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HTA Initiative #23 ● December 2005

The triangle of enhancement medicine, disabled people, and the concept of health: a new challenge for HTA, health research, and health policy

Gregor Wolbring

AHFMR

ALBERTA HERITAGE FOUNDATION
FOR MEDICAL RESEARCH

HTA Initiative #23
The triangle of enhancement medicine, disabled people, and the concept of health: a new challenge for HTA, health research, and health policy

Prepared by:
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PREFACE

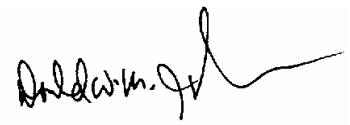
The emergence of the individual fields and now the convergence of nanotechnology, biotechnology, information technology and cognitive sciences raise new opportunities and challenges for humanity and specifically for health technology assessment, health services research and health care policy making. At one level the paper addresses the topics of enhancement medicine, disabled people and the concept of health and their interconnection. Like all the publications in the Health Technology Initiatives Series – a critical look is cast toward what is emerging and what some of the concerns and strategic responses might be.

This exploratory primer was undertaken with the view of beginning to unpack and interrogate the potential issues and problems that will be emerging in our society in the coming years. The promising opportunities for humanity arising from the science and technology on the one hand are immense but our ability to respond in the policy environments to emerging issues in a timely fashion which are socially just and fair is often reactive. This exploratory study is an attempt to identify the areas where issues may arise and to suggest some strategies to begin addressing them in a proactive way.

The author of this paper is keen to engage in a discourse with the broader community about the relevance and usefulness of the ideas presented here. Dr. Wolbring has established a discussion forum where people may choose to discuss the report and the many issues it highlights. To join the discussion group please visit the URL at:

http://health.groups.yahoo.com/group/htapaper/join

This is a new approach for encouraging discussion within the heath technology assessment and other affected communities with the objective of increasing the knowledge and understanding of this exciting and new field of endeavor. As with all of our products I would be happy to receive any feedback in respect to this paper.



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INTRODUCTION

"No other priority [health] speaks so directly to the decisions we have made as a country about how we will live as a society".[1] Health care is Canadians' number one priority.[2] Many Canadian reports,[3-15] international charters,[16-21] and other international documents,[22-34] identify problems and suggest solutions and actions.

Evaluating advances in science and technology applicable to health, health care, health technology, health systems, and health research is of imminent importance within the Canadian and global context, with the wish for an effective, inclusive, accessible, and innovative health and health care system. Managing new technologies and treatments is critical to ensure that the health system can deal with the evolving needs of Canadians.[14]

Solutions follow perceptions and perceptions are changed by solutions.

Science and technology usage, research, and development are human activities that are often articulated in terms of human betterment in general or in terms of better and/or more sustainable health care, better health, more wellness, more efficient health systems, and health care delivery in particular.

However, intentions, purposes, and actions that shape direction, advances, and policies regarding science and technology usage, research, and development in general and regarding health-focused science and technology usage, research, and development in particular embody the perspectives; purposes; prejudice; particular objectives; and cultural, economical, ethical, moral, spiritual, and political frameworks of different social groups and society at large of any given society in which these human activities take place.[35-37]

On the one hand, science and technology usage, research, and development follows social norms, expectations, and markets; on the other hand, science and technology usage, research, and development changes and influences the quality of our lives, our perception as to what is a "good life," and our ability to pursue "the good life."

This dynamic is reflected in the findings of the Health Technology Strategy 1.0 final report,[38] which states:

> Technological change is seen as a major cost escalator in Canada's health systems accounting for an estimated one quarter of health expenditure growth. Technological change and heightened public expectations are seen as the primary sources of escalating costs. Much of this expenditure growth is driven by changing technology and consumer demand.

Purpose

This report is intended as a discussion primer for two challenges increasingly faced by health technology assessment (HTA), health impact assessment (HIA),[39] health needs assessment,[40] parliamentary technology assessment (PTA),[41] participatory technology assessment,[42] policy makers in numerous areas, health care administrators, health workers and health care workers, government officials such as those from Alberta Health and Wellness, health researchers, medical and other academic researchers, Social Development Canada, people involved in the social well-being index, marginalized groups such as disabled people, and the general public.

One challenge relates to the ever-increasing ability of science and technology research and development (R&D) products to modify the appearance and functioning of the human body beyond existing norms and species-typical boundaries and to modify the appearance of a third-generation model and determinants of health, disease, disability, and well-being, which incorporate, condone, and even support human performance enhancement beyond species-typical boundaries.

The other challenge relates to the changing role of disabled people in the public and policy sphere from a passive recipient role toward an active, participatory, and shaping role.

Structure

The report is divided into eight sections and one appendix. Section 1 provides the context and background for the report. Section 2 reflects on the evolution of meaning, models, and determinants of health, disease, disability, and well-being.

Section 3 evaluates the debate around human body structure and functioning enhancement.

Section 4 inspects the current development of the transhumanist/enhancement model. Section 5 examines how the content of Sections 2, 3, 4, and 6 impacts evidence-based medicine, evidence-based decision making (EBDM), and the methods and tools available to and employed by HTA for evaluating evidence. Section 6 explores the triangle of disabled people, concept of health and disease, and emerging technologies. Section 7 summarizes the results of a horizon scanning exercise of emerging technologies as they relate to health.

Section 8 provides conclusions and suggestions for moving forward. Suggestions and highlights of problems are also offered throughout the report.

Appendix A highlights the results of keyword combination searches of journal databases performed to obtain a feeling for how HTA relates to emerging technologies and disabled people.

Objectives

- To provide information and suggestions on emerging and converging health sciences, technologies, products, and services and on arising challenges related to a changing perception of disabled people.
- To evaluate the impact of emerging science and technology usage, research, and development on:
  - health sciences and health technology;
  - the process and future tasks of health technology, health impact, health needs, parliamentary technology, and participatory technology assessment;
  - the concepts, models, and determinants of health, disease, wellness, and disability; and
  - the field of health promotion and public health[43,44].
- To investigate the relationship between disabled people; the concept and determinants of health, disease, and well-being; emerging science and technology usage; R&D; and health technology, health impact, health needs, parliamentary technology, and participatory technology assessment.

Key Findings

Two opposite views of health exist. The World Health Organization (WHO) sees health as an umbrella term for a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity (WHO scenario). Within the Canadian context, health is not seen as an umbrella term but interpreted as "the absence of disease and illness" within an individualistic medical model of health. Health is thus positioned as a medical determinant of well-being (Canadian scenario).

International and national documents use the WHO and Canadian scenarios, often both in the same document, making many documents unclear as to what is meant by the term "health."

The term "health" (WHO and Canadian scenarios) loses its endpoint measure of normative, species-typical boundaries because of the ability of science and technology products to improve and modify the human body beyond species-typical boundaries, leading to the endpoint where the human body in general is seen as defective and in need of improvement. This endpoint changes the meaning of the term "healthy" and the scope of action implied with the term "staying healthy."

An individualistic approach to health and feeling healthy or ill is on the rise.

The medicalization and disease-mongering phenomenon increases and moves toward the transhumanization of medicalization, where enhancing, improving and modifying

the human body beyond its species-typical boundaries is part of the concept of being healthy.

The health consumer is on the rise, as is consumerism and comodification of the human body.

More and more bodily interventions might be perceived as medically necessary.

It becomes increasingly more difficult to draw a line between therapy and enhancement in general and therapeutic and non-therapeutic enhancement in particular.

Augmentative/enhancement medicine is on the rise and the increased capabilities of this field and its products might be seen as enhanced medical goods.

Enhanced medical goods might become normal medical goods.

Control of diffusion is negatively affected. The use of therapeutic interventions for non-therapeutic purposes is increasing and not controllable.

Basic health interventions do not trickle down to the needy in developing countries, which is a distributive problem (How much do developed countries distribute down with affordable prizes?) and a political problem (How much do societal structures within developing countries allow for the deployment to the needy?).

The interrelationships and interdependencies between a person and other individuals and the community are decreasingly taken into account.

Disabled people for the most part are not part of the governance of science and technology research or development and health research, nor are they part of the discussion around the concepts of health, disease, well-being, and even disability.

The discussion around the concepts of health, disease, well-being, and disability within the discourse of health research and the governance of science and technology R&D medicalizes disabled people and further marginalizes disabled people who are poor in general and who are from low-income countries in particular.

The medical model/medical determinant of disability is promoted, whereas the medical model/social determinant and the social model/social determinant combination is rejected by many people, including the founder of the disability-adjusted life year (DALY).

HTA deals with disabled people mostly as patients and looks nearly exclusively at a medical model/medical determinant combination of disability/ impairment, ignoring other disability models and determinants.

HTA in Canada and many other countries seems to use the Canadian scenario of health.

HTA seems not so far to have covered how emerging science and technology products and applications lead to certain societal developments and societal and individualistic desires (medicalization of the human body in general) and vice versa, how social

well-being influences the desire for medical interventions, and how these dynamics impact healthcare costs (i.e. increase in drug costs due to increased use) and the definition of health and disease.

Evidence gathering, evaluation, and measuring tools need to be revamped because:

- they do not take into account the transhumanist/enhancement beyond the norm facet outlined in this report;
- they are discriminatory against disabled people and other marginalized groups;
- some, like the DALY, are leading to health inequity; and
- they cannot really trade medical determinants/interventions against social determinants/interventions.

THE EVOLUTION OF MEANING, MODELS AND DETERMINANTS OF HEALTH, DISEASE, DISABILITY AND WELL-BEING

Definitions of and relationships between health, disease, disability, and well-being that change over time[45] are at the root of being able to identify and act upon the health, disease, disability, and well-being of individual members of society and society at large. Definitions have local and global implications for the content, meaning of, and action attached to terms such as public health, [46] population health,[47,48,] health research,[49,50] healthy community, health promotion,[16] health care, health systems, HTA, HIA, health needs assessment (HNA), social health, social well-being assessment, social well-being technology assessment (STA), and social index of health. These terms also have implications for the mandate and action of government agencies, academic and non-academic funding agencies, policy makers, national and international non-governmental agencies, Civil Society Organizations, and others.

Step 1: Health a determinant of well-being (Canadian scenario) or well-being a determinant of health (WHO scenario)?

Clarification of language

In many documents people use the term "health". Many academic fields use the term "health" i.e. health research, health technology assessment…..But what is meant by health? Two options exist. One can see health as just the absence of disease and illness. This version looks at what I call the "medical health" of people. It ignores the "social health" of people. The WHO definition of "health" uses the term health in a way that medical and social health is covered with the term "health". To clearly show the distinction, I use the term ***"health"*** if medical and social health are included and the term ***"medical health"*** if health is just about the absence of disease and illness.

The WHO definition of health, *"Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity,"*[51] considers different domains of well-being as determinants of the umbrella term "health" (WHO scenario of health) and is used as a reference point in many international documents, including the 1978 Alma Ata declaration[52] and the 1986 Ottawa Charter of the first global health promotion conference.[53]

Policy implications

The WHO scenario allows one to identify non-medical needs and to improve the social situation and the social well-being of someone without having to perceive that someone as a patient or as medically ill, making health the responsibility of people, institutions, and government departments within and outside of the medical domain.

Canada,[54-60] other countries,[10,61,62] and the 2005 Bangkok Charter of the 6th Global Conference on Health Promotion,[21] do not follow the WHO scenario. The Canadian Index of Wellbeing (CIW)(*54*) sets "well-being" as the umbrella term and interprets health as "the absence of disease and illness" within an individual, medical model of health, positioning health as a medical determinant of well-being(Canadian scenario).

> ***Policy implications***
>
> In Canada, different government agencies have jurisdiction over domains that fall under the various elements of the WHO definition of health. Physical and mental well-being is under the jurisdiction of the health system. Social well-being or "social health" is under that of Social Development Canada.[63] This separation plays itself out among policy makers, academics, and even civil society. Little to no integration exists in Canada for the different facets of health as defined by WHO. As social well-being impacts on physical and mental well-being and vice versa, it is logical to increase the quality and quantity of linkages between people and organizations involved in physical, mental, and social well-being in order to develop a more holistic way of dealing with health and well-being.

Which hierarchy one uses—well-being as a determinant of health (WHO scenario), medical health as a determinant of well-being (Canadian scenario), or an interplay of the two has many implications, as outlined in the following six points.

1. The intended audience for this report changes.

Under the WHO scenario, the audiences includes members of the HTA, HIA,[64] HNA,[40] PTA,[41] participatory technology assessment[42] community, policy makers in numerous areas, health care administrators, health workers and health care workers, government officials such as those from Alberta Health and Wellness, health researchers, medical and other academic researchers, marginalized groups such as disabled people, and the general public. It is assumed that the preceding audiences cover social well-being as part of their health debate.

Under the Canadian scenario, which separates health from social well-being, the audience has to be extended to include Social Development Canada and people involved in the social well-being index and social well-being technology assessment (STA), social well-being impact assessment (SIA), and social well-being needs assessment.

Policy implications

If one chooses the Canadian scenario of health, more weight has to be given to fields dealing with well-being, including social well-being, to make up for the gap left behind by moving from the WHO to the Canadian interpretation of health. As this report shows, medical/health technologies (Canadian scenario) impact medical health and social well-being and social well-being impacts the demand for medical/health technologies. Many medical/health technologies can be portrayed as social well-being technology and vice versa.

Under the Canadian scenario, HTA and related assessments might not have the mandate to cover social well-being, which might make it essential to support existing assessments or to generate from scratch STA, SIA, and social well-being needs assessment.

Under the Canadian scenario, HTA might miss certain societal dynamics that impact on the health care system, making it imperative that policy makers obtain additional knowledge from sources outside of HTA. This fragmentation makes it very difficult for policy makers to acquire the bigger picture needed for tackling the systemic problems that the Canadian health care system faces now and in the future.

2. The interpretation, mandate, scope of action, determinants, and models of health, public health, health research, HTA, HIA, and HNA change as do the affected groups.

Policy implications

Every piece written and every oral statement should clearly identify which interpretation of the term "health" one has in mind. To just give one example, the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) defines health technologies to include "drugs, (including vaccines), devices, medical and surgical procedures and health systems (such as telehealth) used in the maintenance, restoration and promotion of health."[65]

Many international health promotion charters and conferences follow the WHO definition of health, raising the question about whether the above statement by CCOHTA is to be interpreted within the WHO or the Canadian scenario of health.

3. Following the WHO scenario, one can include research, action, and policies related to non-medical components of health, such as social well-being. If one follows the Canadian scenario, the mandate of health terms is limited to medical health, which means that, for the term "social determinant of health," one would only investigate and identify how social determinants generate ill medical health (medical model of health) and not how social determinants impact the social well-being of a medically ill or healthy person.

Policy implications

Who would be responsible for funding research into social determinants of social well-being in Alberta? Is such research funded by the Alberta Heritage Foundation for Medical Research (AHFMR), or could it be funded by the AHFMR, or does the mandate of AHFMR only allow funding related to social determinants of medical health? Would one have to fund two totally different streams of social determinants research (social determinants of medical health and social determinants of social well-being)? How much would these streams influence and interact with each other and how much would each stream influence the health system, health promotion, public health, and health care delivery? Could Alberta Health and Wellness be the engine for bringing the different research streams together in order to provide a holistic picture of health (WHO scenario) or health and well-being (Canadian scenario)?

4. The interpretation of the term "health" has implications for disabled people, a group for which health is mostly associated with disease and illness (medical health) and rarely with social well-being (health), and a group that is classified as patients with ill medical health. Consequently, medical determinants are mostly examined for their contributions to the disease or illness of disabled people. Rarely are social determinants examined for their contributions to furthering illness and disease of already ill disabled people and social determinants are studied even less for their positive and negative influence on the social well-being of disabled people.

Policy implications

The WHO scenario allows disabled people to fill the term "health" with content more relevant to their living situation than does the Canadian scenario. There are two ways to make the Canadian scenario more relevant to disabled people. One way would be to add "well-being" to all of the preceding "health" terms: public health and well-being, health and well-being research, determinants of health and well-being, models of health and well-being, health and well-being technology assessment, health and well-being impact assessment, and health and well-being needs assessment. Another way would be to build linkages locally, provincially, nationally, and internationally between the different streams of health and well-being to allow for a synchronized, coherent, and complementary way of dealing with the terms "well-being" and "health."

5. The legal concept of a right to health and well being is affected

An international legal concept of the human right to health and well-being exists.[66-72] The Universal Declaration of Human Rights[73] Article 25-1 states: *"Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of*

livelihood in circumstances beyond his control." The preamble to the WHO constitution states: "*The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being..."*[74], which, using the WHO definition of health, means that "the enjoyment of the highest attainable standard of physical, mental and social well-being is one of the fundamental rights of every human being...".

Policy implications

It is of consequence in the light of models of health and well-being explained elsewhere in this report that the right to well-being is seen by some as a positive right that comes with obligations by those other than the person who wants to obtain well-being.[73,75] It will be interesting to see how the CIW will look at the right to well-being, especially with certain legal interpretations related to the Chaoulli case.[76]

6. The implication of the Chaoulli case

Up to now, the above-mentioned right to health and well-being was seen as not applicable to Canada, as the Canadian Charter of Rights and Freedoms does not use the language of a right to health or right to well-being. However, the Chaoulli case might just have opened the door for a legal argument for the right to health.[76] The press release by Premier Ralph Klein on 9 June 2005, "Premier's Statement, "*Supreme Court Chaoulli Decision" states: "The Supreme Court of Canada has ruled that Canadians have the right to timely access to health services. This includes ruling that prohibiting patients from using private financing and private insurance where wait times are excessive, violates the Charter of Rights. The Alberta government is very pleased with this decision. Premier Klein fully supports any change that will allow Canadians more choice in getting timely access to the health care services they want."*[77] This statement comes very close to stating that a Canadian has a right to health. If a Canadian has a right to health that could mean that a Canadian also has a right to well-being, if one uses the WHO scenario of health. If one follows the Canadian scenario, which separates health from social well-being, this extension might not be self-evident. However, it might be logical following the concept of the CIW to extend that right to well-being, a right that is also covered by the Universal Declaration of Human Rights[73] Article 25-1.

The Canadian Health Coalition describes the Chaoulli case as follows:

> Jacques Chaoulli, a Quebec doctor, and George Zeliotis, his patient, challenged sections in the Quebec health and hospital insurance laws that make private health insurance illegal. They claimed that because delays in the public system place their health and security at risk they should be allowed to take out insurance to permit them to access private services. The Quebec trial judge dismissed the claim. The Quebec Court of Appeal agreed. The Supreme Court of Canada split 4 to 3 on the issue, giving three separate sets of reasons. The majority of four justices held that the appeal should be allowed and that the

Quebec prohibitions on private health and hospital insurance are inconsistent with the Quebec Charter. Justice Deschamps held that the Quebec Charter protection of life and personal security had been violated and the provision banning private health insurance is not justified. Chief Justice McLachlin and Justice Major (with Justice Bastarache concurring) held that the Quebec laws also breach s. 7 of the Canadian Charter of Rights and Freedoms. They held that delays in treatment could breach the right to life and security of the person. The laws prohibiting private insurance were contrary to the principles of fundamental justice because they were arbitrary and not justified under s. 1 of the Charter.[78]

Policy implications

Many people interpreted the Chaoulli case as supporting a two-tiered healthcare system.[79-83] However, others interpreted the Chaoulli decision as opening the door to a so far non-existent right to health care in Canada.[76]

> Canadians had so far very narrow rights in regards to health care and decisions about how and when patients could access medical services were considered beyond the purview of the Charter and the courts, and solely the responsibility of the democratic legislatures.(*76*)

Makarenko suggests that "What the majority did in Chaoulli, more than anything else, was assert that there exists a right to timely access to health care under Section 7 of the Charter." (It is important to note that the constitutional status of this right is still somewhat unclear – while 4 of the 7 judges asserted such a right, only three did so explicitly under the Canadian Charter, while one judge did so under the Quebec Charter.)[76]

He muses further that the reasoning of the courts could be extended:

> Take, in example, a situation in which a person is unable to access medical treatment because they cannot pay for it. Timely access to health care is definitely limited in this case—in fact, the person cannot receive medical treatment at all. Further, this would seem to trigger the Section 7 interests of life and security of the person (as the majority has defined them in the Chaoulli). If one cannot access health care at all, then there is a great risk of suffering and death. The courts could then, and with little further justification, extend the right to include situations in which other barriers (besides the absence of opportunity) limit persons' access to timely medical treatment. This would definitively make the Section 7 right to timely access a full-fledged social right.[76]

The author of the present report believes one could also use Article 15(1), as "equal benefit in front of the law" would demand that the courts reasoning would extend to people who can't afford health care treatments. Indeed, as Makarenko states:

> If a parallel private health system were allowed under government legislation, the quality of service under the public system would have to be relatively equal to the private system. Otherwise, persons in the public system could assert that they were being discriminated against on the grounds of wealth/income.[76]

Although the Canadian government and the courts could use the concept of reasonable accommodation to limit actions related to the above line of reasoning, the Chaoulli case and its possible interpretations might impact the health care system.

Step 2: Determinants and models of health, disease, well-being, and disability

Existing models and determinants of health (medical, social, and transhumanist/enhancement) [43,84-87] obtain different meanings, depending on if one perceives health as a determinant of well-being (Canadian scenario) or if one perceives well-being as a determinant of health (WHO scenario).

The first generation: Medical model of health, disease, and well-being

Within the medical model of health and disease, health is characterized as the normative functioning of biological systems and disease is seen as the subnormative functioning of biological systems. This model does not deal with social well-being. This model fits the Canadian scenario but is too limited for the scope of the WHO scenario.

Policy implications

1. The medical model/medical determinant combination puts the blame squarely on the shoulders of the individual without taking into account external factors influencing the life of the individual.
2. Advances in technology generate forms of diagnosis that are more likely to depend on the language of risk and probabilities than the language of causality. Indeed, genetic and non-genetic tests increasingly enable the targeting of presymptomatic people, giving people and insurance companies, for instance, a sense of the probability and risk attached to the person developing a certain medical problem.[88]
3. The medical model/medical determinant combination contributes to the dynamic of medicalization.
4. This model advances a divide between rich and poor individuals and countries, as most of the new individualized therapies coming down the pipeline will only be available to people or countries with money.
5. This model is too limited to address the needs of "subnormative functioning" disabled people and other marginalized groups and indeed the population at large, contributing to overall global health inequities and the likelihood that the United Nations (UN) Millennium Development Goals (MDGs) will not be met.

Locating the cause of ill medical health comes in two flavors. Medical determinants of health place the cause of subnormative functioning within the individual, leading to medical interventions on the level of the individual (medical, individualistic cures).[43,84] Social determinants of health in the medical model are external factors that lead to ill medical health of an individual (see *"The second generation: social models of health and disease"*). Social determinants relating to the social well-being of an ill or healthy person are not investigated. Social determinants that worsen the already existing ill health of a "patient" are described within the medical model of "disability/impairment."

The starting point of the medical model of health and disease is a healthy individual who loses his or her medical health because of unfavorable medical and social determinants. This model is a prevention model trying to prevent one from becoming "ill."

As soon as one is labeled medically ill or is exhibiting subnormative functioning—or in the case of the embryo or fetus, a characteristic in the genetic or morphological make-up is detected, which leads to the expectation that the person will be born medically ill or exhibiting subnormative functioning after birth—one is covered by the medical model of "disability/impairment."

The first generation: medical model of disability/impairment

A clarification of language

Within the medical model, "disability" is used interchangeably with terms such as impairment, disease, illness, chronic disease, and defect.

A more accurate description of the model would be "medical model of impairment"; however, the literature uses the term disability. To avoid confusing the reader, I will use the term "disability/impairment" henceforth to flag the cases in which the term "disability" means impairment, disease, and illness.

The term "people with disabilities" within the medical model means people with impairments (in the pure medical model/medical determinant scenario) and people who are socially discriminated because of their impairment (in the social determinant/medical model combination).

The most accurate description would be "medical model of patients." However, this report uses the term "medical model of disability/impairment," as many people would not relate the term "patient" to disability.

1. Medical model of disability/impairment

Within the medical model of disability/impairment, disability/impairment is viewed as a defect, a problem inherent to the person; directly caused by disease, trauma, or other medical health conditions; and a deviation from certain norms. The person obtains the label "patient."

Locating the cure for the disability/impairment comes in mostly one flavour. Management of the disability/impairment of the person or person-to-be is aimed at cure, prevention of birth, deselection at the embryo level, or normative adaptation. Medical individualistic care and prevention (in the case of the fetus/embryo) and individualistic normative rehabilitation are viewed as the primary endpoint, and, at the political level, the principal response is to make curative and preventive medicine more efficient.

"Disabled" people can opt to see themselves and can be seen by "non-disabled people" as inherently defective and subnormal, as impaired (in relation to the non-disabled

people), and as in need of being fixed by science and technology products to a societal norm of the so-called non-disabled (e.g. giving legs to amputees that will be as good as or worse than biological legs (the patient/medical model/medical determinant type).[43,84] However, the social well-being/health and the medical health/well-being of people/patients with disabilities/impairments are also affected by social determinants.

More than 80% (400 million) of disabled people live in developing countries, 150 million of them between the ages of 10 and 24.[89] Disabled people have limited access to education (as low as 3%), employment, and basic health care (as low as 2%) and experience profound economic and social exclusion. Most disabled people live in poverty, prevented from fully participating in their families and communities and from benefiting from their socio-economic rights.[90]

The exclusion and discrimination of disabled people has a long history and exists worldwide today.

In the USA, the Americans with Disabilities Act (ADA) states:

> Historically, society has tended to isolate and segregate individuals with disabilities, and, despite some improvements, such form of discrimination against individuals with disabilities continue to be a serious and pervasive social problem.[91] Discrimination against individuals with disabilities persists in such critical areas as employment, housing, public accommodations, education, transportation, communication, recreation, institutionalization, health services, voting, and access to public services.[91] Individuals with disabilities are a discrete and insular minority who have been faced with restrictions and limitations, subjected to a history of purposeful unequal treatment, and relegated to a position of political powerlessness in our society, based on characteristics that are beyond the control of such individuals and resulting from stereotypic assumptions not truly indicative of the individual ability of such individuals to participate in, and contribute to, society.[91]

2. *Medical model/social determinants/social well-being combination model of disability/impairment*

Rarely does someone use the concept of social determinants of health within the medical model of disability/impairment to investigate how external factors further the already existing ill medical health and negatively impact the social well-being of the "patient," the person with a "disability/impairment."

Even rarer does someone seek modifications of social determinants to make them instrumental in diminishing the ill health and increasing the social well-being of the "patient," despite the necessity of doing so for the "disabled/impaired" person/patient.[92]

As Wolfensohn, the former World Bank president, stated: "Eliminating world poverty and meeting the MDGs is unlikely to be achieved unless the rights and needs of disabled people are taken into account."[92] Access to education is not extended to people with disabilities/impairments. The debate around water and sanitation, which is an

important area of social determinants of health, does not take into account people with disabilities/impairments and their specific needs in this area. The UN report on water does not mention people with disabilities/impairments at all.

Disabled people can opt to see themselves and can be seen by non-disabled people as inherently defective and subnormal (in relation to the non-disabled people) and in need of having the physical environment, the interaction with the physical environment, and the societal climate changed to accommodate their biological reality (e.g. giving wheelchairs to amputees and making the physical environment wheelchair accessible, or using teleportation devices if they are ever developed) and to improve their social well-being (the patient/medical model/ social health/social determinant/social well-being type).[43,84]

Policy implications as related to disabled people, the patients

The medical model of disability/impairment focuses on medical care and cures, ignoring the options of social care and cures.

Quotes from the Prime Minister's National Forum on Health:

> "We believe that the social and economic determinants of health merit particular attention."
>
> "We have known for some time that the better off people are in terms of income, social status, social networks, sense of control over their lives, self-esteem and education, the healthier they are likely to be."
>
> "The more equal a society the more widely shared are feelings of self-esteem and control, the more empowered are its members, and the better is overall health status. (Empowerment refers to the idea that in order to further the democratization process of our societies, we have to better apportion power, with the likely effect of improving people s health.)"

Quote from the Kirby report:

> "A good health care system is only one of numerous factors that help keep people healthy. Some experts have suggested that only 25% of the health of the population is attributable to the health care system, while 75% is dependent on factors such as biology and genetic endowment, the physical environment and socio-economic conditions."[9]

Quotes from these sources, the ADA, and others justify research into the worsening of ill health and the social well-being of patients by social determinants and research into needed modifications of social determinants to make them instrumental in diminishing the ill health and increasing the social well-being of the "patient."

Social determinants need to be part of the medical model of disability/impairment because it is far from certain that one's illness, defect, impairment, or disability is best dealt with through medical individualistic interventions rather than by changing the social determinants that a person faces.

People with disabilities who accept the label of "medical ill health" might still be better served by increasing their social well-being than by having their "medical health" reflecting the reality that many "medical cures" are not affordable to the majority of disabled people/patients and that disabled people who see themselves as impaired need social support.

Other problems of the medical model of disability/impairment that should be dealt with are as follows:

1. This model looks at what the individual costs the system (due to non-normative functioning) without taking into account what the person contributes to the system or by ignoring certain types of contributions.
2. This model leads to a devaluing and objectifying of subnormative functioning people in general and disabled people in particular. It sees subnormative functioning people as "other" and as inherently deficient and costly.
3. This model is too limited to address the needs of "subnormative functioning" disabled people and other marginalized groups and indeed the population at large, contributing to overall global health inequities and the likelihood that the UN Millenium Development Goals will not be met.

s

The second generation: social models of health and disease

Because of an increasing sentiment that something was missing from the framework around the medical model and medical determinants of health,[9,93] numerous so-called social models of health, which incorporate "social determinants" of health,[8,10,94-96] and the view that health is also influenced by social, spiritual, economic, ethical, and political factors, and not just medical factors,[9,97-104] were developed. WHO recently set up a social determinant of health commission.[105]

The scope of the social model and the social determinants of health differ widely between the WHO and the Canadian scenarios. Within the WHO scenario, the social model of health could look at how social determinants influence social, physical, and mental well-being. Within the WHO scenario of the social models of health, one does not have to be identified as a "patient" or "patient to be," as a person in ill medical health or in danger of becoming medically ill.

Under the Canadian scenario, the social model of health is really a medical model of health combined with social determinants, leading to ill medical health as described under the medical mode earlier. Under the Canadian scenario, "patients" are still the client and the focus is on them not becoming ill, not on their social well-being.

A real social model of health using social determinants of health would examine how social determinants influence "physical, mental, and social well-being" and would not be limited to looking at how social determinants influence and worsen "medical health." One does not have to be identified as a "patient" or "patient to be," as a person in "ill medical health," or in as a person in danger of gaining ill/bad medical health in order to be covered and investigated under the social model of health.

Policy implications

Under the Canadian scenario, social determinants of health cannot be used to inquire about social well-being. They can hardly be used to research their impact on the already existing ill health of a "patient." One would have to rename "social determinants of health" as "social determinants of well-being" to obtain that mandate. Another option would be to use the term "social health." An index of social health was actually developed and social determinants of well-being,[106-111] exist.

Social determinants of health would have to be actively pursued by Social Development Canada[112] and others such as the people involved in the Canadian Index for well-being. Regarding HTA, the WHO scenario would give HTA a much more holistic mandate than would the Canadian scenario.

Many problems exist for the implementation and acceptance of the social model of health[113] and disability,[114-118] whether one looks at the social model and social determinants of health from the WHO scenario or from the Canadian scenario. To discuss these problems and challenges would be beyond the scope of this report.

However, one point is essential for the further reading of this report. Not having health and not experiencing well-being is still based on certain standards of societal parameters that allow one to feel "healthy" and "well." A diversion from these standards toward a substandard societal situation leads to subnormative functioning of a person and subnormative health and well-being. The third generation models of health, disease, well-being, and disability remove this point of reference (*see* below).

The second generation: social model of disability

Language usage

This model does not see the disabled person as intrinsically impaired. Under the social model, "disability" is the correct term to use, meaning social discrimination based on ones as subnormative perceived non-normative body structures and functioning.

Ableism is the discrimination of people who are perceived as having subnormal or non mainstream set of human body based abilities whereas vari-ableist, vari-ableism is the notion that one should not discriminate against that group. Vari-ableism in the same way as feminism includes cultural aspects of people belonging to this group. Vari-ableist, vari-ableism is the positive expression counterpart to able-ism simlar to the usage of the term feminism versus sexism.

The social model moves beyond the medical model/social determinant combination by linking the use of social determinants to social well-being and by uncoupling social determinants from the prerequisite of being or becoming medically ill. The biological reality of disabled people is seen as a variation of being, not in need of fixing, but in need of having the physical environment, the interaction with the physical environment, and the societal climate changed to accommodate their biological reality. It does see disability mainly as a socially created problem and as a matter of the full integration of individuals with different biological realities and abilities into society. Disability is not seen as an attribute or defect of an individual, but as caused by the reaction of society toward the biological reality of the individual.

Disabled people can opt to see their biological reality as a variation of being (on par with non-disabled people), not in need of fixing, but in need of having the physical environment, the interaction with the physical environment, and the societal climate changed to accommodate their biological reality (e.g. giving wheelchairs to amputees and making the physical environment wheelchair accessible, or using teleportation devices, if they are ever developed) and to improve their social well-being (the social model/social health/social determinant/social well-being type).

This model fits with the reality that many so-called medical labels are contested, that a medical identity does not fit with the self-perception of many disabled people (see Section 6), and that current understanding about what constitutes a disability has reframed disability as an issue of social entitlement, economic opportunity, and human rights. This reality is evidenced by the flurry of progressive legislation and new programs around the world, including a UN international convention to promote and protect the rights of disabled persons.

Problem: rejection of the social model of disability

Disabled people are mostly perceived and accepted as "patients" and rarely accepted and perceived within the social model of disability[114-116], or the social model of health (WHO scenario).

Policy implications

1. The management of the problem requires social action, and it is the collective responsibility of society at large to make the environmental and emotional modifications necessary for the full participation of people with different biological realities in all areas of social life. The issue is therefore an attitudinal or ideological one requiring social change, which at the political level becomes a question of human rights. The social model allows "ableism"[119] (discrimination based on the lack of expected abilities) to be seen in the same light as racism or sexism.

2. The social model of disability should be promoted and the limited focus on medical determinants within a medical model of "disability/impairment" should be abolished. Looking at the global and local situation of disabled people, it is evident that disabled people need both the social model of disability and the medical model of "disability/impairment" paired with social determinant actions.
3. A societal and policy framework devoid of prejudice and bias has to be put into place to allow the disabled person a real choice in defining and perceiving his or her own identity, whether that identity is within the medical or the social mode.

The third generation: transhumanist/enhancement model of health, disease, and well-being

Advances in science and technology—in particular the converging of nanotechnology, biotechnology, information technology, and cognitive sciences (NBIC)—give life to a third generation model of health that takes into account the increased ability of science and technology R&D products to modify the appearance of the human body and its functioning beyond existing norms and species-typical boundaries, which allows for an increased consumerization/objectification of body appearance and functioning and an increasing tendency to medicalize/transhumanize the human body, characteristics, and problems.

Within the transhumanist/enhancement model of health, the concept of health no longer has the endpoint that someone is "healthy" if the biological systems function within species-typical, normative frameworks. Within the transhumanist/enhancement model, all *Homo sapiens*—no matter how conventionally "medically healthy"—are defined as limited, defective, and in need of constant improvement made possible by new technologies appearing on the horizon (a little bit like the constant software upgrades we do on our computers). Health in this model is the concept of having obtained maximum (at any given time) enhancement (improvement) of one's abilities, functioning, and body structure. Disease, in this case, is identified in accordance with a negative self-perception (confined to the "normal" human body) of one's non-enhanced body.

Interventions on the level of the individual that add new abilities or improve on existing abilities of *Homo sapiens* are seen as the remedy for ill "medical and social health" and bad physical, mental, and social well-being (transhumanist determinants). Enhancement medicine is the new field providing the remedy through surgery, pharmaceuticals, implants, and other means.

This model leads to a subjective understanding of health in which anyone can consider themselves or be considered by others as "unhealthy." Anyone could demand

treatment for themselves based on a self-identified need and anyone could decide that someone else has to be fixed (this point is further explored in Section 5). This model redefines the term "social well-being," linking it to the availability of bodily appearance and functioning enhancement. The notions of disease prevention, public health, healthy community, and health promotion, and the actions they entail, all change substantially within a transhumanist/enhancement model of health, disease, and well-being.

> ***Policy implications***
>
> It will be increasingly difficult to distinguish between NBIC "health products," which lead to "therapies toward the norm" and "therapies that will exceed a norm."

The third generation: the transhumanist/enhancement model of "disability/impairment"

The transhumanist/enhancement model of health and disease sees every human body as defective and in need of improvement (above species-typical boundaries), leading to the transhumanist/enhancement model of "disability/impairment," in which every unenhanced human being is, by definition, "disabled" in the impairment /patient sense. The only way out of the impairment/patient label is to enhance oneself beyond species-typical boundaries. Everyone who cannot afford the enhancement of their body will be labeled as "impaired."

Medical model/transhumanist/enhancement determinants/social well-being combination model of "disability/impairment"

Disabled people who have a subnormative/perceived non-normative functioning of biological systems, based on the *Homo sapiens* species-typical, normative frameworks, can opt to see themselves and can be seen by non-disabled people as inherently defective and opt not only to be fixed to a norm, but also to be enhanced, augmented beyond species-typical boundaries (i.e. giving bionic legs to amputees, which work better than the "normal" biological legs or using brain-machine interfaces for thought controlling the environment)(*43*) (the patient/health consumer/transhumanist/enhancement model/transhumanist/enhancement/enhancement determinant/transhumanist well-being type).

The pure transhumanist/enhancement model of "disability/impairment" (43)

Within the transhumanist/enhancement model of "disability/impairment," disabled people are those who perceive their normative functioning of biological systems, based on the *Homo sapiens* species-typical, normative frameworks, as deficient. They can or cannot be seen by non-disabled people as inherently defective and opt not only to be fixed to a norm, but also to be enhanced, augmented beyond species-typical boundaries

(i.e. giving bionic legs to amputees, which work better than the "normal" biological legs or using brain-machine interfaces for thought controlling the environment)(*43*) (the transhumanist/enhanced disabled person/the patient/health consumer/transhumanist/enhancement model/transhumanist/enhancement determinant/transhumanist/enhancement well-being type).

The transhumanist/enhancement model is a variation of the medical, individualistic, deficiency model using transhumanist/enhancement determinants, which are medical determinants but with the difference that they include enhancement, augmentative medicine.

Because the transhumanist/enhancement model of health and disease sees every human body as defective and in need of improvement (above species-typical boundaries),[43] every human being is "disabled" in the impairment/patient sense and would fit into the transhumanist/enhancement model of "disability."

The transhumanist/enhancement model of "disability" views science and technology, including NBIC, as having the potential to free "all disabled people" from the "confinement of their genes" (genomic freedom) and the "confinement of their biological bodies" (morphological freedom). Section 5 explains further the relationship between disabled people and transhumanism.

Policy implications

1. The number of "patients" increases dramatically.
2. The medicalization phenomenon accelerates.
3. A two-tiered healthcare and health system might develop: one dealing with the basics and one dealing with augmentative/enhancement medicine.
4. If one leaves the growing augmentative/enhancement field unregulated, without standards and supervision, one might see an increase in people becoming clients of the basic health care system due to botched procedures and side effects.
5. A brain drain toward the augmentative/enhancement cutting edge medicine might develop.
6. An ability divide will appear because many people, especially the traditional disabled people, will not be able to afford the enhancement treatment.

The involvement of disabled people in the debate around health concepts, models, and determinants

Disabled people are for the most part absent from the public, academic, and government discourse—Canadian and international—around the terms, models, and

determinants of health. Disabled people are, for example, not mentioned in the documents of all but the Swedish global health promotion conferences.

Within Canada, the final report of the Prime Minister's National Forum on Health stated:

> There appear to be significant gaps in the knowledge about women's health, ethnic and cultural influences, non-medical determinants of health, and alternative or complementary practices and therapies…. Knowledge about cultural and gender determinants of health is still very limited.[7]

This and many other quotations attest to the fact that disabled people-specific determinants of health (WHO or Canadian scenario) and social determinants (WHO or Canadian scenario) in relation to disabled people are not on the radar screen in Canada and globally. It is indicative of this systemic oversight that Canadian Institutes of Health Research (CIHR) exist for Aboriginal people's health and gender and health but not for disabled people's health.

Policy implications

The preceding omission and bias should be rectified.

On reading the report, "Select Highlights on Public Views of the Determinants of Health,"[58] by the Canadian Population Health Initiative, one cannot help but notice the total lack of discussion about disabled people. In answer to the question "Do you believe there are any particular groups of people in Canada that are in worse health than other Canadians?," the top five ranking groups reported to be in worse health than others were the economically disadvantaged (30%), First Nations/Inuit (19%), elderly (9%), children/youth (5%), and none (24%).

Policy implications

Disabled people not making this list might reflect a Canadian sentiment that disabled people are just seen as patients who are ill, making it redundant to state that disabled people/patients are in worse health than other people.

It should be worthwhile to investigate the validity of this deduction.

The report found further, "When participants were presented with a list of factors that might have an impact on the health of Canadians through a series of closed-ended questions, environment and personal health behaviors were rated relatively higher than social and economic factors such as income and community support."

This finding is of consequence for disabled people who often feel that their ill health (WHO and Canadian scenarios) is triggered or perpetuated by social and economic factors, such as lack of income and community support.

Policy implications

It is not clear whether disabled people were interviewed, although it is very likely that, for the most part, people were interviewed who did not perceive themselves as unhealthy at the time of the interview. One should go back and interview disabled people/patients to see what they envision as impacting on their health.

The invisibility of disabled people might reflect the lack of acceptance of the social model of disability,[114-116] that their views are seen as irrelevant,[114] and the simplistic viewing of disabled persons as patients. It might be explainable by the difference in how one perceives non-disabled people and disabled/impaired people.

As outlined earlier, health interventions as they relate to non-disabled people are based on preventing them from becoming ill. In this way, indigenous health and gender considers the specifics around gender and cultural influences that lead to ill health, making it useful to consider social determinants. However, disabled people, as those who are already ill, are patients, and so it would make no sense to involve them or think about them in terms of social determinants and preventative medicine.

This invisibility was recognized in the final documents of the 1999 UNESCO World Conference on Sciences,[120;121] from the Declaration on Science:

> 25. . . . . there are barriers which have precluded the full participation of other groups, of both sexes, including disabled people, indigenous peoples and ethnic minorities, hereafter referred to as "disadvantaged groups."

Policy implications

Something has to change on the level of policy makers, academics, and funding agencies to rectify this invisibility of disabled people in the "health" discourse. The rejection of the social model of disability has to decrease. The UNESCO World Conference on Sciences suggested the following remedies.

From the Declaration on Science, UNESCO/ICSU World Conference of Sciences	
34.	Science education, in the broad sense, without discrimination and encompassing all levels and modalities is a fundamental prerequisite for democracy and for ensuring sustainable development. In recent years, worldwide measures have been undertaken to promote basic education for all. Special attention is still required for marginalized groups. It is more than ever necessary to develop and expand science literacy in all cultures and sectors of society as well as reasoning ability and skills and an appreciation of ethical values, so as to improve public participation in decision-making related to the application of new knowledge.

42.	Equality in access to science is not only a social and ethical requirement for human development, but also a necessity for realizing the full potential of scientific communities worldwide and for orienting scientific progress towards meeting the needs of humankind. The difficulties encountered by women, constituting over half of the population in the world, in entering, pursuing and advancing in a career in the sciences and in participating in decision-making in science and technology should be addressed urgently. There is an equally urgent need to address the difficulties faced by disadvantaged groups which preclude their full and effective participation.
From the Science Agenda-Framework for Action	
17.	Scientists, research institutions and learned scientific societies and other relevant non-governmental organizations should commit themselves to increased international collaboration including exchange of knowledge and expertise. Initiatives to facilitate access to scientific information sources by scientists and institutions in the developing countries should be especially encouraged and supported. Initiatives to fully incorporate women scientists and other disadvantaged groups from the South and North into scientific networks should be implemented. In this context efforts should be made to ensure that results of publicly funded research will be made accessible.
59.	Governments should promote the further development or setting up of national statistical services capable of providing sound data, disaggregated by gender and disadvantaged groups, on science education and R&D activities that are necessary for effective S&T policy-making. Developing countries should be assisted in this respect by the international community, using the technical expertise of UNESCO and other international organizations.
79.	The full participation of disadvantaged groups in all aspects of research activities, including the development of policy, also needs to be ensured.
81.	Governments and educational institutions should identify and eliminate, from the early learning stages on educational practices that have a discriminatory effect, so as to increase the successful participation in science of individuals from all sectors of society, including disadvantaged groups.
91.	Special efforts also need to be made to ensure the full participation of disadvantaged groups in science and technology, such efforts to include: - removing barriers in the education system; - removing barriers in the research system; - raising awareness of the contribution of these groups to science and technology in order to - overcome existing stereotypes; - undertaking research, supported by the collection of data, documenting constraints; - monitoring, implementation and documenting best practices; - ensuring representation in policy-making bodies and forums.

None of the suggestions are—but should be—acted on internationally and in Canada, and additional actions and solutions should be identified to decrease the invisibility of disabled people in the public discourse.

Policy implications

If one sees disabled people mostly within the medical model with medical determinants and if one actively and passively rejects the social model of disabled people, the logical consequence is that disabled people move on toward the transhumanist model.

Table 1: Characteristics of the three models of health

	Medical Model Medical/Social Determinants	**Social Model WHO/Canadian Index on Well-being**	**Transhumanist/ enhancement Model**
Individualistic approach/ health	+++/0	+---/+++	+++++
Deficiency/problem within the person or person to be	+++/0	0/+++	+++
Based on a norm/standard	+++/++	+++	0 or constantly shifting toward enhancing the norm
Body modification (appearance and functionality)	+/0	0/0 or +	+++
Acceptance of human performance enhancement	0 or+/0	0/0 or +	+++++
Enhancement part of medicalization	0 or+/0	0/0 or +	+++++
Life extension/ immortality/cryonics through bodily interventions	0 or +/0	0/0 or +	+++++
Model of health enticing to disabled people	+++ Switching over to transhumanist/+	++ But frustrating because of lack of acceptance of social model of disability; people might also move to transhumanist/enhance ment model//0 switching over to transhumanist	+++
Subject is a patient	+++/0 or +	---/+++	+++
Subject is a “health” product consumer	+++/0	0/+++	++++++

Policy implications

The scope, process, direction, and outcome of HTA will be different depending on which model and determinants of health, disease, and disability (medical model/ medical determinants, medical model/social determinants, social model, or transhumanist model), and which health scenario one chooses: medical health a determinant of well-being (Canadian) or well-being, including social well-being, a determinant of health (WHO scenario).

Table 2: Consequences of the three main models and their determinants

	Medical Model Medical/Social Determinants	Social Model WHO/Canadian Index on Well-being	Transhumanist/ Enhancement Model
Social justice	0 or + or -/0 or +	+++++/++	0 or --
10/90 Gap	0 or +/-	---/--	+++++
Health care costs	++/0 or -	--/ 0 or ++	+++++
Increases medicalization of the "healthy dynamic"	+++/0	0/ 0 or +	+++++
Adding enhancement as part of the concept of being "healthy"	0 or +/0 or -	0 or --	+++++
Promoting augmentative/enhancement medicine	0 or +/ 0 or -	---	+++++
Increases negative/ individualistic deficiency perception of so-called non-disabled people	+++/0	0	+++++
Drug prizes	++/0	0 or –/ 0 or++	+++++
Increases demand for prenatal screening	+++/0	0/ 0 or+	+++++
Global health	0 or +/0 or ++	+++	0 or --
Increases negative/ individualistic deficiency perception of disabled people	+++/0	---/0 or++	+++++
Marginalizes further the disabled in low-income countries	+/0or --- or +++ Depends how disabled people are part of the social determinants	--/-- or 0 or++	++++
Consumerism of the human body	0 or++/0	0/-- or 0 or ++	+++++
Comodification of the human body	+/0	0/-- or 0 or ++	+++++
Taking into account interrelationships and interdependence of a person with other individuals and the community	---/0 or +	+++++	-----

+ means that it has a positive effect or leads to an increase; 0 indicates that it is neutral or that it has no effect or that it is not applicable; - means that it has a negative effect or leads to a decrease

Table 3: Implication of NBIC advances/transhumanist/enhancement model and determinants

	Provincial Government Funding	Health Authority Delivery	Healthcare Delivery	Providers	Global Health	For Disabled People	Dealing with Disabled People	Public Health
Mandate change	+++	++	+++	++	++	N/A	+++	+++
Scope change	+++	++	+++	++++	+++	++++	+++	+++
Money needed	+++++	++++	++++	++++	++++	++++	++++	++++
Human resources needed	++++	++++	++++	++++	++++	++++	++++	++++
Access to service	++++	++	+++++	+++	+++	+++	N/A	+++
Medically necessary	+++++	+++++	+++++	+++++	++ or 0	+++++		++++
Enhanced medical good	++++	++	++	++	0	++++	++++	++++
Enhanced medical good becoming "normal medical goods"	+++++	++++	++++	+++	0	++++	++++	++++
Quality of care	++++	Dept on funding – or 0 or ++	Dept on funding – or 9 or ++	Dept on funding – or 0 or ++	0	Dept on funding – or 0 – or ++	N/A	Dept on funding – or 0 or ++

+ means impacted by; 0 means not much impacted by; -- means negatively impacted by; N/A means not applicable

Table 3: Implication of NBIC advances/transhumanist/enhancement model and determinants (cont'd)

	Provincial Government Funding	Health Authority Delivery	Healthcare Delivery	Providers	Global Health	For Disabled People	Dealing with Disabled People	Public Health
Reduction of risk	N/A	) or --	0 or --	N/A	N/A	0 or --	0 or --	0 or --
Provision of alternative in the beginning	+++	+++	+++	+++	0	+++	+++	++++
Provision of alternative can become the new norm	+++	+++	+++	+++	9	+++	+++	++++
Credentialing	++++	++++	++++	++++	0	N/A	+++	N/A or +++
Efficacy	0 or --	0 or --	0 or --	0 or --	---	N/A	N/A	0 or --
Safety	Needs more funding	Impacted	Impacted	Impacted	Impacted	N/A	Impacted	Impacted
Effectiveness	0 or --	0 or --	0 or --	0 or --	0 or --	N/A	++ or 0	0 or --
Cost-effectiveness	0 or --	0 or --	0 or --	0 or --	0 or --	N/A	N/A	---
Control of diffusion	--- Decrease in control	--- Decrease in control	--- Decrease in control	--- Decrease in control	--- Decrease in control	N/A	N/A	--- Decrease in control
Dealing with disabled	++ or 0 or --	++ or 0 or --	++ or 0 or --	++ or 0 or --	++ or 0 or --	N/A	N/A	+++

+ means impacted by; 0 means not much impacted by; -- means negatively impacted by; N/A means not applicable

THE DEBATE AROUND HUMAN BODY STRUCTURE AND FUNCTIONING ENHANCEMENT

The most consequential part of advances in sciences and technology products—enabled in particular by the converging of NBIC—and the new transhumanist/enhancement model of health, disease, disability, and well-being as it relates to health and health care is the increasing ability, demand for, and acceptance of improving and modifying the human body (structure, function, capabilities) beyond its species-typical boundaries. n increasing number of people, those in the so-called transhumanist movement being just one example, believe that we can, will, and should try to overcome our biological limitations by means of reason, science, and technology and that the move toward the enhancement of the human body is not preventable.[122-133]

A lively discourse exists around the rights and wrongs of human genetic enhancement but is much quieter or non-existent for many other forms of enhancement in existence (see Table 4). This absence of discussion occurs despite the fact that many of these latter forms are of much more immediate relevance because of the appearance of products related to the concepts of health, disease and disability, HTA, and other assessments and policy makers responsible for health systems, public health, population health, and health care.

Table 4: Type of enhancements

Type of Enhancement	Description
Somatic genetic enhancement	Genetic alteration of genetic material of human cells or tissue other than reproductive cells. Thus, the new genetic makeup will not be passed onto subsequent generations.
Germline genetic enhancement	Genetic alteration of reproductive cells (sperm and egg) of humans in such a way that the introduced genetic material is incorporated into the host genome and passed onto subsequent generations
Enhancement for medical reasons/therapeutic enhancement	Genetic or non-genetic enhancement of human characteristics, functions, and abilities performed with the intent of alleviating suffering by disease
Enhancement for social reasons/ non-therapeutic enhancement	Genetic or non-genetic enhancement of human characteristics, functions, and abilities not performed with the intent of alleviating suffering by disease (as the report will show this definition is very interpretable related to the definition of disease and suffering)
Positional enhancement	Genetic (and non-genetic) enhancement aimed at the obtainment of goods that are desirable only in so far as they provide a competitive advantage[134]
Intrinsically good enhancement	Enhancement that adds functions and abilities to the human body that are seen as good
Body structure enhancement	Enhancement of body structures without changes in body functions

Table 4: Type of enhancements (cont'd)

Type of Enhancement	Description
Body function enhancement	Enhancement of body structures leading to changes in body function
Neuro structure and function enhancement	Enhancement of neuro structures leading to changes in cognitive functions
Ex ante enhancement[135]	Enhancement done before the child is born
Ex post enhancement[135]	Enhancement done after birth

Arguments used against enhancement

- There is something inherently wrong or morally suspect in using science to manipulate human nature
- Enhancement is against human dignity and increases the co-modification of a human being.
- Enhancements will lead to a change in the human species.
- Inequality: some people would get an unfair advantage.
- What is going to happen to equality of opportunity?[136,137]
- Why shouldn't the enhanced start demanding superior political rights for themselves and seek to dominate the unenhanced, since they will in fact be superior, not just as a result of acquired social status and education, but as a result of genetic enhancements as well?[136-138]
- Users of the technologies are buying individual well-being at the expense of some larger social good. I may improve my own athletic ability by taking steroids, but I set off a steroid arms race that destroys my sport. I may get cosmetic surgery for my 'Asian eyes' or use skin lighteners for my dark skin, but I reinforce the implicitly racist social norms that say that Asian eyes or dark skin are traits to be ashamed of. The worry is that some aspect of the way we live together, collectively, is going to be damaged by actions that we take individually.[139] Elliot states further: *"My worry is that we will ignore important human needs at the expense of frivolous human desires; that dominant social norms will crowd out those of the minority; that the self-improvement agenda will be set not by individuals, but by powerful corporate interests; and that in the pursuit of betterment, we will actually make ourselves worse off."*
- What is going to happen to international conflict, when other, hostile societies are not just culturally different, but not fully human, either?[137]
- As we discover new and better ways to "improve" our given bodies, minds, and performance, are we changing or compromising the dignity of human activity? Are we becoming too reliant on "expert chemists" for our achievements? Do

such potential enhancements alter the identity of the doer? Whose performance is it, and is it really better? Is the enhanced person still fully me, and are my achievements still fully mine? Have I been enhanced in ways that are in fact genuinely better and humanly better? And, beyond these questions regarding individuals, we would need to consider the implications for society should such uses of biotechnology become widespread—in school; at work; or in athletics, warfare, or other competitive activities.[140]

- Germline enhancement violates the rights of the unborn.
- Genetic enhancement could have negative side effects.
- The promise of mastery is flawed. It threatens to banish our appreciation of life as a gift and to leave us with nothing to affirm or behold outside our own will.[141]
- We might be blamed for not improving ourselves or others.[141]
- We must bear increasing responsibility for the presence or absence of characteristics in ourselves and others and the effects this may have on human solidarity.[141]
- It would profoundly affect our self-perception as "persons," that is, as autonomous beings.[142]
- Even if social agreement on the "ideal" human being is reached, it will inevitably reinforce stigmatization and discrimination of those who do not fall into the accepted standards of genetically desirable traits.[143]
- Who is able to define now the ideal human characteristics for the future?[143]
- There is the idea of diminishing marginal utility, according to which the benefit someone gets out of a given improvement in his condition decreases the better off he is. Hence, we do more good if we help those who are worse off than if we help those who are already better off.[135]
- There is greater moral value in helping people who are worse off in absolute terms, even if we produce a smaller benefit to them than we could to people who are better off. This is known as prioritarianism.[135]
- People are not products to be designed.[135(p.11)]
- If someone wants to have a child, should they not focus only on the most basic goods, such as having a normal child to love?[135(p.11)]
- In the relation of parent to child, a parent will simply have greater control over the child's nature, whether she seeks it or not.[135(p.12)]
- If each parent individually tries to do what is best for its child, all parents will end up making the situation worse for all their children.[135(p.12)]

- Pursuit of perfection by biomedical means is vain, selfish, and unrewarding and other arguments against enhancement can be found.[139,144-150]

Arguments to justify enhancements

- One cannot draw a line between therapy and enhancement.
- People's right to alter their bodies (concept of morphological and genomic freedom.) is seen and sold as an extension of other rights such as the 'right to life', right to freedom, right to seek happiness; and the right to one's body.[151]

  The argument is one of autonomy and choice. Terms such as self-determination (technological or otherwise), human rights, autonomy, and freedom of choice, used in the civil liberties movement, and terms such as morphological freedom and genetic freedom,[151] are increasingly used to justify that "sane, adult citizens have a right to control their own bodies and minds."[152] Morphological freedom is seen and sold as an extension of one's right to one's body covering, not just self-ownership, but also the right to modify oneself according to one's desires and the right to seek happiness.[151] It is stated that we have a long history of changing our bodily appearances, such as through plastic surgery, and technological advances now only allow for additional means of body modification that not only include appearances, but also the physical and mental functioning of the human body. It is reasoned that the disability movement, as well as the postmodern critique of the normal body, is a natural supporter of morphological freedom in all its forms. The transhumanist/enhancement model of health, disease, and disability takes into account the concept of morphological freedom. It also takes into account that, increasingly, the lines blur between lifestyle and "normal" medication. The section on medicalization in this report shows how many truly lifestyle 'medications' are sold as 'disease medication'.
- People already enhance themselves.
- People would be happier and more successful.
- If, in the case of intelligence enhancement, the positive externalities outweigh the negative externalities, then a prima facie case exists not only for permitting genetic enhancements aimed at increasing intellectual ability, but for encouraging and subsidizing them, too.[134]
- Caplan uses the following reasons[139]:
  - a) Putting the brakes on biologically driven human betterment would have real consequences for science. c) Some lines of research would be slowed or restricted. d) Their application would be declared off-limits or at least tightly regulated. e) Beating up on the pursuit of perfection is silly. f) Many religious traditions and spiritual movements seek perfection:

He further adds:

- g) We are clearly creatures who have long tinkered with ourselves, using all manner of technologies from clothing to telescopes to computers to airplanes. Our view of our "nature" is closely linked to the technologies that we have invented and to which we have adapted. We are already technological creatures. h) Nor is there any normative guidance offered by our evolutionary history that shows why we should not try to improve upon the biological design with which we are endowed. Augmenting breasts or prolonging erections may be vain and even a waste of scarce resources, but seeking to use our knowledge to enhance our vision, memory, learning skills, immunity or metabolism is not obviously either.

It is beyond the scope of this report to evaluate every argument raised in the enhancement discourse. However, two questions are of particular importance to the readers of this report. Can one draw a line between therapy and enhancement in general? And can one draw a line between therapeutic and non-therapeutic enhancements in particular?

Drawing a line: therapy versus enhancement and therapeutic versus non-therapeutic enhancements

Although many people maintain that a line can be drawn between therapy and enhancement,[153] this might not be as easy as it sounds, and it may be impossible. Many therapies have enhancement aspects. Many enhancements can be classified as therapies and many therapeutic interventions can and are used later on for non-therapeutic purposes. Besides, the very meaning of health and disease is highly contested and more and more variations of human body structure and functioning are labeled as deviations as diseases (dynamic of medicalization). The transhumanist/enhancement model of health and disease defines the human body in general as defective, or as a work in progress, elevating the medicalization dynamic to its ultimate endpoint, namely, to see the enhancement beyond species-typical body structures and functioning as a therapeutic intervention (transhumanization of medicalization).

Policy implications

1. If one links the possible inevitability of enhancement (at least some of them) with the increased popularity of the transhumanist model of health, disease, disability, and well-being, with the dynamic of medicalization, and with the transhumanization of medicalization, one can expect augmentative/ enhancement medicine to become a growing, flourishing field of medicine, similar to curative, palliative, and preventative medicine.
2. An accepted and growing field of augmentative/enhancement medicine will impact the health system (WHO and Canadian scenarios) in general and the healthcare system in particular. It will impact funding policies by governments and academic funding bodies, public and private insurance policies, drug development, recruiting medical professionals into traditional medical fields after they are trained, the very concept of well-being and the viability of the WHO definition of health, disabled people (especially those who cannot afford the augmentations), and global health equity.
3. HTA would be well advised to evaluate the enhancement field quickly, continuously, and thoroughly. Interestingly, because of the way that augmentative/enhancement medicine is defined (so far over 500 Google hits), it fits with HTA definitions.
4. Medicalization is one of the main factors in the increase of drug use, which in turn is the main driver of drug costs (*see* Section 7, "New Drugs: Nanodrugs, Pharmacogenomics, and Pharmacogenetics"). The transhumanization of medicalization adds to this drug cost driver by further increasing the demand for drugs.
5. Enhancement will lead to similar cost explosions for other health technologies, such as implants (*see* Section 7, "Cost of Implants").
6. Costs will also be added to the healthcare system as some/many people become medically ill because of poorly performed or generic side effects of medicalization and transhumanized medicalization applications, actions, and products. To quote Elliot, *"An alarming number of supposedly risk-free enhancements have later been associated with unanticipated side effects, some of them deadly. Wyeth has set aside over $16 billion to compensate the thousands of patients who have developed valvular heart disease and pulmonary hypertension after taking fenfluramine-phentermine (Fen-Phen). A 2002 National Institutes of Health study found that hormone replacement therapy was associated with such an elevated risk of heart disease, stroke, pulmonary emboli and breast cancer that the study was stopped prematurely. Selective serotonin reuptake inhibitors are currently embroiled in controversy over whether they are associated with an elevated risk of suicide."*[139]
7. Costs might also develop as the system pays for the education of physicians and others only to lose them to the private sector to perform these medicalization and transhumanized medicalization procedures.

REALIZATION OF THE TRANSHUMANIST/ENHANCEMENT MODEL

Step 1: Make "healthy" people feel bad about themselves

The transhumanist/enhancement model of health, disease, disability, and well-being perceives the human body in general as defective. This sentiment is the ultimate endpoint of the existing medicalization of the "healthy",[154] where perfectly healthy persons are made to feel badly about their appearances or functioning. It sells to healthy people the idea that they are sick. Disease-mongering is a term some people use.[155-158]

The reality of medicalization is acknowledged by many among them the Canadian National Forum on Health.[159] An editorial in the British Medical Journal,[160] which rephrased an editorial of Amartya Sen in the same issue,[161] stated:

> "Amartya Sen, an even more distinguished economist, discusses the paradox that people in America feel much less well than those in Bihar, India, though their life expectancy is much better."[161(p.860)]

In a recent issue of the Seattle times one reads:

> The number of people with at least one of four major medical conditions has increased dramatically in the past decade because of changes in the definitions of disease. "The new definitions ultimately label 75 percent of the adult US population as diseased," according to calculations by two Dartmouth Medical School researchers."[154]

A growing number of medical technologies are employed to improve the looks, performance, and psychological well-being of people who are healthy. The traditional form of medicalization artificially assigns a subnormal label toward normal variations of human characteristics. More and more variations of normal characteristics of the human body are labeled as defective and in need of fixing, with the endpoint being the transhumanist/enhancement model of health and disease and the transhumanization of medicalization. The non-existence of a clear line between therapy and enhancement is exploited by many people.[139] Elliot describes selective serotonin reuptake inhibitors, hormone replacement therapy, and the diet drug fenfluramine-phentermine (Fen-Phen) as the three most commercially successful medical enhancements of recent years.[139]

Direct-to-consumer advertising

In 1999, Americans saw an average of nine prescription drug advertisements a day on television, portraying the dual message of a pill for every ill and "an ill for every pill."[160] Day quotes the Royal College of General Practitioners as accusing drug companies of "*disease-mongering*" in order to boost sales.[162] "*Once the need has been established and created, then the product can be introduced to satisfy that need/desire,*" states

Harry Cook in the Practical Guide to Medical Education, published by the UK-based Pharmaceutical Marketing magazine.[163]

Direct-to-consumer advertising (DTCA) is a contested area, with some evidence that it increases the use of healthy making products[155] and increases the medicalization of human characteristics. Interestingly, since the Food and Drug Administration (FDA) approved DTCA in 1997, US retail drug costs have increased from $20.8 billion to $131.9 billion from 1999 to 2000, according to the US National Institutes of Health Care Management.[164] Sharratt has listed the top 10 direct-to-consumer drugs by sales for 2003 in the USA.[164]

According to American Medical Association Trustee William E. Jacott, MD, physicians are increasingly feeling pressured by patients to prescribe a drug that they have seen advertised.[165] As Elliot states:

> For example, GlaxoSmithKline marketed paroxetine (Paxil) by promoting the previously obscure diagnosis of "social anxiety disorder" through phony support groups, celebrity spokespeople, a direct-to-consumer illness awareness campaign and generous payments to key opinion leaders. The manufacturers of estrogen replacement therapy marketed the hormone in the 1960s by funding a "research foundation" for Robert Wilson, the gynecologist and author of the best-selling book Feminine Forever. Wyeth marketed Fen-Phen by funding obesity research centers, launching public fitness campaigns, contracting with a medical education company to produce a series of ghostwritten journal articles and making generous payments to academic physicians who then published extensively and testified for the drug's safety to the Food and Drug Administration.[139]

Many problems with drug advertising exist. A double-page advertisement by the manufacturer of sildenafil (Viagra), Pfizer, told Australians recently "that 39% of men who visit general practitioners have erection problems."[157] However, as Moynihan et al explains further: "The 39% claim in the advertisement was referenced to an abstract of a survey finding. The full version of the published survey[166] revealed that the 39% figure was obtained by tallying all categories of difficulties, including men who reported having problems only 'occasionally,' and the average age of those reporting complete erectile dysfunction was 71 years."[166] Furthermore another Australian study, which estimated that erection problems affected only 3% of men above 40[167] was not cited.

Although DCTA[168-170] is not allowed in Canada at this time, pressure is mounting to legalize it.[171,172]

A recent report by the health committee of the parliament of Canada[173] recommended that:

- Health Canada immediately enforce the current prohibition of all industry-sponsored advertisements on prescription drugs to the public;
- Health Canada ensure the provision of independent, unbiased and publicly financed information on prescription drugs to Canadians;

- Health Canada dedicate specific resources to the Health Products and Food Branch Inspectorate for vigorous enforcement of the direct-to-consumer advertising regulations on prescription drugs, including active surveillance of all relevant media, identification of potential infractions, appropriate corrective action, and production of annual public reports;
- Health Canada ensure that all direct-to-consumer advertising complaints about prescription drugs received by Advertising Standards Canada or the Pharmaceutical Advertising Advisory Board are forwarded to Health Canada for investigation and action.

Indeed many problems exist with DCTA[174-183]

Medicalization triggered by the availability of drugs

The antidepressant Aurorix (moclobemide) was sold as a valuable treatment for social phobia in 1997 in Australia.[157] The timing went hand in hand with a media strategy that portrayed a variation of how we behave—shyness—as "social phobia," a medical condition in need of treatment. Simultaneously, the number of people labeled as having social phobias increased in Australia from 370,000 to two million.[157] Selective serotonin reuptake inhibitors (Celexa, Desryl, Effexor, Luvox, Paxil, Prozac, Serzone, Zoloft) are described as the latest treatment for anxiety disorders[184] such as generalized anxiety disorder, panic disorder, phobias (special phobias, social phobias formerly known as shyness), obsessive-compulsive disorder, and post-traumatic stress disorder without much questioning the medical label.

Another drug, Rogaine, also called minoxidil, has been sold in the past to lower blood pressure.[185] One of the side effects of this drug is hair growth. This outcome led to advertising the drug for the "treatment" of hair loss in men[186,187] and "hereditary hair thinning" in women, which, according to the company, affects over 30 million women in the USA alone.[188] The drug does not cure hair loss, however. It is a maintenance drug. If one stops using the drug even after five years of use, one will lose all of the hair grown previously and any hair that the minoxidil kept one from losing.[188]

Medication used to treat attention deficit hyperactivity disorder (ADHD) is another example of the medicalization of human characteristics. According to one report, "The number of preschool children being treated with medication for ADHD tripled between 1990 and 1995."[189] "The number of children ages 15 to 19 taking medication for ADHD has increased by 311 percent over 15 years."[189] "The use of medication to treat children between the ages of 5 and 14 increased by approximately 170 percent."[189,190]

As Claudia Malacrida outlines:

> "In 1995 in Alberta, approximately 2.5 percent of school-aged children were prescribed Ritalin alone, representing a fourfold increase since 1987 when record keeping began (Alberta College of Physicians and Surgeons, 1999[191])."

According to Malacrida the increase in diagnosing ADD/ADHD is contributed to many different factors, such as aggressive pharmaceutical marketing strategies and middle-class parent support groups seeking a medical label for their children's behavioral problems, reductions in educational funding and restricted classroom discipline policies, general increase in the psychiatric labeling of children, and rise of the fields of special education and educational psychology, through which an increasingly broad array of assessment tools have been employed in classifying and identifying differences in children.[192]

Malacrida states: "*In Canada, where ADD/ADHD is a highly medicalized phenomenon, and teachers have few alternative forms of social control available to them in classrooms, it appears that educators are prepared to identify problem children and press for medical treatment with remarkable vigor. In Britain, where medicalization remains incomplete, and where teachers and special educators have more stringent alternative forms of social control available to them, educators were often described as gatekeepers who will refuse the label or to administer medication.*"[192]

A recent investigative report in the Seattle Times by Susan Kelleher and Duff Wilson[154] looked intensively at obesity and the area of medicalization. The market for prescription drugs for weight loss is worth $0.5 billion.[193] Xenical[194], a diet drug produced by pharmaceutical giant Roche, has been nicknamed the "bikini drug."[195] In May 2001, Time reported that sales of the drug have exploded over the Internet, where clients do not have to prove they need the drug.[196,197] Meridia (sibutramine hydrochloric monohydrate), manufactured by Knoll Pharmaceutical Co., works to suppress appetite via serotonin (and norepinephrine) reuptake inhibition:

> In one 12 month study, patients who took 10 mg of Meridia daily lost an average of 10 pounds, while those taking 15 mg daily lost an average of 14 pounds. The average weight loss in people on only a reduced calorie diet was 3.5 pounds. Study participants lost most of their weight in the first six months and maintained statistically significant weight losses for up to a year.[198] Although Meridia's efficacy profile is modest, the drug's sustained actions are advantageous since obesity tends to be a chronic condition." "The primary goal of this drug is not necessarily to make you look better, but to help you lose enough weight to eliminate health risks associated with obesity. People taking Meridia or considering it should also be reminded that Meridia must be used in conjunction with major lifestyle changes, such as increasing physical activity and eating right."[199]

And, according to Arena Pharmaceuticals:

> Obesity affects tens of millions of adults and children in the US and poses a serious long-term threat to their health and welfare. The number of overweight and obese people has substantially increased over the past several decades. Approximately two-thirds of all adults in the US are obese or overweight. Medical and related costs of obesity in the US were more than $117 billion in 2000. Being obese or overweight is associated with a number of conditions, including heart disease, stroke, diabetes, cancer and osteoarthritis. Medical treatment options for obese and overweight people are currently limited.[200]

Recently Arena Pharmaceuticals reported the following: a 28-day regimen of its experimental obesity drug resulted in an average weight loss of 2.9 pounds. Patients taking a placebo in the Phase II trial lost less than a pound.[201]

> "*The results of this trial are very supportive of further study and provide hope that obese individuals could have a new therapeutic option in the future to help control their weight in an effective, safe and controlled manner,*" said Steven Smith, MD, principal investigator and associate professor of the Pennington Biomedical Research Center.[202]

Medtronic recently acquired Transneuronix, Inc., a company that sells electrical stimulation therapy for the treatment of obesity.[203] The Transcend system has been commercially available in Europe for over three years and has received approval in Canada.[203] Medtronic estimates the cost for treatment as between $15,000 and $20,000.[204] For those patients who do have success with the implant, the average loss is about 40% of excess body weight.[205]

Others drugs triggering medicalizations are Botox for wrinkled faces, Humatrope for short stature, and Sarafem for premenstrual discomfort. In addition, the International Network of Cholesterol Skeptics takes issue with the recently revised cholesterol-lowering guidelines, saying they will *"result in millions more people being placed on statins – putting them at risk for side effects unnecessarily."*[206] Hormone replacement therapy (with synthetic estrogen derived from horse urine) was touted as the "cure" for the "disease" of menopause. Formerly a natural process in life, menopause is now treated as a disease on a par with diabetes or hypothyroidism.[207]

Policy implications

According to a 2005 report by the Canadian Institute for Health Information,[208] increased drug spending in Canada relates to the volume of drug use and the entry of new drugs (typically introduced to the market at higher prices) and not to an increase in price of the old drugs. This conclusion was also reached by the Standing Senate Committee on Social Affairs, Science and Technology, which states that prescription drug spending could be attributed to increased utilization of existing drugs (50%), sales of new drugs in their first full year (32%), and price increases of existing drugs (18%).[209] (For more information on drug costs, see Section 7, "New Drugs: Nanodrugs, Pharmacogenomics, and Pharmacogenetics.")

As Moynihan states,"Medicalization may help feed unhealthy obsessions with health, obscure or mystify sociological or political explanations for health problems, and focus undue attention on pharmacological, individualized, or privatized solutions."[157]

Medicalization of aesthetics (body appearance)

If we move from drugs to surgery procedures, examples of medicalizations are as follows: endoscopic thoracic sympathectomy surgery for blushing or excessive sweating[210]; rhinoplasty (surgery of the nose)[211]; eyelid surgery (technically called

blepharoplasty), a procedure to remove fat and excess skin and muscle from the upper and lower eyelids[212]; Botox injections, which temporarily reduce or eliminate frown lines, forehead creases, crow's feet near the eyes, and thick bands in the neck;[213] browlift; camouflage cosmetics,chemical peel, the use of "a chemical solution to improve and smooth the texture of the facial skin by removing its damaged outer layers," described as "helpful for those individuals with facial blemishes, wrinkles, and uneven skin pigmentation";[214] chin surgery; dermabrasion; ear surgery; endoscopic plastic surgery; face lift; facial implants; hair replacement; injectable fillers; laser skin resurfacing; lipoplasty or liposuction;[215] microdermabrasion, "a skin-freshening technique that helps repair facial skin that takes a beating from the sun and the effects of aging";[216] permanent eyeliner, which involves "a procedure called micropigmentation in which an organic pigment is embedded beneath the skin to add permanent color";[217] skin management treatments; spider vein treatment; tummy tuck or abdominoplasty, which flattens the abdomen by removing excess fat and skin and tightening the muscles of the abdominal wall;[218] and upper arm lift, also known as brachioplasty, which removes loose skin and excess fat deposits in the upper arm.[219] All of these procedures are listed at the American Society of Plastic Surgeons website.[220]

Breast implants are a $500 million industry.per year. In the last 30 years, two million American women have chosen to obtain silicone breast implants, 80% of them for aesthetical enhancement.[221] Sixty per cent of these women were at risk of complications afterwards.[221] Since 1992, a moratorium has been in place for silicone implants in the USA, which has recently been renewed,[221] except for women who had their breast removed or who have very small breasts (micromastia). However, this has not stopped the process of breast augmentation.

The American Society of Plastic Surgeons estimates that in 2004, about 260,000 women received breast augmentation for cosmetic purposes only, and about 60,000 women received augmentation after undergoing a mastectomy.[222] The medicalization of beauty as health is a fruitful field. The statement by the American Society of Plastic and Reconstructive Surgeons to the FDA in defense of breast implants concisely summarizes the argument by which breast augmentation has become medicalized:

> The female breast that does not achieve normal or adequate development. . . [is] really a disease which in most patients results in feelings of inadequacy, lack of self-confidence, distortion of body image and a total lack of well-being due to a lack of self-perceived feminity.[223]

Another level of medicalization is achieved in the television show "Scalpel: Nobody's Perfect," which films people having plastic surgery in front of their loved ones. The show gives away free surgery to help people "to fix their defective bodies."[224]

Step 2: Add enhancement to the mix

> "'*I believe in transhumanism': once there are enough people who can truly say that, the human species will be on the threshold of a new kind of existence, as different from ours as ours is from that of Peking man. It will at last be consciously fulfilling its real destiny.*" Julian Huxley, First Director-General of UNESCO.[225]

The transhumanization of medicalization moves the dynamic of medicalization one step further by adding the enhancement of body appearance and functioning above species-typical norms and boundaries to the mix.

Policy implications

1. One can expect augmentative/enhancement medicine to become a growing, flourishing field of medicine.
2. Medicalization is one of the main factors in the increase of drug use, which in turn is the main driver of drug costs (see Section 7, "New Drugs: Nanodrugs, Pharmacogenomics, and Pharmacogenetics"). The transhumanized medicalization adds to this drug cost driver by further increasing the demand for drugs. It will lead to similar cost explosions for other "health technologies" such as implants (see Section 7, "New Drugs: Nanodrugs, Pharmacogenomics, and Pharmacogenetics").

Examples of enhancements that could be seen as therapies and therapies that have enhancement aspects

- If one gives a gene to a person that makes this person immune to acquired immunodeficiency syndrome (AIDS), this would be a therapy, but it would also be an enhancement of the genetic makeup of the person.
- If one implants electrodes into the skull of a person that allows the person to have thought control over their environment (see Section 7, "Brain Machine Interfaces"), it could be seen as a therapy for a person with cerebral palsy, as that person would be able to compensate for "subnormative" mobility capabilities. However, that person would also be enhanced because humans normally do not have thought control over their environment.
- Bionic legs, arms, skins, organs, and other modifications, listed in Section 7, "NBIC Products Envisioned for Disabled People" in this report, have not only therapeutic but also enhancement potential. The bionic leg pictured in that section makes that leg more capable in certain ways than "normal" biological legs, through, for example, its high-tech knees, which make recipients of these legs jump higher than the "normal leg people." The same scenario could be envisioned for other implants. If a bionic eye ever works well enough to be therapeutic in restoring "normal" vision, then there should be no reason that this

device could not enhance vision beyond the biological norm. The Cyborg 2.0 experiments of Warwick already use implants to enhance/add new capabilities to the human body, adding a whole new sense to the human experience, namely, the ability to read radio signals and to react to them.[226,227]

- Anti-aging interventions are another area defined by some people as "therapeutic enhancement." If we could gain an extra decade by strengthening our immune system or our antioxidation and cellular repair mechanisms, this would clearly be a human enhancement. But it would also be a preventive therapy, because it would delay cardiovascular disease, senile dementia, cancer, and other illnesses of aging, which we spend billions trying to treat.[137]

This list of modifications with enhancement and therapeutic potential could be extended with no end in sight.

Examples of therapeutic interventions that are used for non-therapeutic purposes

Many therapeutic interventions are eventually used for non-therapeutic interventions.[228] For instance, many psychoactive drugs, including alcohol, caffeine, nicotine, heroin, cocaine, cannabis, and 3,4 methylenedioxymethamphetamine, were used first for therapeutic and then for non-therapeutic applications.[229] Modafinil, sold in Canada as Alertec, was developed for the treatment of narcolepsy.[230] In September 2003, an advisory panel to the FDA endorsed its use for treating shift-work sleep disorder and obstructive sleep apnea.[231] Modafinil is also attracting attention from the military and from "healthy" people as a possible alertness drug.[232] There are about 150,000 Americans with narcolepsy, but as many as 250,000 Americans are using modafinil.[232] The drug is increasingly used to alleviate sleepiness from all sorts of causes, including depression, jet lag, or simply working long hours with too little sleep. Cephalon is now focusing on moving the drug through late-stage clinical trials for ADHD in children.[233]

Nootropic drugs[234] or cognitive enhancement drugs,[235] used to treat Alzheimer's disease, are another example of therapeutic interventions that may be used for non-therapeutic purposes.[236,237] According to the *Economist*, 4.5 million people in the USA suffer from Alzheimer's disease.[236,238] At least 40 potential cognitive enhancers are currently in clinical development:[236]

> Over the last 3 years, the value of the Alzheimer's disease market has grown by an average of 19% per year. Growth has been driven by increasing availability and reimbursement of Alzheimer's drugs. Nootropic drugs or anti-Alzheimer's drugs are one of the largest segments of the neurodegenerative market and accounted for 31% of global sales (US$3.0 billion in 2004 and equivalent to 5% of global CNS drug sales). The market for drugs to treat Alzheimer's disease has grown steadily since the launch of Aricept in 1997 and experienced 21% growth year-on-year in 2003. In 2004, Aricept generated global sales of US$1.2 billion, accounting for approximately 40% of the market by value. Whilst the US accounts for approximately 50% of global Alzheimer's drug

> sales, the majority of growth occurred outside the US with European sales increasing to 29% of sales in 2004.[239]

But people with mild cognitive impairment may also be interested in these drugs:

> "Mild Cognitive Impairment (MCI), defined as memory loss without any significant functional impairment, is estimated to afflict at least another 4.5 million people."[236]

These are the primary targets for these cognitive enhancers. However the Economist continuous to say "There are now about 85m people aged 50 and over in America, many of whom may already fit the definition of "age-related cognitive decline", a category so vague it includes people who become distressed over such mild glitches as forgetting their keys or glasses," and asks the question whether "cognitive enhancers" should also be given to them.[236]

Adderall/Ritalin is a drug that was originally developed for ADHD but is used today by college students to increase their ability to study for long hours.[240-244] CX717 is being considered by manufacturer Cortex for treating narcolepsy and ADHD. However, this drug has also been found to improve people's smarts. CX717 works by increasing levels of the chemical glutamate, which is involved in learning and remembering.[245] Around the country, companies such as Memory Pharmaceuticals, Sention, Helicon Therapeutics, Saegis Pharma-ceuticals, and Cortex Pharmaceuticals are racing to bring memory-enhancing drugs to market before the end of this decade. Beta-blockers were originally designed for congestive cardiac failure. However, a study in the late eighties indicated that 27% of symphony orchestra musicians were taking beta-blockers.[246] At anxietysecrets.com, one reads: "Beta Blockers are used to calm certain anxiety symptoms such as shaking, palpitations and sweating all over yourself. The medication is fast acting and non-habit forming but should not be taken with other pre-existing medical conditions (e.g. asthma, congestive heart failure, diabetes, vascular diseases, hyperthyroidism and angina). Beta-blockers are not FDA approved for the treatment of anxiety but are generally used to do so."[184]

Policy implications

The concept of medicalization is by itself very important for HTA. It increases the pool of people who are seen and see themselves as patients. Medicalization is one mechanism that explains the increased use of drugs, which was identified as the main cost driver for drugs (see Section 7). The transhumanization of medicalization might lead to an acceptance of enhancement drugs and surgery and the establishment of the new field of augmentative/enhancement medicine. The concept of body appearance and function enhancement was identified earlier as a general challenge to HTA and the medical system and marginalized groups. Even if a public health plan does not pay for the procedures, which is not altogether clear (i.e. Alberta pays for breast augmentations), it these procedures might still have an impact on the health care system if they are not closely monitored. Many people end up in hospitals as a result of defective breast implants. According to Elliot, *"An alarming number of supposedly risk-free enhancements have later been associated with unanticipated side effects, some of them deadly. Wyeth has set aside over $16 billion to compensate the thousands of patients who have developed valvular heart disease and pulmonary hypertension after taking Fen-Phen. A 2002 National Institutes of Health study found that hormone replacement therapy was associated with such an elevated risk of heart disease, stroke, pulmonary emboli and breast cancer that the study was stopped prematurely. Selective serotonin reuptake inhibitors are currently embroiled in controversy over whether they are associated with an elevated risk of suicide."*[139]

Implants can be a big cost driver in the future. As outlined in the drug section (See Section 7, "New Drugs: Nanodrugs, Pharmacogenomics, and Pharmacogenetics") the second biggest cost driver is that new drugs are always more expensive than old drugs. The same can very likely be said for implants. New versions of implants will be more expensive than the older versions. We perform more and more implants, even under the traditional health care system. For example, over 44,000 hip replacements and 35,000 knee replacements were performed in 2002.[247] Insulin pumps for diabetes patients are increasingly used. Since May 2004, Canadians using an insulin pump have been eligible for a tax credit. The long-term left ventricular assist device is seen as an alternative to heart transplants, and the list goes on. The market for implants is already exploding, as we are only now starting to generate really usable implants.

HOW TO EVALUATE

Step 1: What kind of assessment?

Countries recognize that they should evaluate health technologies on the horizon.[248] Many countries use horizon scanning as a tool,[249-253] including Canada.[254] A range of different instruments is available to perform different kinds of assessments, such as HTA,[255-259] HIA,[260-263] HNA,[264-266] PTA,[41,267] and participatory technology assessment (PTTA),[42] through which one can gain relevant information for decision marking about health and health technology.[42,268-270]

Numerous reports[14,271-273] state that"current HTA efforts in Canada are insufficient to meet the needs of policy makers within the healthcare system."[38,271] Canada recently adopted a new Health Technology Strategy,[274] which is slated for implementation in 2005,[275] but it remains to be seen whether the new strategy will be sufficient. It is less clear how much attention HNA and HIA is receiving; however, it is reasonable to assume that, because HTA is seen as underfunded, HIA[276] and HNA are underfunded as well.

PTA[41,267] does not exist in Canada in a systematic fashion. Although one could envision that the Canadian Biotechnology Advisory Committee was set up as a tool fitting a PTA unit, this committee has a much more limited agenda than PTA units have. PTTA[42,277] is more common in Europe than in North America. Consensus conferences, which are a tool of PTTAs, are rarely used in Canada. The Canadian Health Services Research Foundation developes something they call a deliberative process towards a more meaningful, informed, and effective public consultation. One has to see how good that process is and whether it will be widely used.[278,279]

Besides the generic issue of whether enough attention is given to different methods of assessments, new challenges for HTA, HNA, HIA, PTA, and PTTA are emerging and old challenges[280-283] still have not been solved.

Step 2: How to perform assessments

Advances in health and non-health-related science and technology do not just generate products for HTA units to assess but also affect how HTA units do business. Numerous guides for the execution of HTAs exist.[268,284,285] The HTA Unit of AHFMR published a report titled "Elements of Effectiveness for Health Technology Assessment Programs."[286]

According to the German Agency for Health Technology Assessment at DIMDI - German Institute of Medical Documentation and Information, an HTA should contain:

- an exact definition of the problem;
- a definition of the research question(s) to be answered by HTA;

- a description of the starting situation, technical characteristics of the technology, and data concerning efficacy and effectiveness under everyday conditions in relation to other methods and under consideration of factors that depend on the context, such as practicality, acceptance, compliance, and demands on quality;
- the influence of the technology on the organization of health care and within specific settings of providement;
- ethic, legal, social, and psychological implications;
- economic assessment (under consideration of direct and indirect costs);
- conclusions; and
- options and recommendations.[268]

However, if one takes into account Sections 1 to 7 of this report, this list does not come without challenges.

Problem 1: Impact of the WHO/Canadian scenario and the different models and determinants of health, disease, disability, and wellness (medical, social, transhumanist/enhancement) on the scope, process, direction, and outcome of HTA.

According to the German description, HTA starts with the exact definition of the problem, a definition that will differ depending on which model and determinants of health, disease, and disability (medical model/medical determinants, medical model/social determinants, social model, or transhumanist/enhancement model) and which health scenario (WHO versus Canadian) one chooses. Every step described by the German agency is affected by that choice.

A case in point is the mandate of HTA which, according to CCOHTA, is about the evaluation of medical technologies.[254,255] On one side of the spectrum, every intervention applied to the human body could be classified as a medical intervention and therefore seen as a medical technology if one follows the transhumanist/enhancement model of health, disease, disability, and well-being, especially under the Canadian scenario of "health."

On the other side of the spectrum, if one follows the WHO scenario of health and the social model of health, disease, disability, and well-being, health technology is much more than medical, clinical technology and HTA would have to discard its pure focus on medical technologies if it wanted to live up to the broader understanding of health.

Even the combination of the Canadian scenario of health paired with the medical model of health and social determinants of medical health moves the mandate of HTA away from pure medical/clinical technologies toward including technologies such as water and sanitation technologies, which have an impact on the medical health of 'patients.'

Policy implications

1. It is to be expected that an increase in HTA-eligible technologies (even under the narrow CCOHTA definition) increases the need for money and human resources in order to be able to fulfill the HTA mandate.
2. Other assessment methods such as HIA, HNA, STA, SIA, and social well-being needs assessment are also affected by the different models and determinants of health, disease, disability, and well-being and have to be taken into account.
3. HTA can move to cover technologies that improve social well-being and/or can consider the social well-being aspect of every "health technology" or do additional assessments to give policy makers and others a complete picture regarding the impact of any given "health" technology.

Problem 2: Who is a patient and why? The increase in the number of patients

CCOHTA includes in HTA investigations into the impact of health technology on patients' health.[254] Linking HTA to the term "patients" leads to a few consequences. Different models, determinants, and scenarios of health, disease, disability, and well-being lead to different amounts of patient/health /healthcare consumer.

Transhumanists, which are on the rise, are the ultimate health and healthcare consumers, as they are eager to improve their medical, transhumanist health and they perceive themselves as ill, defective, and in need of cures and fixes. The number of people who define themselves and who are defined by others as "patients" is increasing. On the one hand, people are made to feel ill about themselves and their body structure and functioning ("medicalization creep," see Section 4: Realization of the transhumanist/enhancement model: Step 1: Make "healthy" people feel bad about themselves) in order to generate the desire in people for fixes. On the other hand, people are forced to label themselves as patients with a disease or disability (medical model) in order to receive reimbursement for body function and appearance changes, whether one believes them to be defective, ill, or impaired or not. People who want to change their sexual orientation accept the label of "gender identity disorder" in order to have someone pay (the health system) for their sex reassignment surgery (Alberta pays for it). Many transsexual people do not see themselves as having a disorder but accept the label in order to have someone pay for their body modification.[287] The organization Egale[288] accepts the medical label to fight for the public payment of the surgery under the term "medical necessity."

Disabled persons, whether they see themselves as deficient or not, have to prove that they are medically deficient in order to be recognized as disabled persons, which in turn is a requirement for accessing government programs, including certain health technologies. Many disabled people do not see themselves as deficient but just as different, and they would like to be supported by society for their different needs.

However, no mechanism exists to judge, evaluate, and act on the needs of disabled people if they are voiced through the social model of disability. Indeed, many disability rights laws,[91,289] such as the ADA, still depend on some medical model of assessment of the "disability."

> ***Policy implications***
>
> Every human being at any stage of human development becomes a patient and therefore a client for HTA as soon as this "patient" or "client" modifies his or her body structure or functioning or has it modified by others, if one follows the transhumanist model of health, disease, and disability, especially under the Canadian scenario of "health."
>
> This perspecive will increase the need for money and human resources in order to be able to fulfill the HTA, healthcare, and health system mandate.

The term "patient" puts the subject of the assessment within the medical/ transhumanist category, leading to a preset road of perceptions, preconceived notions of the problems, and preconceived determinants of health (medical/transhumanist/enhancement determinants), with preconceived sets of solutions (medical/transhumanist cure).

> ***Policy implications***
>
> HTAs that follow this road will have no mandate to evaluate impacts on social well-being and investigate social cares and social cures and how they relate in efficacy and effectiveness to medical/transhumanist cures/cares.

Problem 3: If one reads the mandate of CCOHTA one gets the impression that the Canadian HTA's mandate seems not to include the investigation of non-clinical evaluations of science, technology, health research, health care, health deliverance, meaning of health, health care, and health technologies.

Hennen, a member of the German Office for Technology Assessment at the German Parliament states:

> It is, however, also plain to see that apart from issues which could be said to be merely clinical ones, we also find studies dedicated to more general questions of ethics (such as, e.g. the moral status of brain dead patients), of social consequences (the acceptance of disease and disabled persons in society), social acceptance of new technologies for medical treatment (gene therapy), statutory regulation of application or studies dealing with the development of health care in general. In recent years the growing importance of this type of questions for HTA is widely discussed as a new challenge for the HTA community. It is held to be necessary to expand the scope of HTA studies by including social effects and the social objectives of the health care system (growing importance of

prevention) and to include the different ethical perspectives held by social groups on the application of new health technologies.[41,269]

Hennen[41] sees the fields of HTA and PTA converging and complementing each other. According to Hennen, HTA looks mostly at the problem area of physicians and patients in the clinical setting, with efficiency and costs at stake and with clinical guidelines and recommendations for healthcare management as outcomes, whereas PTA looks at the problem area of technology and society in the political setting, with contested values and interests at stake and with input to public debate, research policy, and legislation as outcomes (see Table 4 in [41]).

Policy implications

The report presented here strongly makes the point that HTA in Canada has to look at issues so far mostly looked at by PTA. The CCOHTA definition of HTA is artificially narrow and does not suit present and future challenges to the "health system." Other much broader HTA definitions exist, which seem to be better able to deal with the challenges outlined in this report.[259]

Problem 4: Biased languages within HTA assessment

On the website of the Swedish Council on Technology Assessment in Health Care (SBU), one finds the report "Maternal Serum Screening for Down Syndrome," which highlights a systemic problem within HTA as it relates to disabled people, namely, a high degree of biased language. In this case, the SBU Alert reflects a high degree of bias toward Down syndrome.[290] Defining the birth of a child with Down syndrome by using risk language, *"The risk of having a child with Down syndrome increases with the age of the mother,"* is out of sync with the self-perception of many people with Down syndrome and the perception of people/organizations affiliated with them.[291] The handling of the term "risk" needs close scrutiny within HTA. It highlights one problem with the HTA process, namely, how to ensure that the right people are involved with a concern that is also shared by others in different contexts.[292]

Policy implications

1. HTA has to become much more aware of their biased language and thinking.
2. HTA has to revisit all of their reports, identify biased language, and change the language accordingly.
3. HTA might be well advised to use a framework, a list of possible biases against which to check their reports, to prevent biased language in the future.

Problem 5: Who is part of the HTA team?

It is not clear who is part of HTA teams. However, from reading the literature, it seems that marginalized groups are not part of HTA teams and that the teams are often very much anchored within the medical profession.

> ***Policy implications***
>
> A much more balanced and broad group of experts has to be involved.

Problem 6: Horizon timeline too short

If one looks at the definitions of new and emerging technologies,[251,253] of the National Horizon Scanning Centre in the UK, their horizon scanning timeline is a maximum of two years into the future. The Canadian horizon screening service seems to assess only technologies that are already in use.

This short timeline is interesting when one considers that others, such as the military, use timelines of 20 to 25 years, if not longer. Some people might say that is too long and many of the people who want technologies to move forward state that no problems attached to a technology can be envisioned that far ahead. This short timeline might be one reason that none of the technologies and societal changes covered in this report has shown up in HTA documents so far. The author of the current report read all available online assessment reports from the UK and Canada; the SBU, Sweden; the horizon scanning reports of the Australian HTA; and the Euroscan database. None deal with emerging technologies related to bionics, human enhancement, brain machines, or artificial organs, despite their increasing feasibility, their coverage within the PTA and PTTA, and their significant impact on the concept of health, disease, well-being, and disability.

Even the Nanotechnology Horizons[293] report, which by its name suggests a cutting edge HTA, is too nearsighted. The nanotechnology reports from PTAs such as the German Parliament Office for Technology Assessment and others have to date provided much more far-sighted evaluations of this technology.

> ***Policy implications***
>
> It seems useful to change the short timeline.

Problem 7: Lack of coverage of social implications and lack of inclusion of the voices of marginalized groups

Having looked at every project listed on the website of horizon scanning HTA organizations, it is evident that few if any of the reports completed or in preparation

looked at the social implications, including the voices of marginalized groups or any other group that is not within the clinical field/industry.

Policy implications

The issue of social implications has to have much more in-depth coverage and the voices of marginalized groups have to be given reasonable visibility.

Problem 8: Missing ethical framework

Numerous definitions of and statements about HTA seem to suggest that looking at ethical implications of health technology is an integral part of HTA.[41,255,294] However, who defines what the ethical implications are? What ethical frameworks should HTA use? Is there one ethics theory that could be used? Is there the possibility of global ethics for HTA? Health Technology Assessment International just offered a workshop in June 2005 with the title, "Integrating Ethical Considerations into HTA." The description of the workshop acknowledges that no consistent ethical framework exists within HTA. Despite concern for the ethical implications of technological development, it is difficult to find a rigorous acceptable model of ethical implications in HTA studies.[294] This workshop focused on the following questions:

- What are the different (practical) approaches for incorporating ethical implications in HTA?
- What are the barriers and facilitators to using these approaches?
- How useful are these approaches?
- Can we develop practical recommendations for incorporating ethical considerations into HTA?[294]

The workshop description read as follows:

> We will focus on different approaches to incorporating ethical implications of the development and use of health technology. Ethical aspects of health technologies and issues of legitimacy, social justice, and public controversies that arise around HTA will be addressed by experts in the field. Differences and similarities between the approaches will be discussed, as well as needs for practical recommendations to include ethical inquiry in HTA.
>
> The session will start with a general introduction to emphasize the necessity for integrating ethical implications in HTA. Thereafter, five experts from different countries will present different approaches to incorporate ethical implications in HTA. All presentations will be practice-oriented and we will aim to have an interactive workshop - involving the audience in discussing this topic. For this purpose we will present the audience with two "case-studies" (PSA screening and first trimester diagnosis of fetal abnormalities), in which they have to identify ethical issues at stake, identify approaches to analyze the ethical issues, identify barriers and facilitators for applying certain approaches and discuss the practical implications of applying different approaches.[294]

HTA Policy implications

If one takes into account the two challenges described (transhumanism and the role and understanding of disabled people) and the horizon scanning of emerging technologies performed for this report (see Section 7), numerous questions come to mind.

1. Many different ethics theories were developed over time and are in use today. Some relate to mechanisms, some are based on outcomes, and some, such as the feminist approach to bioethics, are tailored toward the needs of certain social groups of society. How does HTA decide which ethics theory to use?
2. If a feminist approach to ethics theories and bioethics issues is acceptable to the ethics/bioethics field, does that mean such an approach is also acceptable to frame ethical considerations of HTA? If yes, does that mean that approaches of other social groups toward ethics theories, such as an indigenous people approach and a disabled people's approach, are also acceptable to HTA and informing ethical deliberations of HTA? If a disabled people's approach is acceptable, which disabled people are we talking about: the patient, the social justice, the transhumanist type, all of them, or none of them? Is there another type of disabled people not mentioned?
3. Within the academic debate over bioethical issues, certain ethical principles are put forward time after time, namely, the principles of autonomy, beneficence, nonmaleficence, and justice. Should these principles guide HTA? If yes, all of them or some more than others? If some but not all, which principles? If all, how would that play itself out in HTA, especially if one takes into account the two challenges raised in this report?
4. If one looks at the biased language ("abnormality" is a biased, subjective term) of the workshop, ("first trimester diagnosis of fetal abnormalities"), one has to wonder what ethical framework HTA will adopt and how much this framework will rise to the challenge regarding disabled people and their self-perception, as outlined in this report.
5. How will concepts such as transhumanism, medicalization, transhumanization of medicalization, augmentative medicine, enhancement medicine, and global health play themselves out with the ethical framework that the HTA profession might choose?

Problem 9: HTA and disabled people

The topic of HTA and disabled people is presented in Section 6, (se*e* "HTA and Disabled People").

The problem with evaluation, measuring, analysis, and outcome tools

Evidence-based medicine/evidence-based decision making

"Evidence-based decision-making (EBDM) became part of the health sector's lexicon during the 1990s."[295] The National Forum on Health defined EBDM as "the systematic application of the best available evidence to the evaluation of options and to decision-making in clinical, management and policy settings"[296] and states in the same report that:

> Evidence-based decision making is not tyranny over providers; it is not value free; it is not a suggestion that evidence is not being used now; it is not a methodological strait-jacket; and it is not an excuse for inaction. Nor is evidence-based decision making based solely on evidence. It is influenced by individual values, interests and judgments as well as external pressures and conditions. It is simply getting the best information in place so that people can make the best decision which is consistent with their values and circumstances.[297]

The Public Health Agency of Canada states:

> The aim of evidence-based decision making (EBDM) is to ensure that decisions about health and health care are based on the best available knowledge. To use EBDM one must first assess what constitutes evidence, both in relation to health-enhancing interventions and to organizational or policy level decision making. One also needs to explore the availability and accessibility of reliable information and knowledge that identifies how interventions, practices and programs affect health outcomes.[298]

Policy implications

How does one perform EBDM if EBDM is not value free? How does one ensure that one gathers evidence reflecting different values and perceptions? How does one decide which values to follow? How does one ensure that certain values are not overlooked? How does one ensure that one gets the best information in place? The current report showed that certain values and perceptions are underrepresented (Section 6) and that certain biases exist in what constitutes evidence (*see* Section 6 and below).

The emerging transhumanist value raises numerous new challenges to existing values. The landscape of what kind of competing or complementing values one can expect is changing.

HTA embraces a diverse group of methods.[299] Table 2 lists different types of evidence as generated by different types of research methods and research designs.

Table 5: Types of evidence, research methods and purpose of research[300]

Types of Evidence	Type of Research Methods	Purpose/Use
Experimental and *quasi-experimental* evidence	(1) Randomized controlled trials (2) Controlled before-and-after studies (3) Interrupted time-series studies (4) Various types of matched comparison studies	Relative effectiveness of a policy intervention
Survey and administrative evidence		(1) Experimental and quasi-experimental studies (2) Providing valuable information about the nature, size, frequency, and distribution of a problem or a topic under investigation
Qualitative research evidence	(1) Theory-based methods (2) Goals-based evaluation methods (3) Goals-free evaluation methods (4) In-depth interviews (5) Focus groups (6) Consultative techniques (7) Ethnographies (8) Observational and participant-observational studies (9) Conversation and discourse analysis	*(1) The question of why* a policy works (or fails to work), *how* it works, *for whom*, and *under what conditions* it works or fails to work (2) Importantant for the successful implementation and delivery of policies, especially across a range of populations and subgroups
Economic evaluation evidence	(1) Cost-effectiveness analysis (2) Cost-benefit analysis (3) Cost utility analysis (uses QUALY) (4) Opportunity cost appraisal (5) Deadweight and counterfactual appraisal (6) Cost-of-illness analysis (7) Cost-minimization analysis (8) Cost-consequence analysis	(1) Decisions about the use and allocation of scarce resources (2) Most cost-effective way of achieving a given objective (3) The greatest benefit and utility that can be achieved from the available resources
Philosophical and ethical evidence	(1) Consultative techniques (2) Needs analysis (3) Critical incidence analysis	(1) Evidence about the range of values involved in a policy decision or initiative and about ways of adjudicating between competing values
Systematic review evidence	(1) Narrative reviews (2) Vote counting reviews (3) Systematic reviews (4) Meta-analyses (5) Best-evidence synthesis (6) Meta-qualitative reviews (7) Rapid evidence assessments	(1) Establishing standards of inclusion and exclusion of single studies (2) Separating high-quality from low-quality research evidence (3) Providing syntheses of what the high-quality evidence is telling us about a topic or policy area

The National Forum on Health highlighted some problems with evidence gathering, the use of evidence, and EBDM,[301] of which many are not solved as yet, including lack of useful evidence, lack of consensus, inappropriate use of evidence, lag time in diffusion and uptake of information, overwhelming amounts of information, decisions made without consideration of health outcomes, differing and changing values, lack of accountability, tradition and judgment, privacy and confidentiality of information, and uncoordinated development of health information systems.

It is beyond the scope of this report to evaluate these problems and their possible solutions. Instead, the report will evaluate two sets of problems not mentioned previously. The first set relates to disabled people and is covered in Section 6. The second set relates to the appearance of the transhumanist/enhancement model and the increased ability to improve body structures and functionality beyond species-typical boundaries.

Problem 1: The increased ability to improve body structures and functionality beyond species-typical boundaries is not taken into account

The transhumanist/enhancement view of health, well-being, disease, and disability and the increased ability to improve body structures and functionality beyond species-typical boundaries are not taken into account by the research methods (consisting of evaluation tools and types of measures used) used within HTA to gather different types of evidence and by EBDM within HTA.

Under a transhumanist/enhancement framework, different and often new questions, objectives, problems, and solutions appear that influence the methods of evidence gathering, the type of evidence that can be gathered, and the interpretation of the gathered evidence. Philosophical and ethical evidence regarding transhumanism, enhancement technologies, and disabled people are generated, reflected, and evaluated; however, this evidence does not yet make it into HTA.

The following measuring tools are used within HTA: WHOQOL-100; WHOQOL-BREF; Multi-attribute utility instruments such as Expanded Disability Status Scale (EDSS) EQ-5D; SF-6D Medical Outcomes Study Short Form 36; Nottingham Health Profile (NHP); the Sickness Impact Profile (SIP); EuroQol instrument (EQ-5D); the Quality of Being Scale QWB); AQOL Health Utilities Index (HUI); Health Utilities Index Mark III; Health-related quality of life (HRQoL); Calvert-Henderson Quality of Life Indicators; Quality of Life indicator of the Quality of Life Research Unit within the Centre for Health Promotion in the Department of Public Health Sciences, University of Toronto; The DALY; Comprehensive QoL Scale; General Health Questionnaire; Goteborg QoL Instrument; Health Measurement Questionnaire; Lancashire QoL Profile; Lehman's QoL Interview; Life-as-a-Whole Index; Life Experiences Checklist; Life Satisfaction Index; MOS Short Form 36; Multifaceted Lifestyle Satisfaction Scale; Nottingham Health Profile; QoL in Depression Scale; QoL Enjoyment & Satisfaction Questionnaire; QoL Index; QoL Index for Mental Health; QoL Interview Schedule; QoL Inventory; QoL

Questionnaire (Shalock); QoL Questionnaire/Interview (Bigelow); QoL Scale; QoL Self-Assessment Inventory; QoL Systemic Inventory; Quality of Well-Being Scale Satisfaction With Life Scale; Schedule for the Eval of Individual QoL; Sickness Impact Profile; SmithKline Beecham QoL Scale; performance indicators for the Health System according to the 2003 First Ministers' Accord on Health Care Renewal; Public Health Agency of Canada Determinants of Health; and Comparable Health and Health System Performance Indicators for Canada, the Provinces and Territories, November 2004.

These tools are used for guidance about:

1. the use and allocation of scarce resources;
2. the most cost-effective way of achieving a given objective; and
3. the greatest benefit and utility that can be achieved from the available resources.

The interpretation of gathered economic evaluation evidence and the terms of reference under which evaluation tools are used will change significantly under a transhumanist/enhancement framework.

QALY indicators

Quality-adjusted life year (QALY) indicators are seen as critical outcome measures of cost-effectiveness, cost-utility, and other factors used to generate economic evaluation evidence.[302-304] However, in the Norwegian guidelines for pharmacoeconomic analysis in connection with applications for reimbursement of the Norwegian Medicines Agency, one reads:

> Research in recent years has shown that priority setting between programmes according to the cost-per-QALY-method in many cases does not correspond well with the societal perspective of what is fair and ethical. The QALY-approach is based on a wish to maximize health production. But a society such as the Norwegian society primarily seeks to nprioritise according to degree of severity, where effective treatment does exist. This can mean for example that moderate improvements for the critically ill are sought prioritized above large improvements for the moderately ill. Technically speaking there are two reasons why the QALY-calculations can be misleading as a basis for decisions involving societal priority setting. One is that the life quality scores (on a zero-one scale) attributed to different health problems is often too low. The consequence of this is that programmes for moderate health problems are given far too great an emphasis in the analysis compared to programmes for serious health problems, and symptom alleviation and functional improvement are generally given too great a value compared to live-saving measures. The second reason is that the QALY-approach places an excessive importance on the number of years for which patients will benefit from a treatment. This can lead to the value of treatment programs for elderly patients being set too low compared to the value of treatment programs for younger patients.[305]

Every health consultation done in Canada in recent history showed strong concerns for fairness and equity in health care,[306] which seems to fit with the preceding Norwegian concern about QALY. Current economic evaluation models, such as the conventional QALY model (cost-utility analysis), fail to capture these concerns.

Other demands and criticisms about QALY are as follows:

1. Quality-of-life data obtained from patients should replace hypothetical valuations of health states.
2. The standard gamble does not capture all aversion to risk.
3. Life years gained in disabled/impaired people should be valued as much as life years gained in non-disabled/non-impaired people.
4. Formal economic evaluation should be restricted to budget decisions (as opposed to clinical decisions).
5. Cost-per-QALY league tables falsely assume that "winners should take all."[307]

> ***Policy implications***
>
> The measurement tools are not broad enough to cover challenges such as the transhumanist models and the change in the role of disabled people. The measuring tools have to be revamped in order to be able to meet the challenges.

Problem 2: Most of these outcome measures and analysis tools are used to look at medical determinants of health

None of the measurement, evaluation, and evidence-gathering tools are equipped to compare interventions between the medical and social domain. HTA does not compare whether a social intervention is better cost-wise, benefit-wise, and value-wise than a medical intervention. Within HTA, one compares two medical technologies or two drugs. Very rarely would one look at whether prevention of bad eating habits are better, more cost-effective, or more beneficial than using anti-obesity drugs.

Recently, Arena Pharmaceuticals stated that a 28-day regimen of its experimental obesity drug resulted in an average weight loss of 2.9 pounds. Patients taking a placebo in the Phase II trial lost less than one pound.[201]

> ***Policy implications***
>
> On the surface, the effect of the drug by Arena Pharmaceuticals in helping people to lose 1.9 pounds in 28 days seems rather unimpressive. There are two ways in which HTA could evaluate this result. It could compare this result with other drugs or it could compare the drug with other non-medical interventions tailored toward social/environmental changes. However, to date, HTA has not been done in this way.

THE TRIANGLE OF DISABLED PEOPLE/CONCEPT OF HEALTH AND DISEASE/EMERGING TECHNOLOGIES

The impact of science, technology, and health research, including HTA, on disabled people

Science and technology R&D, health research, and HTA can have an impact on disabled people by developing tools to adapt the environment that disabled people live in and by giving disabled people tools that would allow them to navigate environmental challenges to make their life more livable without changing the identity and biological reality of the disabled person. Science and technology R&D, health research, and HTA can have an impact on disabled people by developing tools that would eliminate the part of their biological reality seen as deficient, defect, impaired, and "disabled." Which path science and technology R&D, health research, and HTA will follow depends on, among others things, how disabled people are perceived and how they perceive themselves.

To understand the impact of science and technology R&D, health research, and HTA on disabled people, one needs to explore a few questions: Which and whose values and perceptions are reflected in the definitions of what it means to be "healthy," of the "problems of disabled people," and of the attached "suffering"? Which and whose values and perceptions are reflected in the choice of solutions for these identified "problems"? How do the predominant societal values and perceptions that define health, the problems of disabled people, the attached suffering, and the proposed solutions affect the self-esteem and self-understanding of disabled people? Does the self-perception of disabled people match the perception that the "non-afflicted" have of disabled people? Do disabled people define their "problems" and the solutions to them in the same way as do the "non-afflicted"?

Policy implications

Answering these questions requires an examination of the complex interdependent fabric of perceptions, values, and choices. It also calls for a review of the development and application of science and technology and health research and HTA from within different cultural, economic, ethical, spiritual, and moral frameworks, with a particular "disability" lens.

Perceptions shape solutions. Well-intentioned science and technology R&D, health research, and HTA can lead to troubling consequences because people's view of a problem is obstructed by their own prejudices and unexamined assumptions about how the world works. Science and technology R&D, health research, and HTA are offered as well-intentioned solutions to the problem of human "disabilities." But those who offer these solutions are rarely—indeed, almost never—themselves "disabled" and disabled

people are rarely involved; if disabled people are involved, they are nearly exclusively representing the medical identity looking for medical determinant solutions and are referred to as patients.

It comes therefore as no surprise that the problem that science and technology R&D, health research, and HTA are trying to solve is framed through the lens of the medical model of "disability/impairment." What might come as a surprise to most people is the fact that the prevalent medical view of disabled people is often at complete odds with the experience, desires, and self-perception of disabled people themselves.

Perception of and self-identity of disabled people

The concept of health and disease is one variable in deciding how to direct science and technology R&D in general and health sciences and health technology in particular.

In regard to disabled people, there are two other variables that influence the use and direction of science and technology R&D and health research, namely, (a) how disabled people perceive themselves and (b) how disabled people are perceived by the so-called non-disabled people.

Self-perception of disabled people

Parallel to the four possible combinations between models and determinants of health and disease (see Section 2), disabled people can choose from four variations that describe their self-identity, their relation to so-called non-disabled people, and the usage of science and technology (see Section 2 for extensive coverage of models of disability).

1. Disabled people can opt to see themselves as inherently defective and subnormal (in relation to non-disabled people) and in need of being fixed by science and technology products to a societal norm of the so-called non-disabled, for example, giving legs to amputees that will be as good as or worse than biological legs (the patient/medical model/medical determinant type).[43,84]
2. Disabled people can opt to see themselves as inherently defective and subnormal (in relation to non-disabled people) but in need of having the physical environment, the interaction with the physical environment, and the societal climate changed to accommodate their biological reality (e.g. giving wheelchairs to amputees and making the physical environment wheelchair accessible, or using teleportation devices if they are ever developed) and to improve their social well-being (the patient/medical model/social determinant/social well-being type).[43,84]
3. Disabled people can opt to see themselves as inherently defective (in the same way as the so-called non-disabled people are defective following the transhumanist/enhancement vision, which perceives the human body in general as defective) and opt not only to be fixed by science and technology products to a norm, but also to be enhanced and augmented beyond species-typical boundaries

(i.e. giving bionic legs to amputees, which work better than the "normal" biological legs or using brain-machine interfaces for thought controlling the environment) (the patient/health consumer/transhumanist/enhancement model/transhumanist/enhancement determinant/transhumanist well-being type).

4. Disabled people can opt to see their biological reality as a variation of being (on par with the non-disabled people) not in need of fixing, but in need of having the physical environment, the interaction with the physical environment, and the societal climate changed to accommodate their biological reality (e.g. giving wheelchairs to amputees and making the physical environment wheelchair accessible, or using teleportation devices if they are ever developed) and to improve their social well-being (the social model/social health/social determinant/social well-being type).

For the longest time, disabled people viewed themselves as the patient/medical model/medical determinant type, and some still do. Recently, a shift in self-perception of many disabled people toward the patient/medical model/social determinant type/social well-being and the social model/social health/social determinant/social well-being type emerged,[308] which correlates with their current understanding about what disabled people can contribute to society and their efforts for disabled people's human rights, as evidenced by the flurry of progressive legislation and new programs around the world, including a UN international convention to promote and protect the rights of disabled persons.[309]

A very recent development is the self-understanding of disabled people as the patient/health consumer/transhumanist/enhancement model/transhumanist/enhancement determinant/transhumanist well-being type.

Perception of disabled people

Public perception of disabled people follows mostly the patient/medical model/medical determinant type, sometimes the patient/medical model/social determinant type, and very rarely the social model/social health/social determinant/social well-being type. The patient/health consumer/transhumanist/enhancement model/transhumanist/enhancement determinant type is slowly appearing in some circles.

Disabled people are normally perceived as having a low quality of life, as being subnormal, as being people with a medical deficiency, and as being patients. The term "disabled" is mostly used to describe a person who is perceived as having an intrinsic defect, an impairment, disease, or chronic illness leading to subnormal functioning and expectation. Suffering, in the preceding understanding of disabilities, impairments, diseases, and defects, describes the situation of having to live in an undesirable (subnormal) state of existence and is linked to the perception that society will never support and accept disabled people with their variation of being.[310]

A Nike advertisement from 2000 reflects such a view:

> Fortunately the Air Dri-Goat features a patented goat-like outer sole for increased traction so you can taunt mortal injury without actually experiencing it. Right about now you're probably asking yourself 'How can a trail running shoe with an outer sole designed like a goat's hoof help me avoid compressing my spinal cord into a Slinky on the side of some unsuspecting conifer, thereby rendering me a drooling, misshapen non-extreme-trail-running husk of my former self, forced to roam the earth in a motorized wheelchair with my name embossed on one of those cute little license plates you get at carnivals or state fairs, fastened to the back?[311]

The quote from "The History of Thalidomide" by Stephens and Brynner adds the claim that disabled people destroy the quality of life of so-called non-disabled people:

> How did parents endure the shock [of the birth of a thalidomide baby]? The few who made it through without enormous collateral damage to their lives had to summon up the same enormous reserves of courage and devotion that are necessary to all parents of children with special needs and disabilities; then, perhaps, they needed still more courage, because of the special, peculiar horror that the sight of their children produced in even the most compassionate. Society does not reward such courage…because those parents' experience represents our own worst nightmare, ever since we first imagined becoming parents ourselves. The impact upon the brothers and sisters of the newborn was no less horrific. This was the defining ordeal of their family life – leaving aside for now the crushing burden on their financial resources from now on.[312]

A clash of perceptions and values

The literature shows that people with different experiences and perspectives (disabled versus so-called non-disabled) perceive the same condition differently. One study, performed in 1994 at the Craig Hospital in Englewood, Colorado, asked a set of questions about disability to people with a spinal cord injury (SCI; n = 168) and non-disabled people working in the intensive care unit (ICU) of the hospital (n = 233). The non-disabled workers were asked to answer the questions as they related to their real being and also to envision themselves as having an SCI. The study showed that the self-rating between the disabled and non-disabled is not that much different, but there is quite a discrepancy between imaging oneself with a disability versus having one (Table 6).

Table 6: Self-esteem ratings following severe spinal cord injury (SCI)[313]

	No disabled providers self-rating	No disabled providers imagining self with SCI	SCI survivors *Comparison group*
	% Agreeing with the statement		
I feel that I am a person of worth	98	55	95
I feel that I have a number of good qualities	98	81	98
I take a positive attitude	96	57	91
I am satisfied with myself on the whole	95	39	72
I am inclined to feel that I am a failure	5	27	9
I feel that I do not have much to be proud of	6	33	12
I feel useless at times	50	91	73
At times I feel I am no good at all	26	83	39

Indeed, those with a "condition" very often perceive it as less serious than do those without the "condition" and many studies show how disabled people rate their own quality of life as equal to, or higher than, their non-disabled counterparts.[314-337] The medical model seems to be in contradiction to the fact that many disabled people do not see themselves as having a medical condition. Most disabled people, whether they have spina bifida, achondroplasia, Down syndrome, or other mobility and sensory differences, perceive themselves as healthy (in the medical sense), not sick. They describe their "conditions" as givens of their lives, the equipment with which they meet the world. They do not perceive themselves as "subnormal." For example, in the case of the characteristic spina bifida, it seems to be a forgone conclusion that spina bifida is a medical condition in need of prevention through, for example, the use of a folic acid supplement in the mother's diet. But one of the resolutions of the 12th International Conference for Hydrocephalus and Spina Bifida in Toulouse, 2000, states that: "people with spina bifida and hydrocephalus live a full life with equal value to that of any other citizen and they should not be seen as a medical condition. Their views should be sought and heard by Governments and Health professionals, who should acknowledge the right of people with spina bifida and hydrocephalus to speak for themselves."[338] At the 8th working meeting of the UNESCO International Bioethics Committee, the group Inclusion International (a group representing people with Down syndrome and their parents and friends) was listed as a "patient" group. Inclusion International denounced this description, as they do not see people with Down syndrome as patients per se and

they see Inclusion International as a human rights group, not a patient group (personal communication).

The Canadian Down Syndrome Society states:

> Down syndrome is a naturally occurring chromosomal arrangement that has always been a part of the human condition. The occurrence of Down syndrome is universal across racial and gender lines, and it is present in approximately one in 800 births in Canada. Down syndrome is not a disease, disorder, defect or medical condition. It is inappropriate and offensive to refer to people with Down syndrome as "afflicted with" or "suffering from" it. Down syndrome itself does not require either treatment or prevention. The sole characteristic shared by all persons with Down syndrome is the presence of extra genetic material associated with the 21st chromosome.[291]

The same is true for people with chronic conditions such as cystic fibrosis, diabetes, hemophilia, and muscular dystrophy. These conditions include intermittent flare-ups requiring medical care and adjustments in daily living, but they do not render a person unhealthy, as most of the public and members of the health profession imagine.[339] Furthermore, the notion that disabled people destroy families, as reflected in the Stephens and Brynner quote and elsewhere,[340-354] is refuted in many academic studies.[337,355-392]

An area where that clash of perception plays itself out is the QALY. QALY indicators are seen as critical outcome measures in cost-effectiveness, cost-utility, and other evaluation tools used to generate economic evaluation evidence.[304,302]

However, how can a QALY work if the perception of disabled people and the self-perception of disabled people often do not match and if disabled people perceive their quality of life as being higher than the quality of life of their life as perceived by non-disabled people?

This problem is recognized by others, such as Nord, who states:

> The desirability of a condition to people who are not in it themselves is only moderately correlated to the experienced well-being of people with the condition and hardly correlated at all to the worth of those people.[393]

Nord concludes from this reality:

> A single score for a health state, of the kind used in QALY calculations, cannot express all these three types of value…one needs to distinguish between the desirability of a condition to people who are not in it themselves (ex ante judgments), the experienced well-being of people with the condition (ex post judgments), and the worth of those people.[393]

Nord points out another truth, long claimed by disabled people, that being medically healthier does not mean that one feels less miserable and more valuable,[393] and if one is less "medical healthy," one does not necessary feel less valuable and more miserable. This report provided an example in the table "Self Esteem Ratings following severe Spinal Cord Injury (SCI)."[313] Nord provides the following example:[394] "*Take a person in a*

wheelchair. His condition is to most people highly undesirable compared to being in full health.[304,393] *But his subjective well-being, i.e. his mood or inner feeling of happiness, may be comparable to that of non-disabled people."*[304,393] Nord concludes: *"In QALY-calculations the distinction seems to have been completely disregarded, if not explicitly rejected."*[304,393]

Problem: As troubling as the fact is that there is this difference in perception between the "afflicted" and the "non-afflicted," even more troubling is the fact that the non-afflicted, for the most part, do not accept the self-perception of the afflicted if the self-perception does not fit the agenda of the non-afflicted. The views of disabled people and their families (the afflicted, the experts) who do not see themselves within the patient/medical model are rarely heard or blatantly ignored—a fact that was recognized in the final documents of the 1999 UNESCO World Conference on Sciences[120,121]—seen as irrelevant,[114] or even actively questioned and rejected,[115-117,395-397] in the shaping of the research agenda, government policies, and public debate and education, as they relate to the development and use of science and technology and health research and HTA.[86,337,398-400]

Taking intro account the reality of (a) the negative perception of disabled people, (b) legal decisions indicating that disabled people have the obligation to fix themselves,[401,402] and (c) the non-acceptance of a social model of disability by many "non-afflicted people" and the neglect even of social determinants within a medical model of "disability," it comes as no surprise that the governance and debate around health research, HTA, and R&D of science and technologyfocuses mostly on offering disabled people medical solutions (prevention or cure/normative adaptation) and might move toward transhumanist/enhancement solutions (augmentation, enhancement of the human body) but rarely offers social solutions (adaptation of the environment, acceptance, societal cures of equal rights and respect) and science and technology. NBIC "health" products are sold with the promise to diminish/prevent the suffering of disabled people through (a) increasing their "abilities," (b) fixing their "disabilities," or (c) preventing them from being born through a variety of eugenic measures.

> ***Policy implications***
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> If one sees disabled people mostly within the medical model/medical determinant framework, and if one actively and passively rejects the medical model/social determinants and social model/social determinants combination, the logical consequence is that disabled people move on toward the transhumanist model/transhumanist determinant combination.

Science and technology, disabled people, and transhumanism

The transhumanist/enhancement model/transhumanist/enhancement determinant combination is seen by an increasing number of disabled people as a valid solution for

two reasons. One reason is that the medical model views disabled people as deficient in relation to non-disabled people, which is hard for many disabled people to swallow. Another reason is that many disabled people do not feel that society will ever accept them for who they are and will never provide the "social cures" needed. In their eyes, the transhumanist/enhancement model allows disabled people to seek out transhumanist/enhancement solutions without feeling inferior to so-called non-disabled people and without having to wait for social cures. Alan Pottinger started the first advocacy group for disabled transhumanists, the Ascender Alliance (UK) in 2001.

John Hockenberry, a paraplegic journalist, states in *Wired* magazine:[403]

> We live at a time when the disabled are on the leading edge of a broader societal trend toward the use of assistive technology. With the advent of miniature wireless tech, electronic gadgets have stepped up their invasion of the body, and our concept of what it means and even looks like to be human is wide open to debate. Humanity's specs are back on the drawing board, thanks to some unlikely designers, and the disabled have a serious advantage in this conversation. They've been using technology in collaborative, intimate ways for years – to move, to communicate, to interact with the world.

He goes on to describe in many examples how disabled people are pushing the boundary of the human body and what it means to be human. Disabled proponents of medical "therapeutic" fixes are not just proponents of the medical model/medical determinant combo, but, because of our future inabilities to distinguish between therapies toward a norm and therapies that outdo a norm (brain machine interfaces and artificial legs are just two examples), are also inadvertent proponents of a transhumanist/enhancement model/transhumanist/enhancement determination combo, even if they do not actively promote such a model.

Many people see "disabled/impaired" people as a natural fit for transhumanism and as paving the way for transhumanist philosophies and developments. On the website of the World Transhumanist Association, one reads:

> Disabled people using the latest assistive technologies with their eyes fixed on medical progress are a natural constituency for transhumanism[404]…Disabled people in the wealthier industrialized countries, with their wheelchairs, prosthetic limbs, novel computing interfaces and portable computing, are the most technologically dependent humans ever known, and are aggressive in their insistence on their rights to be technologically assisted in fully participating in society.

James Hughes, the executive director of the World Transhumanist Association, states:

> The healthy and able-bodied systematically underestimate the quality of life of the technology-dependent disabled. The able-bodied blithely say such things as, "Oh, I'd never want to live hooked up to a machine like that," only to discover that life is still pretty sweet in a wheelchair or with a breathing machine. Transhumanism, on the other hand, argues that we can and should all live better lives in the future through technological enhancement. Although few disabled people and transhumanists realize it yet, we are allies in fighting for technological empowerment.[152]

According to George Dvorsky, a leading non-disabled transhumanist:[405]

> No, this particular prosthetic barely resembled a human arm, looking more like something out of a Terminator movie. It was robotic, sleek and very high tech. In fact, I think I was jealous. Compared to a natural human arm, however, it did lack in functionality and grace. Still, just looking at it made me realize that it won't be long before future prostheses, for all intents and purposes, will be better than my biological appendages. And what's more, the disabled will in all likelihood be encouraged to try out the latest models, to experiment with the latest in prosthetic neural interfacing and advanced cybernetics. Those in the handicapped community tend to be more willing to accept people in various forms and to be more open in their ideas about what it means to be "normal," or even human. And as the disabled are discovering, when it comes to prostheses and other assistive devices, the sky's the limit; they no longer feel compelled to mimic the human form. For the handicapped, the impetus toward "human normalization" is as irrelevant and useless a notion as it is offensive. Indeed, the disabled are no longer accepting the limitations of the "normal" human body. They are truly bridging the gap between the biological and the mechanical, the human and the posthuman.

Dvorsky quotes Alan Pottinger, the founder of Ascender Alliance who is an outspoken disability activist:

> *"Pottinger advocates for the removal of political, cultural, biological and psychological limits to self-realization and augmentation."*[405] *"Humanity,"* states Pottinger *"has always adapted the environment to suits its needs."* The cyborg transformation of human society is already underway, he argues, and is one of the driving factors in the creation of a posthuman society. Pottinger concedes, however, that the path taken to posthumanity will be markedly different for the disabled. *"Within the able-bodied world there is little variation from person to person, at least in terms of physical form,"* he says, but *"within the disabled community there are a huge number of variations."* This variation, argues Pottinger, means that the disabled "agenda will differ from that of the able-bodied as our augmentation will require different procedures." Furthermore, the disabled are openly acknowledging that human normalization is not on the agenda. *"Is walking ability that important?"* asks Pottinger. In the past perhaps, but Pottinger believes humanity has reached a point in its development where physical capability has begun to be overtaken by mental agility. *"Machines,"* says Pottinger, *"which take their orders in the form of simple physical inputs, now control most of our production processes, while in other cases other machines build the machines themselves."* Human input is slowly dropping off, he notes, so much that disabled people might be right in arguing that physical ability is not as vital as society makes it out to be. *"The development of a computer-orientated society is well underway, if not already complete,"* contends Pottinger, *"and it is something that has brought major benefits to both the disabled and able-bodied community."* [405]

Dvorsky goes on to say:

> Interestingly, many in the disabled community will choose to be willing test subjects; many have nothing to lose and are eager to try out the latest innovations – if not for themselves, certainly for those in the disabled community who will follow after them.[405]
>
> And as the disabled courageously experiment with their bodies and strive to overcome the injustices and indignities of their disabilities, they will subsequently reinvent themselves for the future. They will be undaunted and unfazed by their departure from

human morphology and functionality, while the rest of humanity will watch and take inspiration. And then play catch-up.[405]

Policy implications

It seems logical to assume that if the disabled are allowed to enjoy (or forced to enjoy) new abilities, whether they are entirely new or incremental improvements of "normal" abilities, others such as the non-disabled would also be allowed to add all kinds of augmentations to their bodies, helping themselves to fulfill their own desires and freeing themselves from the "confinement of their genes"(genomic freedom) and the "confinement of their biological bodies" (morphological freedom). The argument of therapeutic versus non-therapeutic interventions as a means to draw a line becomes futile under a transhumanist model of health, disease, well-being, and disability, where everyone belongs to the class of disabled people.

However, the match between transhumanists and disabled people might not be quite the glove-on-hand fit as the preceding quotes indicate.

It is understandable that disability groups and individuals who follow the patient/medical model/social determinant type and the social model/social health/social determinant/social well-being type have problems with the scope of transhumanism, which is not just about enhancing oneself,[406] but also about enhancing one's children (born or to be born) and preventing the birth of humans if they test unfavourably in the prebirth state. From the World Transhumanist Association FAQ page:

> Transhumanists uphold the principles of bodily autonomy and procreative liberty. Parents must be allowed to choose for themselves whether to reproduce, how to reproduce, and what technological methods they use in their reproduction. The use of genetic medicine or embryonic screening to increase the probability of a healthy, happy, and multiply talented child is a responsible and justifiable application of parental reproductive freedom.[407]
>
> Beyond this, one can argue that parents have a moral responsibility to make use of these methods, assuming they are safe and effective. Just as it would be wrong for parents to fail in their duty to procure the best available medical care for their sick child, it would be wrong not to take reasonable precautions to ensure that a child-to-be will be as healthy as possible.[407]
>
> This defense of procreative liberty is compatible with the view that states and charities can subsidize public health, prenatal care, genetic counseling, contraception, abortion, and genetic therapies so that parents can make free and informed reproductive decisions that result in fewer disabilities in the next generation. Some disability activists would call these policies eugenic, but society may have a legitimate interest in whether children are born healthy or disabled, leading it to subsidize the birth of healthy children, without actually outlawing or imposing particular genetic modifications.[407]

The resolutions of the bioethics workshops at the 6th World Assembly of Disabled People International (DPI) 2002 stated under the theme of bioethics and the topic of genetics and discrimination":

I. We demand the right to be different

II. We believe that no parent has the right to design and select their unborn child to be according to their own desires and no parent has the right to design their born child according to their own desires.

III. We defend and demand a concept of "person" that is not linked to a certain set of abilities.[408]

The Disabled People International (DPI) Solihull declaration states, among other things:

> We demand an end to the bio-medical elimination of diversity, to gene selection based on market forces and to the setting of norms and standards by non-disabled people.
>
> "Biotechnological change must not be an excuse for control or manipulation of the human condition or bio-diversity.
>
> An absolute prohibition on compulsory genetic testing and the pressurizing of women to eliminate – at any stage in the reproductive process – unborn children who, it is considered, may become disabled.
>
> That disabled people have assistance to live – not assistance to die.
>
> That having a disabled child is not a special legal consideration for abortion.
>
> That no demarcation lines are drawn regarding severity or types of impairment. This creates hierarchies and leads to increased discrimination of disabled people generally.[409]

The Ascender Alliance also might not quite fit the transhumanist agenda if one reads their manifesto:

> Technology exists now, and in the future, to enable us to achieve one hundred percent of our potential and even beyond.[410] We have as much right to see the future; we have equal rights to plan our future. Our lives are as valuable as everyone else's. We may have limitations; some of us have overcome them, and others have not. But that does not mean that we should be terminated, bred out and institutionalized. At the same time it is our right to remain as we are, we should not have to change to suit anyone but ourselves. We understand why some DMP (disabled member of the public) are satisfied the way they are and respect their wishes; we support no program of forced normalcy but expect other DMP to understand and respect our wishes. Ascenders do not advocate any program that "cuts out" any proportion of humanity, as would be the case with eugenics and other selective breeding programs. An Ascender needs only the will to improve them selves. An Ascender realizes the potential power of genetic engineering; but we feel that small genetic elite should not control society or dictate the future course of the species. We seek to improve life for all of humanity. Ascenders do not subscribe to the belief that what we believe to be the best course for society will be approved by future generations, hence the desire to limit the amount of irreversible genetic intervention. Moreover, no being should be forced to have superior physical and mental attributes; the right to self-determination begins even before conception. There is only one condition

> under which pre-natal manipulation is expectable; when it is necessary to repair life-threatening mental and physical deficiencies.[411]
>
> We do not want a world were disabled people "suffer" but it is time for the world at large to realize that a disability does not mean we have a lesser quality of life; disabled people have the same right to life as everyone else and the same rights to use new and emerging technologies to negate their disabilities if they see fit to do so. If we are to end disability, both in terms of the medical effect it has on those who have said disabilities and the way in which society hampers disabled people, it has to be on our terms and not by shedding the blood of innocent men and women.[412]

The preceding quotes contain a few key demands by the Ascender Alliance regarding the use and development of science and technology:

Key demands by the Ascender Alliance are:

1. The right for self-determination, which is interpreted to be extended to the prebirth stage and the future generation.
2. The prohibition of negative eugenics through, for example, prenatal deselection.
3. The prohibition of germ-line genetic intervention.
4. The prohibition of somatic genetic and non-genetic intervention of children and fetuses.
5. As it is may be impossible to ensure that somatic manipulations will be confined to somatic cells and will not affect germ-line reproductive cells, points 1 and 3 might also mean the prohibition of somatic genetic intervention of adults.
6. The prohibition of non-genetic interventions of children and fetuses.
7. The acceptance of the right of adults to modify themselves through somatic genetic (maybe) and non-genetic interventions.

The general message of the Ascender Alliance Manifest is twofold:

1. No one has the right to judge biological realities/characteristics of others independent of the stage of human development available for judging and prevent or change them based on that judgment; and
2. Everyone has the right to change themselves as long as these changed abilities are available for everyone and are not transmitted to the next generation.

Policy implications

1. It is to be expected that the support for transhumanism by disabled people will increase if social determinants are not taken more into account for disabled people and if the social model of disability is further rejected.
2. This will lead to an increase in the medicalization and the transhumanization of medicalization phenomenon (see Section 4: Realization of the transhumanist model), an increased cost for the health system, and an ability divide between rich and poor within a country and between countries.
3. Taking into account certain interpretations of the Chaoulli case and article 7 and 15 of the Canadian Charter of Rights and Freedoms, the increased medicalization and transhumanization of medicalization might have to be funded by the government.
4. The transhumanist model might make concepts such as "medical necessity" obsolete.

HTA and Disabled People

> Health Technology Assessment (HTA) is the process of evaluating medical technologies (devices, equipment, procedures and drugs) and their use. HTA researchers collect, synthesize and critically evaluate the available research on medical technologies. Based on an interdisciplinary approach, an assessment can encompass analyses of safety, efficacy, effectiveness, quality of life and patient use. Other important factors such as economic, ethical, and social implications and other effects which may be unintended, indirect or delayed may also be considered.

The preceding quote indicates that HTA, in principle, investigates how disabled people are impacted by the existing discourse around health, health care, and "health" technologies. The question is how much are disabled people on the horizon of HTA and are they on the horizon within or outside the patient label? One way to gain a crude idea is to look at how many database hits show up with a variety of keyword combinations related to HTA and disabled people (Table 4; for a description of the databases, see Appendix 1).

Table 7: Keyword hits for different keyword combinations

CSA Database/Keywords	Hits
Health technology assessment	26,481
Health technology assessment and patient	4461 16.9%
Health technology assessment and patients	4616
Health technology assessment and disabled persons	347
Health technology assessment and persons	872
Health technology assessment and disabled person	3
Health technology assessment and person	241
Health technology assessment and disabled people	13
Health technology assessment and people with disabilities	30

Health Knowledge Database/Keywords	Hits
Health technology assessment	3229
Health technology assessment and patient	1376 42.3%
Health technology assessment and patients	1620
Health technology assessment and disabled persons	3
Health technology assessment and persons	239
Health technology assessment and disabled person	3
Health technology assessment and person	255
Health technology assessment and disabled people	11
Health technology assessment and people with disabilities	2
Health technology assessment and persons with disabilities	1

Patient/patients are terms used for people who are seen within a medical model of health, disease, disability, and well-being. If one sets HTA to 100%, the two databases generate 42.3% hits (Health Knowledge Database) and 16.9% hits (CSA Database) for the keyword combination "HTA and patient." The difference between the two databases might be explained by the fact that the first database is more medically oriented than the second database.

If one searches the databases with HTA and variations of the term "disabled," it is stunning to find only 0.6% hits in the Health Knowledge Database and 1.4% with the CSA Database. The database search leads to two conclusions:

1. Disabled people are simply not part of the HTA horizon and culture or they are just in the mix under the umbrella term "patient."

2. HTA does not deal with disabled people within the social model of health, disease, disability, and well-being but perceives disabled persons exclusively as patients within the medical model.

> ***Policy implications***
>
> HTA should look further than the patient type of disabled people and the medical model of disability.

Having gone through many HTA technology evaluations, the author of the current report confirms the absence of the term "disabled people" or its variations.

The few reports that relate to disabled people contain a high degree of biased language. The SBU Alert "Maternal Serum Screening for Down Syndrome" shows a high degree of bias in describing Down syndrome[290] by defining the birth of a child with Down syndrome with risk language: "The risk of having a child with Down syndrome increases with the age of the mother."[290] The non-biased, factual term "higher probability" should have been used in this case. The biased description is out of sync with the self-perception of many people with Down syndrome and the people/organizations affiliated with them.[291] It highlights one problem with the HTA process, namely, how to ensure that the right people are involved, a concern also shared by others in different contexts.

> ***Policy implications***
>
> 1. HTA has to become much more aware of their biased language and thinking.
> 2. HTA has to revisit their reports, identify biased language, and change the language accordingly.
> 3. The term "risk" needs to be used in a much more careful, reflective manner within HTA.
> 4. In order for this reflection to be successful, disabled people of all flavours should become part of the HTA culture.
> 5. Employment of a framework, a list of possible biases against which to check HTA reports, to prevent biased language in the future might be useful.

Evidence gathering, evaluation tools, measuring tools, and disabled people

Experimental and quasi-experimental evidence/survey and administrative evidence

Experimental and quasi-experimental evidence is described as being useful for looking at the effectiveness of a policy intervention, and survey and administrative evidence is described as being useful for (1) looking at experimental and quasi-experimental studies and (2) providing valuable information about the nature, size, frequency, and distribution of a problem or a topic under investigation.[300]

Problem: These types of evidence heavily depend on who asks the questions, who designs the questions, who tries to articulate and identify problems, who is invited to answer the questions, and what is compared in the studies. The invisibility of disabled people within academia, within policy deliberation, as policy makers, and in other areas mentioned earlier gives an indication as to the bias that might result during the gathering of this type of evidence. Another possible entry point of bias is the selection and interpretation of the evidence. The evidence outlined in earlier in this chapter in the section "A Clash of Perceptions and Values" is a showcase of this problem. The perception of disabled people seems not to fit with the self-perception of disabled people. Conflicting evidence exists. Which evidence is used to inform the discourse? It is well documented in the earlier section that certain evidence is chosen over other evidence and that the self-perception of disabled people is rarely accepted as evidence, especially if it goes against the mainstream perception that non-disabled people have of disabled people. It is also obvious that the transhumanist and the social model people will define the problem differently, will ask different questions, will seek out different people to answer the questions, and might even interpret the same answer to a given question in a different way.

Policy implications

1. Disabled people in all their flavours and other marginalized groups have to be involved in a meaningful way.
2. Disability studies at universities have to be funded much more so that it can be part of the discourse in a meaningful way.
3. One has to be as multi-faceted as possible; however, often the instigators of the evidence gathering are not aware of emerging and all existing facets, which makes it hard to be multi-faceted. The problem is more pronounced as the circle of people gathering the evidence gets smaller. Lack of money is often the problem that prevents an issue from being looked at in a multi-faceted way.

Qualitative research evidence

Qualitative research evidence involves the following methods:

- Theory-based methods;
- Goals-based evaluation methods;
- Goals-free evaluation methods;
- In-depth interviews;
- Focus groups;
- Consultative techniques;
- Ethnographies;
- Observational and participant-observational studies; and
- Conversation and discourse analysis.

This type of research is supposed to be important for:

1. *the question of why* a policy works (or fails to work), *how* it works, *for whom*, and *under what conditions* it works or fails to work; and
2. the successful implementation and delivery of policies, especially across a range of populations and subgroups.[300]

Problem: This gathering of evidence could be good for disabled people if they were involved, but they are not. This omission is attested to by the fact that none of the Canadian reports on health and hardly any of the international charters and other international documents give any thought to the models of disability, the concept of the social determinants of disability, or the concept that "disability health" could be looked at outside of the patient framework.

Interestingly, the World Bank funds a project called "Development of Qualitative Survey on Disability and Living Standards" and the rationale for the project very much follows the social model of disability, something ignored in the preceding description of evidence-gathering methods. It reads:

> To sustain and promote economic growth and well-being, it is essential to incorporate the concept of human functioning into development programs. People's functioning levels vary significantly – whether in relation to physical capabilities, intellectual capabilities, sensory abilities (hearing and vision), or the impact of mental health. Not accounting for these differences can seriously limit the effectiveness of programs designed to promote economic and social well-being. When individuals with different levels of functioning encounter barriers to health services, education, employment, public services, and infrastructure, they are disabled. That is, disabled in the sense that their ability to participate in economic activities and lift themselves from poverty suffers. Disability is thus an interaction between human functioning and an environment which does not account for different levels of functioning. In other words, people with physical

or mental limitations are often disabled not so much because of their functioning level, but because they are denied access to education, labor markets, and public services. This exclusion leads to poverty, and in a vicious circle, poverty can lead to more disability by making people more vulnerable to malnutrition, disease, and unsafe living and working conditions. According to estimates by WHO, approximately 10 percent of the population has a disability, and this is probably a conservative estimate. Within developing countries, this population numbers at least 400 million and they are among the poorest of the poor. Furthermore, the effects of "disability" go beyond those with functional impairments themselves. Family members must often absorb extra responsibilities that inhibit their participation in the economic and social life of their communities. And, of course, the less productive any citizen is, the less economic growth is possible. Even for those people not classified as "disabled," different levels of human functioning can have an impact on their access to the economy and the community.[413]

Policy implications

Involvement of disabled people of all flavours has to be ensured. International documents highlighting the problems, such as the final documents of the UNESCO World Conference on Science (1999),[120;121] have to be acted on.

Economic Evaluation Evidence

If one investigates the gathering of economic evaluation evidence, the question arises as to how much and in which way the evaluation and measuring tools are used for disabled people and with what identity disabled people are in mind (Table 5). (None of the measurement tools in Table 5 has the patient/health consumer/transhumanist/enhancement model/transhumanist/enhancement determinant type in mind, although it is something they will have to deal with eventually.)

Table 8: Models of health and disability reflected in different measures

	Target Is Seen as the Patient/Medical Model/Medical Determinant Type	Target Is Seen as the Patient/Medical Model/Medical Determinant Type or the Patient/Medical Model/Social Determinant Type	Target Is Seen as the Social Model/Social Health/Social Determinant/Social Well-Being Type
WHOQOL-100		X	
WHOQOL-BREF		X	
Multi-attribute utility instruments such as Expanded Disability Status Scale (EDSS), EQ-5D, SF-6D Medical Outcomes Study Short Form 36 Nottingham Health Profile (NHP), the Sickness Impact Profile (SIP), EuroQol instrument (EQ-5D), The Quality of Being Scale QWB), AQOL, Health Utilities Index (HUI), Health Utilities Index Mark III	X	X	Some of the MAU's could be used without seeing someone as medically ill/disabled but found no examples where that is the case
Health-related quality of life (HRQoL), which refers to a person or group's perceived physical and mental health over time		X	
Calvert-Henderson Quality of Life Indicators		X	
The Quality of Life Research Unit within the Centre for Health Promotion in the Department of Public Health Sciences, University of Toronto, developed a quality-of-life model			X
The DALY emerged as a measure of the "burden of disease"	x		
Comprehensive QoL Scale		X	X
General Health Questionnaire		X	X

Continued on next page

Table 8: Models of health and disability reflected in different measures (cont'd)

	Target Is Seen as the Patient/Medical Model/Medical Determinant Type	Target Is Seen as the Patient/Medical Model/Medical Determinant Type or the Patient/Medical Model/Social Determinant Type	Target Is Seen as the Social Model/Social Health/Social Determinant/Social Well-Being Type
Goteborg QoL Instrument		X	
Health Measurement Questionnaire		X	
Lancashire QoL Profile		X	
Lehman's QoL Interview		X	
Life-as-a-Whole Index		X	
Life Experiences Checklist		X	X
Life Satisfaction Index		X	
MOS Short Form 36		X	
Multifaceted Lifestyle Satisfaction Scale			X
Nottingham Health Profile		X	
QoL in Depression Scale		X	
QoL Enjoyment & Satisfaction Questionnaire		X	
QoL Index		X	
QoL Index for Mental Health		X	
QoL Interview Schedule		X	
QoL Inventory		X	
QoL Questionnaire (Shalock)		X	X
QoL Questionnaire/Interview (Bigelow)		X	

Continued on next page

Table 8: Models of health and disability reflected in different measures (cont'd)

	Target Is Seen as the Patient/Medical Model/Medical Determinant Type	Target Is Seen as the Patient/Medical Model/Medical Determinant Type or the Patient/Medical Model/Social Determinant Type	Target Is Seen as the Social Model/Social Health/Social Determinant/Social Well-Being Type
QoL Scale		X	X
QoL Self-Assessment Inventory		X	
QoL Systemic Inventory		X	
Quality of Well-Being Scale		X	
Satisfaction With Life Scale		X	X
Schedule for the Eval of Individual QoL		X	
Sickness Impact Profile		X	
SmithKline Beecham QoL Scale		X	
Considerations for Data Production for Reporting Comparable Health Indicators in November 2004	x		
Performance indicators for the health system according to the 2003 First Ministers' Accord on Health Care Renewal	X		
Public Health Agency of Canada Determinants of Health		X	
Statistical Report on the Health of Canadians prepared by the Federal, Provincial and Territorial Advisory Committee on Population Health for the Meeting of Ministers of Health 1999		X	X

Continued on next page

Table 8: Models of health and disability reflected in different measures (cont'd)

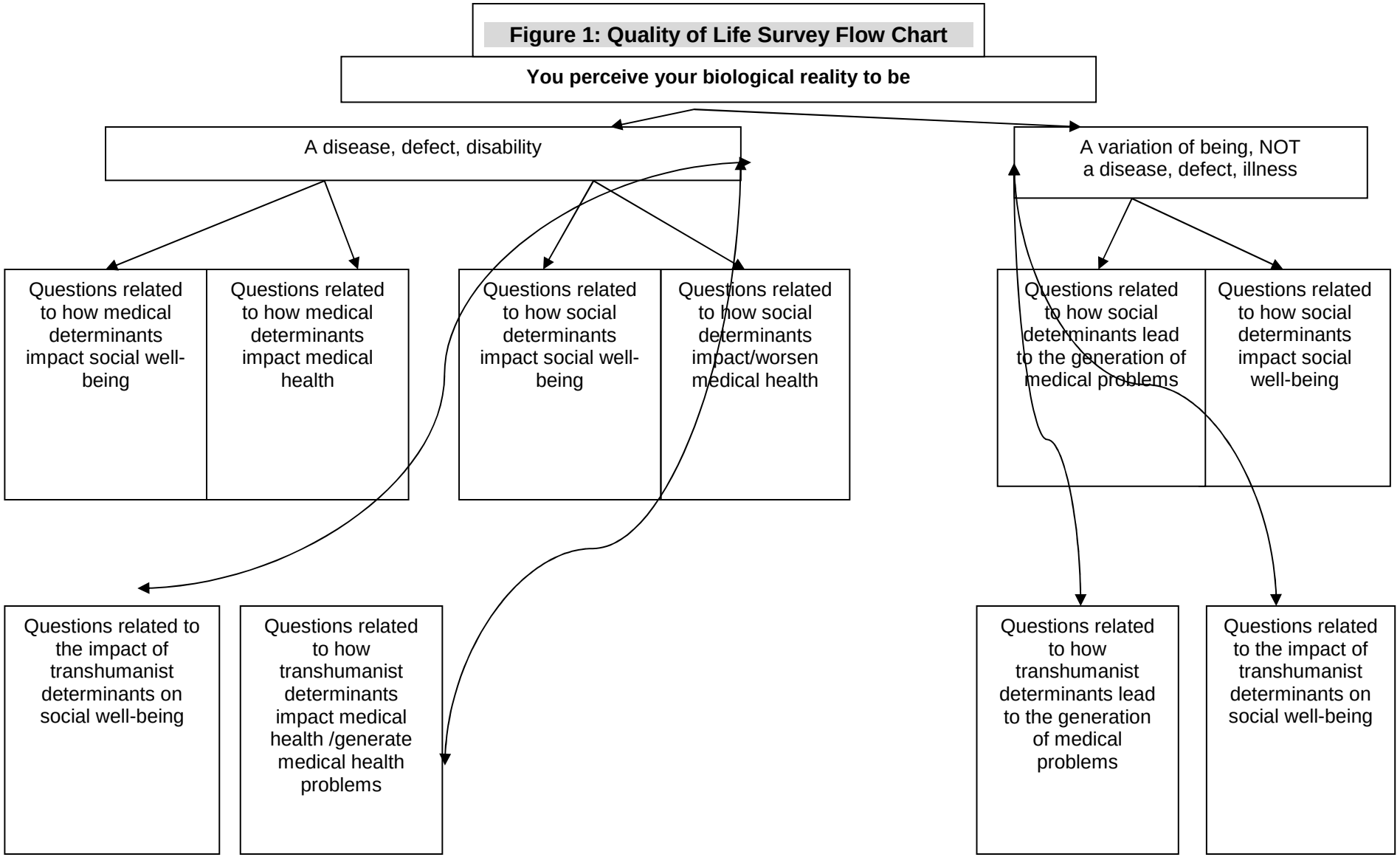
	Target Is Seen as the Patient/Medical Model/Medical Determinant Type	Target Is Seen as the Patient/Medical Model/Medical Determinant Type or the Patient/Medical Model/Social Determinant Type	Target Is Seen as the Social Model/Social Health/Social Determinant/Social Well-Being Type
The Social Health Index covers: Comparable health and health system performance indicators for Canada, the provinces, and territories, November 2004	X		
The Standing Senate Committee on Social Affairs, Science and Technology Interim Report on the state of health care system key determinants of health		X Although it looks at many social determinants, it still looks at them as an outcome to medical ill health and not non-medical well-being	
Determinants of Health by the Canadian Population Health Initiative		X	X depends on how it is used but in principle it could be used for this

Problem: Only one of the measuring tools from Table 5, the quality-of-life model from Toronto, is intended to look at determinants impacting disabled people following the social model/social health/social determinant/social well-being type. Many of the existing measurement and outcome tools target the patient/medical model/medical determinant type or the patient/medical model/social determinant type.

The WHOQOL-100 and the WHOQOL-BREF are two examples of QUALY instruments that cover medical and social determinants within the medical model of "disability/impairment" (at the end of the survey, one is asked to tick off which medical problem one has). These instruments could easily be modified to include the social model/social health/social determinant/social well-being type, as outlined in the flow chart in Figure 1 (developed by the author of this report). The flow chart also incorporates the new reality of the transhumanist/enhancement model, which existing measurement tools are not factoring in yet.

Measurement and outcome tools such as the DALY[414-416] intentionally (see Murray, the father of the DALY, and Acharaya[417(pp.709,723)] do not take into account the patient/medical model/social determinant type but only the patient/medical model/medical determinant type. The DALY emerged as a measure of the "global burden of disease" to support the medical model/medical determinants combination of health and disease. The DALYs suggest that the prevention of impairments or fixing of the individual is the only available strategy for reducing the negative consequences of disability/impairment/ill health. Paraplegia, for example, is treated the same in developed and developing countries, independent of societal parameters.[418] In developed countries, many people with paraplegia have wheelchairs, reducing loss of mobility. In developing countries, many do not have wheelchairs, and their mobility is severely restricted. Furthermore, wheelchairs alone are of no use unless the environment is designed to cater to them—the provision of a wheelchair has different effects within different social/environmental contexts.

Figure 1: Quality of Life Survey Flow Chart



DALYs are inadequate for measuring the global burden of disease because they do not evaluate and measure the roles played by environmental, societal, and other factors in determining the severity and cause of "non-normative functioning," "impairments," "disabilities," and "diseases." DALYs are inadequate for measuring the effectiveness of health interventions because they have not been designed to measure non-medical health interventions (social determinants) such as accessible environments. It was never the intention for DALYs to include such measures. As Murray and Acharaya state:

> The DALY approach does not take into account the likelihood of the fact that effects of illness can be worsened by lack of income, friends and public services etc. because the use of DALYs is to guide public policy that affects directly or indirectly the onset and the treatment of diseases."[417(p.723)] Principle 2. The non-health characteristics of the individual affected by a health outcome that should be considered in calculating the associated burden of disease should be restricted to age and sex"[417(p.709)] "DALYs do not measure fully the impact of ill health on well-being."[417(p.723)]

However, there are other problems with the DALY. According to Murray and Acharaya, one of the motivations behind the development of the DALY was to curtail allocative inefficiency:

> Third, most individuals familiar with the allocation of resources across different health interventions in health systems around the world recognize that there is substantial allocative inefficiency (allocative efficiency is used to mean here the allocation of resources across different health interventions so as to maximize health measured in some fashion). There are clear examples of low-cost interventions with significant beneficial effects on health that are not delivered and examples of expensive interventions with minimal health effects that are delivered.[417(p. 707)]

Murray and Acharaya claim:

> Individuals prefer, after appropriate deliberation, to extend the life of healthy individuals rather than those in a health state worse than perfect health. [417(p.726)]
>
> We remain convinced that most societies prefer the egalitarian approach implied by the restricted information set. Organ donor banks are a good example of how societies choose to allocate a scarce health promoting resource. Following AH's (Anand S. Hanson, the author) principles, we should give preference in organ donation to those that are currently disadvantaged. Apparently, we should always prefer to give a heart transplant ceteris paribus to a poor person as compared with a rich person. We strongly disagree. They also argue that those already in a health state worse than perfect health should be given preference over those in a better health state.
>
> Are we really to believe that AH would give a heart transplant to an individual suffering from complete dementia in preference to an individual with normal cognitive function because the former person is disadvantaged? This viewpoint is not only perverse but completely inconsistent with existing practices in organ donor banks (Starzl et at., 1987) and with the available preference measurement results. [417(pp.726/727)]

This claim seems not to be true at least for the Canadian context, as Canadians value equity of access to health care. However, according to Murray and Acharaya, this means that the Canadian health system is allocative inefficient and wasting resources.

Policy implications

1. To begin with, a new analytical model needs to be built.
2. A model has to fit the Canadian value of equity in health care better than the DALY does.
3. A model has to support a broad definition of HTA and health research—a definition that goes beyond a medical focus on "burden of disease" and leads to equity in health and in the use of health resources.
4. These new instruments must include the societal solutions and the societal dimension of disability and health.
5. An analysis has to take place on how the measuring and outcome tools are affected by the transhumanist model of disability.
6. Public policies, programs, and legislations need to be examined to ensure that they are free of bias that devalue disabled persons and other marginalized groups and do not contribute to their marginalization, exclusion, and poor health.

The model outlined in Figure 1 is able to deal with the multi-faceted domains of health and well-being and their interrelationship, as well as the other challenges outlined earlier. What is now needed is to develop a measuring tool that can weigh the different facets of possible interventions.

Philosophical and ethical evidence

Philosophical and ethical evidence gathering includes the following methods:

- Consultative techniques.
- Needs analysis.
- Critical incidence analysis.

This type of evidence gathering leads to a range of values involved in a policy decision or initiative and ways to adjudicate between competing values.

Problem: It is believed that many negative consequences of science and technology R&D and health research for humankind can be avoided by using ethical principles to govern them. Certain ethical principles are put forward time after time, including the principles of autonomy, beneficence, non-maleficence, and justice. However, different philosophies and approaches to ethical issues interpret the concept and boundaries of autonomy, beneficence, non-maleficence, and justice in different ways and come up with additional principles to define ethical behaviour. These varieties in philosophies

and principles give rise to different possibilities to govern science and technology R&D and health research. How do we decide which philosophy, which ethics to use?

In the same way as science and technology R&D and health research is shaped by societal perspectives, so are ethics. Ethics also embodies the perspectives, purposes, prejudices, and objectives of society and of powerful social groups within society. The ethics debate has not led to more equity to date because it underserves disadvantaged groups.

Regarding disabled people, three problems exist:

1. Disabled people are generally invisible within the ethics discourse.
2. Within a social group-based ethics approach (a feminist approach to bioethics is an excepted field within bioethics), there is a non-acceptance of a disability rights approach to ethics theories and bioethics issues. Disabled people are only accepted within the bioethics and ethics discourse from a medical model of "disability/impairment. The social model of disability is simply rejected by the field of bioethics and influential people within it.
3. An "animal farm" philosophy appears to dominate the debate around the use of ethical theories for bioethics/health issues. In this philosophy, characteristics seen within a medical model (e.g. disabled people) are treated differently from characteristics seen within a social model (e.g. male/female). Many recommendations coming out of the ethics discourse depend on the rejection of a social model of disability. If disabled people are seen within a social model in the same way as males/females, one could not justify many discriminatory approaches within bioethics/health issues and policies, such as the distinction between sex selection and ability selection/"disability" impairment deselection,[337,419-421] genetic discrimination prohibition for asymptomatic but not for symptomatic ("disabled people") people,[84,422] and organ transplant to "non-disabled" and not "disabled people".[423] (see also Murray and Acharaya[417(p.726/727)]

> ***Policy implications***
>
> The biased, animal farm philosophy, discriminatory reality, and medical model/determinants of "disability"/impairment limitation/focus of philosophical and ethical evidence gathering have to change.

Systematic review evidence

Systematic review evidence gathering includes the following methods:

- Narrative reviews.
- Vote counting review.

- Systematic reviews.
- Meta-analyses.
- Best-evidence synthesis.
- Meta-qualitative reviews.
- Rapid evidence assessments.

This type of evidence gathering leads to the following outcomes:

- establishing standards of inclusion and exclusion of single studies;
- separating high-quality from low-quality research evidence; and
- providing syntheses of what the high-quality evidence is telling us about a topic or policy area.

Problem: This type of evidence gathering has the potential to be very useful for disabled people if they were involved. Many meta-analyses exist for numerous issues related to disabled people of different flavours (medical, social). However, none of these analyses have thus far made it into HTA.

Policy implications

1. Studies dealing with disabled people have to make it into HTA. HTA has to become much more knowledgeable and diverse on the issues related to disabled people. Simply seeing disabled people as patients is to neglect, omit, and overlook high-quality evidence, such as the self-perception of disabled people compared with the related perception of disabled people (*see* Section 6: The triangle of disabled people/ concept of health and disease/ emerging technologies Self-perception of disabled people).
2. The preceding evidence suggests that the transhumanist type of disabled person has to be dealt with in the future, as it is the logical extension of the medical type of disabled person.

THE NEW WAVE: NANOTECHNOLOGY AND ITS CONVERGENCE WITH BIOTECHNOLOGY, INFORMATION TECHNOLOGY, AND COGNITIVE SCIENCES (NBIC)

Nanotechnology is an emerging technology able to manipulate materials on an atomic or molecular scale.[424] Nanotechnology or nanosciences enables a new paradigm of science and technology that sees different technologies converging at the nanoscale level, namely, (a) nanoscience and nanotechnology; (b) biotechnology and biomedicine, including genetic engineering; (c) information technology, including advanced computing and communications; and (d) cognitive science, including cognitive neuroscience (NBIC: nano-bio-info-cogno). NBIC technologies capture the convergence of the most powerful frontiers in science. ***"Nano"*** means manipulating materials at an atomic or molecular level. ***"Bio"*** is the calling card of biotechnology and biomedicine. ***"Info"*** dials up advanced computing and communications. ***"Cogno"*** is about neuroengineering and the science of human thought. The USA National Nanotechnology Initiative (NNI) envisions applications for the converging of NBIC in areas such as the environment; energy; water; weapons and other military applications; globalization; agriculture; space exploration; lifespan extension; nanomedicine[425-428] (the preservation and improvement of human health using molecular tools and molecular knowledge of the human body); and enhancing human performances, such as work efficiency and learning, individual sensory and cognitive capabilities, and both individual and group creativity through the use of highly effective communication techniques, including brain-to-brain interactions and human–machine interfaces.[122,128]

The NNI has identified 10 potential R&D targets to reach by 2015:

- Nanoscale visualization and simulation of three-dimensional domains.
- Transistor beyond/integrated ***c****omplementary* ***m****etal* ***o****xide* ***s****emiconductor*CMOS <10 nm.
- New catalysts for chemical manufacturing.
- No suffering and death from cancer when treated.
- Control of nanoparticles in air, soils, and waters.
- Advanced materials and manufacturing: one-half from molecular level.
- Pharmaceuticals synthesis and delivery: one-half on nanoscale level.
- Converging technologies from nanoscale.
- Life-cycle biocompatible/sustainable development.
- Education: nanoscale instead of microscale based.[429,430]

The Joint Centre for Bioethics in Toronto, Canada, recently published a list of top 10 nanotechnology applications[431] they felt were most likely to benefit developing countries and most likely to contribute to the attainment of the UN MDGs):[432]

- Energy storage, production, and conversion.
- Agricultural productivity enhancement.
- Water treatment and remediation.
- Disease diagnosis and screening.
- Drug delivery systems.
- Food processing and storage.
- Air pollution and remediation.
- Construction.
- Health monitoring.
- Vector and pest detection and control.

Importance for HTA policies

If one just looks at the applications from a medical model of health and disease at least three would apply to health (4,5,9). However if one adds social determinants to the mix all of them would fit health.

If one uses the narrowest understanding of HTA namely that it is only to be used for clinical, medical applications number 4,5,9 are future objects targets of HTA if one moves towards understanding that HTA covers technologies. However as this report and others (such as the Kirby report and National Forum on Health) made a case for that non-medical determinants are as important than medical determinants of health it would follow that all of the top 10 nanotechnologies at one time or another might be targets for HTA.

Nanotechnology is fast emerging as a leading technology and an area for R&D investments. According to the 2004 European NanoBusiness Survey, 90% of companies believe that nanotechnology will have an influence on their business, 55% think this will happen within three years; and 84% believe that nanotechnology will have a significant effect on their competitiveness.[433] Based on a study by the NanoBusiness Alliance, a newly minted US trade group, the present-day market for small technologies is around US $45.5 billion. That market will jump to US $700 billion around 2008 and exceed US $1 trillion probably well before 2015.[434] The USA National Science Foundation (NSF) estimates that the total market impact of nanotechnology on worldwide products and services will reach $1 trillion by 2015, the breakdown being as follows: materials, $340 billion/year; electronics, $300 billion/year; pharmaceuticals $180 billion/year; chemical processing $100 billion/year; aerospace $70 billion/year; and tools, $22 billion/year.

The NSF also estimates that nanotechnology will generate between 800,000 and two million new jobs and that half of all drugs will be made with nanotechnology by 2010.[435]

Inherent in the promise of nanotechnology is the creation of superior products and services at a much reduced cost.[436]

Policy implications

How can one ensure that nanotechnology and NBIC cut health system costs? As an Alberta press release states:

> The cost of basic health services increased again in 2003/2004, according to the *Alberta Health Care Insurance Plan Statistical Supplement 2003/2004*. More than $485 million was spent on Alberta Blue Cross plans in 2003/2004, an increase from the $415 million spent in 2002/2003. 77.7 per cent of the total was spent on seniors and their spouses, partners and dependants. Drug costs (95.7 per cent) and ambulance services (3.3 per cent) accounted for 99 per cent of all Alberta Blue Cross expenditures in 2003/2004. 85 per cent received at least one medical service in 2003/2004.[437]

One can predict safely that under a transhumanist model, the demand for medical services and basic and enhanced medical goods will increase. How is one to deal with the increased popularity of the transhumanist model and the increased costs related to it?

Lux Research states in their 2004 report: The year 2004 marked a turning point for the field of nanotechnology. Over the past 12 months, several exponential trends in government spending, corporate research and development (R&D), scientific progress, media coverage, and investment have converged in parallel upon nanotechnology, yielding conditions ripe for extraordinary growth in the field."[435,438] One indication of the maturation of the nanotechnology field is the increase in publications. In 1987, the scientific literature included about 200 "nano" references. By the end of 2001, there were roughly 7700 nano citations for the year. In just the first six months of 2002, there were over 6000 nano citations.[434]

Furthermore, the number of patents and the mentioning of nanotechnology in the popular press also increased significantly.[434] Lux Research expects 2004 will be the last year that governments outspend corporations on nanotechnology, as activity shifts from basic research to applications development. In 2004, established corporations will spend more than $3.8 billion globally on nanotechnology R&D. Approximately 1500 companies worldwide have now announced nanotechnology R&D plans. Eighty per cent of them—approximately 1200—are start-ups, 670 of which are in the United States.[434,435,439] Numbers from 2003 show that the majority of universities and research institutes working in nanotechnology are in the USA (104), Japan (88), the UK (37), and Germany (35). China is listed with 12.[439] For types of players in 2003, 32% are university and research institutions, 40% start-ups/small companies, and 10% large companies.[439] Chunli Bai, executive vice-president of the Chinese Academy of Sciences

(CAS) states: "*According to incomplete statistics, more than 50 universities, 20 institutes of CAS, and over 300 industry enterprises have engaged in nanoscience and nanotechnology R&D, with the involvement of more than 3000 researchers from different institutes, universities, and enterprises across China. The newly established National Center for Nanoscience and Technology in Beijing and the National Center for Nanoengineering in Shanghai are important additions to the list. Government funding in China now stands at about $160 million.*"[440]

Policy implications

How is one to deal on the one hand with the North-South divide in NBIC R&D capabilities and on the other hand with the "emergence of a South-South gap in capabilities between scientifically proficient countries (Brazil,China, India, and Mexico, for example) and scientifically lagging countries, many of which are located in sub-Saharan Africa and in the Islamic world".[441]

A 2004 report by Lux Research[435,438] finds 2004 global spending on nanotechnology to exceed $8.6 billion. Of this, government spending will account for over $4.6 billion, with:

- North America spending approximately $1.6 billion or 35%;
- Asia spending approximately $1.6 billion or 35%;
- Europe spending approximately $1.3 billion or 28%; and
- the rest of the world spending approximately $133 million or 2%.

Meanwhile, corporations will spent an estimated $3.8 billion on nanotechnology R&D in 2004. This will be made up of:

- approximately $1.7 billion by North American companies, equating to 46%;
- approximately $1.4 billion or 36% by Asian companies;
- approximately $650 million or 17% by European companies; and
- less than 1% or $40 million for the rest of the world.

According to Lux Research, in 2004, the US government will spend nearly twice as much on nanotechnology as it did on the Human Genome Project in its peak year.[435,438] Projections say expenditures in nanotechnology will soon outstrip investments to date in genomics and biotechnology.

A press release from Lux Research from October 2004 states:

> Sales of products incorporating emerging nanotechnology will rise from less than 0.1% of global manufacturing output today to 15% in 2014, totaling $2.6 trillion. This value will approach the size of the information technology and telecom industries combined and will be 10 times larger than biotechnology revenues, according to a new report from Lux Research entitled "Sizing Nanotechnology's Value Chain." However, sales of basic nanomaterials like carbon nanotubes and quantum dots will total only $13 billion in 2014: Nanotechnology's economic impact will arise from how these fundamental building blocks are used, not from sales of the materials themselves. In 2014, we project that 4% of general manufactured goods, 50% of electronics and IT products, and 16% of goods in healthcare and life sciences by revenue will incorporate emerging nanotechnology.[438]

Nanobiotechnology

A journal for nanobiotechnology has existed since January 2003.[442] Twenty-five per cent of the USA NNI funding will be in nanobiotechnology according to MC Roco, executive director of the USA NNI. The worldwide nanobiotechnology market is expected to reach over US $3 billion by 2008, with the United States at 65%, Europe at 20%, Japan at 10%, and the rest of the world at 5%.[443] The market impact of nanobiotechnology-based applications is projected to be $300 billion within the next 12 years for the United States alone. Since 1999, venture capitalists have devoted more than US $450 million to nanobiotechnology,[444] 54% for drug discovery, 5% for drug delivery, 37% for diagnostics, and 4% for biopharmaceuticals.[445] The distribution of venture capital for nanotechnology in the period 1998 to 2003 saw 52% spent on nanobiotechnology, 12% on material sciences, 32% on nanodevices, and 4% on nanotools.[445] Other reports covering Nanotechnology funding can be found here.[435,438,446-449]

The USA NSF estimates that half of all drugs will be made with nanotechnology by 2010.[435] Products are developed in many areas including bioanalysis; drug delivery; and therapeutics, biosensors, and medical devices (e.g. nanotubes, nanowires, nanopore structures for single molecule detection, contrast reagents for magnetic resonance images [MRIs] and X-rays, tissue-engineered material such as nanobones, and nanoporous material into retinal implants).

SRI Consulting Business Intelligence stated:

> Today's nanobiotechnology's greatest impact is in the development of bioanalytical research-technology platforms, such as nanoscale labels or tags to improve signal generation and detection in high-throughput, multiplexed biological assays. Leading medical application areas include material technologies for use as medical-device coatings and diagnostic contrast agents and nanoscale devices for biodetection and drug delivery applications. Improved tools to characterize and manipulate the structure and function of living matter at the nanoscale could also inspire biology-based approaches to technology development and fabrication. For example, in medicine, researchers envision an ability to synthesize new molecules, to direct the self-assembly of individual biomolecules, or to create molecular-scale tools for in vivo sensing, diagnostics, analysis, therapy design, and drug delivery. Nanobiotechnology opportunities also span food,

> cosmetics, energy, and electronics applications. For example, improved understanding of nature's processes could facilitate the development of molecular-scale bio-based fabrication approaches for materials and electronics."[450]

Nanomedicine[451]

Nanomedicine refers to "medical intervention at the molecular scale for curing disease or repairing damaged tissues, such as bone, muscle, or nerve".[428] It is also described as "the preservation and improvement of human health using molecular tools and molecular knowledge of the human body."[426]

The Nanomedicine glossary of the webpage 'Nanotechnology' now describes Nanomedicine as follows:

> (1) the comprehensive monitoring, control, construction, repair, defense, and improvement of all human biological systems, working from the molecular level, using engineered nanodevices and nanostructures; (2) the science and technology of diagnosing, treating, and preventing disease and traumatic injury, of relieving pain, and of preserving and improving human health, using molecular tools and molecular knowledge of the human body; (3) the employment of molecular machine systems to address medical problems, using molecular knowledge to maintain and improve human health at the molecular scale.[452]

Journals, projects, and working groups have recently emerged in the field of nanomedicine. The journal *Nanomedicine: Nanotechnology, Biology and Medicine* was launched in March 2005.[453] The US National Institutes of Health recently unveiled a "Roadmap for Nanomedicine" for the next 10 years.[428] Numerous applications for nanomedicine (NBIC-Medicine) are envisioned, in development or in use already.[425,454,455] The Alliance for NanoHealth[456] Houston, USA, was the first collaborative research endeavor aimed solely at bridging the gaps between medicine, biology, materials science, public policy, and nanotechnology.

A nanotechnology working group was formed in the National Heart, Lung, and Blood Institute (USA) to look at nanotechnology and its applications to heart, lung, blood, and sleep diseases,[457] as it is believed that nanotechnology offers new opportunities for diagnosis and therapy of cardiovascular, pulmonary, and hematological diseases and sleep disorders.[457] The University of California, Santa Barbara, will be working with Washington University in St. Louis and UC Berkeley under a $12.5 million grant by the National Heart, Lung, and Blood Institute of the National Institutes of Health, to develop nanoscale agents to provide early diagnosis and treatment of pulmonary artery disease.[458]

D.G. Rickerby[459] writes: *"It is anticipated that applications of biomedical nanotechnology will lead to progress in medical science, principally in the areas of diagnosis of disease, bio-compatible materials and drug delivery systems. Improved in vitro diagnostic techniques employing molecular nanotechnology biosensors and biochips for DNA analysis are already available."* The IST project Optonanogen programme[460] "is to develop a portable biosensor microsystem to detect nucleic acid hybridisation with sensitivity to single nucleotide

variations. Recent progress in micro- and nanotechnology has been significant. The Optonanogen programme aims to apply these new technologies to DNA array production and analysis to achieve both miniaturisation of the biochip format and an increase in the sensitivity of the assays performed."[460] "The final device will be roughly the size of a human hand, allowing it to be used in doctors' surgeries to determine the genetic predisposition of a patient to certain diseases in a matter of minutes. That compares to the hours or even days it can take to carry out the same analysis in a laboratory."[461]

"Advances in biomedical engineering include biomimetic nanostructures for implants and tissue engineering techniques that offer, potentially, the growth of artificial organs and the regeneration of damaged nerve tissue. Therapeutic systems using nanopowders and carbon nanotubes for drug delivery and anticancer drugs targeted at tumours cells are being developed. This convergence of the physical and biological sciences at the nanoscale is expected to revolutionize medicine and healthcare, improving the quality and extending the length of life for a large number of patients."[459]

Nanomedicine taxonomy

The nanotaxonomy developed for the 2003 workshop entitled, "NanoMedicine-NanoHealth: Establishing an Innovative Research Agenda for Canada," funded by CIHR, the Natural Science and Engineering Research Council, and the National Research Council of Canada, gives an idea as to what the vision of nanomedicine is in Canada.

Canadian Nanomedicine Taxonomy[462]

Nanomedicine Taxonomy

Biopharmaceutics
- Drug Delivery
  - Drug Encapsulation
  - Functional Drug Carriers
- Drug Discovery

Implantable Materials
- Tissue Repair and Replacement
  - Implant Coatings
  - Tissue Regeneration Scaffolds
- Structural Implant Materials
  - Bone Repair
  - Bioresorbable Materials
  - Smart Materials

Implantable Devices
- Assessment and Treatment Devices
  - Implantable Sensors
  - Implantable Medical Devices
- Sensory Aids
  - Retina Implants
  - Cochlear Implants

Surgical Aids
- Operating Tools
  - Smart Instruments
  - Surgical Robots

Diagnostic Tools
- Genetic Testing
  - Ultra-sensitive Labeling and Detection Technologies
  - High Throughput Arrays and Multiple Analyses
- Imaging
  - Nanoparticle Labels
  - Imaging Devices

Understanding Basic Life Processes

A Taxonomy was also published recently in the first issue of the new journal *Nanomedicine: Nanotechnology, Biology and Medicine* (Table 9).

Table 9: Freitas nanomedicine technologies taxonomy[430]

Raw nanomaterials	Cell simulations and cell diagnostics	Biological research
Nanoparticle coatings	Cell chips	Nanobiology
Nanocrystalline materials	Cell simulators	Nanoscience in life sciences
Nanostructured materials	DNA manipulation, sequencing, diagnostics	Drug delivery
Cyclic peptides	Genetic testing	Drug discovery
Dendrimers	DNA microarrays	Biopharmaceutics
Detoxification agents	Ultrafast DNA sequencing	Drug delivery
Fullerenes	DNA manipulation and control	Drug encapsulation
Functional drug carriers		Smart drugs
MRI scanning (nanoparticles)	Tools and diagnostics	
Nanobarcodes	Bacterial detection systems	Molecular medicine
Nanoemulsions	Biochips	Genetic therapy
Nanofibers	Biomolecular imaging	Pharmacogenomics
Nanoparticles	Biosensors and biodetection	
Nanoshells	Diagnostic and defense applications	Artificial enzymes and enzyme control

Continued on next page

Table 9: Freitas nanomedicine technologies taxonomy (cont'd)

Carbon nanotubes	Endoscopic robots and microscopes	Enzyme manipulation and control
Noncarbon nanotubes	Fullerene-based sensors	
Quantum dots	Imaging (cellular, etc.)	Nanotherapeutics
	Lab on a chip	Antibacterial and antiviral nanoparticles
Artificial binding sites	Monitoring	Fullerene-based pharmaceuticals
Artificial antibodies	Nanosensors	Photodynamic therapy
Artificial ezymes	Point of care diagnostics	Radiopharmaceuticals
Artificial receptors	Protein microarrays	
Molecularly imprinted polymers	Scanning probe microscopy	Synthetic biology and early nanodevices
		Dynamic nanoplatform "nanosome"
Control of surfaces	Intracellular devices	Tecto-dendrimers
Artificial surfaces—adhesive	Intracellular assay	Artificial cells and liposomes
Artificial surfaces—nonadhesive	Intracellular biocomputers	Polymeric micelles and polymersomes
Artificial surfaces—regulated	Intracellular sensors/reporters	
Biocompatible surfaces	Implants inside cells	Biotechnology and biorobotics

Continued on next page

Table 9: Freitas nanomedicine technologies taxonomy (cont'd)

Biofilm suppression		Biologic viral therapy
Engineered surfaces	BioMEMS	Virus-based hybrids
Pattern surfaces (contact guidance)	Implantable materials and devices	Stem cells and cloning
Thin-film coatings	Implanted bioMEMS, chips, and electrodes	Tissue engineering
	MEMS/Nanomaterials-based prosthetics	Artificial organs
	Sensory aids (artificial retina, etc.)	Nanobiotechnology
Nanopores	Microarrays	Biorobotics and biobots
Immunoisolation	Microcantilever-based sensors	
Molecular sieves and channels	Microfluidics	Nanorobotics
Nanofiltration membranes	Microneedles	DNA-based devices and nanorobots
Nanopores	Medical MEMS	Diamond-based nanorobots
Separations	MEMS surgical devices	Cell repair devices

Policy implications

The preceding nanomedicine technologies that are part of the taxonomy could be classified as "health technologies" and many if not all will influence the "health system" and "healthcare delivery." This shows the urgent need to increase the support for HTA, as in Canada, HTA units would have to evaluate these technologies coming down the pipeline.

Table 10: Nanomedicine products available, in development, or envisioned[463]

US NANOTECHNOLOGY HEALTH CARE PRODUCTS DEMAND(million dollars)					
		% Annual Growth			
Item	**2004**	**2009**	**2014**	**09/04**	**20/04**
Nanotech Health Care Product Demand	906	6500	27,700	48	35
Pharmaceuticals	406	3000	16,600	49	39
Diagnostics	465	1100	2200	19	14
Medical Supplies & Devices	35	2400	8900	133	50

According to an account by Frost and Sullivann, nanotechnological processes in medicine will obtain a sales volume of about $180 billion until 2015.[464] According to the Freedonia group,[463] "demand for nanotechnology health care products in the US is projected to increase nearly 50 per cent per year to $6.5 billion in 2009."[463]

The Freedonia press release continues:

> Gains will be led by the introduction of new, improved cancer and central nervous system therapies based on solubilization technologies. Diagnostic tests based on nanoarrays and quantum dots, and imaging agents based on superparamagnetic iron oxide nanoparticles will also see strong growth. In spite of progress in introducing new products, the vast potential of nanotechnology in the health care field will not be fully realized for at least a decade as stringent regulatory barriers and technical complexities delay the commercialization of targeted drug delivery systems, tissue regenerators and other breakthrough products. However, by 2020, demand for nanotechnology health care products is projected to exceed $100 billion.[463]

Nanoparticles have already improved the availability and efficiency of delivery of some drugs allowed for therapy in radiation-affected tissues using nanoscale devices and the implanting of nanosensors to diagnose and monitor disease. Envisioned actions of nanoparticles are the targeting and destruction of cancer cells using nanomagnetic particles; delivery of drugs directly to the target site with no side effects; delivery of

insulin for diabetics in a natural way, eliminating the need for regular injections; increasingly sophisticated modelling of the effects of new drugs and simulation of new drugs and other medical products, accelerating their introduction and reducing their cost of development; and bio-inspired nanosystems and materials formed by self-assembly that could be used in diagnostics.

Tissue engineering is also seen as being impacted by nanotechnology,[455] nanopumps, nanoneedles, and NEMS (nanoelectromechanical systems).[455] Nanoceramics are already being used as bone replacement agents.[465] Nanoemulsion antibacterial cleansers, nanofluidic tools, and 1 GHz nanodevices are other nanobased tools and compounds related to nanomedicine. The Abiocor IIartificial heart, due out in 2008, will fit most men and 50% of women and will last up to five years.[466]

A pill is being developed that contains a tiny camera and travels through the digestive system, transmitting images to allow physicians to look for worms or signs of disease in people's intestines.[467] The development of implantable smart medical devices that can respond to varying parameters within a patient, and, for example, alter drug dosage; monitor vital signs such as blood biochemistry and cardiac function; indicate the presence of pathogens; and communicate remotely with a PC will soon be a reality according to the Nanoforum (Europe 2003).[455] Chip RX is one company that develops products in this area,[468] another one being Smart Holograms.[469] Arizona State University has developed a so-called "biometric bodysuit," one for medical purposes and one for military purposes.[470] Their press release states:

> Frederic Zenhausern, director of the Applied NanoBioscience Center at ASU's Arizona Biodesign Institute, is coleading the project that sports both fashion and function. The ASU exhibit features two very dissimilar outfits that utilize embedded electronics and fluidics - one is a "wellness" costume designed in the style of a personal health garment, the second is a camouflage military outfit. Both were developed to show how electronics and fluidics could transform clothes into smart biometric bodysuits that respond to a wearer's environment and vital signs.
>
> "*The era of wearable electronics for fashion and health is here,*" said Zenhausern. "*The biometric bodysuit shows how electronics and fluidics can be incorporated into clothing to perform a wide range of tasks, from highly functional (like dispensing medicine, detecting pathogens or providing environmental awareness for personal safety and protection) to the aesthetic (clothes that change colors or display patterns as downloaded from a website to change the fashionable motifs and designs of a garment). This will be the standard of the future for interactive personal communication systems.*" The ASU researchers call their outfits the Scentsory Chameleon Bodysuit, which act as a "smart second skin" through the integration of printed organic opto-electronics and integrated flexible nano-genetic devices on textiles. They enable real-time remote personal health and medical monitoring into multi-media and sensorial clothing. The military camouflage outfit is replete with pathogen detectors; a high-density, low-temperature micro fuel cell that acts as a lightweight, long-life power source; and a flexible electroluminescent display. It was designed to show the functionality of embedded electronics and sensors, many of which are being developed in ASU labs. The sensor technology includes pathogen detectors that are more reliable and more sensitive than current technology. For example, the detectors on the ASU

> military outfit could take bacteria, destroy it, then amplify the bacteria's DNA and look for certain characteristics of specific pathogens, like anthrax or small pox. Future versions could incorporate sensors to monitor a soldier's vital signs and fatigue, Zenhausern said. The outfit also includes a flexible electroluminescent display that can be worn around the wrist to provide soldiers with instant awareness communications and updated commands, or environmental information about exposure to any biological or chemical agents. A third technology demonstrated in the outfit is an advanced micro fuel cell. The micro fuel cell would power an individual soldier's equipment for possibly up to a few weeks. It would be smaller and lighter weight than the conventional batteries that generate equivalent power, Zenhausern said.

Projected market growth for molecular imaging is estimated to be $45 billion by 2010.[471] A new contrast agent based on nanoparticles has been described by Lanza et al. for MRIs and ultrasound.[472]

Nanotubes inspire new technique for healing broken bones. Bone tissue is a natural composite of collagen fibers and hydroxyapatite crystals. Haddon and his coworkers have demonstrated for the first time that nanotubes can mimic the role of collagen as the scaffold for growth of hydroxyapatite in bone.[473]

Nanosurgery455

One wants surgery to be less invasive, with reduced trauma, smaller wounds, and the shortest possible time spent in surgery and recovery in the hospital. New surgical tools, such as nanotweezers, are available. In addition, femtosecond lasers and other approaches to nanosurgery are being tested.[474] The company Gesellschaft für Diamantprodukte has, through the application of nanotechnology and a process termed "plasma polishing," created diamond scalpels with a cutting edge of only a few atoms (approximately 3 nm). The blade possesses three cutting edges and is only 0.12 mm wide. The width of the scalpel blade is approximately one-thousandth that of a metal blade and makes these scalpels officially the smallest in the world, according to the *Guinness Book of Records*.[455] One vision is "to have nanostructured tools which are more corrosion resistant and stronger, will both last longer and decrease the possibility of contamination. Improved biocompatibility and effectiveness would benefit the patient, doctor and society in general. In addition savings in cost would benefit hard-pressed health authorities."[455]

Use of nanotechnology to fight cancer[475]

Many predict that nanomedicine plays a vital role in achieving the federal government's stated goal of eliminating suffering and death from cancer by 2015. Indeed, the National Cancer Institute (NCI; USA) just formed the Alliance for Nanotechnology in Cancer and allocated $US 144.5 million for a five-year plan to use tiny tools to fight cancer.[476] The NCI Alliance for Nanotechnology in Cancer sees at least five areas where nanotechnology can help fighting cancer: (1) role of nanotechnologies in advanced imaging, (2) cancer detection/diagnosis via nanotechnologies and nanosensors, (3) nanotechnology-enabled therapeutics development and delivery, (4) nanotechnology

devices and smart machines, and (5) nanobiology and nanooncology. For a listing of academic papers, see "Nanotechnology-Enabled Therapeutics Development and Delivery," "Nanobiology and Nanooncology," "Nanotechnology Devices and Smart Machines," "Cancer Detection/Diagnosis via Nanotechnologies and Nanosensors," and "Role of Nanotechnologies in Advanced Imaging."

It was recently reported that nanotechnology could find tumours before they were visible on MRIs.[477]

BrachySil by the biotechnology firm pSivida,[478] a silicon-based nanoscale system, takes drugs directly to the tumour site.[479] Its developers expect it to be part of the next generation of brachytherapy: cancer-zapping treatment given at a very short distance from the tumour. BrachySil is manufactured by embedding the pores of silicon with phosphorus. This is then irradiated in a reactor, creating phosphorus-32 for the treatment. Phosphorus-32 has a two-week half-life, almost six times as long as conventional therapy. The bio-silicon is then directed to the tumour by a needle injection. Clinical trials are currently ongoing in Singapore. BrachySil is expected to reach the market by 2006.

Another method envisioned to fight cancer is "through the introduction of nanomagnetic particles into tumours. Under the influence of a magnetic field, these particles heat up and dissolve the tumour cells which are resorbed into the body." A physical method to prepare copper-nickel alloy particles in the submicron range for possible self-controlled magnetic hyperthermia treatment of cancer has also been developed.[480] Dr. Kabanov has already co-invented a polymer formulation that has achieved up to 1000 times higher efficacy against drug-resistant tumour cells than doxorubicin, a widely used chemotherapeutic agent. Dr Kabanov's injectable polymer formulation of doxorubicin is undergoing Phase II clinical trials.[481] Quantum dot particles are also being applied in, among other things, high-content drug screening and the detection of breast cancer cells.[482]

The Nanoforum states that "NASA and NCI are financing a project to develop a method using dendrimers for the detection of cell death (apoptosis) in vivo, for future use in the detection of cellular damage induced by ionising radiation in space."[455]

The company, Nanospectra Biosciences, use in house developed Nanoshells to destroy solid tumours.

> According to the company "Nanospectra Biosciences" "Nanoshells may be combined with targeting proteins and used to ablate target cells. This procedure can result in the destruction of solid tumors or possibly metastases not otherwise observable by the oncologist. In addition, Nanoshells can be utilized to reduce angiogenesis present in certain disease conditions such as cancer, diabetic retinopathy and "wet" macular degeneration."
>
> "The advantages of Nanoshell-based tumor cell ablation include:
>
> - Targeting to specific cells and tissues to avoid damage to surrounding tissue;

- Superior side effect profile than targeted chemotherapeutic agents or photodynamic therapy;
- Repeatability because of:

  no "tissue memory" as in radiation therapy, and
- Biocompatibility and superior side effect profile; and
- Ability to treat non-spherical tumors, such as glioblastomas, metastases, and inoperable tumors. (*483*)

Nanospectra describes the physics of nanoshells as follows:

> "Nanoshells are a new type of optically tunable nanoparticle composed of a dielectric (for example, silica) core coated with an ultra-thin metallic (for example, gold) layer. Gold Nanoshells possess physical properties similar to gold colloid, in particular a strong optical absorption due to the collective electronic response of the metal to light. The optical absorption of gold colloid yields a brilliant red color, which has been of considerable utility in consumer-related medical products such as home pregnancy tests. In contrast, the optical response of gold Nanoshells depends dramatically on the relative sizes of the nanoparticle core and the thickness of the gold shell. By varying the relative core and shell thicknesses, the color of gold Nanoshells can be varied across a broad range of the optical spectrum that spans the visible and the near-IR spectral regions. Gold Nanoshells can be made either to absorb or scatter light preferentially by varying the size of the particle relative to the wavelength of the light at their optical resonance. The ability to "tune" Nanoshells to a desired wavelength is critical to in vivo therapeutic applications. Human blood and tissue minimally absorb certain near-infrared wavelengths of light, enabling us to use an external laser to deliver light to Nanoshells either in a tumour (for thermal destruction or imaging), a wound (for wound closure or tissue repair) or whole blood (to diagnose disease."[484]

Nano pharmaceutical technologies on the horizon: Horizon Scanning

In 1999, the term "pharmaceutical nanotechnology" showed up for the first time in the database PubMed of the National Library of Medicine. The term has been cited 255 times since then. In 2004, the *International Journal of Pharmaceutics* announced that it would add a section on pharmaceutical nanotechnology to their journal. In the pharmaceutical sciences, nanotechnology is being used in such diverse areas as:

- drug discovery, including combinatorial chemistry and synthesis on the molecular and macromolecular scale;
- nanoanalysis, including bioanalysis using miniaturized probes, microarrays, and
- lab-on-a-chip approaches;
- body fluid approaches;
- drug delivery systems having sizes in the nanometer range (e.g. liposomes, nanoparticles, microemulsions, dendrimers);

- implantable devices that can sense blood levels and automatically administer drugs;
- nanoscale biomaterials including biomimetics;
- biological macromolecules (e.g. proteins, enzymes, DNA- and RNA-based nanostructures, molecular assemblies, biomolecules, cells, biochips);
- molecular sensors and biosensors, clinical diagnostic techniques; and
- gene delivery and expression.

New nano-drug delivery systems

The Alberta Premier's Advisory Council on Health recognized in 2001 the existence, potential, and problems of emerging drug delivery systems by stating: "Nanorobotics, liposome technology and other exotic delivery systems will improve treatments but raise costs significantly."[6] Indeed, nanotechnology-based delivery systems are being increasingly explored (see papers published in Pub MED 2005). Many people would say that nanodelivery is nothing new, as scientists have worked for a long time with nanometer-sized liposomes as drug delivery systems.

However, today better techniques exist to produce more consistently sized liposomes and many new nanomaterials are being developed for nanodelivery purposes. The new nano-based delivery systems are being developed for use in several areas, including (a) delivery of cancer-targeted drugs, (b) carriers of genes for gene therapy, and (c) cosmetics (L'Oreal).[485]

Studies have shown that existing drug delivery systems are less than perfect.[486] In the year 2000, 15% of all hospital admissions were due to adverse drug effects, with 100,000 deaths.[486] Adverse drug effects have resulted in $136 billion in healthcare costs.[486] Furthermore, from a commercial viewpoint, drug delivery is a rapidly expanding subsection of the market for therapeutic drugs.[486] The company MediJect estimates the current global drug delivery market to be worth $20 billion.[487] Drug delivery is the fastest growing healthcare sector, currently growing at a rate twice that of pharmaceuticals.[486] Drug delivery industry sales are expected to increase at an annual rate of 15%, and this growth is thought likely to be sustained throughout the 21st century. There are, therefore, significant opportunities for growth and development within this market. The US drug delivery market alone is projected to grow from $14.3 billion in 1998 to $24 billion in 2003 and it is estimated that by 2005,[488] 20% of pharmaceutical expenditure will be used on products using drug delivery technologies.[486] In 2002, the drug delivery market represented about 13.5% of global pharmaceutical sales, that is, $53.8 billion and by 2007, it will account for 39%. Growth in the drug delivery market will continue at an average annual rate of 11%.[455] Wei and Flynn state: *"Historic and projected annual prescription expenditures in the United States for the year 2000 was $117 billion. It is estimated that it will be $366 billion by 2010,[489] making*

nanomedicine applications for drug delivery an attractive market for manufacturers and investors."[471] Current market drivers for development of drug delivery systems, according to Albert Tsai at the USC Technology Commercialization Alliance Greif Entrepreneurship Center, are as follows:[486]

- **Controlling overall healthcare costs** - the cost of developing and launching a new chemical entity can be $300–600 million, whereas the reformulation of an existing product may cost only $50 million and still achieve peak sales of $100-200 million.[490]
- **Enhancing a product's life-cycle** – pharmaceutical companies need to enhance older products reaching the end of their commercial life-cycle in order to optimize the company portfolio and maintain sales against competition.
- **Improving patient compliance** – this can be achieved by improving the choice of delivery system with pain-free, pleasant tasting, convenient alternatives. Patients are also more likely to take a drug which has reduced side effects and which works quickly.
- **Rapid growth in the worldwide biotechnology industry** – this has increased drug discovery and subsequently resulted in promising compounds such as proteins, peptides, hormones and therapeutic biologicals which do not penetrate the body easily.
- **The need to reduce side effects** – this has lead to the development of targeted drug delivery systems so that treatment is localized and systemic side effects can be reduced.
- **The need to deliver peptides and proteins** – there is a demand for an alternative delivery system to injectable or infusion-delivered insulin for the estimated 18 million sufferers of Type 1 diabetes worldwide. A growing number of the 15 million Type 2 sufferers worldwide are also now administering insulin themselves. At present, peptide and protein pharmaceuticals are worth approximately $10 billion worldwide and is expected to increase two to three times over the next decade.[491]

Nanosomes, nanocapsules, nanoporous material, nanocrystals, and dendrimers are just some delivery possiblities. All offer, according to the NanoBusiness Alliance, great potential to send drugs and genes through the body undetected until they reach the intended site.[492] "If you can make little containers out of these substances that are big enough to contain a biologically active substance without letting in the molecular eyes of the body, antibodies, but small enough to move freely through the body, then get these particles to home in on specific cells, you have the basis for an effective targeted drug-delivery system. The container can be a hollow nanoparticle or a solid one with the substance to be delivered embedded in it. The payload could be released by simple diffusion, if the payload molecules were small enough, or the containing structure

could degrade naturally or be broken up by ultrasound. A drug payload isn't even necessary - the material could just produce high temperatures under laser illumination, cauterizing tissue. Many groups are working on such approaches."[492]

The NanoBusiness Alliance, goes on stating "The principle of using nanopores to let some molecules pass but not others holds potential for drug-delivering implants. An insulin-delivery system that contains mouse pancreatic cells in a structure with pores small enough to let glucose in and insulin out, but keep the cells shielded from the body's immune system, is already being tested in mice. The same concept may offer the possibility of shielding drugs from digestive enzymes, allowing them to be taken as a pill where before they had to be injected."[492] Scientists are also studying "a tiny carbon molecule shaped like a soccer ball (a buckyball) as a superior vehicle for delivering medication in precise amounts at exactly the right spot."[493] A buckyball-based AIDS treatment is just about to enter stage I clinical trials."[494] Advectus and Immune Network Ltd. will have the opportunity to develop a nanoscale formulation of the anti-inflammatory drug, dapsone".[495] The TATLYS ("new biocompatible nanoparticle delivery system for targeted release of fibrinolytic drugs") **project is developing a system for targeted release of drugs to break down human blood clots. Biocompatible nanoparticles carry drugs to the exact location at an appropriate concentration."**[496] The University of Alberta demonstrated that poly n-butylcyanoacrylate nanocapsules can be used as vehicles for topical drug delivery in order to improve the skin permeation of anti-inflammatory and anti-tumour drugs such as indomethacin and presumably other more hydrophobic drugs."[455] Medusa, a self-assembled poly-aminoacid nanoparticles system, is a versatile protein carrier for the development of novel and second-generation long-acting native protein drugs. It is produced by Flamel Technologies, which uses Medusa for their pipeline of products like Basulin, which is a long-acting native insulin for the treatment of type I diabetes (the Phase I clinical trial has been successfully completed, confirming a duration of action of 24 hours by glucose monitoring). IL-2 XL is a second-generation long-acting interleukin-2; IFN alpha-2b XL is a long-acting native interferon alpha-2b for the treatment of hepatitis B and C and some cancers; EPO is a long-acting native erythropoietin for the treatment of anemia; and hGH is a long-acting native human growth hormone for the treatment of growth disorders.[497]

Other examples can be found in the Nanoforum report, "Nanotechnology and Its Implications for the Health of the EU Citizen."[455(pp.90-113)] As stated on pages 86 to 87 of this report:

> As has been described nanotechnology is already impacting drug delivery, however this will continue apace. In the future, nanoparticles will contain far more intelligence than the entire current system of drug delivery. These will be able to target and deliver therapeutics to specific tissues and cells with no side effects. For example a nanoparticle taken orally, that passes undisturbed through the stomach and small intestine and into the colon, where it homes in directly on the tumour cells and releases a powerful anticancer drug that destroys just the cancerous cells, could soon be a reality. In this respect antibodies that bind

exclusively to cancerous cells could be attached to nanoshells and injected into patients. Following infrared irradiation of the nanoshell-targeted tumour the resultant heat would destroy the cancer cells. Another possible targeted drug delivery system involves the use of nanomagnets that can be directed to specific sites within the body using external magnetic fields. These magnets could be attached to drugs that could treat specific cellular structures. A drug payload is not even necessary: the material could just produce high temperature under heat or light to destroy the targeted cells. The advantage of such a system is that it allows very focused and intense treatment of diseased cells without harming cellular structures of non-interest. Nanotubes may one day be used in transdermal drug delivery patches as nanoscale needles that can inject substances into the body. In fact, developing nanotubes as nanoscale, intravenous or intradermal, drug delivery devices is medically significant because a) it increases the mechanical and sensing functionality of the resultant nanoneedle, which makes it precise, and b) it is a less invasive and less painful drug administration. Nanotubes offer the potential of targeted drug delivery, for example to muscles, with molecular amounts of material, which maximizes efficiency by permitting lower doses, thereby minimizing possible toxicity and harmful side effects. Nanotubes could even be used as nanoneedles that inject drugs directly into individual cells, as developed at Purdue University. Indeed, many drugs destroy infectious bacteria by poking holes in their cellular membranes and leaking out their nutrients, just like pricking a hole in a balloon. The nanotubes developed by Purdue University could also act in this manner, but in addition, they can be targeted and thus lure bacteria with "a bait" that guides the nanotubes to the bacterial cell membrane where they can start destroying the cell. Scientists are currently studying methods to link quantum dots to drugs or other therapeutic agents to target cancer cells. These dots could serve as "smart bombs" to deliver a controlled amount of drug to a particular type of cell. Moreover, these particles would be able to profile a large number of genes and proteins simultaneously, allowing physicians to individualize cancer treatments based on the molecular differences in the cancers of various patients (indeed, even when cells appear to be similar under the microscope, their genes and proteins may be decidedly different, which explains why cancer patients with apparently similar cancers sometimes respond differently to the same treatment). Other nano-devices will allow the continuous monitoring of the level of various biochemicals in the bloodstream and in response could release appropriate drugs. For example, an insulin-dependent diabetic could use such a device to continuously monitor and adjust insulin levels autonomously."[455]

Nanocapsules have potential applications in agrochemicals, cosmetics, genetic engineering, wastewater treatments, cleaning products, and adhesive component applications. They can be used to encapsulate enzymes, catalysts, oils, adhesives, polymers, inorganic micro- and nanoparticles, latex particles, or even biological cells. Nanocrystals are used to increase the water solubility and bioavailability of drugs.[455,498,499]

Dendrimers are synthetic, nanoscale structures (1 to 100 nm) that can be tailored for many pharmaceutical applications. The term "dendrimer" has 651 citations in PubMed as of April 2005. Dendrimers can act as biologically active carrier molecules in drug delivery to which can be attached therapeutic agents that can act as scavengers of metal ions, offering the potential for environmental clean-up operations because their size allows them to be filtered out with ultra-filtration techniques.[500]

One example of a dendrimer-based drug is VivaGel, a topical microbicide gel for prevention of human immunodeficiency virus and other sexually transmitted diseases in women.[501] According to Starpharma, product opportunities for dendrimers are for a broad range of viral respiratory diseases, as novel chemotherapeutic agents, as angiogenesis inhibitors, to target a range of tropical and exotic diseases, and as biodefense agents.[500] Swiss drugmaker Debiopharm has signed a contract with Labopharm for the application of the latter's nanodelivery system to one of its intravenous cancer drugs.[502] One major focus of the *International Journal of Nanomedicine*, which was just launched, is nanodrugs and nanodelivery systems.

Nanoparticles used for drug detoxification

Serious adverse drug reactions (ADRs) are epidemic in the US. According to a study reported in the mid-April issue of the *Journal of the American Medical Association*, they are the fourth leading cause of death in America. ADRs rank behind only heart disease (743,460 deaths), cancer (529,904 deaths), and stroke (150,108 deaths). More people die in the US from ADRs than from pneumonia and diabetes. The study analysis was drawn from 39 previous studies from various US hospitals beginning in the 1960s. In 1994, 2,216,000 US hospital patients had serious ADRs and 106,000 deaths resulted. "Perhaps the most surprising result was the large number of fatal ADRs," the researchers commented.[503]

On the Particle Engineering Research Centre University of Florida website, one reads the following about nanoparicles and drug detoxification:

> Nanoparticulates for Drug Detoxification focus on nanoparticulate systems for toxicity reversal of overdosed drugs. Drug toxicity in humans as a result of therapeutic miscalculation, illicit drug usage, or suicide attempt is a major health care problem in the United States, not only in terms of cost but also in the context of increased patient morbidity and mortality. For example, almost 300,000 people in the US are admitted annually to the hospital through emergency rooms because of drug toxicity, costing the country more than ten billion dollars per year in health care expenses and lost employee productivity. Unfortunately, the vast majority of life threatening drug intoxications do not have specific pharmacological antidotes to reverse their adverse effects. The PERC's recent advances in particle synthesis (Goal II) and competitive adsorption (Goal I), together with the latest tools of molecular medicine, provide new opportunities to develop highly effective therapeutic strategies aimed at effectively treating drug overdoses. The first objective of Goal IV is therefore to synthesize a series of novel nanobioparticles that effectively reduce the free blood concentration of toxic drugs.
>
> Three complementary drug removal mechanisms are being explored:
>
> a) Partitioning a drug into particles by exploiting differences in physicochemical properties;
>
> b) Adsorbing drug to functionalized internal surfaces of particles;
>
> c) Biotransforming the drug into less toxic metabolites by incorporating P450 enzymes (which catalyze metabolism of xenobiotics, such as drugs, in the body).[504,505]

Physical removal of toxin drug complexes in hand-held magnetic filter is another way developed by others.[506]

New drugs: nanodrugs, pharmacogenomics, and pharmacogenetics

Two new ways of designing drugs are on the horizon. One is nano-formulations of existing drugs or new nano-formulated drugs and the other is the design of drugs using pharmacogenetics/pharmacogenomics.

The NSF (USA) estimates that half of all drugs will be made with nanotechnology by 2010. Flynn and Wei state: *"Historic and projected annual prescription expenditures in the United States for the year 2000 was $117 billion. It is estimated that it will be $366 billion by 2010(489), making nanomedicine applications for drug delivery an attractive market for manufacturers and investors."*[471]

A recent article in *Nanotechnology Law and Business* highlighted the first three nanodrugs approved by the FDA. One nanodrug that did not exist in a "non-nano form," **Emend®**, was approved on 26 March 2003. Two are nano-reformulations of already existing and approved drugs, **Tricor®**, which was approved on 5 November 2004, and **Rapamune®**, which was approved in August 2000.[471,507] As the article states, "Merck utilized technology licensed from Elan to successfully develop and obtain approval to market their nanoparticulate drug, aprepitant. Commercially marketed as Emend®, aprepitant is the first FDA approved drug for treatment that prevents the delayed nausea and vomiting symptoms that many cancer patients experience greater than twenty-four hours after receiving chemotherapy. Wyeth brought their drug sirolimus to Elan for development of a nanoparticulate formulation of sirolimus (Rapamune®). Wyeth applied for and successfully obtained approval to market Elan's nanoparticulate formulation of sirolimus, making this the first commercial launch of a nanoparticulate drug. Abbott came to Elan seeking to formulate their micronized TriCor® commercial drug into a nanoparticulate formulation. Not only was Elan able to reformulate TriCor® to require a smaller dose, the formulation developed also eliminated the variability observed upon administration of TriCor®, in fasted and fed patients."[471,507]

Pharmacogenetics can be defined as "the study of variability in drug response due to genetic factors. In contrast, pharmacogenomics encompasses a broader range of analyses, and is concerned with drug response based on knowledge of the whole human genome and its products."[508] Pharmacogenomics "examines how your genetic makeup affects your response to drugs."[509,510]

Anticipated benefits of pharmacogenomics:[511]

- **More powerful medicines -** pharmaceutical companies will be able to produce therapies more targeted to specific diseases, maximizing therapeutic effects while decreasing damage to nearby healthy cells.
- **Better, safer drugs the first time -** recovery time will go down and safety will go up as the likelihood of adverse reactions goes down or is eliminated altogether.

- **More accurate methods of determining appropriate drug dosages -** current methods of basing dosages on weight and age will be replaced with dosages based on a person's genetics --how well the body processes the medicine and the time it takes to metabolize it.
- **Better vaccines -** vaccines made of genetic material, either DNA or RNA, promise the benefits of existing vaccines without all the risks. They theoretically could activate the immune system but be unable to cause infections.

It is thought/claimed that Pharmacogenomics eventually can lead to an overall decrease "in the cost of healthcare because of decreases in:

- the number of adverse drug reactions,
- the number of failed drug trials,
- the time it takes to get a drug approved,
- the length of time patients are on medication,
- the number of medications patients must take to find an effective therapy,
- the effects of a disease on the body (through early detection)". (*511*)

Policy implications: increase in use and cost of drugs

According to a National Forum on Health report,[512] Canadian expenditures on drugs increased between 1975 and 1994 from $1.1 to $9.2 billion. Expenditures per person, adjusted for inflation, more than doubled, rising from $108 to $232. Total drug expenditure per person in Canada was forecast to have reached $632 in 2003 and $681 in 2004.[513] Drug expenditures increased faster than any other major category of health care; their share of total health spending thus rose from 8.7% to 12.7%.[513]

Since 1997, the second-largest category of healthcare spending has been drugs, after hospitals and before physician spending.[513] According to the executive summary of a 2005 report by the Canadian Institute for Health Information,[513] total expenditure on drugs was an estimated $18.4 billion in 2002, and was forecast to have reached $21.8 billion in 2004. The share of drugs in total health expenditure was 9.5% in 1985. It has increased each year thereafter to reach 16.1% in 2002 and was forecast to have grown to 16.7% in 2004. Since 1997, among major categories of health expenditure, drugs have accounted for the second largest share, after hospitals. In 2002, drug expenditure was equivalent to over 50% of the amount spent on hospitals and exceeded the amount spent on physicians' services.

At the national level, the data indicate that from 1985 to 2002, total drug expenditure grew at an average annual rate of 9.7%, well beyond what can be attributed to economy-wide inflation and growth in the population. Total drug expenditure per capita in Canada grew by 9.3% in 2002. It was forecast to have

risen by 7.7% in 2003 and 7.8% in 2004. Drugs accounted for 3.7% of total public sector health expenditure in 1985 and 8.6% in 2002. In 1985, drugs represented 27.5% of total private sector health expenditure; this proportion rose to 33.4% in 2002.

For Alberta, the data indicate that total drug expenditure as a percentage of total health expenditure is 14.5%, which is below the Canadian average of 16.7%. Total drug expenditure per capita is $618.36, slightly below the Canadian average of $681.09. Drug expenditure in hospitals per capital increased in Alberta from $42.92 in 2000 to $47.23 in 2001 and $51.12 in 2002.

However, what is driving the explosion in the costs of drugs?

"Numerous factors, many of which are interrelated, may influence drug expenditure," states one study.[514] As described in the 2005 report, "Drug Expenditure in Canada 1985 to 2004," by the Canadian Institute for Health Information, drug prices have been relatively stable over the past 10 years and factors affecting increased drug spending in Canada essentially relate to the volume of drug use and the entry of new drugs (typically introduced to the market at higher prices).[513] This conclusion was also reached by the Standing Senate Committee on Social Affairs, Science and Technology, which stated that prescription drug spending could be attributed to increased utilization of existing drugs (50%), sales of new drugs in their first full year (32%), and price increases of existing drugs (18%).[209] Furthermore, the National Forum on Health[7] and others found that drugs are both overutilized and inappropriately used.[515] A recent *Forbes* article,[516] which used data collected by the Agency for Health Care Research and Quality, a US government outfit charged with figuring out where Americans' health care dollars are going, interpreted the data collected, stating: "Of the ten fastest-growing diseases ranked by percentage increase in cost, only one was caused by an increase in the cost of care per patient whereas in the other nine the cost increased because more and more people were diagnosed.

Cost driver: increased price of new drugs

Sales of new drugs in their first full year are the second-highest cost driver for drugs (32%).[209] *Forbes* recently started talking about cancer treatments: "The price tag for treating patients has increased 500-fold in the last decade.[517] Ten years ago, doctors could extend the life of a patient who had failed to respond to chemotherapy several times by an average 11.5 months using a combination of drugs that cost $500 in today's dollars. Now, new medicines such as Avastin and Eloxatin can extend survival to 22.5 months, but at a total cost of $250,000."[517]

One hope has been that with the help of pharmacogenomics, the costs of drugs could be reduced. However, this seems not to be as simple as one might think.[511,517-519] The USA NSF believes that half of all drugs will be made with nanotechnology by 2010. It is too early to say whether nanoformulations of old drugs will be sold with a premium, but if the 32% cost driver for sales of new drugs is an indication, one can expect that this might be the case. It also might be expected that we see an increase in new drugs going onto the market as companies might try to use nanoformulation of their old drugs to increase the

efficacy and effectiveness of their old drugs and might try to protect the outgoing patent of their old drug by patenting a composite of matter and applications of the nanoformulated version of their drugs.

Cost driver: increased use of drugs

An increase in use of existing drugs is seen as the number one cost driver for drug expenditures. New diseases, which have to be served by drugs (medicalization), and the ability of new drugs to enhance human performance (transhumanization of medicalization) will further enhance this trend.

If HTA stays within the framework of evaluation of clinical efficacy and effectiveness of "health" technologies, it will not be able to give policy makers and others any guidance as to what the "health system" and the "healthcare system" will face in the future regarding this cost driver for drugs.

HTA just looks at the clinical setting and is not able to assess why the costs of drugs increase and therefore cannot give policy makers an understanding of how a particular drug or all drugs lead to an increase in costs. It seems that in order to answer this question, HTA has to move out of the clinical setting and look at, among other things, the social drivers for increased drug use. The transhumanist philosophy (discussed earlier) is one driver that will become more dominant in the future; another driver is the increase of the phenomenon of medicalization (discussed earlier). Both very likely will feed on each other and gain even more ground.

Most expensive diseases[516]

Heart Conditions

Annual cost: $68 billion • Heart attacks: $15 billion • Rhythm problems: $8.8 billion • Chronic heart failure: $8.7 billion • Coronary heart disease: $7.5 billion • Valve disorders: $3.1 billion

This category does not include many of the expenses for drugs to lower cholesterol or blood pressure. The bulk of these costs (some $41 billion) are in hospital stays. Almost 20 million Americans have such heart ailments. Source: Agency for Healthcare Research & Quality, 2002

Trauma

Annual cost: $56 billion • Broken bones: $21 billion • Sprains and strains: $7.4 billion • Open wounds: $4.5 billion • Joint disorders: $3.5 billion • Bruises: $2.3 billion

Some 36 million Americans suffer from trauma-related injuries. Most of the resulting spending is for hospital stays ($21 billion) or doctor visits and outpatient care ($19 billion). Source: Agency for Healthcare Research & Quality, 2002

Cancer

Annual cost: $48 billion • Breast cancer: $6.5 billion • Prostate cancer: $3.6 billion • Skin cancers: $2.7 billion

Eleven million Americans received cancer care, half as many as were treated for heart conditions. But the costs were nearly as much. The $23 billion spent on hospital stays and $21 billion on outpatient care probably also includes the cost of cancer drugs, most of which are given intravenously. Source: Agency for Healthcare Research & Quality, 2002

Mental Illness

Annual cost: $48 billion • Alzheimer's and dementia: $7.7 billion • Affective disorders: $19 billion • Schizophrenia and similar disorders: $3.4 billion • Attention deficit hyperactivity disorder: $2.3 billion

Thirty-one million Americans suffer from various mental illnesses. Most of the related costs are for drugs ($16 billion) and doctor visits and outpatient care ($13 billion.) Source: Agency for Healthcare Research & Quality, 2002

Respiratory Ailments

Annual cost: $45 billion • COPD: $4.5 billion • Asthma: $11 billion

Respiratory ailments afflict 50 million Americans. The biggest component of the costs is prescription drugs, which accounts for $15 billion in spending. Most of the remaining costs are split between doctor visits and hospital stays (both $12 billion.) Source: Agency for Healthcare Research & Quality, 2002

Hypertension

Annual cost: $32.5 billion

Thirty-seven million Americans have high blood pressure. Aside from increasing their risk of heart attacks, the condition can lead to kidney damage or even blindness. Most of the costs are for drugs ($17 billion), with another $8.6 billion spent on doctor visits and outpatient care. Source: Agency for Healthcare Research & Quality, 2002

Arthritis and Joint Disorders

Annual cost: $32 billion • Arthritis: $7.8 billion • Other joint disorders: $24 billion

Twenty-three million Americans were treated for arthritis and other joint disorders. Most of the money went to doctor visits and outpatient treatment ($11 billion) and hospital visits ($10 billion.). Source: Agency for Healthcare Research & Quality, 2002

Diabetes

Annual cost: $28 billion.

Diabetes is one of the fastest-growing health problems in the Western world. There were 14 million diagnoses for the condition in the United States. Most of the cost came from prescription drugs ($11 billion) and doctor visits or outpatient care ($6.8 billion). Source: Agency for Healthcare Research & Quality, 2002

Back Problems

Annual cost: $23 billion.

Back problems can be recalcitrant, and often there is little that can be done. For 18 million patients, most of the spending is for office visits and outpatient procedures ($12 billion), with another $6 billion spent on hospital stays. Source: Agency for Healthcare Research & Quality, 2002

Fastest-growing diseases[516]

Esophageal Disorders

Total Cost: $8.9 billion +479%

Per patient costs are going down, but the number of people diagnosed with heartburn and related disorders increased by 509% to 10 million between 1997 and 1996-2002 as new drugs such as Prilosec, Prevacid and Protonix lured sufferers to the doctor's office, driving total costs up. Sources: Agency for Healthcare Research & Quality, 1996-2002.

High Cholesterol

Total Cost: $13.6 billion +212%

Cholesterol drugs like Lipitor and Zocor cut the number of heart attacks by a third and are the drug industry's biggest moneymaker. The number of people diagnosed increased by 145% to 19 billion, and expensive treatments drove costs up even more. Sources: Agency for Healthcare Research & Quality, 1996-2002.

Hemorrhoids

Total Cost: $1.2 billion +174%

The number of people with hemorrhoids increased by only 23% to 1.2 billion. But new technologies helped more than double total costs. Sources: Agency for Healthcare Research & Quality, 1996-2002.

Anxiety Disorders

Total Cost: $9.9 billion +134%

While newer treatments such as Paxil and Zoloft may be pricey, the real cost driver is the fact that the number of patients treated for anxiety doubled to 12 million over five years. Sources: Agency for Healthcare Research & Quality, 1996-2002.

Five major types of anxiety disorders are: • Generalized Anxiety Disorder • Obsessive-Compulsive Disorder (OCD) Panic Disorder • Post-Traumatic Stress Disorder (PTSD) • Social Phobia (or Social Autism http://www.msnbc.msn.com/id/6844737/

Breast Cancer

Total Cost: $6.5 billion +126%

The costs of cancer drugs continue to rise, and while the number of cases of breast cancer rose 65% to 1.2 million, the cost of treating the disease rose twice that much. Sources: Agency for Healthcare Research & Quality, 1996-2002

Nonspecific Chest Pain

Total Cost: $6.6 billion +124%

While the number of cases increased by only 23% to 3.2 million, making sure people don't have heart conditions is expensive, making costs more than double. Sources: Agency for Healthcare Research & Quality, 1996-2002

Arthritis

Total Cost: $7.8 billion +119%

The number of arthritis sufferers rose 30% to 2.8 billion, but costs rose by four times that much. One possible reason: pricey pills such as Vioxx and Bextra, both now pulled from shelves for safety reasons. Sources: Agency for Healthcare Research & Quality, 1996-2002

Viral Infections

Total Cost: $9.1 billion +113%

The number of infections increased 12% to 10 million cases, but newer, more expensive (and effective) treatments caused costs to double. Sources: Agency for Healthcare Research & Quality, 1996-2002

Lupus and Connective Tissue Disorders

Total Cost: $16.8 billion +97%

The 15 million lupus sufferers in the US (up 30% since 1996). Sources: Agency for Healthcare Research & Quality, 1996-2002

Asthma

Total Cost: $10.7 billion +83%

The number of cases of asthma increased 35% to 11 million since 1997, but the total cost rose 83%--the result of newer, more expensive drugs. Sources: Agency for Healthcare Research & Quality, 1996-2002

NBIC products envisioned for disabled people

For the deaf, we will have systems that provide subtitles around the world. We're getting close to the point where speaker-independent speech recognition will become common. Machines will create subtitles automatically and on the fly, and these subtitles will be a pretty accurate representation of what people are saying. We will have listening systems that allow deaf persons to understand what people are saying. For blind people, we actually will have reading machines within a few years that are not just sitting on a desk, but are tiny devices you put in your pocket. You'll take pictures of signs on the wall, handouts at meetings, and so on. You will be able to wear one on your lapel and scan in all directions. These devices probably will be used by the sighted as well, because they will allow us to get visual information from all around us. Such devices also will translate the information from one language to another for everyone. We've put together demonstration technology to show just how the information will be transferred back and forth from English to German, from German to French, from French to English, and so on. Exoskeletal aid for physical impairments. Reconnecting broken nerve pathways. Kurzweil explains *"There have been interesting experiments in scanning brain patterns 15 or 20 years after the injury in spinal cord patients. They are asked to perform certain functions – lift your leg, walk across the room. The brain-pattern activity was the same as in a non-disabled person, but obviously it was not communicating, because the pathways were broken. Still, it will be quite feasible to pick up the patterns in the brain and wirelessly communicate them to the muscles, completely bypassing the nervous system that's no longer functioning."* Ultimately, we will be able to create the muscles as well. We are creating muscle analogs for robots,

> but those could be used for disabled persons as well. There are other challenges—creating a skeletal system to replace one that may not be up to the task, dealing with the cardiovascular implications. These are complex projects, but I believe we will see profound steps forward by 2010. By 2020, I think we will have largely overcome the handicaps of spinal cord injuries. Enhancing our own intelligence: there are many people walking around now who are essentially cyborgs and have computers in their brains interfacing with their biological neurons. The Food and Drug Administration just approved a neural implant for Parkinson's disease that replaces the portion of the brain destroyed by that disease.[520]

In the 2001 report on NBIC, one reads the following about the future capabilities of nanotechnology, in particular, the use of nano implant devices to self-monitor physiological well-being and dysfunction:

> As the scales of nanofabrication and nanotransducers approach those of the critical biomolecular feature sizes, they give the technologist the toolset to probe and control biological functions at the most fundamental "life machinery" level. By the same token, this technology could profoundly affect the ways we manage our health. One outcome of combining nanotechnology with biotechnology will be molecular prosthetics — nano components that can repair or replace defective cellular components such as ion channels or protein signaling receptors. Another result will be intracellular imaging, perhaps enabled by synthetic nano-materials that can act as contrast agents to highlight early disease markers in routine screening. Through self-delivered nano-medical intervention, patients in the future will be able in the comfort of their homes to perform noninvasive treatments autonomously or under remote supervision by physicians. Metabolic and anatomical monitoring will be able to give humans the capability to track the energy balance of intake and consumption. Monitoring high-risk factors will be able to facilitate early diagnosis, when medical treatments can be most effective. Information systems designed to present medical data in ways that are intelligible to laypersons will allow anyone to monitor his or her health. As a result of NBIC-enabled "wonder medicines," there will be a need to develop technology and training modalities to make the patient an essential partner in the process of health monitoring and intervention. As the population ages, more and more age-related diseases and deteriorating functions (e.g., hearing, memory, muscle strength, and sight) will be prevalent; an obvious example is Alzheimer's disease. Some of these dysfunctions are due to molecular changes over time, and some are due to the natural decay of bodily functions. NBIC will provide ways to slow down the aging process or even reverse it.[521]

Other visions in the same paper relate to nano-medical research and intervention monitoring and robotics. The convergence of nano-bio-info-cogno technologies will enhance the toolset for medical research and allow medical intervention and monitoring through multifunctional nanorobots (e.g. a nano brain surveillance camera). A range of nano-enabled unobtrusive tools will facilitate research on cognitive activities of the brain.

In the article, "Quality of Life of Disabled People Using Converging Technologies," in the same book:[1]

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[1] Other visions are "27 Great Expectations for Rehabilitation Mechatronics in the Coming Decade",[522] and "Developing Multimedia Software and Virtual Reality Worlds and their Use in Rehabilitation and Psychology."[523]

> It is understood that NBIC should be used in a way that diminishes the discrimination against disabled people, advances their acceptance and integration into society, and increases their quality of life.
>
> NBIC has the potential to give disabled people, and this includes many elderly, the ability to choose between different modes of information output, whether visual, audio, print, or others, as all these modes can be offered routinely at the same time. It has the potential to change computer interface architecture so that disabled people, including those who are blind, sight impaired, dyslexic, arthritic, immobile, and deaf, can access the Internet and its webpages as transparently and quickly as able-bodied people by means of, for example, holographic outputs; force-feedback, vibrotactile, vastly improved natural speech interfaces; and realtime close captioning. Multimodal access to data and representations will provide a cognitively and perceptually richer form of interaction for all persons, regardless of impairment, handicap, or disability. It will allow for more flexibility in the mode of working (from home or a company building or elsewhere) and representation (in person or virtual). …NBIC will allow for improving assistive devices for disabled people. …NBIC will greatly improve the functionality and design of houses, allowing voice command, intelligent applications, etc., that enable disabled (and elderly) people to be more independent. …NBIC has the potential to change the public space to make it much more user friendly and inclusive. Means will include IT advances to enable wearable computers for use in everyday living (e.g., finding when the next bus is due or where it is now); creation of smart environments (e.g., Remote Auditory Signage Systems [RASS] like talking signs, talking buses, etc., to facilitate way finding, business/object location identification, recognition of mass transit services, and intermodal transfer); use of IT and cognitive technology to develop voice-activated personal guidance systems using GPS and GIS; and multimodal interfaces to assist travel and environmental learning. …NBIC has the potential to improve communication on a global scale (e.g., universal translation devices), which would allow for a greater exchange of knowledge among people and a faster dissemination of advances in NBIC.[398]

Brain–machine interfaces

Scientists have demonstrated in 2002 that human thoughts can be converted into radio waves and used by paralyzed people to create movement.[524] "Unable to move, Matthew Nagle can play Tetris, draw and turn on the TV using the chip in his brain."[525] One team implanted miniature transmitters into the brains of terminally ill people suffering from degenerative conditions that rendered them unable to communicate. Their thoughts alone enabled them to create movement. It was said: "Ultimately the technology will be used for people whose spinal cords are destroyed in accidents or those handicapped by strokes."[524] "Scientists in Australia have developed a "mind switch"[526] that enables people to activate electrical devices (e.g. turn on a radio or open doors) by thinking."[527]

Following is the work of The IDIAP Research Institute, originally referred to as "Institute Dalle Molle d'Intelligence Artificielle Perceptive" (Dalle Molle Institute for Perceptual Artificial Intelligence).[528] As they state in a recent publication:[2]

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[2] Brain machine interfaces are no science fiction. The IEEE Trans. on Biomedical Engineering just had a Special Issue on Brain-Machine Interfaces, Vol. 51, Issue 6, June 2004.

> Brain activity recorded non-invasively is sufficient to control a mobile robot if advanced robotics is used in combination with asynchronous EEG analysis and machine learning techniques. Until now brain-actuated control has mainly relied on implanted electrodes, since EEG-based systems have been considered too slow for controlling rapid and complex sequences of movements. We show that two human subjects successfully moved a robot between several rooms by mental control only, using an EEG-based brain-machine interface that recognized three mental states. Mental control was comparable to manual control on the same task with a performance ratio of 0.74.[529]

The Dalle Molle Institute for Perceptual Artificial Intelligence is not the only ones working on brain machine interfaces.[530-534] There are others, such as the company Cyberkinetics, which received FDA approval to test their product "Brain Gate."[535] Researchers at Duke University Medical Center in Durham, North Carolina, are currently developing a wireless neuroprosthetic that could potentially control robotic limbs for quadriplegics. They are also planning a brain-controlled electric wheelchair and a brain-operated keyboard.[536] Recently a whole issue of the journal of the Banff Centre of the Arts was dedicated to nanotechnology and the dream home.[537,538]

The preceding discussion on brain–machine interfaces relates to disabled people; however, it is logical to expect that these devices will also be used by non-disabled people as a means to control their environment, especially if the brain–machine interface is non-invasive and no implants are needed as in the working model of the Dalle Molle Institute for Perceptual Artificial Intelligence.

Bionic implants

"When Kevin Warwick lifted his finger, his wife Irena felt as if a bolt of lightning ran down her palm and into her own finger. In what they billed as the first direct link between nervous systems, the couple had electrodes surgically implanted in their arms and linked by radio signals to a computer. Blindfolded for the experiment, they could feel when their spouse's finger moved."[539-541] Other examples of bionic implants are described by Benoy George Thomas.[542]

Bionic ear[543,544]

Advanced Bionics introduced the HiRes 90K implant over a year ago and since then more than 2600 implants have been manufactured. The HiRes 90K implant has had an explant rate of 1.1% at 12 months. As of 2000, more than 20,000 people worldwide have bionic ears.[545]

The market for cochlear implants is already well-established; however, some problems with the technology remain such as interference with strong magnetic fields and the risk of infection, eczema, or dizziness. Nanotechnology can be applied to antimicrobial coatings on hearing aids including cochlear implants. Nanostructured coatings, including diffusable silver ions that are released slowly from the coating to prevent infections in the ear, have been developed.

There are two methods of administering antimicrobial remedies to the inner ear following cochlear implant operations: coatings or fluid-based drug delivery systems.[546]

The Bionic Ear Institute in Australia is building an implant for the inner ear that will shock damaged nerves back to health. A small pump showers the nerves with stimulating chemicals while electrodes excite the cells to keep them alive.[466]

Bionic eyes[547]

Retinal implants are being developed to partially restore sight for blind patients who have diseases that destroy the photoreceptor cells of the retina at the back of the eye but leave the visual nerve and visual cortex intact. These diseases include retinitis pigmentosa, Usher syndrome, and macular degeneration. In the EU, there are 70,000 to 100,000 patients with retinitis pigmentosa and 2.1 to 2.2 million patients with macular degeneration.[548,549]

Retinal implant research projects

Since the late 1990s, there have been at least two fundamental retinal implant research projects in the USA and a further two in Germany, funded by the Federal Ministry for Education and Research. The German projects are the Epiret project, which aims to develop a retinal implant located at the back of the ganglion cells that connects directly to the optic nerve, and the Subret project, which aims to develop a retinal implant located in place of the lost photoreceptor cells. The projects have been running in two phases between 1995 and 2003.[550]

Nanotechnology retinal implants

Dr Martin Stelzle, head of Physical Chemistry and Sensors Group, NMI Naturwissenschaftliches und Medizinisches Institut in Reutlingen, Germany, is developing new retinal implants using nanotechnology.[551]

Next generation autonomous wheelchair control

Research is under way to add new capabilities to a wheelchair such that the wheelchair knows its environment, senses where it is and where it must go, and avoids any obstacles. This design challenge is broken into four major steps: wheelchair control, environment recognition, route planning, and obstacle avoidance.[552]

Bionic legs and arms

Many companies work on the development of bionic legs and arms.[553-556] The potential market is huge: roughly 260,000 people undergo lower limb amputations in the United States each year. And that's less than half the G8 market.[557] Victhom's focus is on active amputees from 25 to 55; by the company's calculation, 300,000 above-the-knee amputees in the G8 fit the bill, with up to 40,000 new cases each year.[556] About 8% of the estimated 387,500 amputees in the United States are those that have lost their arms.[558] The Defense Sciences Office (DSO) of the Defense Advanced Research Projects Agency (DARPA) just asked for proposals for upper-extremity prosthesis.[559] The number of

implants in use in the USA indicates their importance to health care and the economic impact of the biomaterials industry. For example, it was estimated in 1988 that 674,000 adults in the US were using 811,000 artificial hips. It was also estimated that 170,000 people worldwide received artificial heart valves in 1994.[560]

Bionic knee

There is a growing need for bionic knees in part because of skyrocketing diabetes rates and because of advances in medicine which have led to more people surviving car accidents and motorcycle accidents.[561] Rheo-Knee, which costs $30,000, uses artificial intelligence—tiny sensors that analyze the knee 1000 times per second, allowing it to adjust to any step or misstep.[562] The 3DKnee is another knee implant from which to choose.[563]

Neural prostheses

Neural prostheses are technical systems that partially substitute neural body functions after traumatic lesions or neurological disorders.[564]

Spinal cord prostheses

More than 200,000 people in the USA alone live with Spinal Cord Injury.[565,566] Repairing spinal cords means finding a way to get nerve cells to grow back across the gap in a spinal cord that has been severed. Nanotechnology is employed to achieve this goal.[567]

Speech

On the betterhuman.com webpage one reads: "A system that converts nerve signals in the throat into computerized speech could soon allow people to speak without saying a word." "The system that the researchers developed is a **neural interface**—a type of data link between the human **nervous system** and an external device, such as a computer or a remote-controlled machine. It uses sensors placed under the chin and on either side of the "Adam's apple"—the laryngeal prominence—to gather subvocal nerve signals and transfer them to a **processor**, then to a computer program that translates the signals into words. Subvocal speech is characterized by movement of the lips or other speech organs without accompanying audible sounds. "A person using the subvocal system thinks of phrases and talks to himself so quietly, it cannot be heard, but the tongue and vocal chords do receive speech signals from the brain," says Jorgensen.[568,569]

Cranial, neural, and other implants

Repairing severe human skull injuries requires customized cranial implants are designed to improve the condition of patients suffering from brain-related diseases, mainly by supplying biochemicals to the brain and monitoring the effects, for example, in the alleviation of the effects of Parkinson's disease. Other neural implants are pacemakers, bladder stimulators, drug dosage systems (Medtronic's), in regards to Parkinson one reads on Medtronic's webpage what is Active® Parkinson's Control

Therapy? Active Parkinson's Control Therapy from Medtronic is one of the most significant advances in the treatment of Parkinson's disease in more than 30 years offering an innovative treatment approach. The treatment uses two surgically implanted medical devices, similar to cardiac pacemakers, to deliver electrical stimulation to precisely targeted areas on each side of the brain. Continuous stimulation of these areas blocks the signals that cause the disabling motor symptoms of the disease. As a result, many patients achieve greater control over their body movements. Since 1997, more than 14,000 people worldwide have benefited from Active Therapy for Essential Tremor and Parkinson's disease. The total cost of Active Therapy varies significantly but often ranges on average from $25,000 to $30,000 per side for the device and the associated physician and hospital fees. Under the new policy, patients will still pay deductibles, coinsurance and co-payments, but Medicare will provide coverage for this therapy.[570]

Finally, for the implant procedure ratio for deep brain stimulator therapy, which is used to control tremors related to Parkinson's disease, there are 21 procedures/million in Belgium, 13/million in Australia, 9/million in the US, and 5/million in Canada.[571]

Other areas

Other areas of nanotechnology involvement in bionic implants are artificial joints,[572] artificial muscles,[573] artificial nose and tongues, nose on a chip,[574,575] bioartificial kidney,[576] artificial liver,[577] artificial lungs,[578] artificial discs,[579] and so on.

Cost of Implants

It is evident that the increasing availability of implants and the development of more and more types of implants together with the increased medicalization of the human body must have an impact on the cost base of the public health and health care system, insurance companies and the private household.

CONCLUSION/THE WAY FORWARD/SUGGESTIONS

> Public Health is an approach which focuses on the health and well-being of a society and the most effective means of protecting and improving it. Public Health encompasses the science, art and politics of preventing illness and disease and promoting health and well-being. It addresses the root causes of illness and disease, including the interacting social environmental, biological and psychological dimensions, as well as the provision of effective health services. Public health addresses inequalities, injustices and denials of human rights, which frequently explain large variations in health locally, nationally and globally. Effective public health works through partnerships that cut across professional and organisational boundaries and seeks and promotes the participation of the populations who are themselves the subject of policy and action.[580]

Within the Canadian context, public health is described as follows:

> Having the medical services we need when we are sick are vital, but public health focuses on what we need to do as a society to help everyone stay healthy. Public health is part of every aspect of our lives, from our homes to our workplaces, and our schools to our communities. It encompasses everything we do, from the food we eat to the safety of our environment, and from access to safe walking/biking trails to preventing the outbreak of disease. Public health is about the way we live.[581]

Tables 11 to 13 highlight many of the challenges related to emerging technologies and different models, determinants, and scenarios of health, disease, well-being, and disability covered in this report.

Table 11: Characteristics of the three main models of health

	Medical Model Medical/Social Determinants	Social Model WHO/ Canadian Index on Well-being	Transhumanist/enhancement
Individualistic approach/ health	+++/0	+---/+++	+++++
Deficiency/problem within the person or person to be	+++/0	0/+++	+++
Based on a norm/standard	+++/++	+++	0 or constantly shifting toward enhancing the norm
Body modification (appearance and functionality)	+/0	0/0 or +	+++
Acceptance of human performance enhancement	0 or+/0	0/0 or +	+++++
Enhancement part of medicalization	0 or+/0	0/0 or +	+++++

Table 11: Characteristics of the three main models of health (cont'd)

	Medical Model Medical/Social Determinants	Social Model WHO/ Canadian Index on Well-being	Transhumanist/ Enhancement Model
Life extension/ immortality/cryonics through bodily interventions	0 or +/0	0/0 or +	+++++
Model of health enticing to disabled people	+++ Switching over to transhumanist/+	++ But frustrating due to lack of acceptance of social model of disability, people might also move to transhumanist model//0 switching over to transhumanist	+++
Subject is a patient	+++/0 or +	---/+++	+++
Subject is a "health" product consumer	+++/0	0/+++	++++++

+ means that it has a positive effect or leads to an increase; 0 indicates that it is neutral or that it has no effect or that it is not applicable; - means that it has a negative effect or leads to a decrease

Table 12: Consequences of the three main models of health and their determinants

	Medical Model Medical/Social Determinants	Social Model WHO/Canadian Index on Well-being	Transhumanist/ enhancement
Social justice	0 or + or -/0 or +	+++++/++	0 or --
10/90 Gap	0 or +/-	---/--	+++++
Health care costs	++/0 or -	--/ 0 or ++	+++++
Increases "medicalization of the healthy" dynamic	+++/0	0/ 0 or +	+++++
Adding enhancement as part of the concept of being "healthy"	0 or +/0 or -	0 or --	+++++
Promoting augmentative/enhancement medicine	0 or +/ 0 or -	---	+++++
Increases negative/ individualistic deficiency perception of so-called non-disabled people	+++/0	0	+++++
Drug prizes	++/0	0 or –/ 0 or++	+++++
Increases demand for prenatal screening	+++/0	0/ 0 or+	+++++

Table 12: Consequences of the three main models of health and their determinants (cont'd)

	Medical Model Medical/Social Determinants	Social Model WHO/Canadian Index on Well-being	Transhumanist Enhancement Model
Global health	0 or +/0 or ++	+++	0 or --
Increases negative/ individualistic deficiency perception of disabled people	+++/0	---/0 or++	+++++
Marginalizes further the disabled in low income countries	+/0or --- or +++ depends how disabled people are part of the social determinants	--/-- or 0 or++	++++
Consumerism of the human body	0 or++/0	0/-- or 0 or ++	+++++
Comodification of the Human body	+/0	0/-- or 0 or ++	+++++
Taking into account Interrelationships and interdependence of a person with individuals and the community	---/0 or +	+++++	-----

+ means that it has a positive effect or leads to an increase; 0 indicates that it is neutral or that it has no effect or that it is not applicable; - means that it has a negative effect or leads to a decrease

Table 13: Implication of NBIC advances/transhumanist/enhancement model and determinants

	Provincial Government Funding	Health Authority - Delivery	Health Care Delivery	Providers	Global Health	For Disabled People	Dealing With Disabled People	Public Health
Mandate change	+++	++	+++	++	++	N/A	+++	++++
Scope change	+++	++	+++	++++	+++	++++	+++	+++
Money needed	+++++	++++	++++	++++	++++	++++	++++	+++++
Human resources needed	++++	++++	++++	++++	++++	++++	++++	++++
Access to service	++++	++	+++++	+++	+++	+++	N/A	+++
Medically necessary	++++++	++++++	++++++	++++++	++ or 0	++++++		+++++
Enhanced medical good	++++	++	++	++	0	++++	++++	++++
Enhanced medical good becoming “normal medical goods”	+++++	++++	++++	+++	0	++++	++++	++++
Quality of care	++++	Dept on funding – or 0 or ++	Dept on funding – or 0 or ++	Dept on funding – or 0 or ++	0	Dept on funding – or 0 or ++	N/A	Dept on funding – or 0 or ++
Reduction of risk	N/A	0 or--	0 or--	N/A	N/A	0 or--	0 or--	0 or--
Provision of alternative in the beginning	+++	+++	+++	+++	0	+++	+++	++++
Provision of alternative can become the new norm	+++	+++	+++	+++	0	+++	+++	++++

Continued on next page

Table 13: Implication of NBIC advances/transhumanist/enhancement model and determinants (cont'd)

	Provincial Government Funding	Health Authority - Delivery	Health Care Delivery	Providers	Global Health	For Disabled People	Dealing With Disabled People	Public Health
Credentialing	++++	++++	++++	++++	0	N/A	+++	N/A or +++
Efficacy	0 or --	0 or --	0 or --	0 or --	---	N/A	N/A	0 or --
Safety	Needs more funding	Impacted	Impacted	Impacted	Impacted	N/A	Impacted	Impacted
Effectiveness	0 or --	0 or --	0 or --	0 or --	0 or --	N/A	++ or 0 or --	0 or --
Cost-effectiveness	0 or --	0 or --	0 or --	0 or --	0 or --	N/A	N/A	---
Control of diffusion	--- Decrease in control	--- Decrease in control	--- Decrease in control	--- Decrease in control	--- Decrease in control	N/A	N/A	--- Decrease in control
Dealing with disabled people	++ or 0 or --	++ or 0 or --	++ or 0 or --	++ or 0 or --	++ or 0 or --	N/A	N/A	+++

+ means impacted by; 0 means not very impacted by; -- means negatively impacted by; N/A means not applicable.

Key findings of this report

- Two opposite views of "health" exist. WHO sees health as an umbrella term for a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity (WHO scenario). Within the Canadian context, health is not seen as an umbrella term but interpreted as "the absence of disease and illness" within an individualistic "medical" model of health. "Health" is thus positioned as a "medical" determinant of "well-being" (Canadian scenario).
- International and national documents use the WHO and Canadian scenarios, often both in the same document, making many documents unclear as to what they mean by the term "health."
- The scope, process, direction, and outcome of everything related to the term "health" will be different depending on which model and determinants of health, disease, and disability (medical model/ medical determinants, medical model/social determinants, social model, or transhumanist/enhancement model) and which health scenario—medical health as a determinant of well-being (Canadian) or well-being, including social well-being, as a determinant of health (WHO scenario)—one chooses.
- The term health (WHO and Canadian scenarios) loses its endpoint measure of normative, species-typical boundaries because of the ability of science and technology products to improve and modify the human body beyond species-typical boundaries, leading to the endpoint where the human body in general is seen as defective and in need of improvement. This endpoint changes the meaning of the term "healthy" and the scope of action implied with the term "staying healthy."
- An individualistic approach to health and feeling healthy or ill is on the rise.
- The medicalization and disease-mongering phenomenon increases and moves toward the transhumanization of medicalization, where improving and modifying the human body beyond its species-typical boundaries is part of the concept of being healthy.
- The health consumer is on the rise, as is consumerism and comodification of the human body.
- More and more bodily interventions might be perceived as medically necessary.
- It becomes increasingly more difficult to draw a line between therapy and enhancement in general and therapeutic and non-therapeutic enhancement in particular.

- Augmentative/enhancement medicine is on the rise and the increased capabilities of this field and its products might be seen as enhanced medical goods.
- Enhanced medical goods might become normal medical goods.
- Control of diffusion is negatively affected. The use of therapeutic interventions for non-therapeutic purposes is increasing and not controllable.

  Basic health interventions do not trickle down to the needy in developing countries, which is a distributive problem (How much do developed countries distribute down with affordable prizes?) and a political problem (How much do societal structures within developing countries allow for the deployment to the needy?).
- The interrelationships and interdependencies between a person and other individuals and the community are decreasingly taken into account.
- Disabled people for the most part are not part of the governance of science and technology R&D and health research, nor are they part of the discussion around the concepts of health, disease, well-being, and even disability.
- The discussion around the concepts of health, disease, well-being, and disability within the discourse of health research and the governance of science and technology R&D medicalizes disabled people and marginalizes disabled people who are poor in general and who are from low-income countries in particular.
- The medical model/medical determinant of disability is promoted whereas the medical model/social determinant and the social model/social determinant combination is rejected by many people, including the founder of the DALY.
- HTA deals with disabled people mostly as patients and looks nearly exclusively at a medical model/medical determinant combination of disability/impairment, ignoring other disability models and determinants.
- HTA in Canada and many other countries seems to use the Canadian scenario of health.
- HTA seems not so far to have covered how emerging science and technology products and applications lead to certain societal developments and societal and individualistic desires (medicalization of the human body in general) and vice versa, how social well-being influences the desire for medical interventions, and how these dynamics impact healthcare costs (i.e. increase in drug costs due to increased use) and the definition of health and disease.
- Evidence gathering, evaluation, and measuring tools need to be revamped because:

- they do not take into account the transhumanist/enhancement beyond the norm facet outlined in this report;
- they are discriminatory against disabled people and other marginalized groups;
- some, like the DALY, are leading to health inequity; and
- they cannot really trade medical determinants/interventions against social determinants/interventions.

The Way Forward

This report has highlighted many new NBIC applications and products (Section 7), the implications of the new abilities made possible by advances in NBIC (Sections 2 to 6), and the impact of the issues discussed in Sections 2 to 5 and Section 7 on disabled people (Section 6) and vice versa.

The question is: How can one tackle the problems outlined throughout the report under "Key Findings of this Report"?

What should be done? Ensuring equity in health care

Fairness and equity in health care is a strong concern for Canadians.[306] How can HTA, the health system in general, policy makers, marginalized groups, and the public at large work together to ensure public health and equity in health care[582] (meaning equal access to available care for equal need, equal utilization for equal need, and equal quality of care for all) and to ensure that the national principles that govern the Canadian health care system (public administration, comprehensiveness, universality, portability, and accessibility) are met? Lexi Bambas has some ideas,[583] and Bravemen suggested the following eight steps for monitoring equity in health and health care:

Step 1. Identify the social groups of a priori concern. In addition to reviewing the literature, consult representatives of all social sectors and civil society, including advocates for disadvantaged groups.

Step 2. Identify general concerns and information needs relating to equity in health and its determinants. Again, in addition to the literature, consult representatives of all social sectors and civil society, including advocates for disadvantaged groups.

Step 3. Identify sources of information on the groups and issues of concern. Consider both qualitative and quantitative information.

Step 4. Identify indicators of (a) health status, (b) major determinants of health status apart from health care, and (c) healthcare (financing, resource allocation, utilization, and quality) that are particularly suitable for assessing gaps between more and less advantaged social groups.

Step 5. Describe current patterns of avoidable social inequalities in health and its determinants.

Step 6. Describe trends in those patterns over time.

Step 7. Generate an inclusive and public process of considering the policy implications of the patterns and trends. Include all the appropriate participants in this process (e.g. all relevant sectors, civil society, NGOs).

Step 8. Develop and set in motion a strategic plan for implementation, monitoring, and research, considering political and technical obstacles, and including the full range of appropriate stakeholders in the planning process.[584]

Canada performs to some degree the suggested eight steps. However challenges remain:

- Within the Canadian context, more social groups and their particular needs have to be identified. Disabled people are just one social group that is underserved.
- One should strongly look at how the changing landscape triggered by advances in science and technology and the resulting change in understanding health (transhumanism) impacts equity.
- One has to broaden the sources of information.
- One has to update the content and execution of indicators, measurement, and outcome tools to allow for the change in understanding of health (transhumanism) and to be more responsive to local and global social inequalities.

The Canadian index of wellbeing (CIW) and this report

The CIW is a measure of the quality of life of all Canadians, "of people's life chances—that is the probabilities of good or bad things happening to them as they go through their lives."[585] Researchers working on the new Index are looking at seven specific areas or "domains" that affect the lives of everyone: the living standards domain, the healthy populations domain, the community vitality domain, the environment domain, the education domain, the family domain, and the civic engagement domain (see Figure 5).[585] The researchers want to move the illness model of health care to a wellness model.[585] They also recognize that well-being is influenced by culture.[586]

Policy implications: the CIW faces many challenges

Challenge 1: The transhumanist scenario

How is the CIW influenced by the transhumanization of well-being? Will there be a standard, a norm, which is seen as the maximum possible well-being? How does the transhumanist model of health and disease, disability, and well-being, which includes body structure and functioning modifications beyond species-typical boundaries within the concept of self-care and responsible living, impact the CIW?

It can be anticipated that having body structure and functioning enhancement beyond species-typical boundaries will impact at least three of the domains of CIW (work, health, education) and might, in the end, impact all of the domains.

The CIW is still very early in its development (the launch is to happen in the fall of 2005) and incorporating a debate on these questions is critical for the design of a CIW that is of use to the Canadians of the future.

Challenge 2: How much does the CIW take marginalized groups into account?

Well-being is seen as having a cultural component (i.e. the Inuit Genuine Well-being Indicators system for Nunavut). CIW researchers are now undertaking an analysis of what well-being means to Canada's First Nations communities.[586] However, from the description of CIW, it is not clear what the role and perception of disabled people would be. Does the CIW perceive disabled people as patients or as a cultural identity a concept that might have some merit if one uses the UNESCO declaration on cultural diversity?

> Reaffirming that culture should be regarded as the set of distinctive spiritual, material, intellectual and emotional features of society or a social group, and that it encompasses, in addition to art and literature, lifestyles, ways of living together, value systems, traditions and beliefs.[587]

Challenge 3: How are the domains related to and how do they weigh against each other?

Figure 5 in the CIW publication[585] shows a pyramid with CIW on the top as the umbrella term; the next layer below containing the domains of health, work, and family; the next layer below containing environment and education; and the bottom layer containing the domains of community and civic engagement.

Are the domains really related to each other in a hierarchical fashion? The pyramid seems not to make sense, as all of the different domains of well-being impact each other and the overall CIW. Ill medical health influences all other domains. It is so important to investigate not only how social determinants impact the generation of ill medical health (as in the medical model of health and disease), but also how social determinants of well-being are impacted by "ill health." One of the critiques of the Canadian scenario of health voiced in this report spoke to the fact that the Canadian scenario does not look at how social determinants of health impact "patients" and how being a "patient" impacts the

social determinants of well-being. One can only investigate these dynamics if the domains are not set up in a hierarchical fashion. The CIW is only useful if every domain is seen as impacting every other domain.

Challenge 4: How is the health domain linked with the other domains and how do the other domains relate to the impact on healthcare delivery?

In an interview with Roy Romanow,[585] it is stated that one has to move from an illness model of health care to a wellness model. It seems to be logical to assume that what is meant here is the move to a wellness model of health care. On the Health Canada website, one reads about "…wellness as an essential component of change in contemporary healthcare delivery. Lifestyle and prevention, rather than mitigation and cure, is becoming the focus"…[588] and the Office of Natural Health Products should:

1. increase public awareness of the benefits of prevention, wellness, and self-care;
2. promote lifestyle change and the benefits of prevention, wellness, and self-care, particularly among our youth and emerging adult sectors;
3. promote a wellness model of healthcare delivery that accommodates and celebrates the cultural and ethnic diversity of Canada;
4. encourage research that further defines the benefits of prevention, wellness, and self-care with respect to health optimization and risk reduction, and act as an international ambassador for a wellness-centred model of health management.

This shift in language leads to numerous questions. What would the consequence be for the regional health authorities to move into a wellness model of health care and delivery? If one sees the different domains as interrelated, what would the impact be on the day-to-day of healthcare delivery and the scope and mandate of Alberta Health and Wellness, regional health authorities, hospitals, the medical profession, and the "patient." Many of the CIW domains do not fall traditionally within a sphere of action by the regional health authorities. Would that mean that other groups are getting involved in healthcare delivery?

Which if any of the products sold under the wellness model of healthcare delivery would be basic medical goods or enhanced medical goods or goods not to be dealt with by the regional health authorities? The question posed to Roy Romanow might have been better phrased as whether one should move from an illness model of health to a wellness model of health, which is the WHO scenario of health in which health is the umbrella term and different determinant facets of well-being make up health. However, the WHO scenario of health and a wellness model of health care and delivery do not fit with the pyramid image of CIW.

Another unanswered question is whether one can have ill well-being without having ill health and vice versa. The answer to this question will have immense impacts on Alberta Health and Wellness, regional health authorities, hospitals, the medical profession, and the "patient."

What should be done? Alberta and this report

Getting on with better health care—the third way[589]

Alberta just revealed its 12-step plan for healthcare reform.[589] A new Health Policy Framework will be announced in October 2005. The language around Action 1 states: "We need an overall health policy that focuses on wellness and personal responsibility." This language has different meaning depending on the models, determinants, and scenarios of health, disease, disability, and well-being that one follows. In short, the transhumanist/enhancement model will interpret personal responsibility as the responsibility to improve oneself even outside of species-typical boundaries as a way to ensure that one stays as "healthy" as long as possible. The statement from Action 3, "The best thing we can do to improve the health of Albertans and drive down spiraling health care costs is to encourage people to stay healthy. That means individual Albertans have to take responsibility for their own health," will also be seen as supporting the transhumanist/enhancement model of health. And this statement, "And it means government, health regions, and other partners have to step up their efforts to create one of the healthiest populations in the world," might be interpreted as a mandate for the government, health regions, and other partners to integrate the transhumanist/enhancement model of health.

Under Action 8, one reads: "Provide choice in enhanced medical goods and services. People will be able to choose enhanced medical goods and services beyond what doctors decide is medically necessary – for example, a special kind of hip replacement. Regional health authorities will be able to charge reasonable fees for enhanced goods and services over and above basic services." This action is supposed to come into force in September 2005.

Policy implications

The new ability for someone to choose enhanced medical goods and services for which regional health authorities will be able to charge reasonable fees might lead to some problems, in particular, keeping in mind some of the issues covered in this report such as the transhumanist model of health, disease, and disability; the dynamic around medicalization; and transhumanization of medicalization.

1. There will be an increase in inequity, as the people with money will receive the better artificial leg, knee, or hip versus those without money, who will only be able to access the basic artificial leg, knee, or hip.
2. The basic service might lose good physicians who might opt to do the cutting edge treatment.
3. The regional health authorities might become a business tailoring not to "basic needs patients," but to health consumers, of which the transhumanists are the most consequential consumers.
4. Enhancement/augmentative medicine might become a lucrative venture for the regional health authorities as organ transplantation and In Vitro Fertilization are for hospitals in other countries.

Under Action 9, one reads: "The provincial government spends a billion dollars a year on prescription drugs in Alberta now, and in the next five years, that amount will double. Drug costs are the fastest growing part of the health care budget and while there's no doubt they bring substantial benefits to patients, we need to seriously look at how we're going to pay the bill for drugs now and in the future. At the same time, current government drug plans only cover about 18% of Albertans, including seniors, children and people with lower incomes. Most Albertans get their prescription drugs covered through private insurance plans. But about 27% of Albertans have no coverage at all."

Policy implications

The proposed solutions all deal with giving more people access to affordable drugs. Action 9 does not look at the reality and impact of increased drug use, as extensively explored in this report. Policies and dynamics are needed to curb the medicalization dynamic, which leads to an excessive drug use under the medical banner.

A new Health Care Assurance Act is proposed, which could include "a clear commitment to reasonable access to medically necessary, basic medicare services at no cost for all Albertans."[589] Medical necessity is a term used in the 1966 Medical Care Act[590] and the 1984 Canada Health Act.[591] Under Alberta's Health Care Protection Act,[592] all Albertans who have a condition that necessitates medical services will receive treatment—and they will receive it regardless of their individual ability to pay. However, what does "medically necessary" mean? A variety of "medical necessity" definitions exist.[593-597] Some make a distinction between medical necessity and core services, meaning that one could exclude certain medically necessary treatments by not adding them to the core service list.[597] The Public Health Forum from 1997 felt that "no list of medical necessary treatments can and should be developed but that a flexible definition of "medical necessity" which incorporates the concepts of evidence, appropriateness and effectiveness of services, however, may be useful in some jurisdictions."[598] On the other hand, some believe that their services are necessary without being medical.

Policy implications

1. How does the language of the new health policy framework relate to the issues outlined in this report?
2. An interpretation of the language of the 12-step program, keeping in mind the issues raised in this report, might be useful.
3. The term "medical necessity" might have a different meaning under the transhumanist model of health and disease, especially when taken together with the language of Actions 1 and 3 of the 12-step reform program described earlier.
4. A new proposed Health Care Assurance Act should be looked at, with the results and knowledge presented in this report in mind.

Regional health authorities

The mandate of the regional health authorities is very much impacted by the debate around models; determinants; and scenarios of health, disease, disability, and well-being and their linkage to the CIW and the 12-step program of the Alberta government.

What does "promote health" mean? What are "health needs"? What does "reasonable access to quality health services" mean?

How will "promote health services in a way that responds to the needs of individuals" be interpreted within the transhumanist/enhancement model of health and disease or the social model of disability?

How might the priorities in providing health services in the region, and allocation of resources, change within the different scenarios discussed in this report?

Policy implications

It might be useful to go through the language that the regional health authorities use in their mandate and other documents, keeping the different developments in mind that are dealt with in this report. Once done, one might want to develop policies for all the different scenarios so that one is prepared for whatever combination will become dominant in the future.

The Leduc-Nisku region 2005 Genuine Wealth Project and this report[599]

It is beyond the scope of this document to critique the Genuine Wealth system. However, it might be interesting to look into how this system is influenced by the transhumanist/enhancement model changes in the perception of health, disease, well-being, and disability and how it is able to incorporate marginalized groups.

Alberta quality matrix for health of the Health Quality Council of Alberta[600]

In the Alberta quality matrix for health, on the X-axis, one has the dimension of quality, as follows:

Acceptability - Health services are respectful and responsive to user needs, preferences, and expectations.

Accessibility - Health services are obtained in the most suitable setting in a reasonable time and distance.

Appropriateness - Health services are relevant to user needs and are based on accepted or evidence-based practice.

Effectiveness - Health services are provided on the basis of scientific knowledge to achieve desired outcomes.

Efficiency - Resources are optimally used in achieving desired outcomes.

Safety - Risks are mitigated to avoid unintended or harmful results.

And on the Y-axis, one has the area of need such as the following:

Being healthy - Care related to achieving health and preventing occurrence of injuries, illness, chronic conditions, and resulting disabilities

Getting better - Care related to acute illness or injury

Living with illness or disability - Care related to chronic or recurrent illness or disability

Supporting end of life - Care that aims to relieve suffering and improve quality of living or dying from advanced illness or bereavement

Any evaluation one performs using the Alberta quality matrix for health with these dimensions on the X- and Y-axes changes drastically on the basis of whether one uses as a point of reference the WHO or Canadian scenario of health, which combination of models/determinants of health and disease (medical, social, or transhumanist) one uses, and what model of disability one uses.

AHFMR

This report dealt extensively with HTA, which should give the AHFMR's HTA unit ample food for thought. The report and the outlined challenges and problems, however, do touch also on other areas of the AHFMR, such as the Impact Analysis Unit, which "advises, coordinates, commissions, and conducts impact analysis activities related to AHFMR's programs." "Impact" refers to the broad and diverse effects stemming from AHFMR activities, which can be short, medium, and long term in nature. "Analysis" refers to the judging, appraising, or determining of the worth, value, or quality of activities, in terms of their relevance, effectiveness, efficiency, and outcomes. The scope of the impact analysis activity includes all AHFMR activities".[601] From what one can gather from the AHFMR website, none of the issues raised in this report have been used to inform an impact analysis of AHFMR activities.

Policy implications

It would be useful to perform an impact analysis of AHFMR programs, especially of the population health section, with the different models of health, disease, disability, and well-being in mind.

This report is also of use to other AHFMR programs, such as the Applied Health Research Programs, the SEARCH Program, the AHFMR's Swift Efficient Application of Research in Community Health program, the Community Research Ethics Board of Alberta (CREBA), the Alberta Research Ethics Community Consensus Initiative (ARECCI), the Health Research Transfer Network of Alberta (RTNA), Alberta Consultative Health Research Network (ACHRN), the Communications and Education program, and the Evaluation, Analysis and Information Services.

Women's health and aboriginal health show up as keywords, but nowhere is the social group of disabled people targeted for research, as they are not the social determinants of disability and impairment. Only some individual "diseases" are listed. Issues related to transhumanism and enhancement "medicine" also seem not to be part of AHFMR research. None of the topics covered in this report show up in the AHFMR researcher database,[602] suggesting that they are not covered by AHFMR researchers.

Policy implications

It would be useful to introduce the topics covered in this report into the research scope of AHFMR.

Alberta's Office for Disability Issues[603,604] and this report

> Equality for all citizens, regardless of their race, creed, background or abilities, is a fundamental right in Albertan and Canadian society. But equality doesn't exist for the half a million people in Alberta who have a disability. Persons with disabilities are not free from intolerance and discrimination. They do not have adequate personal or financial supports to live a life of dignity. They cannot go everywhere in the province and have ready access to buildings, offices or public facilities. They are not treated equally when vying for employment and educational opportunities. [605]

That's how the executive summary of the Alberta Disability Strategy (ADS) starts. The ADS purpose is to create an environment where full citizenship is possible through improvements in the areas of personal supports, financial supports, learning supports, and employment, according to Alberta's Premier's Council on the Status of Persons with Disabilities, and it offers numerous recommendations.

Policy implications

How can the problems that disabled people face as outlined in the ADS quote be met if one diminishes the perception of a disabled person to "just a patient" and simply looks for medical determinants?

How much can the health system help to fulfill the vision of ADS, or is the health system as it is organized a hindrance to this fulfillment?

Can a CIW system better meet the needs of disabled people? Which needs? And under what circumstances?

How well is the "health system" or a "CIW system" equipped to provide personal care services, technical aids, assistive devices and equipment, transportation, and housing to disabled people?

What will be the impact of a transhumanist model of disability? Could it, with its medical/techno fix view of disabled people, diminish the focus on social determinant fixes as outlined in ADS? Could it lead to a gap between the rich and poor disabled people, as the government will never pay every intervention a disabled person wants? The system is already not paying many social and medical "treatments" for disabled people.(*606*)

Will the transhumanist model lead to the removal of resources for bettering basic interventions for all by moving them to high-tech interventions for a few?

What should be done? Health Research

According to the Bangkok Declaration on Health Research for Development,[607] an effective health research system requires "coherent and coordinated health research strategies and actions; an effective governance system; a revitalized effort from all involved in health research to generate new knowledge which addresses the problems of the world's disadvantaged and it is the responsibility of an active civil society through their governments and other channels to set the direction for the health research system, nurture and support health research, and ensure that the outcomes of research are used to benefit all their peoples and the global community." Although the above was written for a global context, it is also applicable for the Canadian situation.

The world report on knowledge for better health[34], which was discussed in Mexico City in November 2004 at the ministerial summit on health research, had seven key messages:

1. Science must be turned into action to improve people's health; it must focus more on the "how" rather than the "why", "where" or "what".
2. Knowledge must be accessible to all, in a form which is useful and can be acted upon by different people and groups.
3. All countries must create an environment in which research for health is seen as a systematic effort, and will thus flourish.
4. Research must be conducted according to universal ethical standards thus ensuring that it will improve equity in health.
5. A broader, more inclusive view of health research is needed and civil society has a vital part to play.
6. Research is an investment, not a cost, and governments must spend on it.
7. Action Plan needed-***now!"***

Insert 5.4 of the *10/90 Report on Health Research 2001-2002* shows a variety of recommendations from a variety of groups: Commission Report (1990), Ad Hoc Committee Report (1996), Advisory Committee on Health Research (1997), ENHR projects, International Conference (2000), and 10/90 Reports.

Health research priorities

Health research priorities are inequity and inefficiency in the delivery of health services, health policies, health costs and financing, health information, health equity and gender, health systems performance, capacity building in health policies, health behaviour research, gender and socio-cultural research, public-private collaboration and elimination of poverty, malnutrition, ignorance, unemployment.

The executive summary of the *10/90 Report on Health Research 2003-2004* recommends:

> Few priority-setting exercises for health and health research systematically take into account key actors and factors beyond the biomedical field (i.e. the individual, behavioral and community dimensions; sectors other than health which have a profound effect on the health status of a population; and macroeconomic policies); these dimensions need to be systematically included in the priority-setting exercises in the future, to ensure the most effective and efficient use of the limited resources available for health research.[32]

What should be done? HTA and other assessments

Many suggestions for HTA were given throughout the report. At the moment, HTA in Canada, according to the CCOHTA definition, follows the Canadian scenario of health and focuses on traditional "medical, clinical" healthcare technologies, covering the combination medical model/medical determinants of health and ignoring the changing landscape of definition and dynamic around science and technology for the "health" of the people and the impact of social determinants such as social discrimination on health.

Policy implications

1. HTA should move away from the restrictive definition that CCOHTA is using, which would enable HTA to cover any possible combination between health scenario (WHO, Canadian) and health, disease, and disability models and determinant. Even the combination of the Canadian scenario paired with the medical model of health and social determinants of medical health would move HTA away from pure medical/clinical technologies toward technologies such as water and sanitation technologies, which have an impact on the medical health of "patients."

   If HTA stays with the Canadian scenario of health and the medical model/determinants of health, one has to add STA, social well-being needs assessment, and SIA to the mix in order to be able to deal with the challenges outlined in this report.
2. In order to be useful for disabled people, HTA has to look further than the medical, patient level of disability.
3. HTA has to take into account that social discriminations that lead to ill health.[608]
4. In order to be up to the challenges outlined in this report, HTA has to broaden their horizon scanning practices and has to develop new or revamp evidence gathering, evaluation, measuring, analysis, and outcome tools.
5. HTA has to involve more marginalized groups.
6. HTA should work more closely with other assessment fields such as HIA, HNA, PTA, and PTTA and should link up more with Social Development Canada and people involved in the social well-being index and make their reports also of use to them, as they are important for public health and for meeting the challenges outlined in this report.
7. Every HTA report should have a global perspective as global health impacts on local health and vice versa.

What should be done? Governance of science and technology

Many documents, recommendations, thoughts, and language deal with the governance of science and technology. So far, very few of the recommendations have been acted upon. The UNESCO World Conference on Science has very good language in particular, as it relates to marginalized groups. Quotes from the UNESCO World Conference on Science documents are as follows:

From sections of the Declaration on Science: UNESCO/ICSU World Conference of Sciences:[120]

25. . . . . that there are barriers which have precluded the full participation of other groups, of both sexes, including disabled people, indigenous peoples and ethnic minorities, hereafter referred to as "disadvantaged groups".

34. Science education, in the broad sense, without discrimination and encompassing all levels and modalities is a fundamental prerequisite for democracy and for ensuring sustainable development. In recent years, worldwide measures have been undertaken to promote basic education for all. Special attention is still required for marginalized groups. It is more than ever necessary to develop and expand science literacy in all cultures and sectors of society as well as reasoning ability and skills and an appreciation of ethical values, so as to improve public participation in decision-making related to the application of new knowledge.

42. Equality in access to science is not only a social and ethical requirement for human development, but also a necessity for realizing the full potential of scientific communities worldwide and for orienting scientific progress towards meeting the needs of humankind. The difficulties encountered by women, constituting over half of the population in the world, in entering, pursuing and advancing in a career in the sciences and in participating in decision-making in science and technology should be addressed urgently. There is an equally urgent need to address the difficulties faced by disadvantaged groups which preclude their full and effective participation.

From the Science Agenda-Framework for Action:[121]

17. Scientists, research institutions and learned scientific societies and other relevant non-governmental organizations should commit themselves to increased international collaboration including exchange of knowledge and expertise. Initiatives to facilitate access to scientific information sources by scientists and institutions in the developing countries should be especially encouraged and supported. Initiatives to fully incorporate women scientists and other disadvantaged groups from the South and North into scientific networks should be implemented. In this context efforts should be made to ensure that results of publicly funded research will be made accessible.

59. Governments should promote the further development or setting up of national statistical services capable of providing sound data, disaggregated by gender and

disadvantaged groups, on science education and R&D activities that are necessary for effective S&T policy-making. Developing countries should be assisted in this respect by the international community, using the technical expertise of UNESCO and other international organizations.

79. The full participation of disadvantaged groups in all aspects of research activities, including the development of policy, also needs to be ensured.

81. Governments and educational institutions should identify and eliminate, from the early learning stages on educational practices that have a discriminatory effect, so as to increase the successful participation in science of individuals from all sectors of society, including disadvantaged groups.

91. Special efforts also need to be made to ensure the full participation of disadvantaged groups in

- science and technology, such efforts to include:
  - removing barriers in the education system;
  - removing barriers in the research system;
  - raising awareness of the contribution of these groups to science and technology in order to overcome existing stereotypes;
  - undertaking research, supported by the collection of data, documenting constraints; monitoring ,
  - implementation and documenting best practices; and
  - ensuring representation in policy-making bodies and forums.

Canada played a leading role at that conference. However, the Canadian system of governance of science and technology does not involve marginalized groups in their deliberations. The Canadian Biotechnology Advisory Committee refused consistently to involve disabled people. Marginalized populations are not seen as experts or as groups who have something to contribute; even worse, their views are simply negated, as they often do not fit the mainstream line of arguments (see Sections 2 and 6). The nanotechnology governance in Canada so far does not involve disabled people and other marginalized groups in a meaningful way. The Nanotechnology Centre for Excellence in Edmonton has no mechanism in place to tackle the societal challenges linked to nanotechnology, as covered in this report.

Clearly a focused research policy response is needed to clearly define priorities in the advancement and governance of science and technology and health research to ensure that the emerging field of nanotechnology and its convergence with other technologies results in equal benefits to both the poor and the affluent.

Many recommendations exist how to govern science and technology in general and nanotechnology/NBIC in particular, as found in the following reports: Final Report of the International Dialogue on Responsible Research and Development of

Nanotechnology [609] the WHO Genomics and World Health report for the usage of biotechnologies,[610] the World Report on Knowledge for better Health,[122] the documents of the UNESCO World Conference on Sciences,[120,121] the European Report on "Nano-Bio-Info-Cogno-Socio-Anthro-Philo-Geo-Eco-Urbo-Orbo-Macro-Micro-Nano",[122] and the author's papers for forum 8,[611] which have excellent language and recommendations that could be drawn from in this regard.

Dr. Roco, senior advisor for nanotechnology at NSF USA, in answering a questionnaire for the USA, which hosted a recent (June 2004) International Dialogue on Responsible R&D of Nanotechnology,[609] came up with the following thoughts on key issues that need to be addressed in order to ensure the responsible development of nanotechnology (Appendix F):[609]

- Proper selection of R&D priorities for a balanced and equitable development of nanotechnology that includes research into its potential economic, social and legal implications.
- Environmental, health and safety implications associated with nanostructured materials.
- Avoiding possible adverse EHS (environment/health/safety) aspects of nanotechnology by practicing "green chemistry" (clean processes and processing) and "environmentally benign manufacturing".
- Using nanotechnology to understand, measure, and reduce/control pollution from our current processes.
- Ethical aspects related to the distribution of the benefits of nanotechnology.
- Best mechanisms for communicating with the public.
- Issues related to individual rights, such as privacy, have access to healthcare, and various topics at the confluence of nanotechnology, biotechnology, information technology, and cognitive sciences.

Dr. Roco suggested the following measures to ensure the responsible development of nanotechnology (at national, regional, and global levels):

- Develop better understanding on environment, health and societal implications of nanotechnology through continued support of R&D programs.
- Promote exchange of information on the results of R&D on environment, health, and societal implications of nanotechnology.
- Prepare "Best practices" statements for handling and use of engineered nanomaterials, particularly in industrial or manufacturing environments and research laboratories.

- Prepare "Best Practices" statements for protection and handling natural and process-by-product nanomaterials, such as those from combustion engines or welding.
- Disseminate precompetitive research results and develop collaborative activities in order to advance broader goals such as water purification; energy conversion, storage, and transmission; and treatment of chronic illnesses.
- Evaluate various issues in the broader societal context and from an international perspective.
- Promote two-way interactions with the public at the local, national, and international levels."

The report[122] by the "Foresighting the NewTechnology Wave" Expert Group within the European Commission, identified the following challenges under "Dealing with Converging Technologies (C*TEKS)*: Ethics and Social Empowerment":

- To ensure the consideration of ethical concerns from the beginning and in advance of the developments of norms for CTEKS development through the EuroSpecs process.
- While some approaches consider engineering *of* mind and brain, to promote in Europe engineering *for* the mind and improvements of the cognitive environment.
- While some approaches to CTs promote an increasingly homogeneous technical culture, to pursue C*TEKS* as a tool for the development of local solutions that foster natural and cultural diversity.
- To balance CT-based solutions against low-tech or no-tech policy alternatives.
- To promote sustainable development, environmental awareness, precautionary approaches.
- To empower citizens and consumers to understand, use, and control CTs and to maintain a sense of ownership.

And the report makes the following recommendations, among others:

Recommendation 7: Commission and Member States need to recognize and support the contributions of the social sciences and humanities in relation to CTs, with commitments especially to evolutionary anthropology, the economics of technological research and development, foresight methodologies and philosophy.

As CTs pursue the perfectibility of humans and society, evolutionary anthropology needs to study and communicate the meaning of seeming imperfection, diversity and human limitation.

Reports and surveys about nanotechnology and converging technologies, including this one, make economic assumptions as they compare international expenditures and corporate profits, evaluate market potentials and consumer demand, or predict returns on public investment. These assumptions require careful scrutiny.

Current Foresight methodologies should be expanded through a "Hindsight for Foresight" program. Innovation studies, history of technology, science and technology studies, technology assessment and philosophy of science will use historical knowledge and the analysis of international drivers of CTs to shift emphasis from the consideration of presumed outcomes to an evaluation of the visions that go into CT research. Case studies on scientific and technological development should be comparatively investigated to make transparent the underlying dynamics of "rational development." Technology assessment should be moved upstream also through the consideration of anthropological dimensions and the promoting or retarding effects of public resistance in the shaping of CTs.

The construction of an artificial nature requires philosophical and social orientation and critique especially as it regards the foundation of ethics and societal values in concepts of freedom and human nature. It also may create new economic dependencies, opportunities and constraints for wealth-generation that need to be investigated.

Recommendation 8: A permanent societal observatory should be established for real-time monitoring and assessment of international CT research, including CTEKS.

***Recommendation 10*:** The integration of social research into CT development should be promoted through *Begleitforschung* ("accompanying research" alongside science and technology R&D).

Recommendation 12: Upon advice from the European Group on Ethics (EGE), the mandate for the ethical review of European research proposals should be expanded to include ethical and social dimensions of CTs. Funding organizations in Member States are asked to take similar steps.

Recommendation 13: In the face of new models for participatory research governance, transparent decision making processes need to be developed and implemented.

Recommendation 14: The question of intellectual property rights must be addressed proactively and on an international level.

Recommendation 15: Member and Associated States are encouraged to stimulate national discussions of CTs and the CTEKS perspective.

***Recommendation 16*:** CT modules should be introduced at secondary and higher education levels to synergize disciplinary perspectives and to foster interaction between liberal arts and the sciences.

What should be done? The disabled people

The inclusion of disabled people—whereby disabled people does not just mean disabled patients—in the governance of science and technology, health research, HTA, and other assessments is essential for "disabled" and "non-disabled people" for many reasons. One of the reasons is that an increased emphasis on individualized interventions (medical model, transhumanist/enhancement model of health) makes the line between so-called disabled and non-disabled people fuzzy. The health promotion field has to start involving disabled people actively on a broad scale for the good of disabled people and the health promotion movement.[86] The goal of involving disabled people fits well with the language from all six health promotion conferences, with the recent statement by the Global Forum for Health Research at the conclusion of Forum 8 Mexico City, 16-20 November 2004,[26] the UN Convention on the rights of disabled people[612] in the making, many positive national legal advances,[289] and the suggestions about disabled people in other international documents such as the final documents of the UNESCO World Conference on Science.[120,121]

A new health policy/research agenda is called for to address (a) the new understanding of disability, (b) the needs of disabled people and other marginalized groups, (c) the emergence of the transhumanist/enhancement model of health and disease, and (d) the increased medicalization/transhumanisation of human beings and their characteristics**.**

Using this framework, a new research agenda can be developed. From the beginning, this work must actively involve disabled persons and other marginalized groups; their assessment of what they need to be healthy would inform the development of the research framework and the nature of the research questions. Several core sets of questions would likely emerge. These include questions focused on the following:

Identifying the nature of the problem. For example, "Is more health gained by fixing a person with a certain characteristic or by fixing the societal parameters?" or "Taking into account the societal realities of disabled persons, are medical fixes affordable, feasible, and the most efficient use of resources? Do societal solutions better serve the persons in question, lead to improved well-being, broader health equity, and better use of limited societal resources and research dollars?"

Probing for existing biases in existing policy, research and measurement instruments, and pointing to ways for removal of the biases. For example, research needs to be undertaken to determine the extent to which many already medicalized characteristics are indeed medical conditions in need of medical interventions or whether they simply reflect intolerance of diversity and the subsequent pathologization of anyone different from the norm. Research would need to explore who gains and who loses when these biases are left unchecked and the resulting impact on achieving health equity, the MDGs, and reducing the 10/90 gap in health research. For example, how useful is the definition of unipolar major depression as one of the leading global "burdens of

disease" for understanding what the "problem" is, its root causes, and whether medical/drug interventions are the most efficient way to deal with the "problem"?

Identifying the determinants and corequisites for health of disabled persons. These would focus on the non-medical components of health as they relate to disabled people and would allow the measurement and monitoring of policy decisions and their impact on disabled people and their health.

Monitoring shifts in the understanding of health and disease following advances in science and technology (see transhumanist/enhancement model) and identifying and monitoring shifts in health research resource flows.

Measuring the impact of new technologies on the health of disabled persons and other marginalized groups. How would the emerging and converging NBIC technologies be best used to increase maximum health—in its fullest sense? How can research agendas for emerging and existing technologies be shaped to decrease rather than increase the 10/90 gap? In the case of nanotechnology, for example, an informed research agenda may identify that more money should be invested in Nanowater—whose application might provide cheaper ways to clean and desalinate water, benefiting many—than on technologies to give humans new abilities through bodily modifications, which can be afforded by and would help only the affluent few.

Monitoring and evaluating the governance of the entire research process and subsequent technological developments and the extent to which disabled persons and their values have informed them. Questions would probe for biases in the governance, monitoring, and evaluation processes. They would point to ways to ensure that disabled people and other marginalized groups play an active role in the development and applications of research agendas and new technologies; in defining science and technology and health research questions; and in the decision making regarding health, science, and technology and health research priorities. This work would be underpinned by the establishment of an ethical framework for conducting critical analysis and evaluation of emerging technologies—NBIC—and actively involving disabled people and other marginalized groups to ensure that their rights are protected. A core part of the overall governance could be the establishment of a network of disabled and other marginalized people to provide guidance for shaping the policy and research questions, agenda, and priorities and the most effective and equitable use of new emerging technologies on a local, national, and global scale.

A policy and research agenda that perpetuates a pervasive bias, leading to the pathologization of people different from the norm, and supports their prevention, marginalization, exclusion, and elimination must be questioned. It results in gross inequities and discrimination against disabled people and has opened the door to the encroaching transhumanist/enhancement model and its subjective definition of health where anyone can consider themselves as "inherently unhealthy" in a medical sense and in need of a medical cure.

A new framework for disability, health, and health research, grounded in and informed by the lived experience of disabled and other marginalized people, is imperative to achieve health equity and improved health status for the world's majority marginalized population, to meet the MDGs, and to reduce the 10/90 gap.

What should be done? Global health

It would go beyond the scope of this report to look at the global health scene in a thorough fashion. However, two issues are worthwhile exploring. How will the appearance of a transhumanist/enhancement model, the increased phenomenon of medicalization, and the appearance of the transhumanization of medicalization as seen in developed countries play itself out on the global health stage? Will one see an increasing use of drugs for a "disease," ignoring social determinants leading to the "disease"; that is, the prediction is that unipolar major depression will be number two regarding burden of disease in developing countries by 2020.[613]

Table 14 from a 2004 academic article highlights two quite different philosophies toward dealing with global health. Will there be an increased focus for medical/techno fixes (Gates Foundation list) and a diminishing look at social determinants (Journal of Nursing Scholarshiplist)?

Table 14: Two lists of grand challenges in improving global health

Gates Foundation-NIH[a]	Journal of Nursing Scholarship Working List
1. Improve childhood vaccines.	1. Improve societal conditions that affect health.
2. Create new vaccines.	2. Improve child and adolescent health.
3. Control insects that transmit agents of disease.	3. Improve family planning.
4. Improve nutrition to promote health.	4. Prevent spread of infectious diseases.
5. Improve drug treatment of infectious diseases.	5. Reduce substance abuse.
6. Cure latent and chronic infections.	6. Manage physical and mental illnesses.
7. Measure disability and health status accurately and economically in developing countries.	7. Link health systems and society.
	8. Design valid and economically feasible methods of health assessment and analysis.[614]

Note. [a]Available at http://www.grandchallengesgh.org/

Three types of disease exist, if one looks at them from the funding level, namely, not neglected diseases (type I), neglected diseases (type II), and very neglected diseases (type III).

Strategies are under way to increase the dealing with neglected and very neglected diseases. However, will these strategies be based on increasing the distribution of drugs and dealing with "medical determinants" or will social determinant research and solutions also be involved? On 24 February 2005, a letter was presented to the World Health Assembly Executive Board and the WHO Commission on Intellectual Property Rights, Innovation and Health, asking for an evaluation of a Medical R&D Treaty,[615] which states, among other things:

> At the core of the proposed treaty is an obligation to finance Qualified Medical Research and Development (QMRD). This obligation is tied to country GDP. In Draft 4, two different methods of determining the fraction of GDP for QMRD are presented. Alternative 1 uses different rates for each of four income groups (high, high medium, low medium, and low). Alternative 2 is a graduated rate. QMRD would include (1) basic biomedical research, development of biomedical databases and research tools, (2) development of pharmaceutical drugs, vaccines, medical diagnostic tools, (3) medical evaluations of these products, and (4) preservation and dissemination of traditional medical knowledge.

The draft treaty proposes Kyoto-type credit trading:

> Similar to the Kyoto climate treaty, credits would be traded across borders -- and countries that exceed the benchmark obligations can sell excess credits. The credits will be given for a variety of projects including:
>
> - R&D for neglected diseases and other priority research projects,
> - "Open public goods," such as free and open source public databases,
> - Projects that involve the transfer of technology and capacity to developing countries,
> - The preservation and dissemination of traditional medical knowledge, and
> - Exceptionally useful public goods."[616]

Policy implications

It is not clear whether one can trade social determinant interventions in the same way as or against medical determinant interventions.

This report and the just adopted "Bangkok Charter for Health Promotion in a Globalized World"

The "Bangkok Charter for Health Promotion in a Globalized World," adopted on the 11 August 2005,[21] states in its introduction that it:

- identifies the strategies and commitments that are required to address the determinants of health in a globalized world through health promotion;

- affirms that policies and partnerships to empower communities, and to improve health and health equality should be at the centre of global and national development;
- complements and builds upon the values, principles and action strategies of health promotion established by the *Ottawa Charter for Health Promotion* and the recommendations of the subsequent global health promotion conferences which are shared by activists and practitioners around the world and have been confirmed by Member States through the World Health Assembly;
- reaches out to people, groups and organizations that are critical to the achievement of health. This includes governments and politicians at all levels, civil society, the private sector and international organizations.

How do the statements in the introduction relate to the two main challenges covered in this report, namely, the involvement of disabled people and the changing concepts, models, and determinants of health?

The role of disabled people

Organizations of disabled people were not present at the conference and were not much involved prior to the conference. No disabled people were part of the Canadian delegation. That the term "disabled" made it into the charter (in one place), "the vulnerability of children and exclusion of marginalised, disabled and indigenous peoples have increased," is due to the efforts of one "non-disabled" person at the conference and one "disabled" person before the conference. The lack of representations/involvement of disabled people might be one reason that "disability" is not mentioned in other areas of the charter where it should have been mentioned. The definition of health promotion in the Bangkok charter states that "it contributes to reducing both health and gender inequities," which raises the question as to why other inequities are not mentioned, such as inequities faced by indigenous and disabled people, ethnic minorities, and others.

If the claim that the charter "reaches out to people, groups and organizations that are critical to the achievement of health" is to be fulfilled, much more has to happen regarding disabled people. One cannot help but wonder whether the culture around the debate of this charter does not reflect the sentiment raised in this report, namely, that the debate around health is really about "not getting ill" and is performed by those who are "healthy," ignoring the "ill people" and those who lack social well-being.

The non-involvement of disabled people was and still is one problem.

The concepts, models, and determinants of health

This report gives the choice of two scenarios (WHO, Canadian) of health, which can be combined with six possible combinations of models (medical, social, transhumanist)

and determinants (medical, social, transhumanist) of health. How does the charter relate to the scenarios, models, and determinants of health?

Trying to identify the scenario of health, the charter highlights another problem. The charter states that it "builds upon the values, principles and action strategies of health promotion established by the Ottawa Charter for Health Promotion." However, what does "build on" mean?

The Ottawa charter[53] follows the WHO scenario of health when it states:

> Health promotion is the process of enabling people to increase control over, and to improve, their health. To reach a state of complete physical, mental and social well-being, an individual or group must be able to identify and to realize aspirations, to satisfy needs, and to change or cope with the environment. Health is a positive concept emphasizing social and personal resources, as well as physical capacities. Therefore, health promotion is not just the responsibility of the health sector, but goes beyond healthy life-styles to well-being.

The Bangkok charter in its latest drafts from 29 July also followed the WHO scenario of health; however, the final adopted version does not. Its definition of health promotion is markedly different from that of the Ottawa charter:

> The United Nations recognize that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without discrimination. Health promotion is based on this critical human right. It offers a positive and inclusive concept of health as a determinant of the quality of life, and encompasses mental and spiritual well being. Health promotion is the process of enabling people to increase control over their health and its determinants, and thereby improve their health. Health promotion is a core function of public health and contributes to tackling communicable and noncommunicable diseases and other threats to health. It is an effective investment in improving health and human development. It contributes to reducing both health and gender inequities.

Especially where it states that "it offers a positive and inclusive concept of health as a determinant of the quality of life, and encompasses mental and spiritual well being," it moves away from the WHO scenario of health as it makes health a determinant of quality of life. This is similar to the Canadian scenario of health, which makes health a determinant of well-being. It is not quite clear whether one could interchange quality of life with well-being, because the Bangkok charter goes on to outline mental and spiritual well-being as being determinants of health. Of broad consequence is the exclusion/not mentioning of "social well-being" within this framework. The Bangkok charter seems to suggest the following pyramid:

> top = quality of life
> below that = health
> below that = mental and spiritual well-being.

It seems that the foundation/meaning of the term "health" is quite different between the Ottawa and Bangkok charters. How should one interpret the sentence in the

Bangkok charter, that it "builds upon the values, principles and action strategies of health promotion established by the Ottawa Charter for Health Promotion"?

Should one assume that the Ottawa/WHO scenario of health is also the basis for the Bangkok charter understanding of "health" or does "build on" mean that the health promotion fields move away from including social well-being within the scope of their mandate?

Should one assume that "context for health promotion has changed markedly since the development of the Ottawa Charter" means that the context of health promotion of today sees health to mean "medical health" and determinants as being about looking at how medical and social determinants impact medical health?

Should one assume that statements such as "governments at all levels must tackle poor health" and "responsibility to address the determinants of health rests with the whole of government, and depends upon actions by many sectors as well as the health sector" mean "governments at all levels must tackle poor medical health" and "responsibility to address the determinants of medical health rests with the whole of government, and depends upon actions by many sectors as well as the medical health sector"? If yes, who deals with the "non medical issues" of quality of life/well-being, and how are these integrated into the "medical health" responsibility of all departments?

The following quotes are from the Bangkok charter: "healthier world"; "Health promotion has an established repertoire of proven effective strategies which need to be fully utilised"; "advocate for health based on human rights and solidarity"; "commitments to health for all"; "Make the promotion of health central to the global development agenda"; "Health promotion must become an integral part of domestic and foreign policy and international relations, including in situations of war and conflict"; "Health determines socio-economic and political development"; and whole sections such as "Make the promotion of health a key focus of communities and civil society"; and "Make the promotion of health a requirement for good corporate practices." These quotes also obtain different meanings: all lead to quite a different meaning, expected actions, and mandates whether health includes social well-being or whether health just means "medical health."

What does "equal opportunity for health and well-being" mean? Does the quote mean medical health and mental and spiritual well-being? Or which well-being does the Bangkok charter have in mind?

Does the quote "must act to close the gap in health between rich and poor" mean that we just close the "medical health gap"? Where does that leave the people who are already "medically unhealthy"? Does one just focus on trying to fix their "medical problem," ignoring their social well-being problems? Does that quote include making "medical information" accessible to disabled people?

The Bangkok Charter and enhancement medicine (transhumanist medicine, transhumanist model of health, transhumanist determinants)

No language in the charter deals with or takes into account enhancement transhumanist/enhancement models of health appearing on the horizon.

The Bangkok Charter and Canada

Statements of the Bangkok charter such as "Local, regional and national governments must give priority to investments in health, within and outside the health sector, and provide sustainable financing for health promotion. To ensure this, all levels of government should make the health consequences of policies and legislation explicit, using tools such as equity focussed health impact assessment, and intersectoral national or local health plans" leads to quite different actions, whether one sees health to include social well-being or whether it is just about "medical health" and "governments at all levels must tackle poor health," and "Responsibility to address the determinants of health rests with the whole of government, and depends upon actions by many sectors as well as the health sector." All lead to quite different obligations for Canadian health research, HTA, HIA, the health system, the health care system, Alberta Health and Wellness, Social Development Canada, and people involved in the social well-being index.

Depending on how one defines health, the obligations for Canada to fulfill the charter are quite different.

Conclusion

The charter should have been much clearer in its language to give people, organizations, and governments much better guidance on what is expected from them and also to give a much clearer picture as to what the charter cannot do/does not cover. It seems fair to say that the charter moved away from the holistic health concept toward a medicalized health concept, which entails many consequences, as outlined earlier. If this is indeed the correct interpretation of the term "health," then this charter cannot deal with even one problem outlined in this report.

The preceding description highlighted where the Bangkok charter statements fall short or is too murky in its language to be able to fulfill the four statements below from the introduction:

- identifies the strategies and commitments that are required to address the determinants of health in a globalized world through health promotion;
- affirms that policies and partnerships to empower communities, and to improve health and health equality should be at the centre of global and national development;
- complements and builds upon the values, principles and action strategies of health promotion established by the *Ottawa Charter for Health Promotion* and the

recommendations of the subsequent global health promotion conferences which are shared by activists and practitioners around the world and have been confirmed by Member States through the World Health Assembly; and

- reaches out to people, groups and organizations that are critical to the achievement of health. This includes governments and politicians at all levels, civil society, the private sector and international organizations.

This report and the just adopted "UNESCO Declaration on Bioethics and Human Rights"[617]

Bioethics theories are supposed to develop ethical principles, which allow for the governance of science, technology and biomedical research. This makes it essential that the public in general and disabled people in particular. Health Technology Assessment International just offered a workshop in June 2005 with the title *Integrating Ethical Considerations into HTA*[294] suggesting that the HTA field does see the importance of Bioethics/Ethics field. However this report highlighted the lack of involvement of disabled people within the bioethics discourse although they are affected by nearly every bioethics issue including health (care,research) resource allocation and health (care, research) policy direction stemming from the bioethics/ethics discourse. This report made a strong case for indeed involving the public at large and disabled people in particular to enrich and inform the existing discourse. In the same way as a feminist approach to bioethics is an accepted discourse so should be the disabled people approach to bioethics issues or in other words the vari-ableist, vari-ableism (the positive expression counterpart to able-ism like feminism versus sexism) approach to bioethics issues. Able-ism is the discrimination of people who are perceived as having subnormal or non mainstream set of human body based abilities whereas vari-ableist, vari-ableism is the notion that one should not discriminate against that group. Vari-ableism in the same way as feminism includes cultural aspects of people belonging to these groups.

UNESCO just adopted in October 2005 the "UNESCO Declaration on Bioethics and Human Rights". The declaration states among others:

- **Recognizing** that health does not depend solely on scientific and technological research developments but also on psycho-social and cultural factors.
- **Considering** the desirability of developing new approaches to social responsibility to ensure that progress in science and technology contributes to justice, equity and to the interest of humanity.
- **Considering** the desirability of developing new approaches to social responsibility to ensure that progress in science and technology contributes to justice, equity and to the interest of humanity.

- **Stressing** the need to reinforce international cooperation in the field of bioethics, taking into account in particular the special needs of developing countries, indigenous communities and vulnerable populations.
- **Article 10 – Equality, Justice and Equity** - The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.
- **Article 11 – Non-Discrimination and Non-Stigmatization** - No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.
- **Article 14 – Social Responsibility and Health**

  a) The promotion of health and social development for their people is a central purpose of governments, that all sectors of society share.

  b(iv) Elimination of the marginalization and the exclusion of persons on the basis of any grounds.

All of this language supports the notion to open up the bioethics discourse to the public at large and marginalized groups which includes disabled people in particular.

APPENDIX A: METHODS AND RESULTS OF THE AUTHOR'S DATABASE SEARCHES OF DIFFERENT KEYWORDS

Numerous keyword combination searches were performed using different databases.

The Health Services/Technology Assessment Text (HSTAT) is a free, web-based resource of full-text documents that provide health information and support health care decision making. HSTAT's audience includes health care providers, health service researchers, policy makers, payers, consumers, and the information professionals who serve these groups.

Platform	Edition/Date	Single/Combinational Words	Hits
National Library of Medicine (US)	2003	Bionics	1
		Transhumanism	0
		Implant	159
		NBIC	0
		Human enhancement	138
		Cubernetics	0
		Brain machine	3
		Disabled people	78
		People with disabilities	155
		Plastic surgery	19

Academic Search Premier

Academic Search Premier, designed specifically for academic institutions, is the world's largest scholarly, multidisciplinary full text database containing nearly 4700 publications, including more than 3600 peer-reviewed publications. In addition to the full text, this database offers indexing and abstracts for all 8176 journals in the collection. This scholarly collection offers information in nearly every area of academic study, including computer sciences, engineering, physics, chemistry, language and linguistics, arts and literature, medical sciences, ethnic studies, and many more. Academic Search Premier is an enormous collection of the most valuable peer-reviewed full text journals, offering critical information from many sources unique to this database. Examples of titles offered in Academic Search Premier include *American Historical Review*, *American Journal of Political Science*, *American Libraries*, *American Sociologist*, *British Journal of Psychology*, *British Journal of Sociology*, *Central European History*, *Contemporary Literature*, *Early American Literature*, *English Language Notes*, *Family Relations*, *International Journal of Psychology*, *Journal for the Scientific Study of Religion*, *Journal of Aesthetics & Art Criticism*, *Journal of Counseling & Development*, *Journal of Education*, *Political Science Quarterly*, *Journal of General Psychology*, *Journal of Genetic Psychology*, *Journal of International Affairs*, *Journal of Learning Disabilities*, *Journal of Marriage & Family*, *Journal of Politics*, *Journal of Psychology*, *Journal of Social Psychology*,

Library Journal, *Social Forces*, *Sociological Review*, *Theological Studies*, *Women's Studies*, and so forth. PDF backfiles to 1975 or further are available for well over 100 journals, and searchable cited references are provided for more than 1000 titles. The majority of full text titles are available in native (searchable) PDF or scanned-in-color.

Hits for different Keyword Combinations

SINGLE/COMBINATIONAL KEYWORD/SEARCHTERM	HITS
Bionics	208
Bionics and people with disabilities/ disabled people/disability	1
Bionics and health	14
Bionics and health technology	0
Bionics and health system	0
Bionics and health care	1
Bionics and cost benefit or cost utility	0
Bionics and quality of life	3
Bionic	442
Bionic and people with disabilities/disabled people/disability	3
Bionic and health	24
Bionic and health technology	0
Bionic and health system	0
Bionic and health care	3
Bionic and cost benefit or cost utility	0
Bionic and quality of life	3
Body Image	2410
Body Image and health	621
Body Image and health care/healthcare	42
Body Image and health technology	0
Body Image and disabled people/people with disabilities/disability	7/37
Body Image and Nano	0
Body Image and transhuman	0
Cybernetics	4294
Cybernetics and health	51
Cybernetics and health care/healthcare	8
Cybernetics and heath technology	0
Cybernetics and health system	3

SINGLE/COMBINATIONAL KEYWORD/SEARCHTERM	HITS
Global health	6287
Global health and disabled people	8
Global Health and people with disabilities	14
Global health and nanotechnology	11
Global health and Nanomedicine	1
Global health and cybernetics	0
Global health and cyborgs	0
Global health and plastic surgery	15
Global health and NBIC	0
Global health and implants	38
Global health and human enhancement	0
Global health and bionics	2
Global health and transhumanism	0
Global health and health technology	28
Global health and health system	269
Global health and health care	1929
Nanotechnology/nanotechnologies	5414
Nanotechnology and disabled people/people with disabilities/disability	3
Nanotechnology and health	115
Nanotechnology and healthcare/health care	16
Nanotechnology and health technology	2
Nanomedicine	30
Nanotechnology and medicalization	0
Nanotechnology and body image	0
Nanotechnology and cost benefit/cost utility	0
Medicalization/medicalization	402
Medicaliz(s)ation and health	209
Medicaliz(s)ation and health technology	1

SINGLE/COMBINATIONAL KEYWORD/SEARCHTERM	HITS
Cybernetics and disabled people/or people with disabilities/disability	5
Cybernetics and quality of life	2
Cybernetics and cost benefit/cost utility	2
Cybernetics and body image	0
Cybernetic	4294
Cybernetic and health	48
Cybernetic and health care/healthcare	9
Cybernetic and health system	2
Cybernetic and health technology	0
Cybernetic and disabled people/or people with disabilities/disability	7
Cybernetic and quality of life	2
Cybernetic and cost benefit/cost utility	2
Cybernetic and body image	0

SINGLE/COMBINATIONAL KEYWORD/SEARCHTERM	HITS
Medicaliz(s)ation and body image	3
Medicaliz(s)ation and health care/healthcare	43
Medicaliz(s)ation and disabled people/people with disabled people/disability	13
Medicaliz(s)ation and plastic surgery	0
Medicaliz(s)ation and implants	1
Medicaliz(s)ation and bionic	0
Plastic surgery and body image	28
Plastic surgery and quality of life	25
Plastic surgery and health	271
Plastic surgery and healthcare	30
Plastic surgery and health technology	0
Plastic surgery and disabled people/or people with disabilities	0
Transhumanism	24

Another search was performed using the following databases, all belonging to the Ovid cluster of databases.

Ovid Cluster of Databases

Database	Date up to
Books @ Ovid	February 24, 2005
Journals @ Ovid	Full Text February 25, 2005
EBM Reviews:ACP Journal Club	1991 to January/February 2005
EBM Reviews:Cochrane Central Register of Controlled Trials	1st Quarter 2005
EBM Reviews:Cochrane Database of Systematic Reviews	1st Quarter 2005
EBM Reviews:Database of Abstracts of Reviews of Effects	1st Quarter 2005
EBM Reviews:Cochrane DSR, ACP Journal Club, and DARE All	
AARP Ageline	1978 to February 2005
AMED (Allied and Complementary Medicine)	1985 to February 2005
CINAHL - Cumulative Index to Nursing & Allied Health Literature	1982 to February Week 3 2005
EMBASE	1996 to 2005 Week 09
EMBASE	1980 to 2005 Week 09
HealthSTAR/Ovid Healthstar	1975 to November 2004

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R)	1966 to Present
Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations	February 25, 2005
Ovid MEDLINE(R	1966 to February Week 3 2005
Ovid MEDLINE(R) Daily Update	February 25, 2005
PsycINFO	1872 to February Week 3 2005
PsycBOOKS	1950 to January 2005
Global Health	1973 to January 2005
Health and Psychosocial Instruments	1985 to December 2004
Ovid OLDMEDLINE(R)	1950 to 1965

Search History Results Display

The Calvert-Henderson Indicators: 0
Transhumanism: 8
NBIC: 53
Implants: 141792
Human enhancement: 30
Plastic surgery: 40748
Cybernetic: 1955
Cybernetics: 6641
Cyborg: 140
Cyborgs: 70
Bionic: 545
Bionics: 947
bionics and disabled people: 0
bionics and people with disabilities: 1
Bionics and quality of life: 54
bionics and health: 141
Bionics and body image: 2
bionics and health care: 44
bionics and health system: 4
bionics and health technology: 0
Brain machine: 140
cyborgs and people with disabilities: 1
Health: 2886171
Global health: 6287
Global health and disabled people: 8
Global Health and people with disabilities: 14
Global health and nanotechnology: 11
Global health and Nanomedicine: 1
Global health and cybernetics: 0
Global health and cyborgs: 0
Medicalization: 2698
Medicalization and body image: 24
Medicalization and quality of life: 159
Medicalization and Implants: 19
Medicalization and bionics: 0
Medicalization and disability: 228
Medicalization and disabled people: 10
Medicalization and people with disabilities: 15
Medicalization and plastic surgery: 7
Medicalization and health: 1623
Medicalization and health care: 788
Medicalization and health technology: 5
cybernetics and health: 1156
cybernetics and health technology: 0
cybernetics and health system: 19
cybernetics and health care: 92
implants and health: 11733
implants and health care: 2956
implants and health technology: 52
implants and health system: 172
cyborg and health: 37
cyborg and health technology: 0
cyborg and health care: 16
cyborg and health system: 0
implants and people with disabilities: 20
implants and disabled people: 17
cybernetics and health and disabled people: 0
cyborgs and people with disabilities: 1
plastic surgery and people with disabilities: 14
plastic surgery and disabled people: 18

Global health and plastic surgery: 15
Global health and NBIC: 0
Global health and implants: 38
Global health and human enhancement: 0
Global health and bionics: 2
Global health and transhumanism: 0
Global health and health care: 1929
Global health and health technology: 28
Global health and health system: 269
Global health and body image: 54
Global health and quality of life: 1530
Nanomedicine: 67
nanotechnology.mp: 7689
nanotechnology and health: 352
nanotechnology and health care: 120
nanotechnology and health systems: 4
nanotechnology and health technology: 1
nanotechnology and disabled people: 1
nanotechnology and people with disabilities: 1
Nanotechnology and disability: 13
Nanotechnology and body image: 0
Nanotechnology and quality of life: 65
Nanomedicine: 59
nanomedicine and health: 22
nanomedicine and disabled people: 0
nanomedicine and people with disabilities: 0
Disability and global health: 816
Disability and global health and health technology: 5
plastic surgery and health: 4613
plastic surgery" and health care: 1650
Plastic surgery and health care
plastic surgery and health technology: 7
plastic surgery and Health system: 73
disabled people and health: 2221
disabled people and health system: 92
disabled people and health technology: 13
people with disabilities and health: 2813
people with disabilities and health care: 1351
people with disabilities and health system: 119
people with disabilities and health technology: 7
disabled people: 4982
people with disabilities: 6314
Disability: 255355
Disability and health: 100627
Disability and health care: 35424
Disability and Health technology: 380
Disability and health system: 1354
Disability and Body Image: 1391
Disability and quality of life: 30094
Disability and quality of life and Health care: 8852
Disability and Bionics: 25 mostly cochlear implant
Disability and Implant: 2205
Disability and brain machine: 2
Disability and nanotechnology: 13
Disability and global health and health care: 353

A third search string used Multisearch, run by Cambridge Scientific Databases. MultiSearch is a federated searching solution that provides integrated access compatible with more than 1200 electronic resources. Its interface is powered by the acclaimed CSA Illumina platform, featuring both an easy-to-use Quick Search feature as well as powerful search options for the expert. MultiSearch provides users with a single point where they can search for information from any number or type of content sources. The service then delivers organized, integrated, contextually relevant results that are easily analyzed by the researcher. CSA makes trial access to MultiSearch available to interested institutions. CSA Illumina is designed to provide a simple, more user friendly approach to searching for novice users while maintaining powerful options for users who require them. The interface provides access to more than 100 databases published by CSA and its publishing partners. They were accessed through the University of Calgary from the Library Electronic Resources from the Cambridge Scientific Databases site.

CSA Cluster of Databases

DATABASE	DESCRIPTION
Aqualine	1960-Current Water resources, water and wastewater treatment, water pollution
ARTbibliographies Modern	1974-Current Modern and contemporary art, photography and design
BHI: British Humanities Index	1962-Current Literature, language, political science, philosophy
Biological Sciences	1982-Current Biomedicine, biotechnology, zoology and ecology
Biology Digest	1989-Current Life sciences, evolution, genetics, behavioral science
Biotechnology and Bioengineering Abstracts	1982-Current Biochemical applications, genetic engineering, gene therapy, and cybernetics
Communication Abstract	1977-Current Communication literature, broadcasting, public opinions
Communication Studies: A SAGE Full-Text Collection	1982-Current Mass communication, media studies, written communication
Conference Papers Inde	1982-Current Life sciences, environmental sciences, aquatic sciences
Criminology: A SAGE Full-Text Collection	1982-Current Criminal justice, corrections, penology, policing
CSA Technology Research Database	1962-Current Materials, engineering, aerospace, high-technology
DAAI: Design and Applied Arts Index	1973-Current Design, crafts and applied arts
Education: A SAGE Full-Text Collection	1968-Current Methodology, higher education, secondary education, vocational, measurement & testing, educational psychology
Environmental Sciences and Pollution Mgmt	1967-Current Environmental biotechnology, engineering, pollution
ERIC	1966-Current Teacher education, test, measurement, and evaluation
IBSS: International Bibliography of the Social Sciences	1951-Current Anthropology, economics, finance, political science, sociology
Index Islamicus	1906-Current
Linguistics and Language Behavior Abstracts	1973-Current Theoretical and applied linguistics, psycholinguistics, speech therapy
LISA: Library and Information Science Abstracts	1969-Current Library science, online retrieval, archives, information technology
Management & Organization Studies: A SAGE Full-Text Collection	1970-Current Organizations studies, management, business, human resource, marketing, public policy, public administration, industrial relations
Materials Science: A SAGE Full-Text Collection	1995-Current Molecular modeling, polymers, membranes for biological use, biomaterials, composites, plastics, mechanics of solids

DATABASE	DESCRIPTION
MEDLINE	1993-Current Medical research, clinical practice, policy issues
Meteorological & Geoastrophysical Abstracts	1974-Curren Meteorology, climatology, hydrology, glaciology
MicroPatent Materials Patents	1996-Current US and European patents related to materials science and engineering
National Criminal Justice Reference Service Abstracts	1975-Current Criminal and juvenile justice, drug control, law enforcement
Nursing & Health Sciences: A SAGE Full-Text Collection	1982-Current Social studies of health, public policy, health services & administration, health education, community/public health nursing
Physical Education Index	1970-Current Physical fitness, health, sports medicine
Plant Science	1994-Current Pathology, symbiosis, biochemistry, genetics
Political Science: A SAGE Full-Text Collection	1982-Current Political science, American government, policy studies
Psychology: A SAGE Full-Text Collection	1970-Current Applied psychology, assessment, child development, clinical psychology, cognitive psychology, counseling psychology, social psychology
Social Services Abstracts	1980-Current Social work, human services, social welfare, social policy
Sociological Abstracts	1963-Current Social structure, inequality, social change, social problems
Sociology: A SAGE Full-Text Collection	1982-Current Contemporary sociology, comparative sociology, consumer culture
TOXLINE	1999-Current Toxicology, chemicals, pharmaceuticals, antidotes
Urban Studies & Planning: A SAGE Full-Text Collection	1982-Current Anthropology, economic development, economics, education, planning theory, political science, public administration, urban policy

Search History Results Display

global health: 1548
global health and people with disabilities: 2
global health and Nanomedicine: 0
global health and bionics: 0
global health and NBIC: 0
global health and implants: 3
global health and transhumanism: 0
global health and health system: 42
Transhumanism: 8
brain machine: 59
people with disabilities: 2966
Bionic and health: 43
health and people with disabilities: 1045
global health and disabled people: 3
global health and nanotechnology: 0
global health and cybernetics: 2
global health and cyborgs: 4
global health and human enhancement: 0
global health and plastic surgery: 2
global health and health technology: 31
global health and health care: 439
nanotechnology devices: 102
disabled people: 3657
Bionic: 629
Health: 1957684
health and disabled people: 940

health care: 321428
health care and people with disabilities: 430
health systems and disabled people: 8
health technology: 24153
health technology and disabled people: 9
health technology assessment and disabled people: 9
human enhancement: 15
nanotechnology and health: 222
nanotechnology and health system: 2
nanotechnology and disabled people": 1
Nanomedicine: 24
bionics and health systems: 0
bionic and disabled people: 3
Cybernetics: 64274
cybernetics and (health care): 229
cybernetics and (health technology): 5
cybernetics and (people with disabilities): 6
implants and health: 5296
implants and (body image): 86
implants and (health systems): 23
implants and (people with disabilities): 5
Plastic surgery
(plastic surgery) and (people with disabilities): 3
(plastic surgery) and (health): 1097
(plastic surgery) and (health systems): 8
plastic surgery) and (body image) and (health): 56

health care and disabled people: 367
health systems: 5773
health systems and people with disabilities: 11
health technology and people with disabilities: 26
health technology assessment: 23525
health technology assessment and people with disabilities: 24
Nanotechnology: 7138
nanotechnology and health care: 40
nanotechnology and health technology: 15
nanotechnology and people with disabilities: 0
bionics and health care: 8
bionics and health technology: 3
bionic and people with disabilities: 1
cybernetics and health: 830
cybernetics and (health system): 9
cybernetics and (disabled people): 11
Implants: 67268
implants and (health care): 1082
implants and (health technology): 471
implants and (disabled people): 11

(plastic surgery) and (disabled people)
(plastic surgery) and (health technology: 69
(plastic surgery) and (body image): 119

Interpretation of the results from the database search

Searching the Health Services/Technology Assessment Text did lead to very few hits to start with and none related to the issues discussed here.

Looking at the search results for the Cambridge Scientific Databases, a few conclusions can be drawn:

1. Health technology so far seems to have dealt the least with the new emerging technologies.

   If the hits for different new technologies are teamed up with (health care), (health systems), and (health technology), the combination with health technology scores less than with health systems and health care every time. But in general, few hits are found for emerging technologies such as nanotechnology, NBIC, brain machine interfaces, and others.

2. There seems to be little exposure to new technologies under the heading "health"; e.g. only 6.8% of the overall hits on bionics (629) are linked to health (43). Of the 64,274 results found for cybernetics, 830 or 1.3 % show up with (health), 229 or 0.35% for (health care), and only 5 with (health technology). Only 3.1% (222) of the overall hits for nanotechnology (7138) are linked to (health); only 0.5% (40) are linked to health care; and only 0.2% (15) are linked to health technology.

   Of 67,268 results found for implants, 5296 or 7.8% were found for (implant and health), 1082 or 1.6% results were found for (implants and health care), and only 471 or 0.7% were found for (implants and health technology).

3. There seems to be even less consideration in the literature for looking at new technologies under the heading of (disabled people, or people with disabilities): only 0.6.3% of the overall hits on bionics (629) are linked to disability.

4. Of the 64,274 results found for cybernetics, 17 or (0.026%) show up with (disabled people, or people with disabilities). Of 67,268 results found for implants, only 16 or 0.023% were found for (implants and disabled people/people with disabilities). Of 7138 hits for nanotechnology, only one (1) hit is linked to the term disabled people and none (0) to the term people with disabilities.

There are no hits for combining the keywords (disabled people, or people with disabilities) with (human enhancement) and (Nanomedicine).

Looking at the search results for the Ovid cluster of searches, the ratios are not that much different. Of 6641 results found for cybernetics, 1156 (17%) results were found for (cybernetics and health). Of 92 (1.3%) results found for (cybernetics and "health care"), 0 were found for (cybernetics and health technology). Of 14,1792 results found for implants, 11,733 results were found for (implants and health), 2956 results were found for (implants and "health care), and 52 results were found for (implants and "health technology").

Of 2,886,171 results found for health, 0.07% or 2221 results were found for ("disabled people" and health) and 954 results were found for ("disabled people and health care,") and 92 results were found for ("disabled people and health system").

Of 4228 results on health technology, only 0.3% or 13 results were found for ("disabled people" and "health technology"), 0.15% or seven results were found for ("people with disabilities" and "health technology"), 0 results for the keyword 'human enhancement'.

Of the 7689 hits for nanotechnology, only 4.5% (352) are linked to (health), 1.5% (120) to (health care), 0.05% (4) to (health systems), and 0.013% (1) to (health technology). Furthermore, only 0.19% (15) are linked to (disabled people or people with disabilities).

If we look at the term "Nanomedicine," which counts for 59 hits, 37% (22) are linked to (health) but none to (disabled people or people with disabilities).

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