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Influences on the "Health Care Technology Cost-Driver"

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Contents

Highlights

- Technological change in the health care sector will be influenced by many factors in the coming decades; most important among the determinants of the utilization of technology will be genetic sciences (specifically genetic testing), demographic changes, and consumer-directed marketing.
- Progress made in health care technologies over the coming decade will be important, but incremental, when measured in terms of improved population health.
- Technological changes in health care will not be independent of demographic changes, especially the aging of the baby boomer cohort.
- Increased consumer-oriented promotion of new technologies will be a major determinant of changes in the utilization of both new and old technologies in the coming years.
- Predictive genetic testing may become a major cost-driver in the health care system in the coming decades. Products such as pharmaceuticals, and services such as diagnostic imaging, that are sold on the basis of genetic test results may account for a majority of the associated costs.
- Continued upward trends in both the cost and utilization of drug treatments will make pharmaceuticals one of the fastest growing components of health care in the next decade.
- To ensure that technologies are adopted prudently, health care policy should aim not only to evaluate the efficacy and cost-effectiveness of technologies, but also to influence the decisions of thousands of providers in millions of clinical encounters.
- If Canadian policy makers wish to better control the inflationary pressures created by health care technologies, substantial reform in the organization and funding of health care services is needed.

Executive Summary

Technological change will consist not only of *innovation* – the arrival of new products and techniques – but also of changes in the *utilization* of both new and old technologies in the coming decades. Progress made in terms of innovative health care technologies will be important but incremental in terms of improvements in population health. Major "breakthrough" innovations may occur, but they are impossible to predict.

Both the direction of technological innovation and changes in the utilization of technologies will be driven in part by three overarching influences: demographic change, genetic sciences, and consumer-directed marketing of health technologies.

The baby boomers' expected demand for health care goods and services changes the financial incentives that guide research efforts in bio-medical sciences; consequently, technological changes in health care will not be independent of demographic changes. The cost impact of this relationship may be significant given the investment in technologies to address the needs of the elderly, the number of individuals in the baby boomer cohort, and the expectations that baby boomers will carry into their senior years.

Although unquestionably a revolution in thinking about the mechanisms of illness, the impact of genomic sciences on population health will be incremental over the next decade. The ability to identify individuals at elevated risk of illness will (necessarily) outpace the ability to "treat" the related genetic anomalies. Moreover, the complexity of biologic systems dictate that the logical search for "cures" to genetic disorders will be a long and laborious one.

In the coming decade, the cost of genetic testing services and the goods and services sold on testing results may become a major cost-driver in the health care system. The bulk of the related expenses may not be the price of the tests themselves, but rather the cost of the products and services that accompany the testing process and that are sold on the basis of test results. Such complementary services include the consultations with health professionals that may proceed and follow testing, as well as ongoing consumption of products and services for the purposes of disease surveillance or prevention. Expanded use of diagnostic imaging will be particularly focused on individuals at high risk of illness, for which diagnostic and surveillance costs can be justified.

Continued upward trends in both the cost and utilization of drug treatments in major therapeutic classes such as cardiovascular medicines will cause pharmaceuticals to be one of the fastest growing components of health care costs in the coming decade. Important determinants of pharmaceutical expenditure will come from increased "consumer oriented" marketing activities, and on the promotion of pharmaceutical disease management for risks of late-onset illnesses detected by genetic testing.

To reward innovators in a manner that provides incentive for socially valuable research, the price of health care technologies protected by patent should reflect their therapeutic value relative to the existing arsenal of health technologies – both new and old. Moreover, efficient incentives for future innovation also require health care technologies to be used only when appropriate and cost effective. Unlike the case for ordinary goods and services, relying exclusively on consumers' willingness to pay for health care technologies is neither a reasonable

means of establishing a fair price nor an acceptable means of allocating technologies amongst individuals. Health care technologies require expert evaluation and critical assessment, balanced and accurate information for both practitioners and patients, and tailored institutional structures to provide incentives for efficient and equitable allocation decisions.

Through continued, if not more rigorous, technology assessment and evaluation, Canada will be able to negotiate prices to some extent, but the agreed upon prices will likely have to fall within a narrow "price corridor" established by international pricing precedents. Once prices are set, the appropriate and cost-effective allocation of technologies will depend, in part, on how technologies are chosen for individual patients.

To ensure that technologies are adopted prudently, policy should aim to influence the decisions of thousands of providers in millions of clinical encounters. Ultimately, efficient allocation of health care technologies will depend on providing proper information and incentives at the point of the clinical encounter. The essential utilization decisions take place at that time. Consequently, if Canadian policy makers wish to better control the inflationary pressures created by health care technologies, substantial reform in the organization and funding of health care services is needed.

Introduction

"Prediction is very difficult, especially if it's about the future." Nils Bohr

When asked about the importance of technological change to the future of the health care sector, economists might turn to the markets for answers. The message found there is clear, summarized in a recent headline from the business section of the *The New York Times*: "this decade belongs to health care" (Munger Kahn 2002). Average price earnings ratios in high-tech health sectors are currently about twice as high as those in other industries, indicating that investors believe that health technologies are poised to pay big dividends in the near future. These beliefs are no doubt fueled by the highly publicized enthusiasm over medical technology in the 21st century. "Health Technology" is a regular feature in the daily news, particularly in the financial press, where a steady stream of featured breakthroughs promises to change the medical landscape, the health of the population, the financial fortunes of one firm or another, and the future cost of health care.

The recent burst of the e-commerce "bubble" should give one pause when considering economic forecasts based on stock market activity. There are, however, good reasons to believe that health expenditures will be significantly influenced by "technological change" in the coming decades. This technological change will consist of *innovation* and *utilization*. Innovation is the arrival of new products and techniques; it is the flow of new ideas into the stock of available technology. Utilization concerns how both new and old technologies are used in our health care system; it is what is done with the stock of available technology. In this paper, we argue that both technological innovation and utilization will be driven by the following three overarching influences in the coming ten to twenty years: demographic change, genetic sciences, and consumer-directed marketing. We review expert opinions regarding likely innovation in selected components of the health care sector and relate these trends to the overarching influences of aging, genetics, and marketing. Following this, we discuss the "pricing" of health care technologies, highlighting apparent tensions between the incentives created by patents and the desire to regulate health care prices. We then examine issues in the evaluation and allocation of health technologies that are central to achieving efficient utilization of both new and old technologies. We conclude with recommendations as to how various levels of government can work to create the institutional structures necessary to achieve that end.

Future Technological Change in Health Care

"I have seen the future and it is very much like the present, only longer." Kehlog Albran

In past eras of profound change in basic scientific understanding, revolutions in the health of populations and the practice of medicine have not materialized as rapidly as experts predicted (Porter 2000). Consequently, the safest prediction for health care technology in the coming decade is that progress will also be incremental – *important* but incremental nonetheless if progress is measured in terms of improvements in population health. This is because technological progress generally moves in a logical sequence. Most new ideas, products, and techniques tend to build incrementally and somewhat predictably on existing ones. Breakthroughs will occur, but their nature and magnitude are virtually impossible to forecast. Indeed, anyone who could foretell a specific technology that would dramatically improve population health in the near future would be very rich.

While dramatic shocks are almost impossible to predict, changes in the tides of technological progress may be foreseen if forces that influence the direction of scientific inquiry are known to be shifting. Moreover, changes in the rate at which existing technologies are used or new technologies adopted may also be predicted if related and identifiable trends could also be foreseen. In this regard, three major factors that will influence trends in technological innovation and utilization over the coming decade are demographic change, genetic sciences, and consumer-directed marketing of health technologies. Health care planning can (and should) adapt to these reasonably predicable influences – while remaining prepared for unexpected shocks in health care technology.

Technology and the Baby Boomers

Born between 1946 and 1965 in North America (and other developed countries), members of the baby boomer generation are just now entering their years of high health care utilization. The impact that these baby boomers will have on health care costs will not be independent of the availability, cost, and utilization of health care technology. Nor will the availability, cost, and utilization of health care technology be independent of the baby boomers' aging.

The total cost impact of population aging is a function of both changes in average health care needs as the population ages, *and* changes in the quantity, type, and cost of technologies used to meet those needs. When the latter factors are held constant, the needs-related impact of population aging has been a modest cost-driver in recent decades (Fuchs 1984; Barer, Evans et al. 1987; Barer, Evans et al. 1995; Evans, McGrail et al. 2001). It is likely to continue to be a modest contributor to health care costs in the coming decades. However, historical experience suggests changes in the availability, utilization, and price of technologies to meet the needs of the elderly population will be important determinants of the cost-impact of population aging (Evans, McGrail et al. 2001).

Health technology innovation and utilization are related to demographic change because the health care "market" is changing dramatically as the baby boomer generation ages. The changes in the age-related needs of baby boomers increase the financial incentives that guide

efforts for both the development and the promotion of health care technologies. Bringing to market products that can be expected to be in demand by aging baby boomers is good business. "That's where the money is." Baby boomers are not only larger in number than other generations, they are also more affluent and independent than previous cohorts of elderly health care consumers, and they bring to the health care marketplace relatively high expectations about healthy aging and consumer-oriented health care (Clark 1998; Dychtwald 1999).

Significant investment has already been made to develop forms of technology that are likely to be in high demand by the baby boomer generation. Almost two thirds of drugs currently in development by American pharmaceutical manufacturers are intended to "lengthen and improve the quality of life for seniors" (PhRMA 2001a). Therapeutic "markets" currently experiencing rapid growth due to the boomer generation include treatments for hypertension, type II diabetes, high cholesterol, and arthritis pain (Scott-Levin 2001).

Consumer-Oriented Means of Promoting Technological Change

Some believe that increases in the consumer-orientation of health care may be one of the most significant challenges of health care in the coming years (Porter 2000). This shift is driven in part by the advent of new health technologies addressing needs that go beyond the conventional definitions of "health care" and "disease" (Moynihan, Heath et al. 2002; Smith 2002), and in part by a combination of increased affluence and increased access to information that has engendered higher expectations among health care consumers. It is also driven by changes in health care marketing practices, aimed at capitalizing on notions of "consumer empowerment" and "patient centered" health care (Mintzes 2002; Mintzes, Barer et al. 2002).

Health care technologies have traditionally been promoted through marketing activities aimed at health professionals who make allocation decisions on behalf of, and in consultation with, patients. However, recent changes in the marketplace have caused companies – pharmaceutical manufacturers, in particular – to seek new means of promoting sales by marketing directly to consumers, in addition to conventional professional-directed marketing activities. Perhaps most notably, increased emphasis on expenditure controls by managed care organizations (in the US) and governments (elsewhere) appears to have forced manufacturers to seek audience with patients in order to promote the sale of particular brands (Pinto, Pinto et al. 1998; Morgan 2002a). A recent paper commissioned by Pfizer Inc. appears to confirm this by portraying consumer directed advertising as a necessary means of countering unduly restrictive policies imposed by insurance providers (Rubin and Schrag 1999).

While most forms of direct-to-consumer advertising for prescription – drugs are illegal in all but two countries – the United States and New Zealand – the trend toward consumer-oriented marketing is unmistakable (Mintzes 2002; Morgan 2002a; Rosenthal, Berndt et al. 2002). A watershed in this trend came in 1997, when the US Food and Drug Administration relaxed restrictions on television and radio advertisements. This opened the door to an explosion in promotional activities aimed at US consumers that now approaches $3 billion per year – much of which is viewed by Canadians, though these marketing practices remain illegal here (Mintzes, Barer et al. 2002). Pharmaceutical manufacturers are lobbying for the opportunity to advertise to consumers in other countries, including Canada. Companies holding patents on predictive genetic tests will not be far behind.

The consumer-orientation of health care marketing will be a significant factor in determining changes in the utilization of health care technologies in the coming decades. There will undoubtedly be an increase in the use of those technologies most heavily promoted directly to consumers: if this were not the case, firms would not engage in such marketing practices.

Health Technology in the Genomic Era

While human genetics have been studied for some time, the complete mapping of the human genome is said to have launched "the era of post-genomic science" in which many claim that virtually all aspects of medicine will change (Baltimore 2001; Collins and Guttmacher 2001; Collins and McKusick 2001). The promise of this new era is far reaching. When leading scientists were recently asked to report on the prospects of medical research in the twenty-first century, genetics was cited as central to developments in the treatment of most diseases – including cancer (Livingston and Shivdasani 2001), cardiovascular illnesses (Lefkowitz and Willerson 2001), neurological and psychiatric illnesses (Cowan and Kandel 2001), diabetes (Olefsky 2001), and autoimmune diseases (Koopman 2001). Genetic information was also cited as a major impetus for advances in diagnostic imaging (Tempany and McNeil 2001), and pharmacologic and biologic therapy (Bumol and Watanabe 2001; Kaji and Leiden 2001).

The Holy Grail in the genetic era of health care are products that will make it possible for "Physicians […] not only to use therapies to help patients live better with their genetic constitutions, but also [to] use novel therapies to alter the genetic makeup of the patient" (Kaji and Leiden 2001). Despite the high expectations of many involved (or invested) in the race for such discoveries, radical genomic therapies will not appear on our markets, or in our health care systems, within the next decade.

Innovations will occur, but they are likely to come gradually. As the genes and proteins related to more illnesses are identified, the amount of genetic "data" is increasing dramatically; the task of turning that data into useful information, and ultimately useful treatments, will be one that takes decades. For example, the list of potential targets for drug therapy is expected to balloon from the 500 biological receptors currently targeted by conventional pharmacological therapy to as many as 30,000 targets for bio-pharmaceuticals and genetic therapies (Drews 2000; Horrobin 2000; Bumol and Watanabe 2001; Lemonick 2001). It has been questioned whether this impressive gain in "data" has been a case of finding more needles or bigger haystacks (Horrobin 2000).

Even when the genetic origins of illnesses are known, "cures" are hard to find. The genes that cause single-gene disorders such as sickle cell disease, cystic fibrosis and muscular dystrophy have long been known; yet, no cures have been found for them (Baird 2002). As we look to detect the genetic causes of and find cures for common illnesses, the complexity of the problem increases substantially. Most common illnesses are caused by such a complex combination of environmental and multiple genetic factors that few (if any) could be fairly regarded as "genetic disorders" (Baird 2002). The number of genes with links to illness, and the complexity of the biological systems in which they play out, create analytic challenges so immense that "bio-informatics" has emerged as a new sub-discipline of computer science to aid in the analysis of related data (Pennisi 2001). In January 2000, for example, IBM launched a 5-year, $100 million dollar project to develop supercomputers to be dedicated to bimolecular simulation (IBM 1999). These developments portend the kind of obstacles that must be

overcome to convert the massive amounts of data being generated into useful information and, ultimately, "gene therapies."

Though correcting genetic disorders remains science fiction, the information elucidated from genomic research has led to productive pharmaceutical research activity. Researchers are using genetic information about diseased and cancerous cells to find biotechnological "magic bullets" – products that attack the target cells without harming healthy tissues (Drews 2000; Horrobin 2000; Bumol and Watanabe 2001). While the number of such "biotech" products currently on the market is modest, there are an impressive number in clinical testing today; biotech drugs account for approximately one third of drugs currently in clinical testing (PhRMA 2001b). Some therapeutic breakthroughs are expected from these biological products, particularly in the area of cancer treatment – which accounts for half of such products under development today.

Genetic Testing

Among genetic technologies, genetic testing will likely have the most profound influence on health care in the coming decades. While genetic testing has long been used to predict the health of future generations (through prenatal genetic testing and carrier screening), the genetic tests that now capture the imagination of patients, providers, and investors are those that can predict the living generation's future health status (Miller, Hurley et al. 2002). This form of genetic testing has recently been referred to as "medicine's new gold mine," as firms search massive databases of genetic information to discover and patent tests for genotypes that are correlated (however strongly) with illness (Herper 2001).

Though the genetic origins of common diseases are not currently well understood today (Baird 2000; Evans, Skrzynia et al. 2001), some leading genetic researchers predict that risk factor tests for as many as a dozen common illnesses – such as diabetes, cancer, and heart disease – will be available within a decade (Collins and McKusick 2001). This could result in increased utilization of genetic testing due to increased breadth of applicability. The total impact on health care costs stemming from predictive testing may, however, far exceed the cost of the tests themselves. The total cost impact will depend on changes in health behaviours induced by the testing process and its results (Miller, Hurley et al. 2002).

Several cost components must be considered, including the cost of the tests, and the impact the test results have on the use of disease surveillance, prevention, and treatment services. Because of the complexity of gene-environment interactions, and the profundity of certain test results, it is strongly advocated that genetic testing should only be available under supervision, and only following adequate genetic counseling about the strengths and weaknesses of a given test (Caulfield 1999; Emery and Hayflick 2001; Baird 2002). Once a test is administered, both positive and negative test results may induce changes in health care seeking behaviours. Some of these changes may result in lower health care costs; others may be cost increasing. With the benefit of hindsight, some of these changes might be regarded as useful, others wasteful; the balance depends on the ultimate predictive power of the test (Miller, Hurley et al. 2002).

Pharmaceuticals

Pharmaceuticals will be one of the biggest health care cost-drivers in the coming decade. Drugs have been one of the fastest growing components of health expenditures in recent decades,

and current predictions are for continued double-digit growth in prescription drug expenditures for North America until at least 2005 (IMS 2002b). At these rates of growth, prescription drug expenditures can be expected to double in 5 to 7 years.

Pharmaceutical expenditure growth observed in recent years has not been due to a dramatic increase in drug discovery (Drews 1998). Drug expenditures have largely been driven by increases in both the cost of and exposure to treatments in established therapeutic classes (Dubois, Chawla et al. 2000; CIHI 2001; Morgan 2002b). Both expansion of and cost escalation within therapeutic categories are long-standing trends in the pharmaceutical industry, and have often been due to the intensive promotion of new products that offer (at best) incremental improvements over existing therapies (Canada and Canada 1963; Temin 1980; Morgan 2001). This pattern is likely to continue, as utilization of newer, patented products is increasingly driven by direct-to-consumer advertising (Rizzo 1999; Mintzes, Barer et al. 2002; Morgan 2002a).

As mentioned above, the effects of aging baby boomers will, in and of itself, boost demand in several drug segments – including diabetes, hypertension, arthritis, heart disease, depression, certain cancers, and eventually Alzheimer's and other dementias. Investment in pharmaceutical responded to this long ago, and now many products are about to be launched in major therapeutic classes for adult-onset diseases, including anti-hypertensives, statins (lipid lowering drugs), insulins (diabetes), anti-ulcer drugs, and drugs for arthritis pain relief (CCOHTA 2001; PhRMA 2001a; PhRMA 2001b). Most of these products will offer some improvement – often for particular types of patient – over current therapies (CCOHTA 2001). If history is a guide, these entrants will likely achieve wide application through intense promotion (Canada and Canada 1963; Temin 1980; Morgan 1998).

Pharmacogenomics to Tailor Drug Therapy

"Pharmacogenomics," the screening of patients for genes that predict the capacity to benefit from or be harmed by pharmaceuticals, is expected to become more common in the next decade (Phillips, Veenstra et al. 2001; IMS 2002a). Because certain genotypes metabolize drugs differently than others, it may be possible to screen patients to avoid adverse reactions or to select a customized therapy. In the near term, genetic information will most likely be used to reduce adverse reactions among populations taking costly and potent medicines, such as those for the treatment of HIV/AIDS and cancer (Phillips, Veenstra et al. 2001). Manufacturers of products with known relationships between genes and adverse reactions may find commercial advantage in advocating that patient candidates be screened before administering premium priced drugs (IMS 2002a).

Genetic information is now being used to screen patients in the early stages of clinical testing, so that only suitable patients are administered a product during clinical trials, as a means of reducing the cost of bringing products to market (Wallace 2000). When pharmaceutical products are marketed for the treatment of diseases and risk factors identified by specific genotypes, the individual cost of treatment will be substantially higher than conventional therapies. This will be due, in part, to the fact that the value of treatments will increase if customization leads to more certain outcomes. Pressure to place a high price on such therapies will also result from the fact that, to the extent that genotype specificity reduces that potential market size for each customized treatment brought to market, a greater share of the research costs must be born by each user (Drews 1998; Danzon and Towse 2000; Bumol and Watanabe 2001; IMS 2002a).

Pharmacogenomics to Expand Markets

Genetic testing can be used to expand markets for new and existing products, and manufacturers of some products in testing today are expected to seek approval for use to treat genetically identified risk factors (Herper 2002). In particular, genetic testing for common, late-onset diseases has the potential to add substantially to the demand for existing and evolving models of pharmacologic disease management. It is known that the uptake of genetic testing services depends on the test, the context, and patients' perceptions of the value of interventions that follow the results (Marteau and Croyle 1998). Much of the perceived benefit from testing will depend on sources of information regarding the value of tests and complementary preventative care or treatment. Consumer-directed advertising will play a major role in this regard. Both testing service operators – potentially dominated by multinational patent-holding firms – and the providers of preventative therapies will seek to be heard not just by clinicians and genetic counselors, but also by patients.

In the near future, it is likely that treatments used in the management of genetically identified risks will be newer generations of established pharmacologic models. Treatment modalities now used in the management of non-genetically identified hypertension and high cholesterol, for example, may find expanded markets in populations identified as being at risk for elevated blood pressure or cholesterol. Evaluating the clinical utility and economic benefit of treatments used to manage genetic risks of late-onset disorders will require years, in some cases decades, due to the delay between treatment and expected health benefits. Treatments used to manage biological factors associated with the risk of later illness – such as blood pressure or cholesterol levels – have historically been approved based on changes in the biological marker as a surrogate (albeit an imperfect one) of their impact on long-term health. It is yet unknown whether such surrogates will apply to risks of a genetic origin. This may force radical changes in evaluation methods, clinical trials, or even patent length in order to be certain that neither significant finances nor lives are wasted while the world experiments with unproven therapies. If treatments are approved on the conjecture of long-term benefits (a possibility made real by limited patent length), the health care system may bear substantial costs while waiting for evidence of benefits.

Surgical Procedures

Commentators appear to be relatively modest when making predictions about the scale of revolution in the surgical theatre (Mack 2001). Trends in surgery are moving toward less and less invasive procedures, using robotic assistance and other techniques to build on progress made in laparoscopic procedures over the past 20 years (Darzi and Mackay 2002). These changes will result in faster recovery times, fewer complications, and therefore a broader pool of candidate patients. The fixed cost of machinery involved in such procedures is just one of two important cost considerations for health care systems. The most important cost consideration will be the scale and scope of procedures conducted when infrastructure is in place. For, the now-50-something baby boomers create a growing "market" for technologies related to cardiovascular and orthopedic surgical procedures (Boskey 2001; Lefkowitz and Willerson 2001; Hench and Polak 2002; Marshall 2002).

Diagnostic Imaging

Technological advances in diagnostic imaging are expected to come from refinements to and newer applications of existing imaging formats such as computed tomography (CT) scanning, magnetic resonance imaging (MRI), and positron emission tomography (PET) (Tempany and McNeil 2001). The biggest financial consequences of technological change in imaging in the coming decades will come from increased utilization of imaging-based screening technologies. Diagnostic imaging will increasingly be used to monitor individuals at high risk of illness, for which ongoing diagnostic and surveillance costs might be justified. The largest potential growth in candidates for such surveillance will stem from the identification of people at risk of cancers and other illnesses by means of their genetic makeup – e.g., women diagnosed with the BRAC1-2 gene associated with early-onset breast cancer (Tempany and McNeil 2001). Like the genetic testing itself, diagnostic imaging must be rationalized by validity of the information it generates and the clinical utility of interventions that follow. The need for assessment is formidable: for example, despite the use of PET for over thirty years, evaluations of PET scanning are scarce, making it difficult to draw many conclusions about the cost-effectiveness of its use in Canada (ICES 2001).

Technology in Summary

The cost-impact of health care technology in the coming decade will be driven not solely by the discovery of new products, devices, or procedures, but also by changes in the utilization of both new and old technologies. These changes in utilization will only partially be driven by the "natural" increases in needs as the population ages. Major determinants of the utilization of health care technologies – pharmaceuticals and diagnostic imaging in particular – will come from increases in the demand for services induced by testing for genetic risk factors associated with common illnesses, and to a substantial extent by the demand for new technologies that are promoted directly to patients.

Pricing Health Care Goods and Services

Internationally, a great deal of attention has been paid to the pricing of health care technologies, pharmaceutical prices in particular (Andersson 1993; Monaghan and Monaghan 1996; Danzon and Kim 1998; Towse 1998; Berndt 2000; Calfee 2000; Danzon and Chao 2000). Purchasers of health care bemoan the high cost of new products, while providers lament the cost of product development. What is the right price for medical technology?

From an economic perspective, the right price is typically that which is equal to the marginal cost of production. This is the price that prevails in a perfectly competitive market, wherein free-entry ensures that producers earn no more than a fair profit. A market outcome is said to "fail" when the prevailing price does not equal the marginal cost of production. Such failures often provoke calls for price regulation.

Price regulation cannot always mimic that which would result in a competitive market, nor would we necessarily want it to. Marginal cost pricing cannot be sustained in industries where there are high fixed costs of production, including fixed costs of research and development. In such industries, the regulated firm would operate at a loss if it could not charge a price that exceeds the marginal cost of production. The loss would be equal to the fixed costs associated with setting up operations. Where they exist, then, price regulations typically attempt to keep prices as near as possible to the *average cost* of production, including fixed costs.

Should the prices of health care technologies be regulated such that they equal the average cost of production, including the fixed costs of research and development? No.

The price of patented health care technologies should be equal to the benefit that it creates for the health care system relative to all alternative technologies, including those competitively supplied at marginal cost. This price may bear little or no relationship to production costs, or to the costs of research and development. Nor should it.

The purpose of a patent is to provide incentive to innovate. A patent creates a temporary monopoly over the sale of an innovative product or process by prohibiting the unlicensed entry of competitors. If an innovator was not protected from competition, other firms could enter the market and bid prices down to marginal cost. To the extent that potential innovators could expect this to happen, they would have no incentive to pay for the research necessary to innovate in the first place. Allowing prices above marginal cost – during the period of the patent – is the purpose of patents.

But markets do not guarantee that a patent holder will recoup the cost of research investment, nor do they limit the return to the cost of research investment. The market mechanism regulates the value of the monopoly conferred upon patent holders such that the reward for innovation is proportionate to consumers' willingness to pay for the patented product or service. If a patented product is of little value to consumers, the market may not support sufficient sales at a sufficient markup to recoup investment. This should be of no concern to consumers or governments. Firms that gamble sometimes lose. On the other hand, firms that gamble sometimes win.

There is no requirement that a patent holder will charge a price that reflects average costs if the market will support much more. Patentees may charge much higher prices and earn large profits. This, too, should not be a concern to consumers or governments. If prices were held equal to that which covers the cost of production and research, there would be no more incentive for innovations of high value than for ones of little or no value. Moreover, if allowable prices were related to the research expenses on a company's books, there would be incentive for inefficiencies in the research process or "creative accounting" about what constitutes the cost of developing a product – we already observe much of the latter for the purposes of public relations and political lobbying (Young and Surrusco 2001).

The important question to ask is whether patented health care technologies are being rewarded in a manner that provides incentive for research of the greatest value to society as a whole. This would require that the price of health care technologies protected by patent should reflect their therapeutic value relative to the existing arsenal of health technologies – both new and old. Unlike ordinary goods and services, for which consumers' willingness to pay for a product might reasonably approximate its social value, determining the value of health technologies will require expert evaluation and critical assessment (Evans 1984; Rice 1998). The "purchaser" of health technologies – typically the health care funder – must therefore engage in the tasks of clinical evaluation and economic assessment when determining what is a reasonable price – their willingness-to-pay, so to speak. This is discussed further below.

The opportunity to set prices according to domestic goals and evaluations of technologies is decreasing with the internationalization of the price of health technologies, especially pharmaceuticals (Towse 1998; Jacobzone 2000; Willison, Wiktorowicz et al. 2001). While price discrimination does occur on the international market, reduced prices are increasingly attained through hidden discounts or disguised through price-volume agreements. Through continued, if not more rigorous, technology assessment and evaluation, Canada may be able to negotiate prices to some extent, but the agreed upon prices will likely have to fall within a narrow "price corridor" established by international pricing precedents. Once prices are set, the appropriate and cost-effective allocation of technologies will depend, in part, on how technologies are chosen for individual patients.

From a societal point of view, creating efficient incentives for future innovation in health care also requires the creation of an environment in which firms expect to be able to sell their technologies only to those for whom the technology is appropriate and cost-effective. To do this, the system for allocating health care technologies must ensure that utilization is appropriate. It is nonsensical to overuse health technologies, or to rely excessively on newer, more costly ones, in the name of promoting innovation for tomorrow. Doing so provides all the wrong incentives. Once again, health care is unlike ordinary goods and services for which consumers' willingness to pay for a product might serve as a reasonable rationing mechanism. Allocating health technologies may require other forms of rationing. This is also discussed further below.

Technology Assessment and Economic Evaluation

Technology assessment and economic evaluation are tools that may be used, among other purposes, to inform decisions regarding the use of new and existing technologies in clinical settings, to inform priority-setting activities at local and regional levels, and to ration technologies at state or national levels. Each form of assessment involves a systematic attempt to collect and analyze data regarding the consequences and the costs of using a technology. Narrowly defined, "health technology assessment" concerns the former, the evaluation of the consequences stemming from the use of a medical device, product, or technique. Consequences are measured in various ways, including clinical safety and efficacy – that which has been established in the controlled setting of a clinical trial – as well as "real-world" safety and effectiveness. "Economic evaluations" are systematic and comparative evaluations of both costs and consequences (Drummond, O'Brien et al. 1997).

If used to inform priority setting, it is essential to separate evidence from anecdote, and to minimize bias that might stem from assessments conducted at the behest of the health technology industry (Morgan, Barer et al. 2000). Given that at best half of health care technologies have been evaluated for effectiveness, and less for efficiency, formal technology assessment and economic evaluations are used only to a limited extent in the practice of health system priority setting (Hurley, Birch et al. 1997; Robinson 1999; Ham and Coulter 2001). They can play an important role in price negotiations and in certain gate-keeping functions, such as formulary decisions, but play less of a role in day-to-day allocation decisions.

Allocation Decisions

Allocation decisions in health care generally come in two broad forms. Whether based on formal assessment tools or other processes, decisions are often made as to whether to approve the use of a technology in a given setting – a discrete interpretation, either yes or no. After this, decisions are then made about how and under what conditions a technology is used. Much has been written on the use of formal technology assessment in the related areas of coverage decision-making and priority setting, tasks for which assessment takes a discrete – "covered" or "not covered" – approach to assessment. In practice, however, perhaps the more important element in the allocation of health technologies involves decisions made by, or on behalf of, particular patients.

In Canada, assessment issues have typically tended to be framed in terms of coverage decisions with respect to either provincial fee schedules or drug formularies. This framing invites a yes/no discrete decision concerning technologies with potentially broad application. Indeed, this is exactly how de-listing (de-insurance) exercises are framed as a problem of things being in the fee schedule/formulary that should not be. This has led to calls for explicit definitions of medical necessity so that we can make such determinations.

The challenge for coverage decisions is to make a one-time decision wherein good things are covered, and bad things are not. Many technology assessment frameworks set out an algorithm for making such decisions (Deber, Ross et al. 1994; Evans, Barer et al. 1994; Deber, Narine et al. 1997). The most thorough of these processes for identifying the bounds of legitimate coverage aim to meet standards of explicitness, rationality, relevance, and

accountability. Theoretically, after such processes have been used to render coverage decisions, the system may go about operations as usual within the envelope of things that are covered.

There are a number of problems with framing priority setting in this discrete way. First, very few health care technologies are ineffective/inefficient in all circumstances or effective/efficient in all circumstances. Hence, discrete, the yes/no decision criteria for coverage are too blunt. When applied they often result in the broad utilization of technologies appropriate only under defined circumstances, or the blanket denial of access to technologies that are effective in limited circumstances. Therefore, although coverage decisions and the related processes are important in determining ultimate access, traditional applications of broad coverage decisions are too blunt to result in the efficient utilization of available technologies.

This has led to the notion of conditional coverage/access – access to and coverage of technologies only under conditions that render them effective and efficient. Health systems do not necessarily need to be strictly "managed" (as in the practices employed by "managed" care organizations in the US), nor regulated in a top-down fashion in order to make coverage of and access to technologies conditional on appropriateness. However, when adequate information, opportunities, and incentives are given to those taking part in micro-level decision-making, technological adoption may be efficiently rationed from the bottom up.

The information necessary to make judgements regarding whether a health care service or technology is effective and efficient often arises only during a clinical encounter. It is at this point of exchange that information about signs, symptoms, and personal circumstances (including attitudes toward risks and outcomes related to treatments) is revealed. While additional information essential to appropriate rationing – including medical history and evidence about costs and benefits of alternative treatments – may be made available at the point of the clinical encounter, information uniquely accessible to the clinician cannot always be centralized. The lack of this requisite information explains, in part, the failure of top-down strategies for managing health technologies.

Attempts to centralize the approval process and use of inflexible, blunt rules are precisely the aspects of formal managed care that most rile physicians and patients and that are responsible for the backlash against managed care in the US. To ensure that services/technologies are adopted/used prudently, policy might aim to influence the decisions of thousands of providers in millions of clinical encounters. When framed in this way (as it has been in Canada), the focus for addressing the underlying problem of resource allocation (coverage decision-making, priority-setting, etc.) shifts from a formal, defined process (whether or not based on technology assessment) to the means of ensuring providers/patients make good choices that reflect system goals. In this case, the mechanisms expand to consider financial and non-financial incentives, professional norms and socialization, the regulation of technology developers and marketers, etc.

Notwithstanding the desire to decentralize incentives and opportunities to ration specific health care services, formal coverage decision-making processes will remain important. Indeed, with technology blurring the boundaries between what is a medical treatment and what is cosmetic or lifestyle therapy, maintaining a formal boundary around the "medical" nature of public health care will only grow more important in the future. The point of the preceding discussion is that it is too often the supposed solution to the resource allocation problem and is simply an explicit process for making discrete coverage decisions.

International Experiences: The Case of Pharmaceuticals

Prescription drugs are probably the most studied form of "new technology cost-driver" in the international literature on health policy. As such, we focus comments here on international approaches to containing the cost of pharmaceuticals. Virtually no country has successfully held back drug expenditure inflation for a sustained period of time (Morgan 1998; Jacobzone 2000; Willison, Wiktorowicz et al. 2001). This is in part because of the complex nature of the cost pressures at hand, and in part because of the inadequacy of the cost-controls that have survived in the political economy of the pharmaceutical industry. Strategies that are most successful in containing costs are met by the strongest resistance from pharmaceutical manufacturers – who, under the threat of reduced profitability, respond with unprecedented lobbying power backed by the threat of decreased local research investment. Examples of policies that were sufficiently successful at cost-containment to meet strong resistance leading to policy discontinuation or ceased expansion include the reference pricing and global drug budget system in Germany and the independent system of product evaluations in Australia (Busse and Wismar 1997; Henry and Birkett 2001).

"Price" is a common target for policy intervention. In most of developed countries, prices are either negotiated between manufacturers and national purchasing or priority-setting bodies, or they are regulated directly (Jacobzone 2000; Willison, Wiktorowicz et al. 2001). Many countries use pharmaco-economic evaluation in their centralized decision-making and price negotiations. In Australia, where it has been applied most rigorously and (until recently) independently, pharmaco-economic valuation of medicines has been successful in reducing the national price of top-selling medicines (Henry and Birkett 2001; Willison, Wiktorowicz et al. 2001). In some countries – and provinces such as Ontario – expenditure caps or price-volume agreements are negotiated with the manufacturers of new products to restrict financial risk for the public payer when demand is uncertain (Braae, McNee et al. 1999; Willison, Wiktorowicz et al. 2001). The effect of these negotiations is to reduce the unit price of a new product if its sales volume exceeds certain limits. Finally, some countries, such as the United Kingdom, regulate profits. Profit regulations result in less strict price regulation per se – a sacrifice made for the sake of negotiated research investment (Towse 1996; Jacobzone 2000).

Price regulations are not sufficient for expenditure control. As mentioned above, negotiations that result in discrete, yes/no decisions at the aggregate level fail to account for the importance of utilization decisions. No drug will be cost effective for all patients at given prices. Typically, a product will be cost-effective in some cases and not in others. Consequently, decisions at the clinical encounter are critical to determining the cost-effectiveness of drug utilization.

Strategies to address utilization have generally focused on blunt policy tools such as co-payments and prescription limits. Most countries resort to user charges of one sort or another as a means of containing costs (Jacobzone 2000; Willison, Wiktorowicz et al. 2001). These policies have the effect of containing public liability, but there is no sign that they show sustained control of total expenditures. Indeed, un-targeted co-payments and co-insurance has been shown to increase overall health system costs, since patients reduce both essential and non-essential drug use in the face of such charges (Soumerai, Ross-Degnan et al. 1993; Adams, Soumerai et al. 2001; Tamblyn 2001).

More advanced utilization control strategies are those that incorporate information and incentives targeted at the two major partners to prescription drug utilization decisions: patients and physicians. Through the dissemination of unbiased, comparative information about alternative drug treatments, public agencies have been able to temporarily improve the appropriateness of prescribing. Tailored incentives, such as reference-based pricing (for consumers) and the integration of primary care and pharmaceutical budgets (for physicians), have shown promise as a means of "steering" utilization toward more cost-effective choices – as opposed to simply curbing utilization altogether – but the evaluation of these systems has been made complicated by their limited implementation, or by the complex changes that such policies have been a part of (Braae, McNee et al. 1999; Mays, Mulligan et al. 2000; Willison, Wiktorowicz et al. 2001).

Moving Forward

It is necessary to create the institutional structures necessary to deal with the inflationary pressures caused by, among other factors, health technologies in the coming years. If not managed carefully, the inflationary pressures caused by technological change may gradually erode the principles on which the Canadian health care system is based. This does not have to be the case. By ensuring that technologies – both new and old – are used in the most appropriate and cost-effective manner, Canadian policy makers can achieve a health care system for tomorrow that is both more equitable and more efficient than the one Canadians enjoy today.

Through the regulation of safety and efficacy, the federal government should continue to play a "rationing" role by way of limiting access to only those products that can do more good than harm. Through public funding of organizations such as the Canadian Coordinating Office of Health Technology Assessment, the federal government can foster rigorous technology assessment and economic evaluation. And through the dissemination of guidelines (or "guidance's," as is done by the National Institute for Clinical Excellence in the UK), the federal government can help "inform" decision-makers at the provincial, regional, and clinical levels (Ham and Coulter 2001). Furthermore, the federal government may foster the innovation in health care policy necessary to adapt to innovations in health technology by increased investment in the funding of health services and policy research. This can be achieved through institutions such as the Canadian Institutes of Health Research and the Canadian Health Services Research Foundation.

Provinces also play a role in funding research necessary for policy innovations; but they are charged with the additional task of policy implementation. Whether centralized or acting through regional authorities, provincial governments play a major role in the allocation of health care technologies. Provinces and their representatives allocate capital budgets, developing priorities with communities, and are increasingly involved in the monitoring and evaluation of health outcomes and patient satisfaction. Furthermore, the establishment of budgets and operating capacity – e.g., hospital beds or MRIs – by provincial authorities engenders rationing by practitioners within those constraints. The incentive for cost considerations is reduced for services around which no limits are placed. Consequently, perhaps among the most important decisions provinces make is the way they structure and reimburse the systems of health care provision at the clinical level.

Controls over health technology will not work if they are designed and implemented independently of broader primary care reform. Ultimately, efficient allocation of health care technologies will depend on the dissemination of independent, balanced, and unbiased information to physicians and patients, and on the financial incentives of these important decision-makers at the moment of the clinical encounter. Consequently, if Canadian policy makers wish to better control the inflationary pressures created by health care technologies, substantial reform in the organization and funding of health care services is needed.

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