The role of medical innovation in fuelling the growth in private and public spending in healthcare is a contentious issue. It is often being cast in two different lights – as a major cost driver that needs to be more stringently regulated and as a solution to reducing costs. While both of these positions may be valid, one key element is missing from the debate: how financial incentives and social dynamics have driven the design of medical innovations in the past decades and led to the present cost-control debate. This essay argues that although most industrialized countries are now looking at cost-effectiveness analyses as the best way to make rational choices between various medical technologies, such tools do not address the problem at its root. Solving healthcare financial problems requires creating innovations that embody a more thoughtful set of values and this may be achieved through new design strategies and business models.

Willingness and capacity to pay have led to the design of unsustainable medical technologies

According to the Healthcare Marketplace Project, healthcare spending in the U.S. has grown at an annual rate of 9.8% since 1970, about 2.5 percentage points faster than the economy and is estimated to reach $4 trillion in 2015.

As a share of the economy, healthcare has more than doubled over the past 35 years, rising from 7.2% of GDP in 1970 to 16.0% of GDP in 2005, and is projected to be 20% of GDP in 2015.

www.kff.org/insurance/snapshot/chcm030807oth.cfm

Most experts agree that medical technology remains a significant cost driver [5]; some argue that new medical technology may account for approximately half or more
of long-term spending growth (www.kff.org/insurance/snapshot/chcm030807oth.cfm). Such statistics beg the question: Why has healthcare spending consistently risen more rapidly than spending on other goods and services? There is something peculiar about “consumption” in healthcare: while both physicians and patients are the “consumers,” it is third-party payers who generally incur the costs. Hence, during the 1980s and 90s in industrialized countries, a seemingly ever-expanding willingness to pay accompanied by a steadily growing capacity to pay, either through state-run healthcare programs or through private insurers, contributed to the inflationist dynamics associated with medical technologies. Supply and demand fuelled each other [6, 7, 8]. So although a given medical technology may reduce healthcare costs in a given area, the net overall effect is that costs rise continually because innovation always creates new opportunities, transforms medical practices and increases patient expectations [9; see Box 1].

A medical innovation increases costs by:

1) offering new treatments for previously untreatable conditions (for example, terminal conditions such as diabetes, end-stage renal disease and AIDS, for acute conditions such as coronary artery disease, or for conditions that transcend the boundaries of medicine such as substance abuse);

2) providing new diagnostic and therapeutic procedures that address secondary diseases (for example, erythropoietin to treat anemia in dialysis patients);

3) facilitating a broadening of the indications for a treatment to a larger patient population (for example, less invasive procedures, drugs used for prevention); and

4) generating incremental improvements in existing procedures.

Box 1. How medical innovations increase costs (Source: [8])

Today, third-party payers are sending a different message to the medical industry: In order to keep costs under control, only cost-effective innovations will be reimbursed [1]. While this approach makes sense intuitively, it will not solve the financial problems. Telling manufacturers to produce cost-effective technologies is not helpful if one does not realign the incentives and values that have underpinned the design of medical innovations. A more fruitful approach would be to look at how CEOs of medical equipment companies and their engineers, designers and medical advisers could create a new “breed” of medical innovations, one that is capable of meeting the challenges of modern healthcare systems while fulfilling pressing healthcare needs more wisely [9]. This requires examining what kinds of values have driven medical innovation so far [10, 11].

For the purpose of this essay, values are understood as the tacit and explicit assumptions by which we appraise actions. While some ethical frameworks make distinctions between terminal values (goals or objectives), procedural values (means and process for achieving the goal) and substantive values (criteria justifying decisions and actions for goal achievement) [12], this essay is more modest in that it seeks to bring forward the importance of values in the shaping of technological change in medicine. For an example of an axiological framework that articulates essential and instrumental values in order to guide healthcare reform see [13].

Three Stories About Values and Medical Innovations

The technologies we create and the values societies pursue reinforce and influence each other. Sociologists who study innovation call this phenomenon the “co-constitution of technology and society” [14]. Within this perspective, I will examine premature and low birth weight babies, stem cell research, and in vitro fertilization (IVF).

Premature and low birth weight babies: visible short-term miracles, hidden long-term struggles

New drugs and surgical procedures combined with new diagnostic tools now enable physicians to save or prolong the lives of premature and low birth weight babies (Premature babies are those born before 37 weeks’ gestation; babies born before 28 weeks’ gestation are called “extremely premature babies.” Low birth weight babies weigh less than 2,500 grams; 70% of these babies are born premature [15]). Such medical interventions did not exist 50 years ago. Socially, we have moved from a culture in which perinatal death was something that could and did happen, to a culture in which it is to be prevented at almost any cost. There are, of course, good reasons to celebrate this change in culture. The survival of a premature baby is bliss at the onset. But what about the parents whose lives are disrupted by raising children with long-term and complex needs that require an ongoing array of social and healthcare services. Only 20% of extremely premature babies do not have health problems later in life; the other 80% face problems like vision and/or hearing impairment, cognitive and behavioral problems, learning disabilities and cerebral palsy [16]. So while current neonatal technologies generate immediate and often dramatic outcomes, they also create a new set of health and social needs, contributing to a technology-driven inflationist dynamic. Thus, by concentrating our efforts on the design of technologies that enable physicians save lives, we give priority to “heroic” medical interventions, while not giving an equal attention to the design of tools and services that could empower parents in taking care of these babies.

Stem cell research: the sacredness of life meets the dream of longevity and eternal youth

Initially proposed as holding the key to a cure for neurodegenerative diseases that strike older people
diseases like Alzheimer’s or Parkinson’s, stem cell research has now become entwined in religious argument about the moral status of stem cells themselves [17]. The fact that these cells can be collected from “spare” embryos generated through IVF and from miscarried or aborted foetuses raises some challenging questions when it comes to informed consent: Who is the “donor” of the stem cells? Who benefits from stem cell research? Despite such conundrums, scientific research has continued, as scientists try to understand how an undifferentiated cell “chooses” to become a cell of a particular type in response to certain biochemical signals. This knowledge is necessary if researchers are to cultivate stem cells in the lab and predict what they will do when transplanted into a human body.

According to Pfeffer, many scientists would rather obtain stem cells from the tissue of a fetus resulting from an elective abortion than from a miscarried fetus (www.hinnovic.org/women-fetuses-and-stem-cell-science-a-pro-choice-dilemma/#more-443). This is because stem cells derived in this way are likely to be healthier and “work better.” Nevertheless, a fetus, whether aborted or miscarried, can hardly be considered “like” other types of human body tissue. Even when undesired, the fetus possesses the potential of life. A number of women who abort or miscarry may prefer their fetuses being treated with dignity (that is, cremated or buried) [18, 19]. While women who receive IVF treatments may like the idea of having their embryos used for research on infertility, scientists cannot always guarantee that they will be used for this purpose. In practice, pressure by both opponents and proponents keeps growing (in fact, abortion techniques that could better preserve the “quality” of the fetus are now being investigated). Central to the public debate are appeals to “hope” by the proponents of stem cell research. According to Kitzinger, such appeals “serve as a moral imperative to action” and are used to “make criticism of embryo research appear morally reprehensible” (www.hinnovic.org/framing-the-future-of-embryo-stem-cell-research-potential-and-problems/langswitch_lang/fr/#more-441). Within the context of an aging population, proponents are framing the potential future benefits of stem cell research in a way that promotes certain values – longevity and hope for a cure – and downplays others – dignity and the sacredness of life [17].

**IVF: is the desire to control one’s reproductive choices compatible with the many uncertainties of parenthood?**

While IVF has now been around for several decades, many policy and social issues around this medical technology remain unresolved [20]. Despite the high costs (about $12,000/cycle), its efficacy remains low (about 30% of cycles lead to a live birth). It is also becoming apparent that ovarian stimulation may have negative effects [21]. And of course there are significant risks associated with multiple pregnancies, a common outcome when multiple embryos are implanted. Yet not all IVF specialists seem genuinely preoccupied by ethical issues, perhaps because most of them work in private clinics and have to defend their niche in a competitive market. Some IVF specialists say that women are now asking for their embryos to be extracted when they are in their reproductive prime so they can use them later, once their career is established. Some also contend that couples should be able to choose the sex of their offspring through pre-implantation genetic diagnosis techniques, simply because it is possible [22].

The parallel development of prenatal tests has contributed to creating the illusion that having a perfectly healthy child is technically feasible, despite the fact that numerous diseases and conditions cannot be detected. Such tests also reinforce the idea that parents should actively avoid fetuses with certain kinds of physical and cognitive attributes (Down’s syndrome, for instance; see [23]). IVF and other closely related technologies have thus created a strange market place in which couples wanting to have a baby are faced with new moral choices. While capitalizing on the profound human desire of having a family of one’s own, IVF is framed as a tool that increases women’s reproductive choices. However, this putative control over reproductive processes is at odd not only with the uncertainty of IVF itself, but also with the lifelong uncertainties associated with parenthood.

**Rethinking the Values that Underpin Medical Innovations**

The three medical advances discussed above embody values that are significant to industrial societies dominated by the values of productivity, control, choice and individual autonomy [13, 24]. The desire to know more about diseases, to cultivate hope for future cures, and to predict future health states is powerful. And in a very concrete way, such values are reinforced by the kinds of medical research we support through public investments in R&D and health research, and by the kinds of technology we design and introduce into healthcare systems through both private and public investment [2, 25, 26].

**Values that are worth paying for?**

The three examples suggest that some medical advances make certain values appear less relevant and move us away from exploring other solutions, including tackling the most pressing problems that industrialized countries are facing (such as wide variations in access to health care and the growing prevalence of chronic care diseases). For example, research shows that prematurity and low birth weights are associated not just with biological and clinical factors, but also with lower socioeconomic status, physically demanding jobs, exposure to toxic environments, poor access to prenatal care (quality and quantity) and acute or chronic stressful events (death of a loved one, abusive relationship and unsafe neighborhood) [16]. Tackling these broader determinants of health is possible through the design of affordable primary care packages, integrated health promotion and prevention approaches, and healthy public policies.

The values that are left in the dark in the case of stem cell research relate, among other things, to the way priorities are set among competing R&D avenues. According to the EuroStemCell consortium (www.eurostemcell.org), stem
cell research can pursue different goals, including: modeling disease processes in the laboratory as a way of strengthening basic research; providing a resource to test new medical treatments and reduce the need for animal testing; and developing techniques to replace damaged cells, enabling doctors to effectively treat burn victims and restore the blood system in leukemia patients. These different R&D avenues necessitate varying levels of financial and human resources and will lead to applications that may be more or less desirable. The priorities being set among various potential applications in stem cell research has a major impact on healthcare systems [10]. What do we know about how these decisions are being made? Whose interests are driving the process?

An examination of IVF suggests that when an innovation is left mostly to the private sector, it becomes highly malleable to the values that clinicians ascribe to their clients and to the desires of individuals who have the capacity to pay [27]. Furthermore, some of the values that are conducive to a positive experience of parenthood have been left aside. For instance, the balancing of work and family responsibilities as well as the ability to be flexible and adapt to change are central features in raising a family. Other ethical issues are also becoming particularly obvious as the estimated one million children who were conceived through donor insemination and IVF are now seeking information on their biological roots. This is changing the way sperm “donors” (and their families) perceive the notion of kinship – morally, culturally and legally (see CBC’s IDEAS radio series: www.cbc.ca/ideas/features/brave-new-family/index.html).

Each of these examples tells an interesting story about the way in which the medical technologies that we create not only reflect our society’s changing values and aspirations, but also shape our healthcare system. The healthcare financial problem is thus not just a matter of rising costs that need to be controlled; it is the direction in which medical innovation is pushing our society (and vice versa) that should be reconsidered. Shouldn’t innovation rather embody values likely to transform positively healthcare services, patients’ lives and the cultural and political environments in which we live? In essence, values are at the root of the healthcare cost-control debate, and overcoming this stumbling block will require designing more thoughtful medical innovations [9].

**Designing the Next Generation of Medical Innovations**

Design is a creative process that involves problem-solving activities that pay attention to the needs and abilities of users (for example, patients, patients’ families, physicians, nurses and/or technicians) and to the context of use (for example, home care, primary care and/or hospitals) [28, 29]. The ability to generate a large range of scenarios and select those that are the most suitable and promising is key. Therefore, who participates in the creative process and the values, knowledge and experience of healthcare they bring to the table are extremely important [31-33]. Furthermore, considering constraints is as important as envisioning new possibilities. From a healthcare system perspective, “better” innovations are innovations that are easy to use because they require less specialized personnel and less technologically sophisticated environments. And innovations that are financially and organizationally sustainable, accessible, and relevant with respect to the broader array of existing and needed healthcare interventions [4].

**In search of new business models for the biomedical equipment industry**

Consistent with this approach are innovations that increase the autonomy of users by reducing their dependence on specialised expertise. For example, Joshua Silver has designed a pair of eyeglasses made of plastic with liquid-filled lenses. Users do not have to see an ophthalmologist; they simply adjust the liquid to change the curvature of the lens (www.hinnovic.org/adaptive-eyeglasses-an-interview-with-josh-silver/). These glasses could improve the vision of millions of people around the world at a minimum cost ($10 per pair). In industrialized countries, a similar design approach could lead to develop tools that increase the autonomy of chronic care patients.

A major challenge with the design process in the healthcare sector is the for-profit business model: it adds a plethora of intellectual property, manufacturing and marketing constraints [2, 34]. This has led to some very inspiring initiatives to develop alternative, socially responsible business models. The medical devices industry would be wise to examine how these new models could lead to the design of innovations that foster equity, facilitate the empowerment of vulnerable groups and communities, and lead to sustainable healthcare systems.

An example of such an alternative model is the assistive technologies for people with physical and cognitive handicaps that are being developed by community-based organizations. According to Silva, we especially need to move beyond the traditional for-profit business models in this area because of the specificity of users’ needs and small sales volumes (www.hinnovic.org/moving-beyond-market-dysfunctions-towards-community-based-at-development/). The goal of the Open Prosthetics Project, which was created by a robotics engineer who lost an arm in Iraq, is to make prostheses more affordable. They publish design, specification and technical drawings and invite others to copy, modify, build upon and prototype any of their published ideas (www.openprosthetics.org). Better design in healthcare may also mean shifting the attention away from the objects themselves to thinking about the broader environments, in which people live, work and interact [33]. For instance, the mission of the Oxford Health Alliance (www.oxha.org) is to prevent and reduce the global impact of chronic diseases including cancer, heart and lung disease, and diabetes. Their efforts centre on tackling three risk factors – tobacco use, physical inactivity and poor diet. This group provides guidance to architects, urban planners and transport engineers so they “can create environments in which healthy choices are easy choices.” It also targets the workplace in an effort to reduce the clinical, psychological, economic and social impacts of these chronic diseases on employees and their families.
There are also a number of international initiatives that are actively shaping the design of socially responsible innovations. The Institute for OneWorld Health is a nonprofit pharmaceutical company that collaborates with industry and researchers, secures donated intellectual property and builds on the scientific and manufacturing capacity of the developing countries in order to create drugs that respond to their specific needs (www.oneworldhealth.org). Emphasizing innovations that capitalize on social change, ChangeMakers is a global online “open source” community that organizes competitions to come up with the best ideas in the fields of education, health and the environment (www.changemakers.net). The organization’s website presents a variety of inspiring projects, including the Aravind Eye Care System, an Indian initiative whose mission is to eliminate blindness by creating a self-sustaining healthcare system through a combination of service delivery based on ability to pay and local training programs (www.ted.com/talks/lang/eng/thulasiraj_ravilla_how_low_co st_eye_care_can_be_world_class.html).

Conclusion
It would be easy to dismiss such new approaches to design medical innovations and new business models as appropriate only for developing nations. But when 60% of personal bankruptcies in the United States are due to individuals not being able to pay their hospital bills – even though three quarters of these people actually have some form of insurance – radical solutions are needed. These may include lifting patent rights that currently impede the manufacturing of needed innovations, creating financial incentives for companies who respond to the most pressing healthcare needs, or adopting business models that lead to the development of sustainable innovations [9]. Clearly controlling costs in healthcare requires transforming the biomedical devices industry itself. As it stands now, cost-effectiveness analyses will only help choose between innovations that are likely to prove unsustainable over the long run.

The transformations suggested in this paper are possible because industrialised countries have access to a critical mass of the world’s best brains in public health, health economics, business and community-based change. And society is ready for new affordable, responsible and wise innovations – just witness the initiatives mentioned above. It is time to capitalize on our society’s creativity and intelligence, to use these resources to set design priorities that tackle significant health and social problems at their roots. In the current healthcare cost-control debate, we need to recognize that the solution is not just to spend less on certain kinds of medical technology and more on others; the solution is to design innovations that are better from a health care system perspective.

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