POLICY DIALOGUE NO. 10

Medically Necessary: What is it, and who decides?

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The Commission on the Future of Health Care in Canada, in partnership with select Canadian universities, hosted 12 televised policy dialogues on key health care issues. At each session, a moderator guided a panel of leading health care experts in a discussion focussing on a priority health issue for Canadians. These sessions were based on Issue/Survey Papers developed for the Commission by the Canadian Health Services Research Foundation. This report is a synopsis of one of these 12 policy dialogues.
Chair:
Mary Lou Finlay,
CBC Radio

Panelists:
Robert Chernomas,
Faculty of Economics, University of Manitoba

Janet Davidson,
CEO and President, Toronto East General Hospital

Dexter Harvey,
Faculty of Education, University of Manitoba

Dr. Suni Patel,
Rural Physician, president-elect, Canadian Medical Association

Noraloo Roos,
Director, Manitoba Centre for Health Policy

Josie Sima,
Biochemist and Volunteer for Thalassemia Foundation
The Policy Dialogue opened with a brief video that put in perspective the issue of defining medically necessary:

At first glance, the term medically necessary seems relatively straightforward. If you are sick, medically necessary is whatever it takes to make you better. And if you are in good health, medically necessary is that which keeps you well. It’s not quite that simple. Let’s look at it from the perspective of the Canada Health Act, which sets the terms that the provinces must meet in order to receive funding for hospital and doctor services. In the Act, the term is used to identify the services that must be funded by provincial health insurance plans. It stipulates that to receive funding for health care, the provinces must pay for all hospital services that are medically necessary, as well as doctor services that are medically required.

The problem is that the Act neither defines what is medically necessary nor provides a process for doing so. That is up to the doctors to decide. Although from time to time, a province may in fact delist certain services. So when a doctor decides that a service is medically necessary for a particular patient, it is fully funded by the government, and delivered according to the patient’s need and not on his ability to pay. If the service is considered unnecessary, then the patient must pay for it directly. The concept is one that is based on need and not want.

As demands on our health system grow, the pressure is mounting for a precise definition of what is considered medically necessary. Such a definition would then provide the provinces with a clear understanding of the medical services they must provide. Easier said than done. It should come as no surprise that a variety of models and frameworks have been proposed for determining which patients should receive which services. For instance, there are many who feel that our understanding of what is medically necessary is too restricted because it is limited to services provided by doctors and hospitals. These people argue that the concept should be broadened to include a variety of factors that may have a positive impact on an individual’s health. And that is where the debate begins.

The discussion revolved around a position paper prepared for the Commission by the Canadian health Research Foundation. It proposed three possible courses of action, which panelists were asked to discuss.
Course of action #1
The Canada Health Act should provide an explicit definition of what is medically necessary

Presentation by Prof. Robert Chernomas:
Much of the talk around medically necessary revolves around which services can be delisted in order to make up for shortages in technology on the one hand, and the need for user fees, medical savings accounts and for-profit medicine on the other. This talk is premised on the belief that health care spending is out of control and we can no longer afford the system that we have so cherished. This is simply not true. While we always have to make choices with respect to what where we spend our health care dollars, the room to manoeuvre is as great now as it ever has been. We need to understand what is driving our health care costs up, and what is driving our revenue down.

For 20 years, Canada has spent approximately 9% of GDP on health care. There is no crisis of spending in health care. We need to be clear about what the system has been set up to do and what it has not been set up to do. The Canadian system is mandated to control three sub-sectors, and only three: hospitals, physicians and administration. Other sub-sectors such as dental care, pharmaceuticals, long-term care, and so forth are not controlled by the health care system.

Let us look first at expenditure trends in the sub-sectors under the control of the system. According to the Canadian Institute for Health Information, the share of total expenditures on hospitals has fallen from 45% to around 31.5% over a period of about 20 years. The share of total health expenditures on physician services has declined gradually over the past decade, from around 15% in 1991 to a projected 13.5% for 2001. Administration costs have remained relatively stable. Expenditures in the three sub-sectors under the control of the system have either remained stable or fallen over time.

Expenditure trends in areas outside the control of our system are more complicated to analyze, but let us look at just one: pharmaceuticals. Drug expenditures have seen a steep increase in expenditure since the deregulation of Canada’s drug industry. From 9% in 1984, the share of total health expenditures spent on drugs has risen to about 15% today. We now spend more money in Canada on drugs than we do on physicians. Some suggest that drug spending pays for itself by saving on hospital and physician costs, but that is simply not true. The National Institute for Health Care Management in the US reported in May, 2002, findings from the analysis of 1035 new drug applications by the Food and Drug Administration in the 12-year period between 1989 to 2000. The conclusions reached were that in 85% of cases, these new drugs did not provide significant improvements over currently marketed drugs. The active ingredients in most of these drugs are the same as the old ones and they do not have clear clinical advantages. According to the NICHM, brand manufacturers have flooded the market with product line extensions known as evergreening in the industry, in response to perverse incentives related to changes in patent laws.

The disparity between spending on these drugs and their clinical value means that less money is available for other more useful medical interventions. There are billions to be had here for additional medical interventions. Therefore, what is out of control are the expenditures that our health system pays for but has no control over, such as the drug industry.

On the revenue side, KPMG, a major accounting firm, has identified all Canadian cities as cheaper at producing goods and services than any American city. Our corporate taxes are now lower than American corporate taxes. The former finance minister, who is likely to be the next Prime Minister, has repeatedly bragged that he has cut program spending in this country down to
50-year lows. Alberta, which is the leader in telling us that we need for-profit medicine, spends less money on health care as a proportion of their gross provincial product than any other province.

So on the one hand, the costs inside the system are more than in control; the ones that are outside the system are getting out of control, and the revenues are collapsing all around us because governments are making decisions to cut taxes repeatedly. And what does the Canadian public tell us: do not cut taxes if it means you are going to cut our health care system.

The Canadian health care system is not the problem. We need more of what it does, not less. Control of drug quality and costs are a far better alternative than more tax cuts and for-profit medicine. If we stop wasting our health dollars and giving away tax revenue without good reason, we can have more technology if we think that is necessary, and shorten our surgical waiting times if we think that is necessary.

Presentation from Dr. Sunil Patel:
We need first to distinguish between two terms which are often used interchangeably: medically necessary and core services. The first are those services that a qualified physician or other health practitioner determines are required to assess, prevent, treat, rehabilitate or palliate a given health concern or problem, as supported by professional experience and consensus, and/or by scientific evidence that is available. Core services are those services that are available to everyone under government plans.

The two terms are similar, but medical necessity is concerned more with clinical judgement at the individual patient-provider interface, while core services are more akin to the basket of insured services. This distinction is essential in any discussion about how to delineate what is in and what is out, about who decides on behalf of whom, and how.

In its prescription for sustainability, the Canadian Medical Association articulated the need to redefine and broaden the interpretation of core services, based on four key elements:
-- Comprehensiveness: that Canadians should be provided coverage for a basket of core services under uniform conditions and terms.
-- Appropriateness: That the scope of core services should be determined and updated regularly to accommodate and reflect the realities of health care delivery and the needs of Canadians.
-- Transparency: The determination of core services should be done through a federal-provincial process that has legitimacy in the eyes of Canadians and is based on the values of transparency, accountability, evidence-based inclusivity and procedural fairness. The CMA has proposed that a Canadian Health Commission be established which could play a very key role in advising federal-provincial-territorial government on what should be included in this basket of core services.
-- Sustainability: That governments develop a new framework to govern the funding of core services that provides for both full and partial public funding of core services. This would lead to the eventual expansion of core services beyond its current focus on physician and hospital services, but recognize that it would be impossible to provide first dollar coverage for everything and everybody.

The CHA should not be the vehicle through which core services are itemized. Nor should we attempt to define medical necessity on a case by case basis. Federal legislation is simply too unruly an instrument to use in an area where knowledge and technology is evolving rapidly, and where decision-making relies so extensively on clinical judgement. The CHA should continue much as it does now to prescribe in broad terms the basket of insured services. There is even
room under a section of the Act for the federal government to set out a more detailed definition of extended health services. That could also set out the principles and values that should underpin the process through which core services are determined and regularly updated.

This approach has proven to be workable. While there are some minor differences between provinces, coverage for physician and hospital services is remarkably consistent across the country. However, major differences in coverage have emerged over the years in areas outside physician and hospital services due to a lack of consensus between the federal government and provinces on the desirability and feasibility of expanding core services beyond what is currently covered in the CHA. The perceived potential for expansion is a function of federal spending power. When the federal government is taking tens of billions of dollars out of health care, it is hard to argue for comprehensiveness.

Canada is a federation, and we have a decentralized health care system, and ultimately it will be the responsibility of provinces to determine core services, and the challenge is to construct a national framework that respects this fundamental reality. But it also needs to increase cooperation between governments and a recommitment to the ideal of medicare. To do this, we need to confirm the rules of the game at the national level. We need to agree what a renewed health system would look like, and what are the roles, rights, and responsibilities of patients, providers and governments, for example through the development of a Canadian health Charter as proposed by the CMA. We need to put in place mechanisms at the national level to provide ongoing input and advice to help governments make more informed decisions. And the federal government would have to substantially increase its investment in medicare to reestablish itself as a significant and reliable partner in Canada’s health system.
Panel and audience discussion:
Most participants felt that the discussion of medically necessary implied that there was discretionary use of the health care system, which they felt was not true. Users of the health care system are in fact really sick and that we have little to worry from people using health care frivolously. A very small proportion of the population is very sick and uses a tremendous amount of health care.

*Once a person picks up the phone for help or comes into the doctor’s office, they have made the decision that something is medically necessary. Then it is up to the health practitioner to look at the evidence they have available, and advise the patient the best they can, whether it is to give a drug or recommend a procedure, or educate.* -- Brain Henden, Dean of Medicine, University of Manitoba

Much as participants were not convinced of the need to define what was medically necessary, neither were they convinced of the possibility of doing so. Any definition was bound to exclude something important. Dr. Chernomas felt that the health system needed expanding, not contracting, especially in the area of pharmacare, and that technology assessment should be used much more rigourously to assess the value of new procedures and products before they are covered.

Participants did feel that we needed to boost technological assessment, and concentrate it at a national, and even international level, to avoid duplication. This was the best way to eliminate inappropriate interventions. The Canadian Coordinating Office of Health Technology Assessment, set up by the federal government and jointly sponsored by the provincial governments was highlighted as an existing model that could be expanded, though some felt it would need to increase its transparency and inclusion of patients and providers in decisions. The National Institute for Clinical Excellence in Great Britain is perhaps a better model as it includes experts (physicians, health economists, researchers) to really assess technologies and decide whether or not they should be included under the UK’s National Health Service.
Course of action #2
A group of healthcare experts should decide what treatments or services are medically necessary

Presentation by Prof. Dexter Harvey:
I do not think you can put these decisions exclusively in the hands of a group of experts. It has to be a collaborative venture. But decisions about medical necessity have always had a public component. Fewer than 50% of patients actually follow the medical regimen they are prescribed from start to finish. Patients are making decisions about what is medically necessary on a regular basis.

The real meaning of medically necessary or necessary services depends a lot upon the goals of the health care system. At the moment in this country, there is no consensus on what those goals are. Canadians need to develop some sort of consensus on these goals, which run from prevention right through to palliative care, in order to set a policy framework within which we can decide what medically necessary or necessary services we actually need. This debate must involve both health experts and the public to ensure that value issues are not marginalized by scientific evidence.

In all our attempts to improve the health care system, we tend to become fixated on the delivery of medical services, on efficiency, effectiveness, and the control of costs. This approach will not result in any great improvements in the health care system. We need to begin to think outside our traditional boxes and therefore I go back to the primary objective of Canadian health care policy as stated in the Canada Health Act in 1984. I quote, “to protect, promote, and restore the physical and mental wellbeing of residents of Canada; to facilitate reasonable access to health services without financial or other barriers.”

The longest paragraph in the preamble of the Act espouses the benefits of prevention, but the Act is silent on the services that would be necessary to achieve prevention. Protection, to me, implies prevention, and medical science has been extremely effective when coupled with environmental protection in the effort to bring communicable diseases under control and protect the population. However, our epidemics today in Canada are not communicable diseases. They are non-communicable diseases or chronic diseases whose causes are strongly entrenched in social conditions and human behaviour. The health care system has a moral obligation to address primary prevention, which is the prevention of disease in the first instance. We know that a considerable portion of medical services could be rendered medically unnecessary if we focused on prevention. We could reduce premature death and disease rates for heart disease, type II diabetes, chronic obstructive pulmonary disease, and several cancers by anywhere from 20% to more than 50%.

We need to take the lessons we learned from conquering communicable diseases and apply them now to non-communicable diseases. Prevention and treatment are not in competition. They are or should be complementary and integrated across settings, sectors, and stages of life. Prevention with respect to non-communicable diseases focuses on communities rather than individuals and hospitals. It involves partnerships, collaborations with multiple sectors, as well as health care professionals. The evidence in support of prevention is there. What is missing are the partnerships and the funding required to make prevention accessible to the population. In Manitoba, a unique partnership is forming between multiple sectors of government, regional health authorities, the private sector, and non-governmental organizations. One NGO Alliance called the Alliance for the Prevention of Chronic Disease, is inspiring the partners to look at
ways to address prevention in an integrated manner across the continuum of care. And this canbe done at the ground level for between $2 -3 per person annually.

**Presentation by Dr. Nora Lou Roos:**
My family lives in Oregon where 10 years ago they spent a lot of time getting experts together
and trying to rank all kinds of medical procedures to decide whether they should be doing
procedure X on 85-year olds. This reminded me of a procedure that I started studying 20 years
ago in Manitoba, tonsillectomy. When I was a kid, everybody had their tonsils out. I can
remember being told in advance that we would be fed ice cream for the first three days when we
came home. I worked with Paul Handeloff to examine the Manitoba data and see to what extent
kids brought in for tonsillectomy met the standards established by the Academy of Pediatrics.
We found that about 75% of the kids having surgery did not meet those standards.

With this evidence, we might decide that tonsillectomy should be very low on the
necessity list. We could potentially even decide to remove it from the list. But the fact is that
some of the kids receiving tonsillectomies really need them and in this group they are
fundamentally necessary. The patient-physician interface is clearly where these decisions have to
be made.

Experts should contribute to these decisions by evaluating the risks and benefits of
procedures and monitoring their outcomes. We had a perfect example in Manitoba around the
pediatric death problem. There have been very serious concerns around monitoring the outcomes
of the private clinics doing laser eye surgery that are completely unregulated. There are very
serious concerns arising from the study in Vancouver where about 25% of the people coming to
cataract surgery had no benefit from the procedure because they were being operated before they
really had serious eye problems. Many of them ended up with worse vision after surgery than
before.

Experts should also play a role in the waiting list problem. We need to start figuring out
what is a priority, what indications are urgent, emergent, and more elective. The Western
Canadian Waiting List Study has done this systematically for a whole series of procedures. We
need them to help us decide when we need more capacity and when we do not. There is certainly
room to introduce more evidence from experts into our decisions, but not in defining a basket of
services that are medically necessary.

**Panel and audience discussion:**
Discussion was dominated by the need to focus more attention on preventive health measures,
both at the determinants of health level, and in improving risk profiles that contribute so much to
the chronic diseases that require so much care at a later stage. There was some support for Dr.
Harvey’s call to provide dedicated funding for prevention services that are necessary to
protecting and maintaining the health of Canadians. Others felt that this would not address the
access issues patients are preoccupied with today. Josie Sima insisted that Canadian thalassemia
patients were not getting care that was considered essential by international experts. Coverage of
monthly transfusions, drugs, and infusion pumps to administer the drugs varies between
provinces, and some hospitals are now simply asking these patients to go elsewhere.

Ms. Sima brought the prevention discussion closer to the health care system by looking at
rare genetic disorders, such as thalassemia, sickle cell, and cystic fibrosis. “Children born with
one of these diseases will be viewed as burdens on society,” she said. “Preventive investment is
needed to find the carriers of these genes, make them aware they carry a disease, and then let
them make the decision as to whether they will reproduce. When that small investment in prevention is not made, tens of thousands are spent on each patient every year.”

There was much concern about how our system would deal with the chronic diseases that are the eventual outcome of risk profiles that are becoming ever more common. However, this was balanced by evidence of an increase in the healthiness of the population over the past 10 to 15 years. “It is not just that people are living longer, they are living healthier and the improvement in health status is almost the equivalent of wiping out half the cancers which exist,” said Dr. Roos.

Dr. Harvey’s suggestion of a Ministry of Prevention, or, as one audience participant expanded into a Ministry of Screening and Prevention, found some support. These activities were found to be complementary to each other, but involve very different mechanisms than medical care, and require a commitment of dedicated funding. “If we made screening available for everyone and made it part of our universal health system and organized it in a rational way, we might have a major impact on health care costs,” said one participant.

“There is the possibility that screening will become the tail that wags the dog of the medical care system.”-- Richard Gordon, Radiologist at the University of Manitoba

The need for an expert panel that included providers, government, experts, and the public to make decisions about issues such as preventive screening and timing of treatment was mentioned by a number of panelists. But Dr. Roos echoed the majority sentiment when she said it did not make sense to spend a lot of time reviewing procedures with a view to removing them from coverage. “It will not save money and will not bring progress in care,” she concluded.
Course of action #3
The benefit to an individual's health should be used to decide what is medically necessary

Presentation by Janet Davidson:

No, because we do not have any goals for this system. What we have now is a system to support and treat people who are sick. We may well want to move towards a system which is based upon health goals and attempts to improve health. If we really had a goal about supporting better health for Canadians, we would not be debating whether or not to support the tobacco industry.

When people go to their local community health centre, they are dealing with a lot of practitioners who are not physicians -- nurses, nurse practitioners, about physical therapists, dieticians -- who work with them to determine what might be necessary either to support them in their health or to treat them in a particular disease state. So we need to define the spectrum before we can decide what is necessary within that. Is it limited to treatment? Does it include promotion and prevention? What about long-term care, home-care, or public health?

And who are the experts who may be making decisions about what is necessary? We often describe physicians, nurses, researchers and economists as experts. And they have a useful perspective to provide. But patient groups like the Canadian Cancer Society or the Heart and Stroke Foundation know an awful lot more than folks give them credit for, and they need to be more involved in this debate.

Presentation by Josie Sima:

I have an inherited disorder and require blood transfusions on a monthly basis. I have been going to the hospital once a month since I was two and a half. I am now 32. I have not been cured so I will continue to use it next month and the months after that.

Hospitals have changed over the years. I used to be admitted into hospital to get this procedure done. Then they designed an outpatient clinic, which cut costs and eliminated the need for overnight stays. The other major development is a medication that is helping me and my peers to sustain a better quality of life. We were trained in hospital for five days as inpatients to learn how to mix the medication and inject it ourselves, so that we could then administer it ourselves at home. We had hospital support, supplies from hospital, medication covered by the provincial government, but it was our job to do it at home.

The position outlined in the policy paper says that what is medically necessary to best benefit the individual should be decided by the clinician, while I believe it should be decided by doctor and patient together and must consider the patient as part of society, not a lone agent. People using the health care system have families who we support, community organizations we volunteer for, employers we work for. By helping individuals, the health care system is benefitting society as a whole. The less supportive the health care system is, the greater the burden will be on other parts of society.

Another example is in diagnostic tests and waits for specialist appointments. If an individual has early signs of cancer and the cancer develops while they are waiting for more diagnostic tests and an expert, then the person may be untreatable by the time they get to see the health care expert. Then you have a five-year old son who does not have a dad anymore. People are different; their circumstances are different; and even patients who have the same illness will respond differently to treatment.

We need to address the anomalies in the system, the practices and decisions about resources that simply do not make sense, on an individual or a system level. Insulin, for example,
is life-sustaining, it improves health so dramatically that compliance is high. By promoting that compliance and dedication to the medication, an individual is actually “going to prevent himself from getting sicker and ending up in hospital. At the same time, insulin and the supplies necessary to administer insulin are not part of our health care system.

The disaster is when a physician says, “That cancer's too big, we can't take it out. Just make your arrangements and make peace with everything.” Or when my husband at the age of 37 was told he was too old to get his knee operated. Even though, if he could improve his knee, he could also then continue to play hockey and remain healthy, therefore avoiding all sorts of chronic diseases.

Guidelines and best practices exist and will continue to be developed by health care professionals. It would be nice if those other experts, the users, could actually be asked to join in on the discussion from time to time.

Panel and audience discussion:
Discussion strayed into whether the structure of our current system was adequate to provide a full range of services. Some felt that a primary health care system, funded partly through health care and partly through other social programs, could bring us close to a more encompassing, patient-centred system. Others felt our system was adequate and could be expanded on to include more mandates. While some considered that people were dissatisfied with the system, others felt that it was working well and simply needed to find ways to incorporate medical and technological advances.

One audience participant noted how the discussion had strayed and proposed that this was because medically necessary was virtually impossible to define. He suggested that rather than try to head down the road of defining what is medically necessary, we focus on defining when things are medically necessary, such as the 75% of tonsillectomies Dr. Roos referred to. He said that Ontario’s Institute for Clinical and Evaluative Sciences found huge variations in virtually every medical procedure done throughout the province. “We may not know whether the low or the high rates are correct, but we know that one of them is wrong,” he said. “I would like to see us get to a point of defining which patient should be getting a service, not should they get the service but which patient should get the service, and when should they get it.”

There was also objection to the reference to 80% of therapies in medicine, as being “unproven” simply because they have not been subject to randomized controlled trials. It has never been proven in a randomized trial that someone benefits from an appendectomy when they have acute appendicitis. The procedure has been proven by detailed clinical experience over many years. Others, however, felt there was some benefit to examining all procedures, past, present and future, and aligning incentives to encourage effective ones. A clinical trial of bypass surgery in the US led to a dramatic reduction of these surgeries. “When US Medicaid decided they would focus on cardiology instead of surgical interventions and changed the fee schedule to increase those for cardiology and reduce those for cardiac surgery; all of a sudden the volume of activity on cardiology went up and cardiac surgery went down,” said Dr. Roos.

Conclusions:
The proposal to have the Canada Health Act include an explicit definition of medically necessary received no support whatsoever from participants. Roberta Chernomas felt that the attempt to define medically necessary was prompted by the idea that health care spending was out of control. He cited decreases in hospital and physician costs over the past 10-20 years as evidence
that sector which are under the control of the system are not spiraling upwards. He pointed to
drug expenditures as a major problem, because they fall outside system control but must be paid
for, in part, by the system. Revenues for health care were, however, spiraling downwards
through progressive tax cuts. He concluded that the discussion of medically necessary was itself
unnecessary.

Dr. Suni Patel distinguished between medically necessary services, which were decided
at the physician-patient interface, and core services, which were decided by system
administrators. He called for an expansion of core services through mechanisms that would be
continuous, inclusive and transparent, not restricted to government. He felt that where the federal
government needed to play a much stronger role was in outlining what Canadians should expect
from medicare as a way to reduce the inconsistencies in coverage between provinces in areas
outside physician and hospital services.

There was slightly more support for having a panel of experts involved, but this leaned
much more toward effective ongoing technology assessment than defining specific lists of
services. However, the presentations and discussions were dominated by the idea that prevention
was an essential part of our system and was completely left out of current definitions. Dr. Harvey
felt we could render many services medically unnecessary if we focused on prevention.

Dr. Nora Lou Roos felt that the real role for experts was in evaluating the risks and
benefits of procedures, monitoring health outcomes, and establishing sound waiting guidelines.
That would prevent unnecessary risk as well as unnecessary spending in health care. She felt
there was little to gain in the cutting services game.

The third course of action also received little direct endorsement. Janet Davidson focused
on the need to define the goals of our health care system, and realign them to include attempts to
improve health as well as support and treat sick people. Josie Sima felt that deciding what is
medically necessary must be done by patient and physician together. She also wanted the
inconsistencies and anomalies in the system to be worked out.

There was a suggestion to replace the WHAT is medically necessary by WHEN is it
medically necessary, in order to deal with individual patients and situations. Another suggestion,
given the preoccupation with prevention evident in the entire session, was to entrench screening
and prevention in their own Ministry with dedicated funding to ensure that these were dealt with,
though not in competition with the treatment mandate of the health care system.