Defining the Medicare “Basket”: Development of a Taxonomy for Health Care Decision-Making in Canada*

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Executive Summary

Health care decision-making should be seen in relation to the Canada Health Act with its emphasis on medical necessity as a criterion for decision-making. This criterion has had many ramifications on the way in which decision-making occurs at various levels of government and sets the stage for how a decision-making taxonomy unfolds in which each level of government imposes restrictions on those below. In addition, there is a growing concern over accountability tied to constitutional responsibility for providing services. With implications beyond health care, there is a move towards requiring that the level of government that provides or makes the decision to provide particular services--and hence gets the political credit for doing so—pay for them through their own tax revenues. Taking into account these concerns, this project develops a taxonomy of health care decision-making across Canada. The taxonomy has two dimensions designed to examine the cascade or compounding of constraints imposed by one level of government on another and the process of decision-making. These dimensions are (1) The level of government/decision-making from the top (federal) to bottom (patients) and (2) the process of making decisions: “Closed-door/Top-down”, “Bilateral” and “Hands-off/Bottom-up.” As the names imply, these processes refer to how centralized the process is for making decisions by the governing body with control – constitutionally ordained or otherwise – over a particular decision. While this cascade effect is often true, it is also important to recognize that at times decisions are shared across two or more levels of government in a type of bilateral arrangement. Vignettes and discussion are focused on how concerns over accountability affect decision-making within each of these different decision-making styles and how the outcomes fit within the framework of the CHA.
Introduction

In Canada, provincial governments are required to fund all medically necessary hospital and physician services in order to receive transfer funds from the federal government under the Canada Health Act (CHA). Although the term medical necessity is not explicitly defined in the CHA, the various possible interpretations of medical necessity have had a major impact on decision-making at all levels of government. In their report on medical necessity in Canadian health policy, Charles, Lomas and Giacomini (1997) illustrate four definitions of medical necessity along with their implications for decision-making.

The first definition, based on what physicians and hospitals prescribe, can be used as a health policy tool to establish entitlement to a minimum federal floor of publicly funded services and to broaden access to publicly funded health services for all Canadians. The second definition, based on affordability, can be used to make the federal floor the provincial ceiling for publicly funded services in efforts to achieve cost control. The third definition, based on scientific evidence, is normally used to limit public insurance to services and procedures, which achieve improvements in the quality of care. The final definition is based on what is consistently publicly funded across provinces. The proposed use of this definition as a policy tool is to establish, and later negotiate, a consistent package of publicly funded services across the provinces with the objective of promoting equality in entitlement and access to publicly funded services across jurisdictions.¹ Since there is much effort and concern expended over whether a decision will comply with the CHA and its medical necessity provision, we will assume that these definitions will serve as a basis for decision-making.
As well, there is a concern over accountability tied to constitutional responsibility for providing services. With the implications extending beyond the health care system, there is a move towards requiring that the level of government that provides particular services or makes the decisions to provide services, be given the responsibility of funding. In other words, the level of government that receives political credit for the provision of services should be held accountable for their cost/tax burden. There has been a long tradition of the federal government providing transfer funds to provinces and municipalities to assist them in providing their constitutionally designated services. In these instances, federally elected officials often receive little or no credit since service provision is seen as a provincial/municipal function. As a result, the federal government has been recently downloading greater responsibilities for the funding of services to the provinces and municipalities. Simultaneously, it has been calling for greater accountability for how remaining transfer funds are used by provincial governments. This trend has had a major impact on how decisions are made in the health care sector and in the organizational structure of decision-making at all levels of government.

Current decision-making needs to be seen in the light of this growing interest in accountability. One way to assess accountability is whether funds flow to the intended purposes (e.g., the purchase of MRI or CT scanners) while another approach focuses on outcomes – i.e. how much benefit was received from the funds provided. Within the larger goal of elucidating the process for decision-making in the health care sector, this report will examine how both measures are used. Regarding the latter measure, we will include an assessment of the role of cost-effectiveness analysis in decision-making and
how organizational structures enhance or impede the use of such analyses in the process of making decisions.

As new health care technologies and procedures evolve, decision-makers face an ongoing debate over which services to publicly fund. Part of the goal of cost-effective analysis is to maximize the benefit stream given limited health care resources. Such resources are often restricted, and it is important to analyze them from the perspective of both their budget impact and their relative cost and benefits—that is, from a perspective that might be termed medically necessary and reasonable. New technologies often require significant up-front investment and on-going operational outlays, but downstream savings resulting from technical efficiencies, fewer adverse events, and quicker recovery times may offset these additional expenditures.

Since the adoption of new technologies and procedures comprise an ever-greater share of the growth in health care costs, presumably an increased importance would be attached to economic evaluation in the decision-making process; however, this has consistently not been the case. While there are some notable instances where economic evaluation has become of greater importance (e.g. in the approval of new drugs for listing on the formulary in Ontario), one reason for such limited use on cost-effectiveness analysis might be due to the silence of CHA, suggesting that this criterion is of little or no importance in decision-making. Other reasons include decision-maker scepticism over the validity of economic modelling and the emphasis in decision-making circles on budget impact, a factor, which economic evaluation methods often fail to incorporate.

Taking into account concerns over medical necessity and accountability as well as organizational structures, this report will develop a taxonomy of health care decision
making across Canada. The report will be organized by level of decision-making from the top (federal level) to bottom (individual patients) in order to examine the cascade or compounding of constraints imposed by one level on those underneath. While this hierarchy of decision-making is often true, it is also important to recognize that at times decisions are shared across two or more levels of government and some decisions are initiated from below rather than from above. To help illustrate these processes, vignettes within each level will be provided to help illustrate points made and to delineate various processes for making decisions. Discussion will focus on the role that the two aspects of accountability play in arriving at decisions within each of these different practice styles and whether these decisions conform to any of the four definitions of medical necessity provided. The concluding section will pull together material previously presented to show how there have been two somewhat opposite trends: While there has been lately a move by the federal government to download greater responsibility for financing services to the provinces and municipalities, there has also been a move to re-centralize decision-making within the highest levels of government--after a brief period of devolution--to help enhance accountability.

1.0 The Levels and Processes of Decision-Making

The following are the five levels of decision-making to be analyzed in this report.

1. Federal
2. Provincial
3. Regional (Regional Health Authorities)
4. Transfer Agencies (i.e. hospitals, home health care agencies, etc.)
5. Municipalities
6. Individual Practitioner
7. Individual Patient
The role each level plays in decision-making is laid out partially in legislation and in the constitution.

There are three processes of decision-making: “Closed-door/Top-down”, “Bilateral” and “Hands-off/Bottom-up.” “Closed-door/Top-down” decision-making is defined as decision-making done by the governing body with control – constitutionally ordained or otherwise – over a particular decision without publicly transparent consultation with stakeholders. “Bilateral” decision-making involves both the governing body and stakeholders/other levels of government in some type of publicly visible process for arriving at an agreement. This process can either be combative or amenable through consensus-building negotiations. “Hands-off/Bottom-up” decision-making involves the governing body over a particular decision deferring to the stakeholders to make the decision by which it agrees to abide. (See Appendix A for diagram outline of the taxonomy).

2.1 The Federal Role

The federal government is largely left with the role of protection and promotion of health, setting standards and overseeing a number of very specialized aspects of health care. For example, Health Canada assesses new medicines to ensure that they conform to the Food and Drugs Act and Regulations, and the Patented Medicines Price Review Board (PMPRB) regulates the maximum permissible price of each patented drug product. These roles largely involve the setting of standards although the federal government has authority for directly funding services to specific groups of Canadians – inmates in federal correctional facilities, First Nations and Inuit people living on reserves, the Royal Canadian Mounted Police, and the members of the Canadian Armed Forces.
While the federal government’s involvement in health care has been primarily confined to the use of federal spending power, the allocation of money has an obvious impact on provincial health policy.³ The Canada Health and Social Transfer (CHST) has been the largest federal transfer to provinces and territories, providing them with cash payments and tax transfers in support of health care, post-secondary education, social assistance and social services.⁴ The CHST has given provinces and territories the flexibility to allocate payments among social programs according to their own priorities, while upholding the principles of the Canada Health Act.

The federal government role viz-a-viz the provinces is governed largely by the Canada Health Act and associated regulations which stipulate that in order for the provincial health insurance plans to receive their full federal cash contribution, they must satisfy the following conditions:

1. **Public Administration**: Healthcare insurance plans must be operated on a non-profit basis by a public authority.
2. **Comprehensiveness**: The plans must cover all services provided by doctors and in hospitals they are medically necessary.
3. **Universality**: All of the residents of a province must be entitled to the benefits of the plan.
4. **Portability**: A province must continue to cover its residents when they are traveling elsewhere in Canada.
5. **Accessibility**: Provinces must provide reasonable access to insured health services on uniform terms and conditions, without financial or other barriers.

Recently, the Royal Commission on the Future of the Canadian Health Care System (Romanow Report, 2002) made the recommendation that a sixth principle, accountability, be added to the CHA “…to address Canadians’ concern that they lack sufficient information to hold the appropriate people accountable for what happens in our health care system.” However, even with this principle, the organizational structure of
decision-making has changed in many instances to enhance accountability. At the federal level, these changes include the following:

The First Minister’s Accord in February 2003 included provisions to separate the Canada Health and Social Transfer into two separate funds, one for health and the other for social services. In addition, the health portion was to be further split into earmarked funds for primary health care reform, diagnostic/medical equipment, home care, and catastrophic drug coverage. The natural effect of splitting up the contributions from Ottawa to the provincial governments is to take away from the provinces some decision-making capacity involving the use of these funds. Ottawa also used this opportunity to split funding into separate streams to enhance accountability by pushing the First Ministers to agree on an annual public report to their citizens on progress made in each of these areas. (First Ministers Accord, February 5, 2003)

As part of their action plan for health system renewal in September 2000, the First Ministers agreed to create a common intergovernmental advisory process to assess drugs for potential inclusion in publicly funded drug plans. The impetus for this process emanated partly out of provincial government concerns that inconsistency in drug formularies was growing between provinces. Beginning in 2003, CCOHTA will be responsible for reviewing new drugs either in-house or externally by contractors. In addition to conducting reviews, CCOHTA will provide support for the Canadian Expert Drug Advisory Committee (CEDAC), which will make listing recommendations regarding new chemical entities (NCEs) to participating federal, provincial and territorial drug plans. As an independent advisory body, CEDAC utilizes efficacy and cost-effectiveness analysis to enhance accountability for funds expended. Under this scheme, provincial and territorial advisory committees will be relegated to the role of advising the provinces/territories as to “how to list” (i.e. general use, limited use, etc.) rather than “what to list”. Pending on what the federal government does with regards to the Romanow Report, the final decision regarding a positive recommendation will still rest with the provinces regarding whether to list and how to list a drug on their publicly funded formularies taking into account factors relevant to their jurisdiction – for example, population need, other drugs provided for benefit on their formulary, or budgetary considerations.

Although the federal government has been traditionally in charge of ensuring safety and setting standards, these vignettes suggest that it is also increasingly concerned with ensuring accountability for how funds are used and ensuring that Canadians from coast to coast have access to a consistent product. To do this, the federal government has been in a struggle with the provinces over the proper role that the federal government
ought to play in the future development of provincial health care systems. Through agreements reached over the last few years, it appears that the federal government is using a two-pronged approach by directing cash contributions for particular services and by increasing its presence in an advisory capacity. One example of the first prong is the splitting of the CHST into two separate transfers, Canada Health Transfer (CHT) in support of health and the Canada Social Transfer in support of post-secondary education, social assistance and social services. In this way, the federal government has restricted the degrees of freedom that provincial health care systems have experienced in previous years.

Regarding the other prong, the federal government has increased its regulatory role in the pharmaceutical industry. Though the federal government has the primary responsibility for regulating pharmacare, their decisions and recommendations can shape decisions made by provincial health ministries, regional health authorities, transfer agencies and individuals. The Common Drug Review (CDR) initiated by provincial governments and later supported by the federal government is a national process for reviewing new drugs and providing listing recommendations to participating federal, provincial and territorial drug plans in Canada. Quebec is the only jurisdiction that does not participate in the CDR. The CDR is comprised of: 1) A critical assessment of the best available clinical and pharmacoeconomic evidence and 2) A listing recommendation made by CEDAC.5 It reports through the CDR Directorate at the Canadian Coordinating Office for Health Technology Assessment.6 A further discussion of how drugs are reviewed and approved can be found later on in this paper.
In light of concerns over increasing microbial resistance to current antibiotic treatments, the Canadian federal government developed an interdisciplinary committee (the Canadian Committee on Antibiotic Resistance (CCAR)) in 1999 to address this problem. The CCAR now facilitates cooperation among many agencies, and has developed a National Integrated Action Plan. The goal of this plan has been to encourage concerned organizations and agencies to reduce the prescribing of antibiotics by 25% over the next three years.

In order to prepare for the previous West Nile virus season, Health Canada worked on a coordinated approach with key stakeholders in Provincial Ministries of Health, Regional Health Authorities, Environment and Natural Resources, and a host of others. They developed a plan to combat this disease involving 6 areas:

1) Canada-wide surveillance for West Nile Virus
2) Keeping Canada’s blood system safe from West Nile Virus
3) Testing for West Nile virus
4) Safe and effective pesticides and insect repellents
5) Keeping Canadians informed about new findings
6) Working in collaboration with First Nations communities on reserves.

This was largely a hands-off process of decision-making given that the federal government was responsible for coordinating the West Nile approach, yet left the ultimate decision-making regarding strategies to the provinces and local health units. Health protection and promotion is the responsibility of the federal government as evidenced by its role in the West Nile strategy even though decision-making devolved largely to more local levels of government.

2.2 The Provincial Role
The provinces have primary responsibility for direct funding of service delivery and are faced with the everyday realities about how to best respond to pressing problems in the organization and financing of services to their population. Given the increasing pressures on the health care system—including demographic pressures, cost escalation in the pharmaceutical sector, and new technologies—provincial governments are concerned about sustainability particularly in light of other pressing needs for social services and education.³

Provincial health care is publicly administered by provincial ministries or regulated by regional agencies. Aside from the CHA, provincial statutes, not federal, bound each province’s health system. Provinces define what is medically necessary, set fee schedules for payment to professionals, and set global budgets for health care institutions. They are responsible for ensuring that all Canadians have affordable, high quality health care across the country.

Although the provinces have ownership over very little in the way of health care facilities—approximately 97% of current funds are directed to transfer agencies like hospitals—it does have control over remuneration for services provided mainly by physicians, through the schedule of benefits. And as a monopsony buyer of services, the provincial governments are able to wield a substantial amount of control over service delivery within their jurisdictions.

Decisions over Funding Health Care Technology:

Provincial ministries directly fund some hospital-based health care services, known in Ontario as Priority Programs, outside of hospital global budgets that are
typically associated with high cost and high growth. Ontario currently manages 15 Priority Programs, which include Acquired Brain Injury, Bone Marrow Transplantation, Cardiovascular Services, Cleft Lip & Palate and Craniofacial Dental, Cochlear Implants, End Stage Renal Disease, Haemophilia Ambulatory Clinics, Hip & Oncology, Provincial Regional Genetics Program, Regional Geriatric Programs, Sexual Assault Treatment Centres, and Trauma.¹⁰

Two services of interest are cochlear implants and magnetic resonance imaging (MRI) services, which combine Ministry funding with hospital funding. Cochlear implants are used to provide hearing assistance to individuals with profound bilateral sensorineural hearing loss. These expensive implants constitute only a small part of the care required for these patients; therapy and rehabilitation are integral to ensure a successful surgery. The MOHLTC will fund the device portion of the surgery while the other services that go along with the surgery are funded through the hospital’s global budget.

The Priority Programs Unit provides designated hospitals with the operating funds to deliver MRI insured services. In return, hospitals are expected to comply with a number of conditions including service level requirements. Hospitals typically purchase MRI machines through fundraising efforts. At the First Minister’s meeting in February 2003, it was agreed to implement a $1.5 billion Diagnostic and Medical Equipment Fund to go towards the purchase of new technologies and diagnostic equipment, some of which may go toward purchasing new MRI machines.¹¹

The decision to fund cochlear implants and MRI services is thus a combination/bilateral funding decision by the provincial government and the hospital.
With cochlear implants, the government will pay for the implant device while the hospital must fund the remaining services associated with the surgery through their global budget. Conversely, the provincial government will fund MRI operational services while it is the responsibility of hospitals to fund, through their global budgets or raised privately, to buy and maintain the MRI machines.

While MRI insured services are funded by the provincial governments, the public provision of Positron Emission Tomography (PET), a highly innovative technology used to test for cancer, heart disease and Alzheimer’s, is a hugely debated topic. As of July 15, 2001, the CCOHTA reported that there were nine PET machines operating in Canada, with only two being used for non-research purposes. The Quebec government funds the first machine in Sherbrooke while the second machine, in Vancouver, requires patients to pay $2,500 a test. Nobody as of yet can receive in PET in Ontario as a publicly insured service outside of participation in a research project, or on compassionate grounds. One private company, CareImaging, is in the process of applying for FDG (the drug used in PET scanning) Clinical Trial approval with Health Canada. Upon approval, they will open a private PET centre in Mississauga, charging $2,500 per test. The emergence of these private facilities is creating a precedent under which some provinces will allow private clinics to charge their patients, while other provinces will not. The developing private PET scanning market might push the provincial government to make a decision in funding PET scans, as it becomes harder to determine where and when to install these machines. This might ultimately become a federal issue.

It is the hope, however, of these private facilities, that the provincial governments will recognize the medical necessity of PET scanning, and include it as a publicly
PET scanning may improve a patient’s care management as well as indicate what type of disease treatment and surveillance to follow. According to International P.E.T Diagnostics Inc, 65% of cancer patients in a clinical trial involving PET changed their care strategy after the scan. Yet, publicly funding PET will be difficult foresee in the near future as the cost of purchasing and maintaining a PET machine is extremely expensive, and the provincial government will not be willing to fund it unless proven medically necessary.

In recent months, Ontario has adopted a stance of evidence-based decision-making regarding PET scanning. This example of hands-off decision-making was presented at the recent ISTAHHC conference in June 2003, where the CEO of the Institute for Clinical Evaluative Sciences (ICES) discussed their planned clinical studies of PET to be conducted in Ontario. Ontario has determined the PET scanners may be introduced to the province on a limited basis, but only as a part of an evaluative process. A PET Steering Committee, commissioned by MOHTLC and ICES is supervising a process that continuously provides updates the published literature involving PET; determines whether the literature is convincing enough to allow PET scanning to specific individuals as an insured service; and fund PET studies. As a result, four protocols are being finalized where PET has been deemed integral in answering clinical questions. This hands-off decision-making strategy is an innovative attempt to use evidence to guide government decision-making regarding the introduction of publicly insured PET scanning in Ontario.

The ten provincial and three territorial health ministries make decisions regarding which health technologies to publicly insure in their particular jurisdictions.
of Health across Canada established the Canadian Coordinating Office of Health Technology Assessment (CCOHTA) to provide national information exchange, resource pooling, and coordination of the assessment of health care technologies to ensure their appropriate use. With recent increased funding to CCOHTA, it can devote further resources to projects requiring a longer time frame and address perceived limitations identified in reviews, such as establishing a program of outreach workshops to improving the uptake of assessments from the CCOHTA and other HTA reports at the health authority and hospital level. As already mentioned, their mandate has recently been extended to include responsibility for managing a common review process and making drug formulary listing recommendations to the drug plans funded by provincial and territorial governments. Although CCOHTA is funded bilaterally between federal, provincial and territorial governments, it is noteworthy that the initiative to extend its responsibility for making general funding recommendations to the provinces actually emanated from below—the provincial governments—rather than from the federal level.

While pharmaceutical/technology adoption is an example of bilateral decision-making, pharmaceutical/technology assessment is often performed behind closed doors even though the process used and the information used is mostly in the public domain. CCOHTA has developed various ways to ensure the transparency and fairness of its pharmaceutical and technology assessment processes. In the case of the Common Drug Review, extensive consultations occurred during start-up to ensure optimal access to the process for manufacturers, plans and the public. As a result, details on every step of the process for each submission are itemized on the CCOHTA web site (http://www.ccohta.ca). The manufacturers and public plans receive a copy of and are
given an opportunity to comment on the results of a review before the CEDAC makes its final recommendations, and these comments are included in the final brief submitted to CEDAC and the drug plans. In addition, manufacturers may ask for a reconsideration of the initial, embargoed recommendations on various grounds. Also, CDR shares CEDAC's recommendations and detailed "Reasons for Recommendations" for every submission on the CCOHTA web site. As part of its first year evaluation, a new strategy to enhance public participation in the CDR has been recently drafted and will be launched soon.

Another provincial issue of funding and service delivery occurs with the provision of genetic testing services. Provincial governments have yet to establish proper decision-making rules to regulate genetic testing services. One of the main issues that these regulatory bodies face is how to control the diffusion of these tests. The results of genetic testing can indicate who might require treatment for a disease years before symptoms appear. Under the CHA, all provinces are required to provide reasonable access to medically necessary services. If a genetic test indicates that someone is more likely than average to get a certain disease, then disease surveillance and preventative treatment may become medical necessary and hence publicly insurable.

With the evolution of private genetic testing services, it is key to evaluate the extent to which genetic tests should be included as a publicly insured service, and the impact of allowing a two-tiered system for genetic testing. The effects of a private market will no doubt have an impact on the public sector. After an individual receives test results, they might proceed to the public sector for advice and treatment, or make lifestyle choices that in the long-run might impose further costs on the public system.
The decision to publicly insure genetic testing will help limit downstream costs that impact the public sector. With the evolving private sector, there is no control of the diffusion of testing. This ultimately puts pressure on the government to control the growth of genetic tests and insure these services.

Genetic testing can be a slippery slope; all provinces and territories are required to provide medically necessary services, thus, are they required to fund the treatment costs of a person who may, or may not, develop a disease in his lifetime? If genetic testing becomes a publicly insured service, then the government will be faced with having to provide medically necessary treatment and prevention costs to many more individuals. Yet, if the government does not provide coverage for a genetic test, then they may limit these downstream costs but will be faced with the likelihood of a two tiered system: those who can access private sector genetic testing plus benefit from publicly funded disease surveillance and preventive treatments, and those who can not. (See Appendix B.)

Decisions over Prescription Drugs

The approval of new drugs in Canada is typically the federal responsibility, however the provincial governments have the ultimate responsibility of what approved drugs to place on their own publicly funded formularies. Federal, provincial and territorial drug plans make independent formulary listing decisions on all CEDAC recommendations based on each plan's respective mandate, resources and priorities. However, with the advent of the CDR at the federal level, provincial advisory committees are now more often relegated the role of advising the provinces/territories as to “how to list” (i.e. general use, limited use, etc.) new pharmaceutical rather than “what to list”
because that is heavily influenced by recommendations from CEDAC.\textsuperscript{17,18} Moreover, a final decision whether to list a new prescription drug with a positive recommendation from CEDAC is less likely to be followed by all of the provinces/territories than a negative recommendation which is tacitly considered binding on all of them.\textsuperscript{*} Decisions regarding the continued listing of already approved pharmaceuticals, however, still rests with the provincial and territorial advisory committees. Generally, decisions regarding drug coverage are “closed-door/top-down” in nature even though input from stakeholders is taken into consideration. (See Appendix C.)

Beta Interferon is an example of a drug for which coverage varies across the country due to each provincial drug program making widely varying decisions regarding coverage. This drug is a part of the treatment regimen for individuals with Multiple Sclerosis (MS) that helps prevent the risk of acute attacks. The federal Health Protection Branch approved this drug in 1995, and it is available in Ontario under the Section 8 process, which is designed to allow Individual Clinical Review (ICR) by members of the Drug Quality and Therapeutics Committee (DQTC) on a case-by-case basis.\textsuperscript{19} Quebec is the only province that fully funds Beta Interferon to those who require it.\textsuperscript{†}

As well, in 1999 DQTC completed a review of all antibiotics listed in the Ontario Drug Benefit Formulary/Comparative Drug Index, to ensure that all antibiotics listed in the Formulary were being used in agreement with current clinical evidence.\textsuperscript{20} As a result,

\textsuperscript{*}A recent negative recommendation from CEDAC regarding the listing of Fabrazyme® to treat Fabry disease—a rare, inherited glycosphingolipid storage disorder—will be a test of the unity among the provinces in response to a negative recommendation.

\textsuperscript{†}In Britain, the government’s advisory body has found that Beta Interferon treatments are not cost-effective, and has recommended that it should not be made available unless there is new money allotted to fund this drug therapy. The National Health Service (NHS) has subsequently decided to negotiate this drug, but has made special arrangements with the pharmaceutical companies that manufacture the drug, to share the financial risk of providing the drug. Should Beta Interferon prove to be ineffective, the NHS can reclaim the profits from the pharmaceutical companies.
several changes have been made to antibiotic listing in the ODB Formulary. The most significant listing change affects the fluoroquinolone antibiotics, some of which were formerly listed as General Benefit products. The committee was particularly concerned about the increasing rates of resistance to this class of antibiotics and the spread of cross-resistance from older to newer fluoroquinolones. Other provinces (e.g. Saskatchewan, Manitoba, Nova Scotia and Prince Edwards Island) have also restricted the use of fluoroquinolones antibiotics for similar reasons as those given by Ontario.

Decisions over Provider Services/Hospital Funding

Decisions regarding provider remuneration and what services to cover are largely made in a bilateral process that involves intense negotiations between organizations that represent provider interests and either the provincial government (in Ontario) or regional health authorities. Every three or four years, the Ontario Medical Association conducts these negotiations on behalf of Ontario physicians and the Ontario Hospital Association does likewise with respect to hospitals. Other provider groups, including those representing nurses, hold similar negotiating sessions either with the provincial government or the regional health authority across the country. Normally these bilateral processes are open and transparent with little apparent public conflict ostensibly to avoid federal scrutiny under the Canada Health Act. Moreover, the potential specter of scrutiny under the CHA probably has had a role in maintaining the open process of decision-making regarding the physician schedule of benefits and funding for hospitals.

Also ostensibly to avoid controversy, Ontario Provider Service Branch has adopted a hands-off/bottom-up decision-making process regarding requests for out-of-
province/out-of-country treatment. In Ontario, determining if the required treatment is medically necessary rests with the physician who refers the case to the Ministry of Health and Long-Term Care (MOHTLC). The MOHLTC subsequently asks an outside expert to confirm the medical necessity of the treatment, and will only fund such out-of-province treatment should there be a concurrence of opinions. If there is no agreement, then the case goes through a medical review board hearing, which is overseen by a layman, who does not have necessarily any medical training. In this tribunal, the opinions of outside experts are sought out but the final decision remains with the head of the review board. The MOHTLC will thus abide by whatever decision is made by this board.

An example of closed-door decision-making is Quebec’s Bill 114, which ordered the provinces physicians to man emergency departments of health care institutions in the event that the maintenance of these departments be threatened or interrupted. Quebec regional health boards determine when to call upon physicians. Penalties for not doing so can amount to a fine of $5000.

Decisions Regarding Long-Term Care/Home Care

The responsibility for the funding and delivery of home care services also rests with the provincial and territorial governments. Government programs pay for two-thirds of home care non-professional services; however, the delivery of such services varies greatly across the country. Home care services through provincial and territorial programs are generally available to the residents of that province or territory that, following an assessment, meet the criteria for receiving home care services. In every jurisdiction, the ministries of health maintain control over home care budgets and levels
of funding for each service. In many provinces, the allocation of funds is based on a population needs-based funding model, where the amount of financial support is approximately proportional to the underlying need for services.\textsuperscript{26}

Most provinces and territories have transferred the responsibility for the allocation and funding of homecare services to regional health authorities, or in the case of Ontario, transfer agencies called Community Care Access Centres (CCACs). CCACs were introduced in 1997 as a single service access point for home care services and are responsible for determining the eligibility of individuals in need of home care; determining the eligibility and authorizing admission to long-term care facilities; and the case management for each client. CCACs are governed by independent, incorporated non-profit boards of directors, who are accountable to the MOHTLC.\textsuperscript{27}

Prior to 1997, the Ontario directly employed staff through its home care programs to deliver in-home services to clients. Beginning in 1997, Ontario required its home care programs to divest themselves of their direct service staff in order to establish a Request for Proposal (RFP) and competitive selection (i.e., contracting out) process. The implementation of this managed competition model through local CCACs was to encourage competition for contracts between for-profit and non-profit home care service providers with twin objectives to lower costs and increase service quality. This allows the MOHLTC to engage in a more “hands off/bottom-up” decision-making role viz-a-viz the affairs of direct service provision in the home care sector. This process also allows government bodies to tacitly consider cost-effectiveness in decision-making by encouraging maximization of output within current budgets or what the economist would term technical efficiency. The incentives embodied in a competitive bidding process
with contract oversight by the governing body is to maximize/increase service provision within fixed budgets—much akin to the goals of cost-effectiveness, but without explicit having to engage in consideration of such factors.

Even with these positive features, however, the Ontario government has not been entirely satisfied with this process, and in 2003, the MOHLTC issued new guidelines for the procurement process to improve consistency in practice across the province and place greater emphasis on the evaluation of client services. These new guidelines were designed to ensure that the allocation of risk between the CCAC and service providers was specified so that contracts could more effectively manage unexpected changes in services volumes and costs as well as other unanticipated changes. More importantly, CCACs must now receive approval before awarding service contracts from regional MOHTLC offices. Thereby, the Ontario government has reclaimed some control over home care service delivery and lessened devolution of these services. While largely maintaining a “hands-off/bottom-up” relationship to direct service provision in this sector, the MOHLTC is now trying to reinforce its accountability for ensuring that the stated services are being delivered.

Public Health Issues
As mentioned earlier, Health Canada has been working with the provinces to combat the West Nile virus. Many provinces have subsequently developed their own provincial strategies to fighting the disease. Ontario has set province-wide standards for larviciding in populated areas to help fight the spread of the mosquito-borne West Nile virus; however, the 37 public health units in Ontario made the final decision on the specific
application of the agents to kill mosquito larvae before they developed.\footnote{28} As was true with the federal role in decision-making in this area, the provinces too adopted a largely hands-off decision-making role with regard to specific applications to be used.

### 2.3 The Regional Role

In the 1990s, most provinces/territories in Canada decentralized decision making regarding their publicly funded health system, through the regionalization and creation of regional health authorities (RHA).\footnote{29} RHAs were initiated as a means for provinces to contain costs and improve service integration.\footnote{30} The local authorities receive funding from the provincial governments through annual budgets that are based on the historical spending levels of the population served. RHAs do not have any role in raising revenue, other than private fundraising for internal use, but all are responsible for local planning, setting priorities, fund allocation, service management and delivery for the defined services, as opposed to the advisory role of the District Health Councils in Ontario, the only provinces without RHAs.

The RHAs incorporate public participation and make decisions and policies for the health of the population of their respective jurisdiction. RHAs are challenged with delivering cost-effective and efficient health priorities. Provincial decentralization of authority to these local establishments leads to shifts in power and new roles among stakeholder groups that by necessity must represent more opinions varying by locale.\footnote{29}

Within a regional structure, the following decision-making processes are normally hands-off/bottom-up at the RHA level:

1) internal allocation by transfer agencies of financial resources to meet volume/deliver expectations;
2) fundraising activities for internal use by institutions;
3) monitoring of quality measures against regional standards;
4) staffing patterns and allocation to meet needs.

Within regional structures, it could be argued that there are relatively few examples of local control over decision-making but many opportunities for local sabotage of regional priorities and initiatives by swaying public opinion.

At the Winnipeg RHA, there is a single drug formulary and single pharmacy/therapeutics review process for all hospitals. This closed-door top-down decision-making method has been highly effective at establishing consistency, yet it is not a popular process in that many believe that institutional differences are not given due consideration.

Contrary to the current trend to re-centralize decision-making, British Columbia’s largest RHA, the Vancouver Costal Health Authority (VCHA), has begun to ask private, for-profit clinics to competitively bid on providing certain types of day surgeries. This contracting out of care is an effort to reduce the extreme waiting lists for surgery in British Columbia’s hospitals and to promote equity given that those injured in workplaces and receive services through provincial worker compensation boards have had access to these clinics for years. For the past four years, a BC hospital has contracted out 620 cataract surgeries a year to a private clinic. The contract cut the wait list for cataract surgery by a third and increased available operating room time in the hospital thereby cutting other surgery waiting lists. This process of contracting out services is an example of hands-off, bottom-up decision-making by regional health authorities much akin to the contracting out of home care services province-wide in Ontario.
This contracting out of such care is thought to be cost-effective because these private clinics consist of high-volume specialists with low overhead costs, low employee turnover and non-unionized staff; as a result, other regional health authorities around the country are considering similar moves. Since hospitals have global budgets, they have an inherent incentive to limit operating room time and to maintain long waiting lists. These private clinics have the opposite incentive since their income is based on volume of patients seen.

2.4 Transfer Agencies

Though the majority of healthcare delivery typically rests with the provincial and territorial jurisdictions, often they will devolve certain authority to transfer agencies, such as hospitals, home care agencies and long term care institutions.

In most provinces, hospital funding is based primarily on a principle of global (or base) funding budgets provided to each hospital annually. These budget allotments are based primarily on past allocations and annual adjustments to reflect changes in costs. For the most part, physicians are not paid by the hospital’s global budget, but through a fee schedule that is negotiated with provider groups.

Through their global budgets, along with additional funding through fundraising or charitable contributions, hospitals must decide on the adoption of new technologies through their respective pharmacy and therapeutics committee. In a study carried out in 1989 among 50 teaching hospitals in Canada, it was found that 23 of the institutions have a formal structured system that is responsible for technology assessment; 15 hospitals appointed a committee whose role is to assess technologies; and 9 hospitals have a
specific department with the mission of purchasing new technologies. To make the best use of new technologies, hospitals must develop specific criteria which decision-making will be based. Technology adoption is an example of closed-door top-down decision-making.

Hospitals also have the power, with the exception of a few regional health authorities (e.g., Winnipeg), to establish an internal formulary for drugs with advise from their individual pharmacy and therapeutics committees. This decision is also an example of closed-door top-down decision-making. Formularies established by health care facilities do not have to include all insured items on the provincial formulary list. If an insured drug is not included in the hospital’s formulary, its provision will be to provincial and regional policies. The hospital drug benefit list is intended to expand on the provincial formulary as required to meet the special requirements of hospitals. This list is monitored and maintained by a specific advisory committee comprised of the Canadian Society of Hospital Pharmacists, the certain drug quality assessment committee of the particular province, and representatives of the Ministries of Health.

### 2.5 Municipalities

Health services at the municipality level are the result of devolution of financial responsibility by the levels above. Municipalities are responsible for basic health activities, monitoring and maintenance. Many enforcement responsibilities have been placed on municipalities and many are encouraging local neighbourhood action groups to alleviate the financial strain of ensuring public health safety. While municipalities make closed-door/top-down decision regarding enforcement of major public health issues, such
as quarantines in the face of infectious disease and restaurant food safety inspections, there are many neighbourhood action groups designed to clean up local areas to prevent the spread of disease and ensure physical safety that municipalities allow to function at an arms length from government.

2.6 Individual Practitioner and Patient

The individual practitioner is in charge of making the most routine medical decisions, such as prescribing medication, determining methods of treatment, etc for their patients. When making treatment decisions, the physician must remain mindful of individual characteristics, and must consider patients' concerns regarding the course of their disease, their distress, and, in advanced disease, their knowledge of a limited life expectancy when making treatment choices. Such considerations will contribute to a more satisfactory patient-physician relationship and superior quality of life.34

An example of closed-door top-down decision-making is the recurrent treatment of chronic conditions, such as asthma, diabetes, HIV, etc. Recently, though, physicians are engaging their patients in helping them make decisions regarding their treatment. A recent shared treatment decision-making model, depicted by Charles, Gafni and Whelan (1997) identifies different important steps in the shared decision-making process such as: that the physician and patient be involved; that both parties share information; that both parties take steps to build a consensus about the preferred method of treatment; and that an agreement is reached on the treatment to implement.35 An example of this bilateral decision-making is an individual’s do not resuscitate (DNR) order, should they require resuscitation.
However, physicians and other providers are increasingly engaging in bilateral or ‘hands-off/bottom up’ decision-making as treatment options become more numerous and patients more educated via the internet. An example is a patient’s decision regarding risky surgery versus drug therapy. Such important decisions must be made at key points in the disease process, and various treatment options exist with different possible outcomes and substantial uncertainty. Many patients, however, do not like to assume full decision-making control but like the share the role with the physician. This way, the patient can benefit from the physician’s clinical research and information before deciding what treatment methods are the best. With the increase in readily accessible information for patients, mainly from the Internet, information flows have increased patients’ ability to engage in more discussion with their physicians regarding their treatment. In line with this trend, John Wennberg, a physician at Dartmouth Medical School, has aided in increasing the patient role in decision-making by developing videos comparing various treatment options for a number of medical problems (e.g., prostate cancer). (Source?)

Interestingly, the perceptions of the value of the internet differs between patients and physicians. The results of a recent study at Toronto’s Princess Margaret Hospital indicated that 42 percent of oncology patients reported that information obtained via the internet helped them cope with their illness and only one percent had a negative effect. This contrasts with 15 percent of physicians reporting a positive impact and 27 percent reporting a negative impact.36

3.0 Conclusion
While funds for health care services have continued to increase at various levels of government, there has been a move to increase the inherent accountability for whatever funds are provided through re-centralizing the decision-making process within higher levels of government. Examples include the common drug review and the splitting of federal transfers into dedicated funds to increase accountability. Yet, there are instances where this re-centralization does not hold true such as at the Vancouver Coastal Health Authority. Typically, worker compensation boards receive care for injuries sustained in the workplace through these private clinics since employers want their workers cared for immediately and sent back to work. This apparent inequity with non work-place injuries has caused other jurisdictions to consider the same path as that in Vancouver: In this way, governments are able to consider cost-effectiveness without explicitly doing so.

Although cost-effectiveness is a potentially valuable tool for program evaluation and decision-making, there has been a resistance to including this criterion in legislation and as a basis for making decisions. Part of the difficulty is a technical one and another is political. With regard to the former, data is often insufficient and techniques are prone to debate such that there is a lack of confidence that results are valid for the decision at hand. This technical difficulty is compounded by a general perception that health care is of priceless value and by applying cost-effectiveness you are drawing a line as to which lives are more valuable. Therefore, the impact of cost-effectiveness is often more subtle having more of an impact on decision-making trends rather than on particular decisions. If the CHA were amended to included a “medically necessary and
reasonable” provision, instead of the current “medically necessary” one, it is possible that this would provide an impetus to use cost-effectiveness more often in the future.

There is evidence that some areas of government experience pressure from private markets to publicly cover new services/technologies prior to their diffusion. Examples of such lateral pressure include the case of genetic services, diagnostic imaging and PET scanning. The evolution of private markets is placing increasing pressure on the public sector. To maintain control, the public market must regulate and restrict the diffusion of these private markets.

Pressure from higher government levels limit decision-making on the government below. Decision-making at each level generally affects the level below; however, there are important instances in which there is a push from below—such as with the provincial territorial initiative to establish a common drug review that the federal government later joined. In the context of the taxonomy put forward, bilateral decision-making at times involves one level of government interacting with another level of government as a stakeholder. Also noteworthy in this model are changes at the lowest levels of decision-making, the patient-doctor relationship, where a rapid transformation is underway in the wake of the recent advent of the internet. No longer are patients entirely passive with regard to treatment decisions. Many are actively engaging physicians regarding treatment decisions from the most mundane issues like which inoculations are necessary to more life and death matters. The pressures are now being reversed with physicians being forced by their patients to better justify their medical judgment rather than physicians urging compliance from patients.
## Appendix A: Taxonomy of Health Care Decision-Making

<table>
<thead>
<tr>
<th>Process of Decision-Making</th>
<th>Centralized</th>
<th>Decentralized</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Top</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Federal</td>
<td>Drug Safety, broad categories of publicly covered services</td>
<td>Combative Public Airing of Grievances CHST/CHT funding</td>
</tr>
<tr>
<td>Provincial</td>
<td>Technology adoption, Provincial retail drug formularies Distribution of priority programs and emergency services (Ontario)</td>
<td>Negotiated Consensus-Building e.g., CHA-type services including physician fees and hospital global budgets</td>
</tr>
<tr>
<td>Regional</td>
<td>Public health initiatives such as pesticide spraying Distribution of priority programs and emergency services (provinces other than Ontario)</td>
<td>Location of health care institutions, Material in Abelson article</td>
</tr>
<tr>
<td>Municipal</td>
<td>Public health safety issues (e.g., enforcement of SARS quarantine)</td>
<td>Public awareness campaigns (e.g., handwashing)</td>
</tr>
<tr>
<td>Public Health Services and Monitoring</td>
<td>Technology purchasing priorities</td>
<td>Outpatient Clinics (e.g., HIV), visitation hours, configuration for private, vs. semi-private vs. ward floorspace</td>
</tr>
<tr>
<td>Transfer agency (e.g., hospitals, home care agencies, long term care institutions)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual practitioner</td>
<td>Recurrent treatment of chronic conditions e.g., asthma, diabetes, Hepatitis C, HIV, etc.</td>
<td>DNR orders</td>
</tr>
<tr>
<td>Individual patient decisions regarding medical options e.g., surgery vs. drugs</td>
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By “Closed Door” decision-making we mean that the decision-making is done by the governing body with control—constitutionally ordained or otherwise—over a particular decision. Bilateral decision-making involves both the governing body and stakeholders in some type of publicly visible process for arriving at agreement (This process can either be combative or more amenable through consensus-building negotiations.) “Hands off” decision-making involves the governing body over a particular decision deferring to the stakeholders to make the decision.
Appendix B: The “Cascade” Of Decision-Making With Respect To Technology

Decision-making with regard to health technology occurs at three levels: The federal level with regard to safety and assessments, the provincial level with regard to both publicly and privately funding of technologies as well as private provision, and at the transfer agency/individual practitioner level with regard to decisions to use/adopt particular technologies. Each level above constrains the level below in terms of the range of choices. There is also some lateral pressures placed on decision-making between the public and private sectors (e.g., the province may face pressure to publicly fund a technology prior to a private provider moving in to provide an “as-of-yet” uninsured service. The province, if it does not act prior to private providers moving in, may lose control over diffusion of the technology if it eventually must relent to pressure to public fund the technology. At that point, all private providers will be “grandfathered” in as publicly funded providers). There is also pressure placed on private insurers to cover certain technologies (e.g., assistive devices) if the province does not fund them.

Hospitals sometimes face a shared funding arrangement for new technology with the province through priority programs whereby hospitals must fund either the device or the operating expenditures out of global budgets. Most often, however, hospitals must fund technology out of global budgets. There are also various circumstances where specialist physicians (e.g., gastroenterologists funding sigmoidoscopy in their own offices) relieve some pressures on hospitals to provide certain technologies. The availability in hospitals, can also relieve some pressure on individual physicians from providing certain procedures in their own offices.

Health Canada licenses a technology based on safety/ethical concerns. CCOHTA performs assessment

Some provinces perform their own assessment while others rely on CCOHTA/Priority programs decide which devices they fund and/or provision of operating funds

If rejected for public funding, private insurers must make decision regarding funding (e.g., assistive devices)

Private providers of certain technologies (e.g., MRI, PET)

Individual hospitals make decision to fund technology from their global budgets

Individual physicians make decisions regarding provision of certain technologies in their offices (e.g., endoscopy)
Appendix C: The “Cascade” Of Decision-Making With Respect To Prescription Drugs

Decision-making with regard to prescription drugs occurs at three levels: The federal level with regard to safety and maximum prices, the provincial levels with regard to both publicly and privately funding of prescription drugs, and at the transfer agency/individual practitioner level with regard to prescribing/dispensing of prescription drugs. Each level above constrains the level below in terms of the range of choices. There is also some lateral pressures placed on decision-making between the public and private sectors (i.e., if one approves / rejects a product, there is pressure on the other to do the same).

- Health Canada determines safety of new drugs and PMPRB sets maximum prices. Central Drug Review under CEDAC provides advice to provinces about which products to fund.
- Provinces determine formulary for publicly funded programs—particularly decisions regarding listing restrictions.
- Private insurers set formulary for different plans.
- Individual hospitals set their formularies through the pharmacy and therapeutics committees.
- Individual physicians make prescribing decisions.
4 Canada Health and Social Transfer Department of Finance Canada www.fin.gc.ca/fedprov/chse.html
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