

# Canadian Cardiovascular Society commentary on implantable cardioverter defibrillators in Canada: Waiting times and access to care issues

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The Canadian Cardiovascular Society is the national professional society for cardiovascular specialists and researchers in Canada. In the spring of 2004, the Canadian Cardiovascular Society Council formed an Access to Care Working Group in an effort to use the best science and information to establish reasonable triage categories and safe wait times for access to common cardiovascular services and procedures. The Working Group has elected to publish a series of commentaries to initiate a structured national discussion on this very important issue.

Access to treatment with implantable cardioverter defibrillators is the subject of the present commentary. The prevalence pool of potentially eligible patients is discussed, along with access barriers, regional disparities and waiting times. A maximum recommended waiting time is proposed and the framework for a solution-oriented approach is presented.

**Key Words:** *Health policy; Implantable cardioverter defibrillator; Sudden death; Waiting times*

The Canadian Cardiovascular Society (CCS) is the national professional society for cardiovascular specialists and researchers in Canada. In 2002, at the Canadian Cardiovascular Congress Public Policy Session, Senator Wilbert Keon stated that an important role of a national professional organization (such as the CCS) is to develop national standards for access to cardiovascular care that could be validated, and adopted or adapted by the provinces. Furthermore, he noted that because policy makers and other stakeholders in the health care system currently grapple with access and waiting time issues, the time is right for such initiatives.

Currently, there are no national standards or targets for access to care for cardiovascular procedures or office consultations. While some provinces have established targets for some cardiovascular procedures, no national consensus exists regarding waiting time targets, issues of regional disparities, or even how to approach the problem. A professional organization such as the CCS, with its broad based membership of cardiovascular experts, is ideally suited to initiate a national discussion

## Commentaire de la Société canadienne de cardiologie sur les défibrillateurs internes à synchronisation automatique au Canada : La question des délais d'attente et de l'accès aux soins

La Société canadienne de cardiologie est la société professionnelle nationale des spécialistes et des chercheurs en santé cardiovasculaire du Canada. Au printemps 2004, le conseil de la Société canadienne de cardiologie a formé un groupe de travail sur l'accès aux soins dans un effort pour faire appel aux meilleures données scientifiques et à la meilleure information en vue de mettre sur pied des catégories de triage raisonnables et des délais d'attente sécuritaires à l'égard de l'accès à des services et interventions cardiovasculaires courants. Le groupe de travail a choisi de publier une série de commentaires pour entreprendre un débat national structuré sur cet enjeu capital.

L'accès au traitement par défibrillateur interne à synchronisation automatique fait l'objet du présent commentaire. Le bassin de prévalence des patients potentiellement admissibles est abordé, ainsi que les obstacles à l'accès, les disparités régionales et les délais d'attente. Un délai d'attente maximal recommandé est proposé, et la structure d'une démarche axée sur les solutions est présentée.

and commentary on waiting times and access to care issues as they pertain to the delivery of cardiovascular care in Canada.

In the spring of 2004, the CCS Council formed an Access to Care Working Group in an effort to use the best science and information to establish reasonable triage categories and safe wait times for access to common cardiovascular services and procedures. The Working Group has elected to start the process with a series of commentaries. Each commentary is intended to be a first step in a process to encourage the development of national targets. The commentaries summarize the current variability of standards and wait times across Canada, where this information is available. They also summarize the currently available data, particularly focusing on the relationship between the risk of adverse events as a function of waiting time, as well as on the identification of gaps in existing data. Using the best evidence and expert consensus, each commentary takes an initial position on what the optimal standard for access to care ought to be for the cardiovascular service or procedure. The commentaries also serve to call upon cardiovascular

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**TABLE 1**  
**Model of plausible growth of new implantable cardioverter defibrillator implants in Canada – prevalence of treated and untreated patients\***

	FY 03/04	FY 04/05	FY 05/06	FY 06/07	FY 07/08	FY 08/09
Total prevalence	92,000	95,700	99,400	103,100	106,800	110,500
Treated	7000	9100	11,690	15,021	19,019	23,617
Untreated	85,000	86,600	87,710	88,079	87,781	86,883
New implants	2300	2800	3500	4500	5500	6500
New implants/ million	72	88	110	141	172	204

\*Presumes 4% annual growth of the eligible population and 10% annual mortality of the treated group. Calculations do not incorporate replacement devices, which would be expected to add an additional 15% per year (at steady state) presuming the longevity of a pulse generator to be seven to eight years. FY Fiscal year

researchers to fill in the gaps of this body of knowledge and to further validate safe wait times for patients at varying degrees of risk.

The safety and efficacy of the implantable cardioverter defibrillator (ICD) have been firmly established in both secondary prevention (1) and primary prevention (2,3) trials. The CCS/Canadian Heart Rhythm Society position paper on ICD use in Canada (pages 11A-18A in the present supplement) (4) recognizes the strength of the evidence and has defined high-risk patient populations with class I and class II indications for ICD implantation, acknowledging that clinical judgment still has a large role to play in decision-making at the individual patient level. Given the large number of potentially eligible patients, concern has been expressed by physicians, administrators and government officials regarding the economic and care-delivery implications of more widespread ICD use, particularly in the primary prevention population. Can we afford to implant ICDs in all eligible patients? Do we have an adequate infrastructure for implantation and follow-up? How can we manage the anticipated growth in demand for ICDs? Fundamental questions about resource allocation, individual and collective fairness, equitable access and acceptable waiting times are entangled in these issues. Defining and understanding the barriers to access to care are the first steps in the process of developing a framework for the resolution of these difficult and complex problems.

The ICD, arguably more than any other treatment, illustrates the access to care issue most starkly. First, it is a device that aborts sudden death; hence, it follows that longer waits would probably be associated with a higher mortality risk. Second, the indications for ICDs are rapidly expanding, creating a need/resource mismatch. Third, the 'high technology' that the ICD represents serves to confine the treatment to highly specialized centres, making regional disparities in care delivery a concern. Finally (largely because the indications are relatively new), most jurisdictions in Canada do not have databases to track waiting times, regional variations, outcomes or other care-delivery variables. Thus, stakeholders find themselves making resource allocation decisions and care-delivery decisions in a virtual data vacuum.

#### What is the prevalence pool of potentially eligible patients?

One of the first and most obvious barriers to ICD access results from our perception of the size of the eligible primary prevention population, or the prevalence pool. This creates a seemingly daunting challenge and leads many to conclude that efforts to even begin to address the treatment of the prevalence

pool may be futile; however, it must be remembered that there is a latency period before new therapies reach their full potential. Even relatively simple therapies, like angiotensin-converting enzyme inhibitors for ischemic left ventricular dysfunction, beta-blockers for postmyocardial infarction patients and statin therapy have taken years to even partially penetrate their target populations.

Nonetheless, it remains instructive to speculate on the size of the potentially eligible ICD population. Many quick and approximate calculations of the potentially eligible primary prevention population have been proposed for the population of the United States; thus, is possible to make some extrapolations to the Canadian population, recognizing that the estimates are based on many presumptions. The following is one representative example.

In December 2004, based on American census data and the Resource Utilization Among Congestive Heart Failure (REACH) study (5), Bernstein and associates (6) estimated that of five million American citizens with heart failure, 2.4 million have systolic dysfunction and 1.4 million of these have a left ventricular ejection fraction 30% or less; furthermore, of these 1.4 million, 950,000 are thought to be on the basis of ischemic heart disease. They further subtracted 23% to account for exclusion of patients with disqualifying comorbidities (ie, they likely would not be considered candidates for an ICD because competing comorbidities would render the ICD less effective in reducing overall mortality). By their estimation, this would leave 725,000 Americans potentially eligible for a "Class I-indicated" (by Canadian standards [4]) prophylactic ICD.

To calculate an equivalent Canadian estimate, one must adjust for the fact that Canada has an older population. In the 2000 census, the American population was 282.1 million, with 9.2% between 55 and 64 years of age and 11.9% over 65 years of age. In Canada in 2002, the population was 31.9 million, with 10.7% between 55 and 64 years of age and 12.8% 65 years of age and over. Therefore, if we can presume that the vast majority of ICD-eligible Americans are over 55 years of age, then 725,000 ICD-eligible Americans would constitute 1.22% of the population over 55 years of age. Given that 23.5% of Canadians are over 55 years of age (7.5 million people), this would make the total Canadian prevalence pool about 92,000 people ( $1.22\% \times 7.5$  million people).

As one might expect, the annual growth of the number of eligible patients is estimated to be only a fraction of the prevalence pool, illustrating the relative magnitude of the prevalent need versus the incident need. There have been ongoing efforts to further risk stratify the population of ICD candidates; however, this could significantly impact these calculations by reducing the size of the potential prevalence pool. There is currently considerable interest in defining a population within the population at risk that derives most or all of the benefit from ICDs.

As indicated earlier, it is unrealistic to expect complete and immediate penetrance into the eligible population. Table 1 depicts one realistic and plausible scenario for growth over the next several years, taking into consideration a slowly increasing acceptance of the primary prevention treatment strategy by the referral community as well as infrastructure limitations. This model starts with the presumption that there are 7000 Canadians currently living with an ICD. It further presumes that patients with an ICD have a 10% annual mortality, that the eligible population grows by 4% each year and that the number of

implants performed each year increases relatively uniformly. The model shows that if by fiscal year 2008/2009, 6500 new devices are implanted annually (up from the 2300 implanted in fiscal year 2003/2004), the rate of new implants would increase from 72 per million to 204 per million and the prevalence of treated patients would increase from 7000 to 23,617. The percentage of the eligible population that is treated would increase from 7.6% to 21.4% over five years – far from complete penetrance, but certainly a significant improvement. Of course, efforts to more precisely define the population at risk could have a significant impact on these calculations, as would the funded volumes and the predicted incidence of the number of eligible patients. This model is offered only as a reasonable starting point for discussion rather than as a recommendation or prediction.

From an economic feasibility standpoint, it is worthwhile pointing out that, presuming total charges of \$25,000 per device implant, this degree of growth (to 6500 devices implanted annually) would represent only about 0.1% of Canada's \$130 billion health care budget, and would be the equivalent of only 13% of the amount spent on wholesale purchases of statin drugs from Canadian drugstores between December 2003 and November 2004 (\$1.24 billion) (7). Framed in these terms, investing in the most effective treatment for sudden death (one of the leading causes of death in Canada) appears very reasonable. The value per dollar also appears to be favourable in the primary prevention population, with three recent analyses calculating the cost-effectiveness to be in the \$30,000 to \$50,000 per life year gained range (8-10).

#### 'Culture of under-referral' and other potential barriers

The barriers to identification and referral of patients, and to implantation of ICDs, are not comprehensively understood but potentially include the following:

- there are not enough specialists to evaluate the eligible patients;
- physicians do not accept the randomized data;
- physicians do not accept the CCS recommendations;
- a perception that the therapy is not cost-effective;
- physicians feel the therapy is unavailable, so they do not bother referring;
- a perception that the risks outweigh the benefits;
- a perception that the waiting lists are so long that referring is not worthwhile; that patients will suffer during the delay due to unfulfilled expectations, angst from a life put on hold and the new knowledge that they are at risk;
- electrophysiologists exercise bedside rationing of the resources in fixed-resource environments;
- patients who are offered an ICD elect not to proceed with the implant; and
- patients who are on waiting lists but do not receive the therapy (implanting centre runs out of funds, patient dies on waiting list, etc).

A recent study of Canadian physicians' attitudes toward ICDs (11) has shed some light on the "culture of under-referral". This survey of Canadian cardiologists and electrophysiologists

presented physicians with typical scenarios of potential ICD-indicated patients. For a patient with an indication for ICD implantation based on the Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II) study, 43% of referring cardiologists cited excessive wait times for initial consultation, evaluation and implant as the greatest impediment to referral. An additional 36% listed cost or cost-efficacy as the primary impediment to referral. Therefore, while excessive wait times for ICDs play a major role in the reluctance to refer patients, physicians' concerns about cost and cost-efficacy may be interpreted to mean that they are playing a 'stewardship' or 'societal advocate' role in the allocation of the ICD resource.

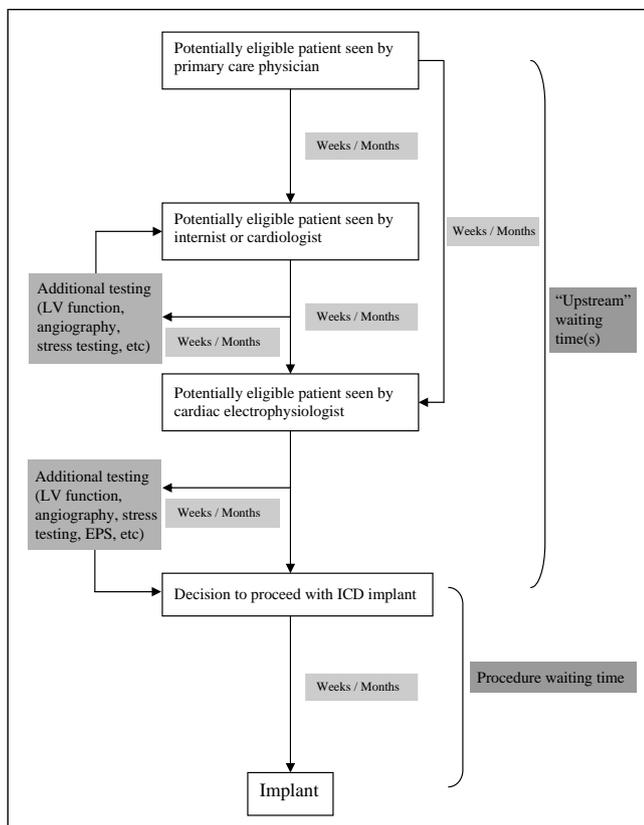
#### Regional disparity

Wilson et al (12) and Gillis (pages 25A-30A in the present supplement) (13) have reported on what appears to be rather marked regional variations in ICD implant rates per million of population in Canada. In 2003, the implant rates were reported to have varied from 29 per million in Prince Edward Island to 134 per million in Newfoundland and Labrador (13). Saskatchewan, New Brunswick and Prince Edward Island, which have no implanting centres, had the lowest implant rates, suggesting that geographical proximity to an implanting centre may be a critical determinant of access. Even within a single province, significant regional differences in implant rates may exist. It is unclear if more implanters and implanting centres would reduce these disparities, or if there is room for maximizing implant capacity at existing centres.

#### Waiting times

Once a referring physician decides that any particular patient should be referred for an ICD implant, that patient moves from the anonymous, nebulous prevalence pool onto a list which can be potentially quantified and analyzed. This patient enters the first of several phases of assessment, each with its own associated waiting time (Figure 1). Initially, the referring physician must make arrangements for the patient to meet with an ICD implanter, usually a cardiac electrophysiologist. This often takes several weeks and sometimes several months. There may be an intermediate-level referral as well, from the primary care physician to an internist or cardiologist, or from an internist to a cardiologist. Once the patient is seen by the implanting physician, further tests such as another assessment of left ventricular function, an electrophysiology study, a noninvasive test of ischemic burden or a coronary angiogram, may be necessary either to properly assess the patient's candidacy, or to complete the preoperative workup. Depending on the nature of the additional testing that needs to be performed, several more weeks may be added to the wait. Once ICD candidacy is established, there is another waiting period until the device can be implanted (the majority of primary prevention ICDs are implanted electively and as outpatients). In total, patients can wait many months from referral to implant.

There is no national registry of ICDs, and thus far all of the implant data come from industry. Currently, there is no way to determine how markedly different implant rates, funding formulas and referral dynamics may influence wait times and outcomes for patients who are on ICD waiting lists. Within Canada, there are strikingly different models. For example, in Nova Scotia, there are no fixed budgets for ICDs – physicians are free to implant devices as deemed necessary. In British Columbia, budgets are set based on estimated demand, but



**Figure 1) From referral to implant – potential bottlenecks in implantable cardioverter defibrillator (ICD) care delivery.** EPS Electrophysiology study; LV left ventricular

implantations at the two electrophysiology centres are performed as clinically indicated. In Ontario and Quebec, however, fixed budgets have created a recurrent boom and bust cycle where implant rates slow down or stop at the end of the fiscal year draws near. Manual, unverified data from the Cardiac Care Network (CCN) of Ontario, for example, suggest that waits for ICDs in Ontario are not only getting longer, but that they vary dramatically from centre to centre (CCN Arrhythmia Management Working Group, personal communication). In the current fiscal year, most Ontario implanting centres reached their funded volumes in January, and at least one implanting centre has taken the rather extraordinary decision to completely shut down their ICD program until the new fiscal year begins. This only serves to further compound the waiting list problem because waiting list patients continue to accrue.

Given that the therapeutic target (ventricular arrhythmias) is one that is frequently fatal, any strategy that allows for prolonged waiting times for ICD implantation must be regarded as potentially perilous; however, without a comprehensive waiting list monitoring strategy, events which may occur on the waiting list remain abstract, amorphous and speculative. As a result, the path of least resistance for Ministries of Health is to allocate funding based primarily on economics rather than on the basis of need, or even safety.

Several organizations in Canada are now tracking wait times for some cardiac procedures. Access to coronary artery bypass grafting (CABG), cardiac catheterization and percutaneous coronary interventions in Ontario, for example, are meticulously tracked to ensure that all patients have appropriate

and equitable access (14). All of the wait list management organizations aim to maintain waiting list mortality below a certain standard. According to CCN data, the CABG wait list mortality in Ontario has been maintained at well below 0.5% (the benchmark) since 1997; a mark accomplished through the implementation of an urgency rating score (URS) system and the establishment of recommended maximum waiting times (RMWT) (14) that are specific to each URS. The mortality rate on the waiting list has become the central measure of success of the entire waiting list strategy.

### CCS Access to Care Working Groups' RMWT for ICD

Although arrhythmia management procedures (including ICD implants) are not yet tracked in a similar fashion, it seems reasonable that the waiting time principles that are applied to patients on the waiting list for CABG could also apply to patients on the waiting list for ICDs. It would seem reasonable to start with the premise that the preventable waiting list mortality should not exceed 0.5% (the benchmark for total waiting list mortality for patients awaiting CABG in Ontario is 0.5%). Although we have no real world registry data regarding ICD wait list mortality, the MADIT-II study (15) provides a means to predict what the preventable mortality would be for each unit of time that passes without an ICD in situ because the mortality curves of the ICD and non-ICD populations in the study diverge. Based on these data and presuming linear risk, the non-ICD treated patient with a MADIT-II indication would face a 0.8% monthly risk of mortality; however, given that this is a high-risk population, slightly less than two-thirds of these deaths would be classified as unavoidable (ie, they would have occurred even if the ICD had been implanted). Therefore, the preventable mortality risk is approximately 0.3% per month. Accordingly, if our goal is to subject patients on the ICD waiting list to a preventable mortality of no more than 0.5% per month, the waiting time should not exceed seven to eight weeks. Of course, such a standard would need to be prospectively tested and verified in a real world registry, but the principle of a waiting time benchmark tied to waiting list mortality would seem to be unassailable given the history of success of the same strategy for CABG wait list management.

## SOLUTIONS

The solution to these access to care barriers can be addressed through the framework of the 10-point plan established by the Canadian Medical Association discussion paper “The Taming of the Queue” (16), which addresses the broader wait time issue:

### Set priorities through broad consultation

ICD use for the primary prevention of sudden death has now been firmly established as a safe, cost-effective treatment that significantly reduces mortality in defined populations. Because sudden death is a leading cause of death in Canada, ICD therapy must be one of the considered priorities when funding allocations are being established. At the same time, investigators must continue to seek to further refine the highest-risk populations within the groups that have been shown to benefit.

### Address patient/public expectations through transparent communications

Patient satisfaction is improved when confidence in the integrity of a waiting list management system is established.

Full transparency and public accountability for the decisions taken are needed.

#### **Address immediate gaps in health human resources and system capacity**

Efforts must be made to plan for the future by assessing the capacity for growth at each existing implant centre and the ability to add new centres in provinces that currently implant ICDs. The potential positive impact of new implant centres in provinces like New Brunswick and Saskatchewan on implant rate disparity should be studied. It should not be considered acceptable for any institution or any jurisdiction to deny or delay access on the basis of artificially imposed fiscal quotas.

#### **Improve data collection through investments in information systems**

A well-constructed ICD waiting list and implant registry that links institutions and provinces must be established. A relatively small investment (relative to the size of the ICD budget) is all that is required to allow the creation of a data collection system that will enable us to plan and deliver care with confidence.

#### **Develop wait time benchmarks through clinical and public consensus**

A URS and RMWT can be developed, tested, verified and implemented in a relatively short period of time if the resources become available. The establishment of a benchmark is a crucial first step to earn public confidence and to establish fair access for those on the waiting list. Based on existing but admittedly limited data, the Access to Care Working Group consensus suggests a maximum seven to eight week wait once it has been determined an ICD is indicated.

#### **Strengthen accountability by way of public reporting**

ICD wait times and clinically relevant outcomes by centre should be in the public domain. ICD per capita implant rates should also be monitored and reported as a measure of completeness of potential referrals from each province, region or health district.

#### **Maximize efficiencies by aligning incentives properly**

ICD funding formulas must be reformed to move toward activity-based funding rather than fixed budgets that artificially constrain service delivery. Working within practice guidelines, and fully accountable for their clinical decisions, physicians should be empowered to make care delivery decisions at the level of the individual patient on the basis of need and consensus-determined eligibility.

#### **Address upstream and downstream pressures by investing in the continuum of care**

Pressure points in the entire ICD care continuum should be considered equally. Barriers to access to initial consultation are as important as the actual ICD waiting list. Adequate resources for ICD follow-up must also be ensured in any growth management strategy.

#### **Expand interjurisdictional care options by enhancing portability provisions**

Patients who are remote from an ICD implant centre (including out of province) would benefit from enhancements to

interprovincial reciprocal billing agreements as well as from a streamlining of processes which allow care to be delivered outside the usual care area. The interprovincial agreement for reimbursement for medical services must be revamped immediately to allow for complete reimbursement, especially for costly medical procedures, such as ICDs. Appropriate future use of transtelephonic or Internet monitoring systems should be encouraged for patients in remote locations.

#### **Commit to adoption of best practices through enhanced research and collaboration**

Canada's electrophysiology community has a long history of productive collaborative research relationships which have contributed significantly to the body of electrophysiology literature. The new Canadian Heart Rhythm Society, representing Canada's electrophysiologists, will play an important role in the coordination of interinstitutional and interprovincial research and clinical care relationships.

## **CONCLUSIONS**

Fears of a potentially large prevalence pool, concerns about the economical implications of more widespread ICD use and a perception that waiting times are too long appear to be contributing to a culture of under-referral of potentially eligible ICD patients in Canada. For patients who are referred and selected for ICD implantation, reliable data regarding waiting times, outcomes and regional disparities are scarce, and thus severely constrain efforts to establish the means to ensure timely and equitable access.

Solutions to the problem should incorporate principles of transparency, accountability and broad consultation. A national ICD registry and a comprehensive waiting list strategy are urgently needed to help guide resource allocation decisions. Declarations of the true need for ICDs would encourage needs-based funding decisions rather than purely economically driven funding decisions. In a single payer publicly funded system, it is no longer acceptable for any institution or any jurisdiction to deny or to delay access on the basis of artificially imposed fiscal quotas. Relatively small investments in information systems that enable interinstitutional and interjurisdictional linkage would provide the means to establish a fair system of ICD resource allocation and access to care that is worthy of the public's confidence and trust.

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