Personalized Medicine:

Altering the Role of Medical Necessity in Health System Policy

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Introduction

Personalized medicine and its various components including personal genomics and other medical ‘omics technologies, such as pharmacogenomics, have generated considerable excitement and have been the focus of significant public and private investment (e.g., CIHR, 2012; Fitzpatrick, 2012). Much of the optimism surrounding investments in these areas is related to their perceived potential for increasing understanding of disease and, ideally, for supporting the development of more effective and efficient treatments – thereby improving patient outcomes and optimizing the allocation of limited health system resources. However, these technologies also spur various policy challenges, not the least of which is how current medical systems can best manage them to optimize their advantages while protecting system sustainability and the interests of the public and individual patients.

In Canada, the concept of medical necessity, or medically required treatment, is central to how the publicly funded health care system is structured in terms of what health care services are or are not covered under provincial and territorial health insurance schemes. However, despite the centrality of these concepts to the health care system, they remain undefined by legislation or, for that matter, any formal health policy. More importantly, there is little or no guidance as to how the concepts are to be operationalized. As a result, the definition and policy value of the concepts has long been the subject of significant debate.

The personalized medicine ‘revolution’, if it ever occurs, may further test existing ambiguities and add to calls for greater clarity in how these terms are conceptualized and operationalized – all with a view to supporting transparent and well-reasoned policy decisions regarding access to medical services. In this paper, we reflect on interpretations of medical necessity under the Canada Health Act (CHA) and consider the impact personalized medicine may have on current and future approaches to the associated resource allocation decisions. This analysis will include an exploration of how these emerging technologies may impact patient access, conceptions of medical necessity and health care provider duties. These questions raise complex legal, equity and social values-based issues which will not be solved by this analysis, but which demand robust and informed debate. The purpose of this paper is to contribute to the on-going dialogue in this area and identify particular areas that require more focused consideration.

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**Context – Health Care in Canada**

Canadians are known in many circles for the value we place on our publicly funded health care system. Indeed, it has been suggested that universal medicare has played - and likely continues to play - an important role in shaping our national identity (Romanow, 2002). The central tenant underlying Canada’s health care system is “universal coverage for medically necessary health care services provided on the basis of need, rather than the ability to pay” (HC, 2014).

In Canada, health care is a matter of shared jurisdiction between the federal and provincial/territorial governments. In essence, each province and territory has its own health care system based on provincial/territorial health insurance plans. The CHA is the federal statute that outlines the conditions under which the federal government will provide funding, via the Canada Health Transfer, to the provinces for those publicly funded health care insurance systems. The CHA outlines a number of conditions provinces must meet in order to be eligible for their full transfer amount. In order for a province to receive its full share of the CHT, its health care insurance plan must be publicly administered, comprehensive, universal, portable and accessible (CHA s. 7). It is important to note that the CHA is essentially a funding arrangement; the only potential penalty for provinces who fail to meet its conditions relates to withholding or claw-back of funding – and enforcement is notoriously lax.

**The Role of Medical Necessity under the Canada Health Act**

As listed above, comprehensiveness is one of the key conditions for federal funding outlined by the CHA. The CHA states the following:

> In order to satisfy the criterion respecting comprehensiveness, the health care insurance plan of a province **must insure all insured health services** provided by hospitals, medical practitioners or dentists, and where the law of the province so permits, similar or additional services rendered by other health care practitioners.(s. 9, emphasis added)

Under the CHA, “insured health services” means “hospital services, physician services and surgical-dental services provided to insured persons…”(s. 2), each of which is defined using the concept of medical necessity. For example, “‘physician services’ means any **medically required** services rendered by medical practitioners” (s. 2, emphasis added); “‘hospital services’ means any of the following services provided to in-patients or out-patients at a hospital, if the services are **medically necessary** for the purpose of maintaining health, preventing disease or diagnosing or treating an injury, illness or disability, namely, …” (s.2, emphasis added), and “‘surgical-dental services’ means any **medically or dentally required** surgical-dental procedures performed by a dentist in a hospital, where a hospital is required for the proper performance of the procedures” (s. 2, emphasis added). Any health services falling into these rather amorphous categories are free at the point of service for patients – assuming the patient has coverage under the provincial health insurance plan.
However, despite their centrality to publicly funded healthcare in Canada, nowhere in the CHA are “medically necessary”, “medical necessity”, or “medically required” defined. These essential terms similarly remain undefined by provincial legislation. For example, the Saskatchewan Medical Care Insurance Act provides that “‘insured services’ means the services that are declared to be insured services pursuant to section 14 . . .” (s. 2(h)). Section 14 provides: “services that are medically required services provided in Saskatchewan by a physician are insured services” (s. 14(1)). Again, “medically required” is not defined in the legislation, nor is it defined by regulation.

While the terms seem expansive, in practice they do not encompass many essential healthcare services and procedures. Indeed, notwithstanding the fact that Canada’s health care system is commonly referred to as a ‘public system’, in reality only about 70% of health care services are funded by the public purse (i.e. from general tax revenues) (Marchildon, 2012 at 61). Many services that common sense might suggest are medically necessary, such as pharmaceuticals (provided outside of hospital) (Tamblyn, 2013), long-term care for the aged or severally disabled or rehabilitation services following stroke, are not covered – or are covered to varying degrees across the country. Accordingly, the boundaries of medical necessity clearly are not determined by clinical value or health care impact. The terms come from a particular historic context, when hospitals were often viewed as the focus of care. This anachronism makes the application of the concept of medical necessity even more challenging and confused in the context of the modern health care environment.

**Interpreting Medical Necessity**

So what does medically necessary/medically required really mean? The concept of medical necessity holds a pivotal role in the Canadian health care system, and yet challenges associated with its definition and application have long been recognized (Charles et al., 1997; Hurley et al., 1997; Greiner, 2002). Indeed, one of the authors initially started considering these issues almost 20 years ago (Caulfield, 1996) and many have suggested it may be impossible (and perhaps undesirable) to arrive at any kind of precise definition – perhaps for good reason (Reis, 2003). Charles et al. (1997) proposed:

> attempts to achieve consensus on the meaning of medical necessity are likely to fail...Consensus regarding a definition of medical necessity is difficult to achieve precisely because its value to stakeholders lies in the ease with which it can be construed to serve multiple policy and ideological ends. For this reason, new meanings are likely to emerge over time, carrying ever new policy agendas into the health care arena. (Charles et al., 1997 at 386)

Various scholars have discussed and reflected on different approaches to the question of how medical necessity currently is and should be determined in the context of publicly funded health care in Canada. For example, Fierlbeck suggests that from a practical perspective, services
determined to be medically necessary are those that a province has decided it can afford to fund (Fierlbeck, 2011 at 89). Charles et al. reflect on four meanings of medical necessity, including “what doctors and hospitals do; the maximum we can afford; what is scientifically justified; what is consistently publicly funded across provinces” (1997 at 370). Flood, Stable and Tuohy note the role negotiations between provincial ministries of health and provincial medical associations regarding physician compensation have in determining which health care services are considered medically necessary and therefore included in the medicare “basket” (2006 at 6). In day-to-day clinical practice, physicians have tremendous power to determine what is and is not medically necessary for a particular patient by deciding what tests will be ordered and what treatment provided.

Calls for clarification of the meaning of medical necessity, often made in the context of conversations surrounding health system reform, and proposals for alternate decision-making frameworks to assist in the work of defining what is and is not included in the publicly funded medicare system (such as, for example, the use of quality of care concepts), are also nothing new (Walters & Morgan, 1995; Hurley et al., 1997). Research has identified areas of consensus as well as areas where more work needs to be done (Deber & Gamble, 2007). Key characteristics of a useful decision-making model for defining medical necessity are suggested to include fairness from the perspective of the public and clinicians, practicality and affordability (Emery & Kneebone, 2013, citing Sabin & Daniels, 1994) – all of which may conceivably be challenged in the context of personalized medicine.

Canada is not alone in our struggles to define what we mean by medical necessity. The introduction of the Patient Protection and Affordable Care Act (ACA) in the United States is bringing some of these same questions (i.e., What is the meaning of “health”? What is “essential healthcare”? What is “medical necessity”?) to the foreground there (Hill, 2012; Skinner, 2013). Interestingly, although “medical necessity” plays a similar gate-keeping function under the ACA, it also remains undefined by the legislation (Skinner, 2013). One of the reasons a lack of definitional clarity is potentially problematic – although perhaps understandable, from a practical perspective – is that it can serve to obscure transparent decision-making in terms of access to publicly funded health care services and impede public debate about attendant resource allocation decisions.

The emergence of new biomedical technologies that seek to change (and improve) the way medicine is practiced can be expected to have implications for how the concept of medical necessity is defined and its boundaries framed. Indeed, when viewed optimistically, if genomically-informed applications of personalized medicine develop as promised, they could serve as the foundation of a useful clinical decision-making support tool. In other words, they could, presumably, add clarity by providing an evidence-based decision-making framework for when a particular treatment will be deemed to be medically necessary for a particular patient. Alternatively, the push toward personalized medicine could simply further cloud an already
confused area by adding another layer of considerations – what are the genetic predispositions of the patient? – to the consideration of what should be deemed medically necessary.

If nothing else, the potentiality of these technologies and the broad aspirations that surround them provide an ideal opportunity to re-examine these long-standing health policy tensions through a new lens. This re-examination may ultimately add fresh insight and innovative proposals regarding how to address and resolve existing challenges surrounding conceptions of medical necessity and access to health services.

**Human Genomics, Personalized Medicine & other ‘Omics Technologies**

Developments in personalized medicine – composed of human genomics applications, including ‘omics technologies such as pharmacogenomics, proteomics and metabolomics, are excellent examples of transformative biomedical advances that may someday have a significant impact on the nature and quality of healthcare services (Green et al., 2011; Mirnezami et al., 2012). In theory, personalized medicine will allow health care providers to customize health care services in accordance with an individual’s unique genetic make-up (Chan & Ginsburg, 2011). Again in theory, its application will extend along with care spectrum from prevention to diagnosis and treatment (Tremblay & Hamet, 2013; Dancey, 2012). Personalized medicine’s potential in the context of drug tailoring is optimistically reflected in the following explanation:

A personalized medicine approach to providing health services involves integrating genomics technologies and advances with clinical and family histories in order to more coherently tailor therapeutics to individual patients. A key component of personalized medicine is translating the science of pharmacogenomics into clinical practice. Pharmacogenomics is increasingly seen as holding the potential for tailoring prescriptions to defined sub-populations and possibly individuals, based upon genetic make-up, and therefore, ultimately improving the effectiveness and safety of drugs. (Issa, 2007 at 53)

It is hoped that using an individual’s genetic information to tailor treatment to his or her specific genetic profile (or, for example, to that of his/her cancer) will optimize patient care by more accurately identifying risks as well as by resulting in fewer adverse reactions to drugs, better treatment outcomes (i.e. facilitating more effective, efficient and targeted interventions) and less exposure to unnecessary toxicity (e.g., chemotherapy). For example, gene expression profiling tests (the Oncotype DX test) purportedly predict the likelihood of some breast cancer recurrence as well as likely benefit from chemotherapy, and have been the subject of consideration and debate in various countries, including Canada (Priest, 2009). Despite remaining scientific and clinical questions about the utility of these tests, research suggests patients place considerable weight on their results when it comes to decision-making regarding whether or not to pursue chemotherapy (Bombard et al., 2014b).
It is also hoped that by extension, personalized medicine will save healthcare systems money “by administering treatments only to those most likely to benefit” (McClellan et al., 2013 at 143). For example, research recent suggests that genetically guided personalised medicine can inform a decision-making model to assist physicians with selecting the most effective and economical drugs to prevent blood clots in patients receiving coronary stents (Kazi et al., 2014). According to the lead author of the study, “What we have shown is that individualizing care based on genotype may in fact be very cost-effective in some settings, because it allows us to target the use of newer, more expensive drugs to the patients who are most likely to benefit from them” (Farley, 2014).

Notwithstanding their potential appeal to patients and health care system operators alike, it remains far from clear whether and to what degree genomic technologies will ultimately fulfill the many expectations associated with their development (e.g., Lenfant, 2013). There are both practical limitations and policy challenges facing effective clinical uptake of personalized medicine (Hamburg & Collins, 2010). For example, risk assessment approaches are increasingly common in relation to breast cancer risk prediction but are far from perfect, and remaining technical limitations lead to questions about the potential for these tools to inappropriately limit access (McClellan et al., 2013). In another instance of results failing to meet expectations, recent research has called into question the effectiveness of genotype-guided dosing of Warfarin – arguably the former star and best example of how personalized medicine will work in practice (Kimmel et al., 2013).

Limitations in information technology and the need for “high-quality, unified systematic databases” are another potential factor pushing against the widespread adoption of personalized medicine in health care systems (Issa, 2007 at 55). Further, current limitations in the knowledge and expertise of front-line physicians, and potential constraints imposed by intellectual property and funding regimes are other challenges to effective integration of personalized medicine advances in clinical practice (Chan & Ginsburg, 2011; Bonter et al., 2011). On the whole, it appears that we remain a long way from routinely using genomics to personalize and revolutionize health care. Indeed, there are reasons to believe that this approach may never provide the promised benefits – either in the context of clinical benefits or economic outcomes (Langenberg, et al., 2014).

Quite apart from limits on the technical side are policy questions surrounding implications associated with these tools. Various issues associated with the rise of ‘low-cost’ whole genome sequencing have been identified (Caulfield et al., 2013; McGuire & Burke, 2008), and whether using personal genetic information to inform health care decision-making could amount to discrimination, by denying access to individuals seeking health care on non-medical grounds, remains an open question (McClellan et al., 2013). Indeed, if and when individuals’ genetic information becomes a routine part of clinical decision-making, with the potential result of limiting access to particular treatments, the associated implications for access, rationing and resource allocation decisions could be considerable.
Implications for Access, Rationing and Resource Allocation

As already noted above, despite the value Canadian society places on the social guarantee that medically necessary services will be provided on equal terms and funded by the state, in reality many medical needs often go unmet (e.g., when an individual must pay for much-needed pharmaceuticals out-of-pocket) (Greiner, 2002). Given that this is not an era of unlimited public resources – far from it - it cannot be disputed or avoided that rationing decisions play a major role in the allocation of resources within our health care system. These decisions occur at various levels within the system, from government (macro) policy levels to, to health region decisions (meso) to physician decisions at the bedside (micro) – and each is associated with its own implications.

As noted above, one of the often touted prospective benefits of personalized medicine is its potential to inform decision making by providing better information regarding what treatment is (or is not) likely to be effective for a particular patient – and, by extension, what treatment is or is not medically necessary for that patient. The benefits of clearer, more predictable and transparent decision-making processes regarding funded access to treatments have been discussed in other contexts (de Lamos 2006). Although proponents of personalized medicine may argue that it could, theoretically, contribute to such frameworks, it is also possible (and arguably likely) that personalized medicine will merely increase the need for evidence-based, logical and transparent decision-making processes, particularly if the result is reduced access to desired treatment.

Indeed, in addition to ideally resulting in better patient outcomes, genomically-informed tailoring of treatments will – at least in theory – limit the potential pool of individuals for whom a particular treatment is available, thereby saving the healthcare system money and acting, in effect, as a rationing tool. Indeed, that is one of the often-stated benefits of personalized medicine. In other words, imagine an individual diagnosed with XX. Today, that individual would be treated with therapy YY. In an age of personalized medicine, genetic information from the patient suggests that he/she is not in fact an ideal candidate for YY because of a low likelihood of responding effectively to the therapy. As such, under new practice standards, the individual is not entitled to public funding for YY (it is not deemed “medically necessary”). Unfortunately, there is not a better option for this patient. If there is not, genetic testing will in effect have blocked access to YY, which may still present the patient with his/her best chance at recovery, even if the odds of success may not be as strong as the system would like.

The potential for the concept of medical necessity to be used as a cost-cutting strategy has been identified in the context of the ACA in the United States (Skinner, 2013). It would likely be wise for Canadian policy makers to be alive to the possibility of similar concerns being raised here. Research by Bombard and colleagues with a citizen’s panel confirms the public is concerned about the possibility that personalized medicine may limit patient access to treatments if it is used to stratify patients (Bombard et al. 2013). This research further pointed to the potential for
public demand for access to treatment, even where genetic test results may point to questionable utility of that treatment (Bombard et al., 2013). Other research involving early-stage breast cancer patients similarly points to concerns about access to a particular genetic test and the role physicians play as gatekeepers (Bombard et al. 2014).

Sweatman and Woollard (2002) reflect on both system level and bedside level categories of rationing decisions and on the difficulty patients have in challenging resource allocation decisions via the courts – which is one of few avenues open to patients who to seek access to treatment that has been denied. It is beyond the scope of this particular paper to delve into rationing debates and priority setting, or the nature and extent of rights-based claims to healthcare services made under the *Canadian Charter of Rights and Freedoms* in a substantive way (for example, see Jackman, 2010; Reis, 2003). It is sufficient for our purposes to note the potential for an increase in such claims where individuals are denied access to particular health services by virtue of their genetic profile. The strength and likely success of such claims is debatable, but it is not unreasonable to anticipate that as we move into a more personalized era of medicine, at least some of these decisions may find their way before the courts. Even without the added complexity of genomically-informed decision-making, it has been suggested that “Governments can expect more litigation in the future and should be prepared to defend their resource allocation decisions by being transparent about limitations on public funding and the principles that guide their decision-making” (Flood, Stabile & Tuohy, 2008 at ii).

No one suggests making access or resource allocations decisions is easy, particularly in the face of often competing priorities. Indeed, the challenges associated with making coverage decisions for new and emerging health technologies have received increasing attention in recent years. Existing resource allocation frameworks tend to vary across Canada depending on the structures in place in a particular province or territory, and front-line practitioners – such as genetic providers in the context of predictive genetic testing in Canada - often have a major role to play (Adair et al., 2009). Academics and practitioners alike have started to give considerable attention to questions about how emerging technologies can and should be assessed and measured – including what decision-making frameworks should look like (e.g., Stafinski et al., 2011) and what role ethical, legal and social issues should take in the analysis (Potter et al., 2008).

“Evidence-informed” decision-making is viewed by many as an important and, ideally, core element of health technology decision-making frameworks (Stafinski et al, 2011) and yet how useful it will be in the context of ‘personalized medicine’- or how useful personalized medicine will be in providing the evidentiary foundation - remains somewhat of an open question. It may depend to a certain extent on how we define and weigh different forms of “evidence”. As Emery and Kneebone suggest:

> Defining medical necessity as contingent on the existence of scientific evidence of service/product effectiveness provides a useful criterion for delisting ineffective or cost-ineffective services, offers an opportunity to contain costs, and
allows for additions of new services. Clinical evidence that the service or product produces health benefits should direct clinical decisions to eliminate unnecessary services and, hence, unnecessary public expenditures. (2013 at 10)

Whether or not personalized medicine will produce the kind of robust evidence contemplated remains to be seen. Others have also raised ethical questions surrounding the application of personalized medicine to limit patient access to health services, given the considerable use of public funds that supported their development (McClellan et al. 2013), among other policy issues (Bombard et al., 2013b). In other words, even if the science develops to a point where we can use it to make resource allocation decisions, will that be considered an appropriate application of the technology?

**Impact on Physicians’ Obligations**

The growing use of personalized medicine and its various components will undoubtedly have an impact on physicians’ practices. For example, research involving practicing oncologists regarding their role as gate keeper to gene expression profiling tests revealed variation in when different doctors would order the (very expensive) tests as well as associated negative impacts on the physician-patient relationship (Bombard et al. 2014).

At minimum, these technologies will be yet another tool to support clinical decision-making, along with information such as family history and lifestyle factors. It was recently predicted that “as personalized medicine enters mainstream medical practice, physicians and other healthcare providers will have to administer or give advice on the application of growing numbers of genomic tests, pharmacogenomically-guided therapies and treatment decisions based on predictive evidence and risk estimation” (Tremblay & Hamet, 2013 at S4). On the other end of the spectrum, as outlined above, it may someday form the basis of a decision-making framework that will (at least in part) dictate care decisions, dependent on genetically-informed factors.

Whenever aspects of treatment decisions are taken out of the hands of individual physicians, it can be expected there will be pushback from the profession (Collier, 2012). As Emery and Kneebone note (2013):

> any approach to defining medically necessary services other than by the clinical judgement of a physician treating a patient may be infeasible to implement. What is more, in Canada we have no way of determining what a physician did to a patient, since we only know that the physician billed for a contact with the patient. Whatever restrictions might be placed on which procedures are considered medically necessary, and so billable to the public player, clinicians can always find ways around those restrictions. (at 11)

The above reality may be particularly salient in the case of a personalized medicine-based approach that limits patient access to particular health services based on certain genetic factors,
given the associated potential for areas of conflict/tension to emerge for physicians (Caulfield & Zarzeczny, 2014). For example, what if the application of such a decision-making tool/framework meant, in the case of an individual patient, that his/her profile suggests he/she would not qualify for a treatment that the physician believed to be in the patient’s best interests? How would/should the physician reconcile his/her obligation to act in the patient’s best interests with the administrative constraints on his/her decision-making?

Research examining the impact of drug funding policies on oncology practice confirms that practicing oncologists in Canada generally did not accept policy decisions that limited access to cancer drugs they believed to be of benefit to their patients (Berry et al., 2007). Physicians participating in this study expressed concern that limits imposed by funding guidelines removed essential flexibility for them to determine what was in the best interests of a particular patient, and some even reported “gaming” the system or “lying” on paperwork to ensure a patient would meet the qualifying criteria for public funding of the drug (Berry et al., 2007). Indeed, many of the participants in this research project expressed their willingness to take whatever steps were necessary to help their patients get access to funding for drug therapies the doctors believed would be of benefit (Berry et al., 2007). Could we expect to see similar reactions and behaviour to limits imposed in relation to patient’s genetic information? If so, potential cost-savings and system efficiencies may effectively be thwarted by competing priorities.

It has been suggested “that the more strict the application of guidelines for patient treatment, the greater the need for an appeals process for patients and physicians who disagree with the guideline for a particular patient” (Emery & Kneebone, 2013 at 12, citing Lomas, 1990). Indeed, should the much anticipated success of personalized medicine finally be the impetus for a new approach to defining medically necessary health services in Canada, perhaps based on a genetically-informed decision-making framework (e.g., Kazi et al, 2014), it would be both appropriate and prudent for any such framework to be associated with a transparent and accessible review and appeals process. Given the potential for such a framework to shift the current status quo wherein physicians have considerable autonomy, the maintenance of some physician discretion and room for exceptions would also likely aid in garnering the kind of public and political support necessary for such a change.

**Conclusion**

Human genomics, personalized medicine, and other ‘omics technologies are widely considered to have significant potential to improve and refine treatment options and patient outcomes for a variety of conditions. They may also support more efficient use of health care resources and provide a foundation for a new evidence-based model of decision-making under the umbrella of medical necessity. However, in so doing, they also have the potential to restrict patient access to treatment, impact conceptions of medical necessity and challenge the fulfilment health care providers’ obligations to their patients. They further highlight long-standing tensions and
ambiguities surrounding how the concept of medical necessity is conceptualized and operationalized within the Canadian health care system.

None of these issues are insurmountable, nor should they impede continued exploration of the possibilities offered by these emerging technologies. They do however raise complex and multi-layered health policy issues. Acknowledging and remaining alive to these potential issues as the technology develops will ideally facilitate more effective integration of potentially valuable technologies into our health care system, once they are ready (McClellan et al., 2013). It is also possible that the introduction of personalized medicine, genomics and other ‘omics technologies may help provide a framework for determining how and where boundaries of medically required treatment will be drawn on a go-forward basis in the larger context of health system reform, however imperfect such a decision may be destined to be (Emery and Kneebone, 2013). Indeed, maximizing the potential scientific, clinical and economic benefits of personalized medicine can only be done if the associated health policy issues are appropriately addressed.

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