apply. The standards of disclosure, both ethical and legal, emphasize the inclusion of social consequences if they can be anticipated, as well as health-related information.



In the commercial for-profit sector, the discretionary assessment of gatekeepers may be influenced by additional incentives in favour of testing.[42] That is, the profit-oriented context may create or amplify existing conflicts of interest. As such, it is important to be explicit and transparent about the possible effect of this conflict and, moreover, consideration should be give to mechanisms that can enhance gatekeeper independence. Thoughtful guidelines, consensus statements and professional standards of practice, developed independently from commercial test providers, should help guide gatekeepers to recognize and avoid undue influence in the profit-oriented context. Given the low understanding which non-specialist providers currently have,[43] a robust education program is also needed to enable physicians to serve this role.[44] However, the rapid development of genetic technologies will make it difficult for many gatekeepers to weigh the benefits and harms of all new tests effectively. Thus a regulatory regime — or, at least, some form of oversight — is required that combines the authority and expertise to evaluate the evidence that a test accurately identifies a genetic factor and that there is, for a specific population, a net benefit. Such a regime would need to support of self-regulating health professionals' efforts to exercise appropriate discrimination in the gatekeeping of genetic test access, since these professionals are likely to be the first point of patient requests for genetic tests.

Another approach to controlling the potential harms (to consumers) associated with private access to genetic tests is to justify public payment for genetic counselling. Genetic counselling may be an effective and economical means of addressing anxiety associated with the perception of genetic risk — anxiety about health risk is, arguably, a legitimate concern

for the health care system to address in a cost-effective and compassionate manner. In such circumstances it might be reasonable to include some partial or full support for such counselling within the public system, even if the testing of the individuals in question is not covered. This service should be evaluated for its effect on utilization of genetic tests, outcomes for individuals and economic impact.

On the other hand, it could be argued that funding genetic counselling in this manner would simply allow the private system to unjustly benefit from personnel and infrastructure support from the public health system. But assuming that the provision of genetic counselling is essential, and that there are limited resources with which to provide such services, there might nonetheless be creative means of ensuring access to pre- and post-test counselling. For example, it might be possible to set up private genetic counselling services (at arm's length from the genetic testing companies), and require potential consumers to first have counselling before testing is permitted. Private genetic service providers might also be required to enter into licensing agreements with existing public counselling services to help support (both financially and with extra staff) the increased demand for counselling that private access will create. While such options raise serious concerns about equitable in access and conflict of interest, the point is that there may be creative ways of co-ordinating expectations for counselling support with various funding arrangements.[45]

More generally, if the goal is to ensure that genetic testing is provided in a safe, respectful and equitable manner, it will be essential to engage in open and pragmatic discussion about the nature of genetic services and their role in health care. This will also mean thinking creatively about ways of addressing the social, ethical and policy issues that arise from commercial genetic testing. The issue of private genetic testing is part of a larger picture; the moral and political task of providing equitable access to health care services and promoting health must also be considered in the context of reflections on "how best to bring capital, morality, and knowledge into a productive and ethical relationship?"[46]

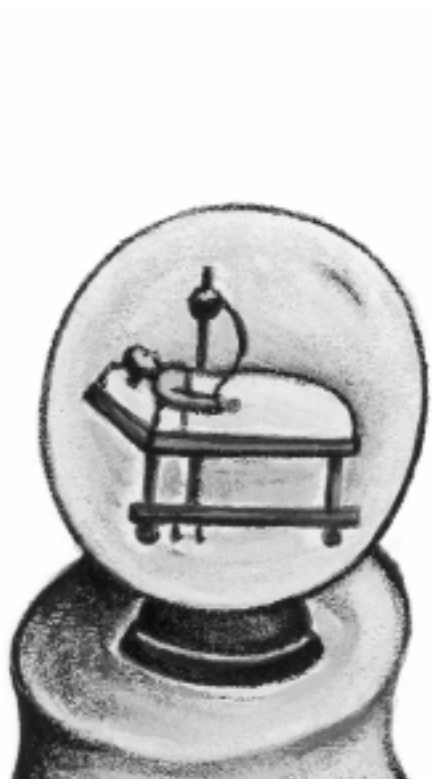
> The rapid development of genetic technologies will make it difficult for many gatekeepers to weigh the benefits and harms of new tests effectively.

Conclusion

Debates about public funding of genetic tests are caught on the horns of a dilemma. On the one hand, the current clinical and population health benefits of most forms of genetic testing seem too limited to justify their inclusion in health care insurance schemes that already exclude more beneficial services and goods (e.g., pharmaceuticals). On the other hand, exclusion from health insurance suggests that genetic tests are consumer goods, and may leave consumers vulnerable to unmediated manipulation by inflated claims designed to produce profit.

If health insurance coverage were rational and sufficiently funded to cover all health services shown on the basis of evidence to have beneficial health effects on individuals or populations, then genetic tests would simply need to demonstrate benefit to be included under health insurance, and there would be little argument for private access. The current health care insurance system in Canada is less than rational and insufficiently funded to cover all effective services. Furthermore, the heavy investment of public and private funding in genomic research and genetic technologies will increase the number of candidate technologies for evaluation, the economic burden for financing evaluation, and pressing issues about who should bear the burden for evaluation. At any given moment there will be technologies and services that are either included but under-funded, or useful but unfunded.

It is into this complex context that we have suggested a series of threshold tests be used to determine whether a genetic test is morally appropriate, effective and safe, efficient and appropriate for public funding, and whether private purchase poses special problems and requires further regulation. It is our hope that this approach can help manage some of the problems associated with the proliferation of genetic technologies without reducing the pressure to assess the nature and funding level more reasonably for the overall health care system. Perhaps most important, the thresholds also identify the research questions around which professional, public and policy debate must be sustained: What is a morally acceptable goal for genetic services? What are appropriate benefits? What are the risks? When is it acceptable that services are not funded under health care? And, how can the harms of private access be managed?



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Endnotes

1. For the purposes of this paper, we define "genetic testing" as "the analysis of a particular gene in order to provide 'predictive' information about the nature or time of disease onset, or 'susceptibility' information about the potential or risk of developing a particular disease." This is a modification of the 1998 World Health Organization definition, and does not explicitly include multiplex or genomic testing, which will likely become more important as the Human Genome Project is completed.
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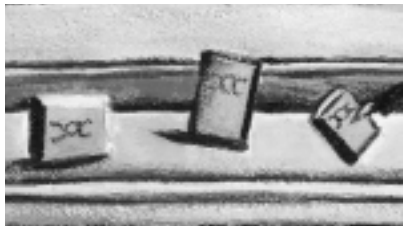

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25. In the context of genetic testing, "analytical validity" is whether the test is positive when the gene or genetic variant being tested for is actually present and whether the test is negative when the gene or genetic variant is absent. This is different from "clinical validity", which is the probability that the test will be positive in people with the disease (or who will get the disease) and the probability that the test will be negative in people without the disease (or who will not get the disease).
26. Interestingly, and as noted by Terry Owen, CEO, Helix Biotech, Canada, some support for formal government accreditation comes from private genetic testing companies and laboratories, which see this as a means of demonstrating credibility in the marketing of their services.
27. DAP Web site: *http://www.dap.org/* (Mar. 6, 2001).
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30. See Holtzman, 1999, and Secretary's Advisory Committee on Genetic Testing

(SACGT), *A Public Consultation on Oversight of Genetic Tests,* Federal Register (Dec. 1, 1999) (64 FR 67273) <http://www4.od.nih.gov/oba/sacgt12-99.htm> (Mar. 6, 2001).

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37. There has been a rapid expansion in the number of Internet-based companies marketing and providing medical services, products and pharmaceuticals direct to the consumer. Given the ease of obtaining material for genetic analysis (e.g., a mouth swab or blood sample), consumers will be able to order testing on-line for a variety of genes or conditions, mail in a sample for analysis, and receive results in the privacy of their homes. Thus Canadians who want and can afford genetic testing will have it regardless of whether the service is publicly provided or prohibited by provincial or federal legislation.

38. A number of Internet health service providers (not specifically genetic testing services) have already taken steps towards self-regulation by adopting rather stringent codes of ethics and conduct—chief amongst their principles are protection of privacy, quality, authority and accuracy of information, and transparency of interests. See for example "e-Health Ethics Initiative, Draft Code" <www.ihealthcoalition.org/ethics/draftcode.html>, "HON Code of Conduct for medical and health Web sites" <www.hon.ch/HONcode/Conduct.html>, and "Health Internet Ethics: Ethical Principles for Offering Internet Health Services to Consumers" <www.hiethics.com/Principles/ index.asp>.

39. C.M. Flood, "The Structure and Dynamics of the Canadian Health Care System," in J. Downie and T. Caulfield (eds.), *Canadian Health Law and Policy* (Toronto: Butterworth, 1999), pp. 5-50.

40. The health care system, health promotion programs and research institutions promote the values of individual responsibility for health and the value of knowing one's genetic risk. Private marketing merely needs to build on these messages from credible sources.

41. See Kennedy, *op. cit*. and McClellan, *op. cit*.

42. Holtzman, 1999, *op. cit*.

43. See Hunter, *op. cit*. and Stephenson, *op. cit*.

44. T.A. Caulfield, "Gene Testing in the Biotech Century: Are Physicians Ready?" *Canadian Medical Association Journal,* Vol. 161 (1999), p. 1122; see also M.M. Burgess, C. Laberge and B.M. Knoppers, "Ethics for Clinicians VIII: Genetics," *Canadian Medical Association Journal*, Vol. 158, no. 10 (1998) p. 1309.

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