Introduction

Technology and technological innovation play a central role in the organization and delivery of health services and are a driver of optimal health outcomes.¹ Coyte and Holmes² describe 21st century health care as technologically mediated and geographically dispersed. Sophisticated diagnostic and testing technologies are being pushed from tertiary to secondary hospitals (e.g., computed tomography [CT] angiography) or even to the community (e.g., portable prothrombin time systems for monitoring patients on oral anticoagulation therapy).

There is no evidence to suggest we are approaching a steady state in terms of the impact of technology and its diffusion on health service delivery or its organization. In fact, the number of new technologies is reportedly increasing, their life cycle is decreasing, and the pace of change is challenging the capacity to effectively implement new technologies.³⁻⁵

The diffusion of technology — that is, its supply and distribution — poses vexing issues for policy-makers.

- Not all new technologies prove to be effective or safe for all patients, despite their perceived promise. Lung volume reduction surgery for severe emphysema is an example of a procedure that was rapidly adopted in the US despite the absence of well-designed trials. Subsequent study showed marginal benefit and, in some cases, harm, and ultimately led to an 80% decline in the volume of such surgeries.⁶

- Equity issues related to technology can also be significant, especially in universal health care systems such as Canada’s. Bevacizumab (Avastin, Genentech/Roche) is an expensive drug shown to be clinically effective (life-prolonging but not curative) in the treatment of metastatic colorectal cancer, but it is not particularly cost-effective.⁷ Some Canadian jurisdictions have refused to cover the cost (permitting patients or insurers to pay for the drug privately), whereas others cover the cost as an insured benefit (British Columbia, Newfoundland and Labrador, Nova Scotia, Ontario, Quebec, Saskatchewan).⁸ Advocacy organizations continue to press all jurisdictions to provide coverage for the drug.

- Studies suggest technology may account for anywhere from 17% to 56% of the growth in health care expenditures outside Canada.⁹,¹⁰ In Canada, technological change has been characterized as a major cost escalator, accounting for roughly 25% of health expenditure growth.⁴ At least one comparative study also suggests Canada is a high user of new technologies.¹¹

Regardless of the relative importance one attaches to issues such as effectiveness, equity, cost, or other issues, policy-makers appear to be confronted with a need to develop policy instruments that promote optimum levels of technology diffusion and use.¹ This paper addresses the potential to address that need especially in the context of non-drug technologies.
Background

Health technologies include drugs, devices, diagnostic agents, equipment, and medical and surgical procedures as well as organizational and service systems that provide health care. Technology diffusion refers to the process whereby innovations are communicated through various channels over time among members of a social system. Although these terms are easily defined, the management or control of technology diffusion is deceptively complex. This complexity flows from the manner in which innovations diffuse in general and the characteristics of health technology and/or health systems in particular.

The Nature of Technology Diffusion

Oh et al. developed the technology diffusion model displayed in Figure 1 based on a review of 51 studies examining the diffusion of specific medical technologies.

Figure 1: A Proposed Model of Determinants of Technology Diffusion

Although it is possible to debate the specifics of the categorization scheme, the model rightly suggests that technology diffusion is a dynamic process involving the interaction of numerous variables. What is less evident is the relative importance of the various categories and/or the significance of specific determinants, particularly regulation, payment methods, and purchasing power.

The literature on innovation identifies 10 critical factors influencing the diffusion of technology:

- **Relative advantage** — The more benefit (i.e., profitability, prestige) expected from adopting a technology, the more rapidly it will diffuse. CT angiography has the potential to diffuse rapidly, because it is associated with the most modern CT scanners (i.e., institutional prestige).

- **“Trialability”** — The ability to which an innovation can be tested offers the opportunity to reduce uncertainty and risk for adopters and will promote diffusion. Pharmaceutical companies routinely exploit this idea by providing physicians with product samples.

- **“Observability”** — The ability to observe an innovation and see if its effect will advance diffusion. Device manufacturers often underwrite the expense of having physicians or other decision-makers visit sites that make use of new technologies.
• **Communications channels** — Diffusion is a social process that depends on the ability to link innovators with those who may adopt a new technology. Medical journals have long provided a forum for communicating innovations, and now e-journals provide even more timely dissemination of information concerning new technologies.

• **Group characteristics** — Innovations spread more quickly among groups with similar characteristics (e.g., physicians).

• **Pace of innovation and/or reinvention** — The degree to which technologies can be altered by their users may result in more rapid diffusion. Drugs or devices that can be used for “off-label” indications have greater potential to diffuse given their larger “market.”

• **Norms, roles, and social networks** — Technology diffusion is influenced by norms, roles, and social networks. In many instances, radiologists may be stronger advocates for CT angiography than cardiologists who remained committed to their “norm,” conventional angiography, which is still seen as the “gold standard.”

• **Opinion leaders** — Opinion leaders effectively reduce uncertainty for others and, therefore, can speed the diffusion of a technology; and technology manufacturers often work to identify and engage opinion leaders.

• **Compatibility** — The ability of a technology to integrate with existing technologies promotes diffusion. Given that most new medical technologies actually build on existing practices, they tend to be highly compatible even at the level of reimbursement systems (i.e., fee codes).

• **Infrastructure** — Technologies for which a supporting infrastructure is in place or unnecessary can diffuse more rapidly. CT angiography, cardiac CT, and CT colonoscopy are examples of technology that can diffuse easily to any hospital with a CT scanner.

Most of the factors mentioned above can be mapped to the categories put forward by Oh et al., which suggests the model has some general utility; for example:

• **Predisposing factors (“needs of users”)** — Relative advantage and the influence of opinion leaders.

• **Enabling factors (“capacity to obtain”)** — “Trialability,” “observability,” communication channels, group characteristics, compatibility, and infrastructure.

• **Reinforcing factors (“system modifiers”)** — Norms, rules, social networks, and pace of innovation.

Noticeably absent in the innovation literature are references to government regulation, payment methods, and purchasing power. Although regulation, payment, and purchasing power cannot be dismissed as factors influencing technology diffusion, it can be argued that they are more germane to purchasing decisions or other points late in the diffusion process than the diffusion process per se. Payment systems, purchasing power, and, to a lesser degree, regulation become relevant only at the point of market approval, which, practically speaking, is generally not the point at which a technology begins to diffuse. Furthermore, the relevance of these factors to some “soft” technologies, such as medical or surgical procedures that emerge from within the medical profession, often without formal scrutiny, is entirely questionable.

This point regarding regulation, payment methods, and purchasing power is perhaps a subtle one, but it has major implications for the management of diffusion. If, as suggested by Oh et al., regulation, payment systems, and purchasing power are endogenous variables in
the diffusion process, then policy-makers almost certainly have tools that permit the management of technology diffusion from within the process. If, on the other hand, these factors are exogenous variables (as seems more likely based on the innovation literature), then the ability of policy-makers to externally influence the diffusion process in a predictable way using these tools is much less certain. To oversimplify in an analogy, the difference is that of steering a car versus pushing the car.

Health Technology in Context

In addition to the general nature of technology diffusion, there are aspects of health technology and health systems that make the management of technology diffusion complex. These include conflicting policy agendas, the volume of new technologies, the availability of evidence, utilization impacts, development costs, health system structure, and international trends.

Conflicting Policy Agendas

Most health technologies are developed, or at least commercialized, by the private sector. Although health ministries or their equivalent struggle to manage the diffusion of technology or the impact of its diffusion downstream, other government agencies (such as ministries of trade and industry) are frequently upstream, actively pursuing industrial development polices to promote high-tech industries such as those involved in the development of health technology.16

Volume of New Technologies

In addition, the sheer volume of new technologies almost certainly requires that any diffusion management process be selective in nature. Estimates suggest that 5,000 to 8,000 new health technologies, the overwhelming majority being medical devices, come to market in the US each year.1,17 There is considerable variability in how technologies come to market. Pharmaceuticals must pass effectiveness and safety hurdles (at least as compared with placebo) before entering the market, whereas other technologies such as procedures emerge within the medical profession with little or no scrutiny.5 Medical devices fall somewhere between pharmaceuticals and procedures in terms of scrutiny, but, in the US, clinical data are rarely required for market approval with fewer than 100 devices undergoing full pre-market approval (i.e., safety and effectiveness) annually.17

The US data regarding the volume of new technologies are informative because smaller markets like Canada seldom represent the initial entry point for new technologies. Nonetheless, the volume of new technologies licensed annually in Canada is also dramatic. In 2005, Health Canada made decisions regarding licensing submissions for 483 drugs and 6,595 devices.18 In the case of drugs, just 24 represented new active substances not previously available for therapeutic use in humans. Overall 61% (295) of the drug submissions received a marketing authorization but, perhaps more importantly, only 6% (29) received a refusal, with the balance receiving interim decisions. The decision process for drugs ranged from 11 to 40 months.18

As in the US, medical devices represent the overwhelming bulk of new technologies licensed annually for the Canadian health market. The proportion of devices receiving marketing authorizations versus refusals is very similar to drugs with 65% (4,284) receiving authorization, 5% (323) being rejected, and the balance
receiving interim decisions. Of those devices receiving authorizations, 1,182 were amendments to existing licences, 2,396 were new Class II devices (low risk; e.g., ultrasound units), 607 were new Class III devices (moderate risk; e.g., artificial joints), and 99 were new Class IV devices (high risk; e.g., pacemakers). In addition to low refusal rates, the decision process was rapid, ranging from 13 to 135 days on average.18

Availability of Evidence

The notion of diffusion management presumes the availability of evidence, which is rarely available. When information is available, it is often imperfect, and the short life cycle of medical devices works against data collection. The life cycle for medical devices is estimated to be 12 to 18 months.17 CT scanners, for example, have gone from two to eight, to 16 to 32, to 64 slices and beyond in just a few years, fundamentally altering the imaging capabilities of CT and also expanding indications; for example, useful imaging of the beating heart is feasible with 64 slices.

Stakeholders interpret available information through their particular lenses, and the resulting dilemmas are often managed politically and/or result in a kind of limbo where it is not a matter of promoting or precluding diffusion but of encouraging or discouraging it in the context of current information.19,20

Utilization Impacts

Even where the evidence clearly supports diffusion of a technology, the results can produce unexpected outcomes. Cost-saving technologies can spread in cost-increasing ways if inappropriately utilized. Oh et al.14 suggest that diffusion needs to be interpreted in the context of utilization and note that limiting diffusion will not address problems of inefficiency.

Development Costs

It is widely assumed that technology diffusion is associated with higher spending, but even in the absence of the utilization issues highlighted by Oh et al., it is not a given that less diffusion means lower costs. If one assumes that some portion of technology spending compensates for upstream development costs, less diffusion simply means manufacturers must recover these costs over a smaller number of unit sales or by other means.21

Health System Structure

It is worth noting the impact of health system structure. Technology management is a function of the structure of a health system and its cultural milieu.22 Health systems can confer more or less autonomy on providers. In Canada, the practice of funding hospitals by way of designated capital budgets and global operating budgets tends to restrain spending on high-cost items but offers almost unlimited autonomy related to low-cost items. Health ministries may control the purchase of high-cost items, whereas low-cost technologies have diffused largely without impediment despite being seen as the major driver of costs.1,22 This situation has been further aggravated by the increased role of hospital foundations in funding high profile, “big-ticket” technologies such as CT scanners. Such structural issues are not easily addressed.

International Trends

Finally, the management of technology diffusion may happen locally, but the process of diffusion crosses all borders and exerts ongoing pressure on policy-makers. The chief effect of this pressure is to make the management of technology diffusion a dynamic process involving the need to review decisions on a periodic basis.
Policy Tools for Managing Diffusion

There appears to be no literature that systematically documents or assesses the policy tools used to manage technology diffusion; however, what is available suggests relatively common approaches across jurisdictions.

Supply-Side Tools

In general terms, supply-side approaches rely on public planning and regulation to provide, distribute, or limit the spread of technologies, facilities, and professionals. In some health systems, competition may also represent a supply-side tool; for example, increased supply of a technology can drive down the cost of services in highly competitive markets. A survey of 12 countries in the Organisation for Economic Co-operation and Development (OECD) confirmed the use of supply-side tools such as legislation and policy; however, for the most part, their use was reported to be quite limited, which may imply something about their relative utility, at least in some health systems or contexts. One supply-side tool that is heavily utilized according to the survey is the development of new health service programs (e.g., stroke service). Whether this most often represents an effort to contain technology to selected sites or is an effort to accelerate access is not clear.

Supply-side tools have been used in Canada in relation to specific technologies such as CT scanners and specific programs such as interventional cardiology. Typically, in these cases, supply has been managed by controlling access to capital and operating funding as opposed to through policy instruments and the like. This may support an observation by Battista et al. that these measures are most often driven by pure cost-containment objectives as opposed to issues such as technology effectiveness.

Supply-side tools are less frequently applied to low-cost technologies, because they have been shown to have less influence on the diffusion of such technologies. The variable impact of the same tools on low- and high-cost technologies raises the possibility that the diffusion of high-cost technologies has a tendency to be self-limiting regardless of the use of supply-side tools. Conversely, the sheer volume of low-cost technologies precludes the use of targeted supply-side tools.

Demand-Side Tools

Demand-side approaches are slightly more complex and dependent on the structure of the health system. In general, countries with less restrictive provider payment and local decision-making controls adopt new technology earlier and to a greater extent than other countries. There are two broad responses to this reality:

- Control spending by capping the pool of resources available (i.e., global budgets) or
- Manage spending at the level of services provided (i.e., coverage and reimbursement decisions).

Single-payer systems such as those in Canada tend to rely on global and regional budgets, whereas multi-payer, social insurance systems use coverage and reimbursement decisions made by insurers to control the use of technology. Global budgets such as those common in Canada are recognized as having neutral or negative influences on technology diffusion, whereas fee-for-service systems encourage technology adoption. The benefit that comes from global budgets comes at the expense of the ability to make detailed coverage and reimbursement decisions (i.e., this is possible for fee-for-service physician services, but the ability to manage decisions affecting hospital services is critical in managing technology diffusion).
The inability to make significant use of coverage and reimbursement mechanisms may represent a small loss, as global budgets appear to be the more potent tool. The US maintains a very elaborate taxonomy of clinical services for billing purposes, including specific codes related to emerging technologies. However, the majority of new devices do not raise issues with billing codes, coverage, or payment, because they fit within existing coding and payment categories (and, therefore, are hidden to some extent).

Where devices are truly new, American physicians are reticent to see an emerging technology code assigned, as this often leads insurers to class the technology as experimental and not eligible for reimbursement.17 Physicians respond by billing the service as something else, a situation that also occurs in Canada. This makes tracking of the use of new technologies virtually impossible without detailed audits of physician and/or hospital records. In short, coverage and reimbursement mechanisms do not deliver the precise control they appear to offer.

The range of demand-side tools is fairly extensive and includes:1
- Budget measures
- Reimbursement
- Clinical practice guidelines
- Information for providers
- Information for the public
- Incentive funding
- Performance management
- Medical audit and review.

With the exception of incentive funding (which seems to be rarely used in OECD countries), demand-side tools are much more frequently used than supply-side tools.1

There are a number of supply- and demand-side tools available to policy-makers, and there is a general belief the tools have some degree of effectiveness. However, it is also acknowledged that the tools are not equally applicable to all technologies or health systems. In addition, the tools can be imprecise and produce unexpected consequences. For example, the use of general versus targeted budget measures to dampen technology diffusion does not necessarily result in choosing the most effective or cost-effective technology, and yet general budget measures may be the only approach to addressing the large volume of low-cost technologies. Furthermore, it is clear that health systems that constrain technology diffusion tend to catch up over time to those that do not.23 The current state of knowledge does not permit assessment of the impact of particular tools, and closer scrutiny is warranted.1,11

Challenges to Managing Diffusion

Policy-makers, who, in the Canadian context, exist at multiple levels of the health system, have been criticized for being unprepared to develop an integrated strategy for managing technology diffusion.3 In fact, the chief challenges to managing diffusion probably have less to do with the attitudes of policy-makers and more to do with the nature of technology diffusion and characteristics of health technology, health systems, and the available policy tools, as discussed above.

Summarized succinctly, the challenges to managing diffusion include:
- The nature of diffusion — Diffusion is a social process with the principal actors being technology users. Those who wish to control
diffusion are generally restricted to trying to influence the process from outside relatively late in the process and with little latitude to change fundamental health system structures. In the absence of certainty regarding the value of a technology, a decision to restrict its diffusion may do little to stop its momentum, especially if other credible jurisdictions choose to let the technology diffuse (or are powerless to stop it).

- **Competing policy imperatives** — Governments frequently express a desire to control technology diffusion, but at the same time are often champions of technological innovation. Although these competing imperatives seldom come into overt conflict, there is little doubt they contribute to the politicization of technology management, particularly in the face of uncertainty. This may challenge traditional approaches to targeting technologies for review as well as evaluative capacity.

- **Nature of technology** — Technologies, especially devices, emerge quickly, in large volumes, and they have a life span that challenges evaluative processes. Technologies are constantly reinvented, and most are improvements on the status quo. Managing diffusion may be more about disinvesting from established technologies than limiting the diffusion of truly new innovative technologies.

- **Availability of evidence** — Technologies are seldom in their final form when they come to market and are likely to change form before formal evaluations are complete. As a result, questions of effectiveness and cost-effectiveness are likely dynamic and not subject to definitive responses. The implications include a need to reassess technologies on multiple occasions and potentially to actively engage in the design and execution of pragmatic trials intended to address uncertainty. Such activities may in themselves represent significant new cost pressures.

- **Impact of restricting diffusion** — Although it may seem counterintuitive, it is actually not clear that restricting the diffusion of technology reduces costs. Cost-saving technologies can diffuse in cost-increasing ways (i.e., inappropriate utilization), and blunt policy instruments (i.e., global budgets) do not necessarily ensure that the most effective or cost-effective technologies will diffuse. There is also a price-volume dynamic associated with technology such that total costs may climb when a cost-saving technology legitimately expands treatment indications and/or eligibility. Furthermore, jurisdictions that successfully restrain diffusion appear to catch up to less restrictive jurisdictions over time (although perhaps dollars are saved in that gap).

- **Health system structure** — From the government's perspective, health service providers (both hospitals and physicians) have significant autonomy to manage resources and make technology acquisition decisions, especially in relation to low-cost technologies. Government is rarely involved at this level of decision-making. Low-cost technologies may represent a bigger cost burden than recognized and the rise of hospital foundations is effectively enhancing local autonomy over technology acquisition though local fund-raising efforts.

- **Policy tools** — The available policy tools are often imprecise and, in many instances, their effectiveness is not clear.
Toward a Coordinated Approach

It seems unlikely that there is a single model for managing technology diffusion. The approach is very much contingent on the technology in question, with some tools working for some technologies, or in some circumstances but not others.

In the absence of a best practice approach and in the multi-jurisdictional publicly funded Canadian health care context, it is probably most productive to think of the key features of a coordinated approach.

Such an approach already exists to a degree in Canada for drugs. The Common Drug Review (CDR) undertakes reviews of the clinical and economic evidence related to drugs and provides formulary advice to all federal, provincial (except Quebec), and territorial drug plans. Drugs can be referred for review by drug plans or by drug manufacturers. CDR provides a strong example of coordinated health technology assessment (HTA) in a multi-jurisdictional environment. It also reflects a general trend toward harmonizing certain regulatory structures by providing a single entry point for drug manufacturers.

The CDR model is facilitated by the smaller number of new drug products, a longer product life cycle, a relatively well-established requirement that manufacturers provide both clinical and economic evidence to support new products, and by the coverage authority vested in formularies. On the other hand, CDR does not capture all drugs (e.g., drugs used exclusively in hospitals are outside its mandate), does not undertake research to address limited evidence (i.e., many clinical trials compare new drugs with placebo and, therefore, fail to establish relative effectiveness), and does not bind drug plans in terms of their coverage decisions. The latter is an important point because it may limit CDR to being a coordinated HTA process as opposed to a truly coordinated approach to managing diffusion.

Despite limitations inherent in the CDR model, an approach to medical devices needs to capture the coordinated HTA concept and further build on it. Key features could include:

- An effective horizon-scanning system to identify emerging and new technologies
- Common criteria for identifying high impact technologies (including existing technologies), thus eliminating the notion of ad hoc referrals
- Coordinated HTA to prevent duplication of effort
- A “coverage with evidence” development strategy or equivalent to address the uncertainty associated with promising technologies for which little evidence exists
- Strategies for identifying and disinvesting from existing technologies, where appropriate, and managing reassessments of technologies
- Links to utilization management
- A commitment to acting on HTA results similar to the one that exists in the National Health Service in the United Kingdom
- A reference-based pricing approach to non-drug technologies.

It is beyond the scope of this paper to assess the feasibility of an integrated approach to technology diffusion in Canada, but it is clear that many of the required capacities are in place.
Conclusion

According to Battista et al., 22 “…technology assessment’s potential is realized only with effective links to technology management.” Although this observation seems completely logical, the management of technology diffusion is deceptively complex. In the context of technological innovation, diffusion management is a “late game” strategy made challenging by the nature of diffusion and characteristics of health technology, health systems, and the available policy tools.

Historically, diffusion management has focused on constraining costs, but its long-term effectiveness in this regard is unclear. Blunt policy instruments can offer at least short-term benefit in terms of cost constraint; but longer-term, the result seems to be cost deferral as opposed to cost avoidance.

There is no single approach to managing technology diffusion. In fact, it is clear that managing diffusion is context- or technology-specific. What works in one situation may not work or may not be available in another. In the Canadian context, the first challenge facing policy-makers may be to develop priorities based on a clear picture of current technology spending in terms of technology types (i.e., medical devices, information systems/information technology), cost (i.e., high cost versus low cost), and volume (i.e., high volume versus low volume). Assuming diffusion management represents the most effective approach to addressing the underlying policy objectives, policy-makers must then ensure the required infrastructure is in place and effectively coordinated to support diffusion management.

References


