

Universal access – but when? Treating the right patient at the right time: Access to electrophysiology services in Canada

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The Canadian Cardiovascular Society Access to Care Working Group has published a series of commentaries on access to cardiovascular care in Canada. The present article reviews the evidence for timely access to electrophysiology services. Using the best available evidence along with expert consensus by the Canadian Heart Rhythm Society, the panel proposed a series of benchmarks for access to the full scope of electrophysiology services, from initial consultation through to operative procedures. The proposed benchmarks are presented herein.

Key Words: Access to care; Arrhythmias; Electrophysiology; Health policy

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 benchmarks for access to cardiovascular care that could be validated and adopted or adapted by the provinces. Further, he noted that the time was right for such initiatives because policy-makers and other stakeholders in the health care system are now in the process of addressing access and waiting time issues.

Currently, there are no national benchmarks or targets for access to care for cardiovascular procedures, office consultations or rehabilitation. While some provinces have established targets for some cardiovascular procedures, no national consensus exists regarding waiting time targets, the problem of regional disparities, or on the mechanisms to address these important issues. A professional organization such as the CCS, with its broad-based membership of cardiovascular experts, is ideally suited to initiate a national discussion and commentary

L'accès universel, mais quand ? Le traitement du bon patient au bon moment : L'accès aux services d'électrophysiologie au Canada

Le groupe de travail de l'accès aux soins de la Société canadienne de cardiologie a publié une série de commentaires sur l'accès aux soins cardiovasculaires au Canada. Le présent article analyse les données probantes relatives à l'accès rapide aux services d'électrophysiologie. Au moyen des meilleures données probantes disponibles et du consensus de spécialistes de la *Canadian Heart Rhythm Society*, le groupe a proposé une série de points de référence pour l'accès à l'ensemble des services d'électrophysiologie, de la première consultation jusqu'au protocole opératoire. Les points de références proposés sont exposés aux présentes.

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

The CCS Council formed an Access to Care Working Group (the 'Working Group') in the spring of 2004 in an effort to use the best science and current information available to establish reasonable triage categories and safe waiting 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. Where information is available, the commentaries summarize the current variability of benchmarks and waiting times across Canada. They also summarize the contemporary data, particularly focusing on the relationship between the risk of adverse events as a function of waiting time, while identifying gaps in existing data. Using best evidence and expert consensus, each commentary takes an initial position regarding the optimal benchmark for access to care for specific cardiovascular services and procedures. The commentaries also call upon cardiovascular researchers to fill the gaps in this body of knowledge to

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further validate safe waiting times for patients at varying degrees of risk.

THE ACCESS ISSUE – ELECTROPHYSIOLOGY SERVICES

Cardiac electrophysiology (EP) is a subspecialty of cardiology that deals primarily with heart rhythm disorders. There are approximately 90 EP specialists in Canada, and nearly all major university medical centres have a full EP program. Some secondary level EP services, such as pacemaker implantation and follow-up, are still performed by non-EP physicians, including cardiac, general and vascular surgeons. In addition, some cardiac surgeons have established advanced expertise in the surgical management of arrhythmias.

As is the case with all of cardiovascular care, EP services in Canada span the continuum of care, from initial consultation, and diagnostic and therapeutic procedures, to follow-up. Full and timely access to EP services continues to be a challenge, owing to the rapid growth in indications and eligible patients (outstripping available funding in many cases), as well as to the fact that most full EP services are restricted to large, university-affiliated centres. Finally, knowledge and technology are advancing very rapidly in cardiac EP, creating a needs-resources mismatch.

In recent years, the implantable cardioverter defibrillator (ICD) has been definitively shown to reduce mortality in patients with significant left ventricular (LV) dysfunction, making an estimated 92,000 Canadians nominally eligible for this treatment (1). More recently, cardiac resynchronization therapy (CRT) has been shown not only to reduce symptoms and hospitalizations secondary to congestive heart failure, but also to independently reduce mortality (2). Finally, spectacular advances in the understanding of the pathophysiology of atrial fibrillation (AF) (the most common, sustained arrhythmia, affecting tens of thousands of Canadians) has led to advances in catheter ablation therapy, which offers, for the first time, a potential cure for an increasing number of AF patients (3). All of these and other advances have created new and somewhat unique pressures on electrophysiologists and other providers of these services in an environment where rapid growth outstrips resources. Yesterday's emerging technologies are rapidly becoming today's standard of care. AF ablation, the use of three-dimensional noncontact mapping technology and CRT therapy have all gone from the drawing board to common clinical practice in less than five years, but only a fraction of the eligible population has benefited to date. Major challenges related to access to these newer procedures and therapies are on the immediate horizon.

ACCESS TO EP CONSULTATION

An EP consultation may be sought for a number of different diagnoses or symptom complexes, ranging from troublesome but benign palpitation and recurrent syncope to malignant arrhythmias. Consultation may be requested by a general practitioner, an internist, a cardiologist or a cardiac surgeon. In many cases, referrals to an electrophysiologist may be made by physicians who themselves have received the consultation through one or even two other physician 'layers'. Many weeks or months may go by from the time a patient presents to his or her primary caregiver with the initial complaint until they make their way through a series of referrals to the electrophysiologist. This is not to say, of course, that unstable, urgent or

emergent patients are made to wait for appropriate care. Such patients typically present to the emergency department, where they are stabilized and risk-stratified. In some cases, electrophysiologists may be consulted urgently or emergently by the emergentologist (eg, for electrical storm), but it is usually the case that emergencies are dealt with by first responders (paramedics in the field) or by family physicians, emergency room physicians, internal medicine specialists or general cardiologists. Electrophysiologists are more often involved in the care plan once patients have been stabilized and are no longer in immediate danger, although an increasing number of centres have established a '24/7' EP on-call schedule to deal with some of these emergent and urgent problems.

Significant differences have been shown in waiting times among hospitals (4) and between countries (5,6) for various 'non-EP' cardiac consultations. It is logical to assume that the same situation would apply to EP consultations as well. There are no strict guidelines or recommendations in the literature for 'acceptable' waiting times to obtain an EP consultation. Many factors can influence access to secondary or tertiary cardiology care, but it has been demonstrated that waiting times are longer in academic medical centres, in larger communities, and for physicians with certification in cardiology, with waiting times varying between four and nine weeks (7). Anecdotally, it is known that many patients in Canada wait much longer than this to see an electrophysiologist.

After the initial EP assessment, additional tests may be ordered to refine the diagnosis or to help determine a treatment plan. For example, an assessment of LV function (echocardiography, nuclear medicine) or a test of ischemic burden (eg, treadmill, thallium²⁰¹ scintigraphy, dobutamine echocardiography, etc) may be performed before a decision is made to recommend an ICD. An ambulatory rhythm monitor may be required to characterize paroxysmal arrhythmias or the ventricular response rate in AF before decisions are made about pharmacological or catheter ablation therapy. Echocardiography with tissue Doppler imaging for LV dyssynchrony may be required before recommending CRT. Each of these specialized tests is usually performed as an outpatient procedure, and accordingly, the timing of these tests is subject to the dynamics of outpatient waiting lists. In the final analysis, the cumulative waiting time from initial consultation to the application of the definitive treatment may be considerable, adding weeks or even months to the patient 'wait experience', which is in addition to the conventionally defined 'waiting time' for the procedure itself.

Finally, we know that when a scoring system or 'rating' is applied to stratify patient risk while on a waiting list, specialist practitioners can assess the relative priority of patients, allowing for a greater delay for those with less acute need (8). This may be particularly relevant in EP, as practitioners become focused on procedures like ICDs, which reduce mortality, while allowing patients referred for, say, catheter ablation for a nonlethal but troublesome arrhythmia (such as supraventricular tachycardia [SVT]) to wait for much longer periods of time.

Benchmark for waiting times to obtain an EP consultation

Waiting time benchmarks for initial EP consultation are shown in Table 1. When a patient is referred for an expert opinion in EP (outpatient consultation), delays will vary depending on the assessment of the risk faced by the patient, as determined by the information provided in the referral letter.

For example, patients with supraventricular arrhythmias carry a very low risk of mortality compared with patients with structural heart disease referred because of a syncopal episode. It is common practice for patients with a worrisome risk factor profile (LV ejection fraction less than 40%, bundle branch block, hypertrophic cardiomyopathy, congenital heart disease, family history of sudden cardiac death, inherited heart disease, pre-excited AF) who are referred for syncope to be seen earlier than patients without this high-risk profile. Because additional tests or procedures are often required before a decision can be made on the treatment plan, the authors suggest that a maximum delay of 30 days before consultation should apply for these high-risk patients; otherwise, the additional delay necessitated by the need for further testing will lead to an increase in the total waiting time for any definitive procedure or treatment. The clinical judgement of the referring physician is critically important here because there may be instances when an even more timely consultation is required. Urgent and emergent situations should ordinarily be routed through the emergency department.

For patients referred for an elective opinion (eg, palpitation not yet diagnosed, SVT, syncope without structural heart disease), a maximum waiting time for referral to consultation of 90 days should apply. While waiting may pose little or no risk to life or limb, it is recognized that these symptoms can cause considerable morbidity.

ACCESS TO EP STUDIES AND CATHETER ABLATION

EP studies and catheter ablation are central to the contemporary management of many cardiac arrhythmias. Newer ablation techniques have emerged using advanced mapping systems that have improved the management of previously untreatable conditions. Timely access to these procedures reduces patient morbidity, decreases medical costs, and in some cases, is life-saving. Cohort studies, clinical trials, cost analyses and a Canadian Health Technology assessment provide the best estimate of the effectiveness of these procedures and, together with guidelines from other jurisdictions, permit the determination of reasonable waiting times. Waiting time benchmarks for EP studies and catheter ablation are shown in Table 2.

Standard EP studies and catheter ablation

Catheter ablation is the first-line treatment for many cardiac arrhythmias, including SVT, atrial flutter (AFL) and for some cases of idiopathic ventricular tachycardia. These procedures are routinely performed on an outpatient basis, with very few complications (9) and, in contrast to most pharmacological and surgical therapies in medicine, are typically curative. As such, catheter ablation dramatically reduces recurrences (10), the subsequent need for medication or hospital visits, improves patient quality of life (11) and is highly cost-effective. In fact, catheter ablation for SVT is among a select group of medical interventions that are economically 'dominant' over alternative therapies – meaning that it is less costly and results in improved patient outcomes (12). A detailed Canadian assessment of catheter ablation (13), commissioned by the Canadian Coordinating Office for Health Technology Assessment, confirmed the cost-effectiveness of this treatment.

Given the nonlethal nature of most arrhythmias treated with catheter ablation, the primary determinants of an acceptable

TABLE 1
Waiting time benchmarks for initial electrophysiology consultation

Emergent or urgent patients	Refer to ER or electrophysiologist on call
Patients with structural heart disease (eg, ejection fraction less than 40%, bundle branch block, hypertrophic cardiomyopathy, congenital heart disease, family history of sudden cardiac death, inherited heart disease, etc) referred for symptoms, such as syncope, that could potentially be associated with a risk of morbidity or mortality	30 days
Patients referred for consideration of implantation of an implantable cardioverter defibrillator (primary prevention) and/or a cardiac resynchronization therapy device	30 days
Patients electively referred for an electrophysiologist's opinion (eg, palpitations, supraventricular tachycardia, syncope without structural heart disease or other medical conditions)	90 days

ER Emergency room

TABLE 2
Waiting time benchmarks for electrophysiology studies and catheter ablation

Patient acuity	Waiting time benchmark
High-risk patients (eg, Wolff-Parkinson-White syndrome with rapid atrial fibrillation or syncope; high-risk arrhythmias with congenital heart disease, significant left ventricular dysfunction)	2 weeks
Low-risk patients (eg, supraventricular tachycardia, atrial fibrillation with structurally normal hearts)	3 months

waiting time are recurrence rate, patient morbidity, resource utilization and costs, and standards of other Canadian jurisdictions. In one study of patients with highly symptomatic SVT (12), 83% of untreated patients had a documented recurrence of arrhythmia within 90 days. Because recurrences are associated with decreased patient quality of life (10) and increased health care costs (11), and are almost completely preventable with timely access to catheter ablation (10), an acceptable waiting time of not more than three months for catheter ablation would be appropriate, as has been proposed in some provinces (14).

For some cardiac arrhythmias, timely access to EP studies and catheter ablation may be life-saving. Patients in this category include those with Wolff-Parkinson-White syndrome who have rapid AF or syncope, those with certain arrhythmias resulting from congenital heart disease, and those with LV dysfunction who are at risk for, or who currently have, documented ventricular arrhythmias. While sudden arrhythmic death is an uncommon consequence of untreated Wolff-Parkinson-White syndrome, it is particularly devastating in these typically young patients with curable disease (15). Patients with congenital heart disease and certain high-risk arrhythmias may also have a preventable mortality risk with early intervention. In patients with ventricular dysfunction and syncope or significant arrhythmias, EP studies are able to identify a subset of patients with a one-year mortality rate of 23% (16) who could

TABLE 3
Waiting time benchmarks for cardiac device therapy

Pacemakers	Waiting time benchmark
Urgent/semiurgent* pacemaker with TTVP	Immediate to 3 days
Urgent/semiurgent* pacemaker with no TTVP	3 days
Scheduled pacemaker, with high risk of syncope	2 weeks
Scheduled pacemaker, with lower risk of syncope	6 weeks
Implantable cardioverter defibrillators	
Secondary prevention	Immediate to 3 days
Primary prevention	8 weeks
Cardiac resynchronization therapy devices	
All cardiac resynchronization therapy devices	6 weeks

*Defined, in the judgment of a physician, as a patient who cannot safely leave the hospital until a permanent pacemaker is implanted. TTVP Temporary transvenous pacemaker

benefit from an implantable defibrillator, while also identifying a large group of patients who could be managed appropriately without a defibrillator. Prompt access to EP studies and catheter ablation for these potentially high-risk conditions may prevent avoidable death. As such, a shorter acceptable waiting period of two weeks is justified.

ACCESS TO PACEMAKER SERVICES

Permanent pacemakers are commonly implanted in many Canadian centres. In 1993, the number of new implants in Canada was estimated to be 268 per million population (17). From April 2004 to March 2005, 20,053 pacemakers were implanted in Canada (18), or approximately 670 per million population. Please see Table 3 for a list of waiting time benchmarks for pacemakers.

Permanent pacemaker implantation may be performed on an urgent or semiurgent basis (the patient is an inpatient who requires the implant of a permanent pacemaker before they can be safely discharged from hospital), or on a scheduled or elective basis. Most patients requiring pacemakers have sinus node dysfunction, AF with a slow ventricular response, or atrioventricular conduction disease. Typically, urgent and semiurgent patients (nonelective) are admitted to hospital either because their bradyarrhythmia has been symptomatic or because there is concern that the patient is at high risk for the development of an adverse event. Symptoms may include presyncope, syncope, fatigue, chest pain or dyspnea. Adverse events include falls with injury, the development of heart failure, and sudden death.

Evidence regarding the impact of waiting times for pacemakers on safety is sparse. However, one Canadian study found a correlation between waiting times for nonelective cases and adverse events (19), many of which were related to temporary transvenous pacing (TTVP). The study further found that rates of adverse events were lower in the centre with shorter waiting times (8% versus 33%; $P < 0.00001$), even though the rate of TTVP was the same. Adverse events included TTVP failure causing presyncope or syncope, pneumothorax, torsade de pointes ventricular tachycardia, infection and pulmonary embolism. The longer waiting times (4.5 ± 3.0 days versus 1.9 ± 1.6 days; $P = 0.0001$) in the centre with the higher rate of AEs were attributed to the fact that pacemakers were implanted

in an operating room (OR) and were therefore subject to delays and cancellations due to other competing priorities. A dedicated implant facility, such as a procedure room or an EP laboratory, facilitated more timely implants as well as shorter overall lengths of stay (3.0 ± 5.5 days versus 8.9 ± 5.7 days; $P = 0.0001$). The study also found that patients who were transferred in from another inpatient facility for a pacemaker implantation waited longer than patients who were primarily admitted to the implanting centre – a difference not found in the centre with a dedicated implant facility. Finally, in both centres, patients with an adverse event had longer waiting times than those without. A subsequent follow-up study (20) found that when the centre in the original study moved implants to the EP laboratory from the OR, waiting times and complication rates were dramatically reduced, and the disparity in waiting times and outcomes between ‘transfer’ patients and ‘nontransfer’ patients disappeared. Another Canadian study (21) in 2000 also supported the safety of an EP laboratory implant strategy. Study investigators found that EP laboratory implants were as safe as OR implants, but that waiting times were reduced in the EP laboratory environment.

Safe waiting times for scheduled (elective) implants have not been evaluated in the literature. Patients who do not require admission for their bradyarrhythmia are generally at low risk; however, they are usually very symptomatic and would therefore benefit from shorter waiting times. Because waiting with a temporary pacing wire in situ appears to be strongly associated with adverse events, permanent pacemaker implantation should be accomplished as quickly as possible (immediate to three days). Those in hospital waiting for pacemaker implantation should wait no longer than three days. Low-risk outpatients should wait no more than six weeks, and higher-risk outpatients should wait no more than two weeks.

ACCESS TO ICD SERVICES

Access to ICDs has been addressed separately by the Working Group and was published previously (22); the reader is referred to this paper for a complete review on access to ICDs in Canada.

ICDs are broadly classified as being either for ‘secondary prevention’ or ‘primary prevention’. Secondary prevention devices are implanted in patients who have survived a cardiac arrest or a dangerous ventricular tachyarrhythmia. Primary prevention patients are those who are deemed to belong to a high-risk group shown to benefit from the prophylactic implant of an ICD, even though a life-threatening arrhythmia has not yet occurred.

Historically, patients who require a secondary prevention device are admitted to hospital and remain in hospital until the device can be implanted. There may be medical reasons for delay, including recovery from the index event, but there are more frequently administrative and economic reasons for delay, including the unavailability of devices due to budgetary restrictions, limitations on OR or EP laboratory time, or other procedures competing for implanting physicians’ time. Ideally, once a patient is deemed fit for the implant, the procedure should be accomplished with a maximum waiting time of a pacemaker (ie, three days).

To derive a justifiable waiting time for primary prevention ICDs for patients not in hospital, the authors applied the principles currently applied to patients on the waiting list for coronary artery bypass graft (CABG) surgery. The benchmark for

total waiting list mortality for patients awaiting CABG surgery in Ontario is 0.5%. It would seem reasonable that the preventable waiting list mortality for patients awaiting a primary prevention ICD should also not exceed 0.5%. Although there is no real-world registry data regarding ICD waiting list mortality, the Multicenter Automatic Defibrillator Implantation Trial II (MADIT II) (23) provides a means by which to predict the preventable mortality for each unit of time that passes without an ICD in situ, because the mortality curves of the 'ICD' and 'no ICD' populations in the study diverge. This study of patients with coronary disease and reduced ejection fraction compared ICD therapy with optimal medical therapy. Based on these data, and presuming a 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 about 0.3% per month. Accordingly, to achieve the goal of subjecting 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 or 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 widespread acceptance of the same strategy for CABG surgery waiting list management.

ACCESS TO CRT PACEMAKERS AND ICDs

Resynchronization (biventricular) pacemakers have been recommended in the CCS/Canadian Heart Rhythm Society Position Paper on ICDs in Canada (24) as a Class IIa recommendation, and by the more recent CCS Position Paper on Heart Failure treatment (25) as a Class I indication. Eligible patients are those with severe (New York Heart Association [NYHA] Class III or IV) symptomatic heart failure, prolonged QRS duration (over 120 ms) and poor LV function (LV ejection fraction 35% or less). Using similar criteria, the European Heart Society 2005 update on heart failure management (26) also suggests a Class I recommendation for resynchronization therapy for such patients.

A decade of clinical trials, including large, randomized, blinded, multicentre clinical trials, have convincingly demonstrated that biventricular pacing, in appropriately selected patients, improves exercise function and clinical well being, reduces heart failure symptoms, leads to objective improvement in ventricular function (reduced ventricular size, improved systolic function, reduced mitral regurgitation), and reduces cardiac and heart failure-related hospitalizations during follow-up (27,28). As a result, this therapy is rapidly becoming mainstream for patients with systolic heart failure who receive optimal pharmacological therapy if their QRS duration is over 120 ms, and if NYHA Class III or IV symptoms are present. The recently published Cardiac Resynchronization-Heart Failure (CARE-HF) study (2), supported by a trend observed in the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) study (29) and a meta-analysis of prior published trials of resynchronization pacing (without an ICD) in heart failure patients (30), suggests that CRT may afford a mortality benefit independent of other therapies.

The issue of which patients should receive a biventricular pacemaker combined with an ICD versus a biventricular pacemaker alone remains unresolved. Furthermore, the issue of whether a biventricular pacemaker combined with an ICD provides greater mortality benefit than an ICD alone is also unresolved, and it is now the subject of multicentre randomized clinical trials, including the Canadian-led Resynchronization/defibrillation for Advanced heart Failure Trial (RAFT).

Although it is likely that CRT prolongs life, it must be emphasized that, even if CRT has not definitively been proven to prolong life, it is a well-documented, established, effective and widely used therapy for the purpose of improving quality of life in patients with severe heart failure.

Recommendations regarding waiting times for CRT

There are no published benchmarks regarding the maximum appropriate waiting time for CRT. Unlike the considerations involving waiting times for ICD therapy (for which estimates of sudden, preventable death while on a waiting list can be obtained), it is not possible to accurately estimate preventable mortality while waiting for a CRT device. Nonetheless, estimates regarding morbidity while on the waiting list can be obtained. Patients with NYHA Class III or IV heart failure symptoms are, by definition, disabled from moderately active physical functioning, have demonstrably poor quality of life and are at high risk for hospitalization (approximately 5% per month for the first three months, with a cumulative hospitalization rate of 45% after an average 24-month follow-up in the control arm of the CARE-HF trial [2]).

As in the case of highly symptomatic patients with angina requiring cardiac revascularization, it is reasonable to propose that waiting times for cardiac resynchronization be no longer than six weeks. This would correspond to less than a 10% incidence of rehospitalization for heart failure while waiting for the procedure. In addition, such patients would have no more than a 0.5% likelihood of unexpected deaths from sudden cardiac causes during the six-week waiting period, which may have been prevented with combined CRT and ICD therapy, when the latter is also employed. Please see Table 3 for a list of waiting time benchmarks for ICDs and CRT.

CONCLUSIONS

While reliable data to accurately assess the morbidity and mortality attributable to the lack of access to cardiac EP and to waiting times for EP services are sparse, some estimates can be inferred from clinical trial data. These data, taken together with expert consensus, have led to the development of the recommended waiting times offered in the present article. Major challenges in access to EP services in Canada lie on the immediate horizon, as promising new therapies with the potential to improve and prolong the lives of thousands of Canadians continue to rapidly enter the mainstream.

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