

# Site-Specific Rates of Shock, Therapy and Death after ICD Implantation in Ontario: Report from the Ontario ICD Database

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#### **About ICES**

The Institute for Clinical Evaluative Sciences (ICES) is an independent, non-profit organization that produces knowledge to enhance the effectiveness of health care for Ontarians. Internationally recognized for its innovative use of population-based health information, ICES' evidence supports health policy development and guides changes to the organization and delivery of health care services.

Key to our work is our ability to link population-based health information, at the patient-level, in a way that ensures the privacy and confidentiality of personal health information. Linked databases reflecting 13 million of 33 million Canadians allow us to follow patient populations through diagnosis and treatment, and to evaluate outcomes.

ICES brings together the best and the brightest talent from across Ontario. Many of our scientists are not only internationally recognized leaders in their fields but are also practicing clinicians who understand the grassroots of health care delivery, making the knowledge produced at ICES clinically focused and useful in changing practice. Other team members have statistical training, epidemiological backgrounds, project management or communications expertise. The variety of skill sets and educational backgrounds ensures a multi-disciplinary approach to issues and creates a real-world mosaic of perspectives that is vital to shaping Ontario's future health care system.

ICES receives core funding from the Ontario Ministry of Health and Long-Term Care. In addition, our faculty and staff compete for peer-reviewed grants from federal funding agencies, such as the Canadian Institutes of Health Research, and project-specific funds are received from provincial and national organizations. These combined sources enable ICES to have a large number of projects underway, covering a broad range of topics. The knowledge that arises from these efforts is produced independent of our funding bodies, which is critical to our success as Ontario's objective, credible source of Evidence Guiding Health Care.

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#### **Executive Summary**

Data collection in the Ontario Implantable Cardioverter Defibrillator (ICD) Database began in February/March 2007 at Type I ICD implanting sites in Ontario. This report represents approximately 31 months of implant data in the ICD Database as of September 30, 2009.

The report cohort consists of 4,638 patients who were implanted for primary or secondary prevention at one of 10 Type I ICD implanting sites throughout Ontario.

We selected 45 days to 6 months for determination of shock, therapy and death rates for these reasons: 1) these times were temporally close to the device implant date, and 2) all sites conducted an initial post-implant clinic visit within 45 days and a large number of patients had a 6-month follow-up.

The number of events and, in some cases, the denominator for the study sites were low, and in the cases where small numbers exist, there may be some instability of the estimated event rates.

The overall risk-adjusted rate of appropriate shock within six months, for primary prevention patients was approximately 3.3%, and the risk-adjusted rate of appropriate therapy for these patients at six months was approximately 5.9%. The overall risk-adjusted inappropriate shock rate in primary prevention patients at 6 months was approximately 3.1%, and the risk-adjusted inappropriate therapy rate in primary prevention patients at 6 months was approximately 3.0%.

Although rates of appropriate and inappropriate shocks and therapies in the Ontario ICD Database were in line with expectations based on published randomized trials, <sup>2,3,4,5</sup> there was variation in these rates depending on the hospital where the ICD was implanted.

The overall risk-adjusted death rate within 6 months for primary prevention patients was approximately 2.5%. While the overall death rates were comparable to those published in landmark randomized trials, <sup>2,3,4,5</sup> there was some variation in the rates of early death across sites for patients who had been implanted with an ICD.

Overall, patients who had an ICD implanted for primary prevention had far lower rates of appropriate shock than those implanted for a secondary prevention indication.

Secondary prevention patients had higher mortality rates across sites than those who were implanted with a primary prevention device.

The quality of care received by patients implanted with an ICD across the 10 Ontario Type I ICD implanting sites is very good but variations exist. Continued monitoring of these events will improve the quality and efficiency of ICD care. Developing better methods to identify primary prevention patients who are more likely to benefit from an ICD are needed to further optimize care and mitigate risk.

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#### 1.0 Background

The Ontario Implantable Cardioverter Defibrillator (ICD) Database was commissioned by the Ontario Ministry of Health and Long-Term Care (MOHLTC) in 2005 to collect data on patients who undergo ICD implantation in Ontario.

An ICD is indicated for either primary or secondary prevention. Such implantable defibrillators are used for primary prevention when the patient has not yet experienced a lethal arrhythmia or cardiac arrest, but might be at future risk for such an event. Implantable defibrillators are used for secondary prevention when patients have had a cardiac arrest or experienced a potentially lethal ventricular arrhythmia and survived the episode.

Currently, three major types of ICDs are available. They are classified based on the chambers of the heart that can be paced:

- a single-chamber device paces the right ventricle
- a dual-chamber device paces the right atrium and the right ventricle
- a cardiac resynchronization therapy (CRT) device has the capacity to pace the right atrium, as well as the left and right ventricles.

The cost of the ICD increases with functionality. The longevity of the devices ranges from six to 10 years, which means that most patients will eventually require replacement procedures.

The Ontario ICD Database is a pioneering effort in outcomes assessment. It is the first population-based data collection initiative of its kind and contains outcomes follow-up data that are not available in other ICD database initiatives. The project utilizes a unique web-based data collection form designed by the programming team at the Institute for Clinical Evaluative Sciences (ICES). This allows for real-time data collection from a geographically diverse network of electrophysiologic facilities and follow-up sites in Ontario.

Information from the database is fed back to hospitals on a regular basis for quality assurance purposes. The quality of the data collected to-date has been extremely high, with a very low rate of missing data. As data from the Ontario ICD Database are linked to other administrative databases held at ICES (e.g., the Canadian Institute for Health Information hospital discharge database, the Ontario Drug Benefit database, and death databases), we expect that the Ontario ICD Database will become one of the most comprehensive databases of its kind for assessing "real-world" outcomes of ICD patients.

#### 2.0 Rationale for this Report

Two of the primary research questions of the Ontario ICD Database are to examine: (1) the occurrence and determinants of ICD therapies (e.g., shock or antitachycardia pacing), and (2) long-term survival after defibrillator implantation.<sup>1</sup>

We have examined 45-day and 6-month "real-world" rates of appropriate and inappropriate shock and therapy in four ways:

- (a) rates by implant indication
- (b) rates by site
- (c) rates for primary prevention patients by site
- (d) rates for secondary prevention patients by site

We have examined 45-day and 6-month "real-world" rates of death in three ways:

- (a) rates by implant indication
- (b) rates for primary prevention patients by site
- (c) rates for secondary prevention patients by site

# 3.0 Appropriate Shock Rates from February 15, 2007 to September 30, 2009

#### 3.1 Appropriate shock rates by implant indication

The report cohort consisted of 4,638 patients who were implanted for primary or secondary prevention at one of 10 Type I ICD implanting sites throughout Ontario.

Table 1a shows the appropriate shock rates by implant indication. The overall risk-adjusted rate of appropriate shock at 45 days was 2.5%. For secondary prevention patients, the risk-adjusted rate was 4.6%. Primary prevention patients had a significantly lower risk-adjusted rate of appropriate shock at 45 days (1.6%).

As expected, the risk-adjusted rates of appropriate shock increased within 6 months for primary, secondary and overall indications, to 3.3%, 9.0% and 5.1%, respectively. Primary prevention patients continued to have a significantly lower risk-adjusted rate of appropriate shock within the 6-month period (3.3%).

Table 1a. Appropriate shock rates by implant indication									
		45 days of	e shock within implant date 100 persons)	Appropriate 6 months of (rates per 1	Appropriate shock within 6 months of implant date (ICD recipients)				
Implant indication	No. of Implants	Crude	Risk-adjusted rates*	Crude	Risk-adjusted rates*	SCD-HeFT			
Primary prevention	3,254	1.6 (1.2, 2.1) <sup>†</sup>	1.6 (1.1, 2.2) <sup>†</sup>	3.2 (2.6, 3.9) <sup>†</sup>	3.3 (2.6, 4.1) <sup>†</sup>	~ 2–3%			
Secondary prevention	1,384	4.8 (3.8, 6.1)**	4.6 (3.8, 5.4)**	9.5 (7.9, 11.2)**	9.0 (7.9, 10.2)**				
Total	4,638	2.5 (2.1, 3.0)	2.5	5.1 (4.5, 5.8)	5.1				

<sup>\*</sup> Adjusted by age, sex and ICD implant type

<sup>†</sup> Significantly lower than Ontario rate

<sup>\*\*</sup> Significantly higher than Ontario rate

#### 3.2 Appropriate shock rates by site

Table 1b shows appropriate shock rates by site. The University of Ottawa Heart Institute's 45-day risk-adjusted rate of 4.3% was significantly higher than the Ontario rate of 2.5%. Toronto General Hospital's 6-month risk-adjusted rate of 7.1% was significantly higher than the 6-month Ontario rate of 5.1%.

Table 1b. Appropriate shock rates by site							
	No. of	45 days of	Appropriate shock within 45 days of implant date (rates per 100 persons)		shock within implant date 00 persons)		
Site	Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*		
Toronto General Hospital	557	3.4 (2.1, 5.3)	3.5 (2.2, 4.8)	6.8 (4.8, 9.4)	7.1 (5.2, 8.9)**		
Hamilton Health Sciences Centre	771	1.6 (0.8, 2.7)	1.6 (0.5, 2.8)	4.0 (2.7, 5.7)	4.0 (2.5, 5.6)		
St. Michael's Hospital	496	3.6 (2.2, 5.7)	3.4 (2.1, 4.8)	6.5 (4.4, 9.1)	6.1 (4.2, 7.9)		
London Health Sciences Centre	772	2.3 (1.4, 3.7)	2.2 (1.1, 3.3)	5.3 (3.8, 7.2)	4.9 (3.4, 6.4)		
Rouge Valley Health System	156	1.9 (0.4, 5.6)	1.8 (0.0, 4.2)	2.6 (0.7, 6.6)	2.4 (0.0, 5.7)		
Southlake Regional Health Centre	520	2.1 (1.1, 3.8)	2.2 (0.8, 3.6)	4.2 (2.7, 6.4)	4.8 (2.8, 6.8)		
Trillium Health Centre	130	1.5 (0.2, 5.6)	1.3 (0.0, 3.7)	4.6 (1.7, 10.0)	3.9 (0.5, 7.4)		
Sunnybrook Health Sciences Centre	387	1.8 (0.7, 3.7)	2.0 (0.4, 3.6)	4.1 (2.4, 6.7)	4.6 (2.3, 6.9)		
Kingston General Hospital	376	2.4 (1.1, 4.5)	2.5 (0.9, 4.2)	4.8 (2.8, 7.6)	5.1 (2.8, 7.3)		
University of Ottawa Heart Institute	473	4.0 (2.4, 6.3)	4.3 (2.8, 5.7)**	5.9 (3.9, 8.6)	5.9 (3.9, 7.9)		
Ontario	4,638	2.5 (2.1, 3.0)	2.5	5.1 (4.5, 5.8)	5.1		

<sup>\*</sup> Adjusted by age, sex and ICD implant type

<sup>\*\*</sup> Significantly higher than Ontario rate

#### 3.3 Appropriate shock rates for primary prevention patients by site

When we examined primary prevention patients only, there was no significant difference in appropriate shock rates between sites.

Table 1c. Appropriate shock rates for primary prevention patients by site							
	45 days of implant of		Appropriate shock within 45 days of implant date (rates per 100 persons)		shock within implant date 00 persons)		
Site	No. of Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*		
Toronto General Hospital	402	2.0 (0.9, 3.9)	1.9 (0.7, 3.1)	4.5 (2.7, 7.1)	4.5 (2.8, 6.2)		
Hamilton Health Sciences Centre	551	0.9 (0.3, 2.1)	0.9 (0.0, 1.9)	2.4 (1.3, 4.0)	2.3 (0.9, 3.8)		
St. Michael's Hospital	322	1.9 (0.7, 4.1)	1.9 (0.5, 3.2)	3.4 (1.7, 6.1)	3.4 (1.5, 5.3)		
London Health Sciences Centre	493	1.6 (0.7, 3.2)	1.5 (0.5, 2.6)	3.0 (1.7, 5.0)	3.0 (1.4, 4.5)		
Rouge Valley Health System	103	1.0 (0.0, 5.4)	1.0 (0.0, 3.4)	1.0 (0.0, 5.4)	1.0 (0.0, 4.3)		
Southlake Regional Health Centre	401	1.5 (0.5, 3.3)	1.6 (0.3, 2.8)	3.5 (1.9, 5.9)	3.6 (1.9, 5.4)		
Trillium Health Centre	72	0.0 (0.0, 0.0)	0.0 (0.0, 2.9)	1.4 (0.0, 7.7)	1.4 (0.0, 5.5)		
Sunnybrook Health Sciences Centre	298	1.0 (0.2, 2.9)	1.1 (0.0, 2.5)	3.4 (1.6, 6.2)	3.4 (1.4, 5.4)		
Kingston General Hospital	279	1.8 (0.6, 4.2)	1.9 (0.4, 3.3)	3.2 (1.5, 6.1)	3.2 (1.2, 5.3)		
University of Ottawa Heart Institute	333	2.7 (1.2, 5.1)	2.6 (1.3, 3.9)	3.9 (2.1, 6.7)	3.8 (2.0, 5.7)		
Ontario	3,254	1.6 (1.2, 2.1)	1.6	3.2 (2.6, 3.9)	3.2		

<sup>\*</sup> Adjusted by age, sex and ICD implant type

#### 3.4 Appropriate shock rates for secondary prevention patients by site

Table 1d shows appropriate shock rates for secondary prevention patients by site. When we examined secondary prevention patients only, there was no significant difference in appropriate shock rates between sites.

Table 1d. Appropriate shock rates for secondary prevention patients by site							
	No. of	45 days of i	shock within implant date 00 persons)	Appropriate 6 months of (rates per 1			
Site	No. of Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*		
Toronto General Hospital	155	7.1 (3.5, 12.7)	7.0 (3.7, 10.4)	12.9 (7.9, 19.9)	13.3 (8.6, 17.9)		
Hamilton Health Sciences Centre	220	3.2 (1.3, 6.6)	3.5 (0.5, 6.4)	8.2 (4.8, 12.9)	8.1 (4.2, 11.9)		
St. Michael's Hospital	174	6.9 (3.6, 12.0)	6.9 (3.7, 10.0)	12.1 (7.5, 18.4)	12.0 (7.7, 16.4)		
London Health Sciences Centre	279	3.6 (1.7, 6.6)	3.8 (1.2, 6.4)	9.3 (6.1, 13.7)	9.3 (5.9, 12.8)		
Rouge Valley Health System	53	3.8 (0.5, 13.6)	3.6 (0.0, 9.2)	5.7 (1.2, 16.5)	5.7 (0.0, 13.5)		
Southlake Regional Health Centre	119	4.2 (1.4, 9.8)	3.7 (0.1, 7.3)	6.7 (2.9, 13.2)	7.1 (1.7, 12.5)		
Trillium Health Centre	58	3.4 (0.4, 12.5)	3.1 (0.0, 8.4)	8.6 (2.8, 20.1)	8.6 (1.1, 16.1)		
Sunnybrook Health Sciences Centre	89	4.5 (1.2, 11.5)	4.3 (0.0, 8.7)	6.7 (2.5, 14.7)	7.0 (0.8, 13.3)		
Kingston General Hospital	97	4.1 (1.1, 10.6)	4.1 (0.0, 8.4)	9.3 (4.2, 17.6)	9.4 (3.6, 15.3)		
University of Ottawa Heart Institute	140	7.1 (3.4, 13.1)	8.1 (4.3, 11.9)	10.7 (6.0, 17.7)	10.6 (5.8, 15.5)		
Ontario	1,384	4.8 (3.8, 6.1)	4.8	9.5 (7.9, 11.2)	9.5		

<sup>\*</sup> Adjusted by age, sex and ICD implant type

## 4.0 Appropriate Therapy Rates from February 15, 2007 to September 30, 2009

#### 4.1 Appropriate therapy rates by implant indication

Table 2a shows the appropriate therapy rates by implant indication. The overall risk-adjusted rate of appropriate therapy at 45 days was 3.9%. For secondary prevention patients, the risk-adjusted rate was 6.9%. Primary prevention patients had a lower risk-adjusted rate of appropriate therapy at 45 days (2.4%).

As expected, the risk-adjusted rates of appropriate therapy increased within 6 months for primary, secondary and overall indications, to 5.9%, 12.8% and 8.0%, respectively. Primary prevention patients continued to have a significantly lower risk-adjusted rate of appropriate therapy within the 6-month period (5.9%).

	Table 2a. Appropriate therapy rates by implant indication									
		Appropriate therapy within 45 days of implant date (rates per 100 persons)  Appropriate therapy within 6 months of implant date (rates per 100 persons)		Appropriate therapy within 6 months of implant date (ICD recipients)						
Implant indication	No. of Implants	Crude	Risk-adjusted*	Crude Risk-adjusted*		MADIT II				
Primary prevention	3,254	2.3 (1.8, 2.9) <sup>†</sup>	2.4 (1.7, 3.1) <sup>†</sup>	5.7 (4.9, 6.5) <sup>†</sup>	5.9 (4.9, 6.8) <sup>†</sup>	~ 8%				
Secondary prevention	1,384	7.6 (6.2, 9.2)**	6.9 (6.0, 7.9)**	13.7 (11.8, 15.7)**	12.8 (11.4, 14.1)**					
Total	4,638	3.9 (3.3, 4.5)	3.9	8.0 (7.2, 8.9)	8.0					

<sup>\*</sup> Adjusted by age, sex and ICD implant type

<sup>&</sup>lt;sup>†</sup> Significantly lower than Ontario rate

<sup>\*\*</sup> Significantly higher than Ontario rate

#### 4.2 Appropriate therapy rates by site

Table 2b shows appropriate therapy rates by site. St. Michael's Hospital's 45-day risk-adjusted rate of 7.9% was significantly higher than the Ontario rate of 3.9%. Its 6-month risk-adjusted rate of 14.7% was also significantly higher than the Ontario rate of 8.0%.

Hamilton Health Sciences Centre and London Health Sciences Centre had significantly lower 45-day risk-adjusted rates of appropriate therapy, at 2.0% and 2.2% respectively, than the Ontario rate of 3.9%.

Rouge Valley Health System had a significantly lower risk-adjusted rate of appropriate therapy within 6 months than the Ontario rate (3.5% vs. 8.0%).

Table 2b. Appropriate therapy rates by site							
	No. of	45 days of i	herapy within mplant date 00 persons)	Appropriate therapy within 6 months of implant date (rates per 100 persons)			
Site	No. of Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*		
Toronto General Hospital	557	3.1 (1.8, 4.9)	3.3 (1.6, 4.9)	6.8 (4.8, 9.4)	7.1 (4.9, 9.4)		
Hamilton Health Sciences Centre	771	1.9 (1.1, 3.2) <sup>†</sup>	2.0 (0.6, 3.4) <sup>†</sup>	6.2 (4.6, 8.3)	6.4 (4.5, 8.4)		
St. Michael's Hospital	496	8.7 (6.3, 11.7)**	7.9 (6.3, 9.5)**	15.7 (12.4, 19.6)**	14.7 (12.4, 17.0)**		
London Health Sciences Centre	772	2.3 (1.4, 3.7) <sup>†</sup>	2.2 (0.9, 3.6) <sup>†</sup>	6.7 (5.0, 8.8)	6.5 (4.7, 8.4)		
Rouge Valley Health System	156	1.9 (0.4, 5.6)	1.7 (0.0, 4.5)	3.8 (1.4, 8.4)	3.5 (0.0, 7.5) <sup>†</sup>		
Southlake Regional Health Centre	520	4.0 (2.5, 6.2)	4.2 (2.5, 5.9)	7.5 (5.3, 10.3)	7.8 (5.4, 10.1)		
Trillium Health Centre	130	6.2 (2.7, 12.1)	4.6 (1.8, 7.4)	11.5 (6.5, 19.0)	9.3 (5.2, 13.4)		
Sunnybrook Health Sciences Centre	387	3.6 (2.0, 6.1)	3.8 (1.9, 5.8)	8.3 (5.7, 11.7)	8.8 (6.0, 11.5)		
Kingston General Hospital	376	5.3 (3.2, 8.2)	5.5 (3.6, 7.5)	9.6 (6.7, 13.3)	10.0 (7.3, 12.8)		
University of Ottawa Heart Institute	473	4.4 (2.7, 6.8)	4.6 (2.9, 6.4)	6.1 (4.1, 8.8)	6.3 (3.9, 8.8)		
Ontario	4,638	3.9 (3.3, 4.5)	3.9	8.0 (7.2, 8.9)	8.0		

Data source: Ontario ICD Database results valid to September 30, 2009

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 <sup>\*</sup> Adjusted by age, sex and ICD implant type
 † Significantly lower than Ontario rate

<sup>\*\*</sup> Significantly higher than Ontario rate

#### 4.3 Appropriate therapy rates for primary prevention patients by site

Table 2c shows appropriate therapy rates for primary prevention patients by site. Kingston General Hospital's 45-day risk-adjusted rate of 4.4% was significantly higher than the Ontario rate of 2.3%.

Hamilton Health Sciences Centre had a 45-day risk-adjusted rate of appropriate therapy for primary prevention patients of 0.6%, which was significantly lower than the Ontario rate of 2.3%.

St. Michael's Hospital had a 6-month risk-adjusted rate of appropriate therapy for primary prevention patients of 11.1%, which was significantly higher than the Ontario rate of 5.7%.

Table 2c. Appropriate therapy rates for primary prevention patients by site							
	No. of	45 days of	therapy within implant date 100 persons)	Appropriate therapy within 6 months of implant date (rates per 100 persons)			
Site	Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*		
Toronto General Hospital	402	1.7 (0.7, 3.6)	1.8 (0.3, 3.3)	4.2 (2.5, 6.8)	4.3 (2.0, 6.6)		
Hamilton Health Sciences Centre	551	0.5 (0.1, 1.6) <sup>†</sup>	0.6 (0.0, 1.8) <sup>†</sup>	3.8 (2.4, 5.8)	3.9 (1.9, 5.8)		
St. Michael's Hospital	322	4.0 (2.1, 6.9)	3.9 (2.3, 5.5)	11.2 (7.8, 15.5)**	11.1 (8.5, 13.6)**		
London Health Sciences Centre	493	1.2 (0.4, 2.6)	1.3 (0.0, 2.6)	5.1 (3.3, 7.5)	5.2 (3.1, 7.3)		
Rouge Valley Health System	103	1.0 (0.0, 5.4)	0.9 (0.0, 3.7)	1.9 (0.2, 7.0)	1.9 (0.0, 6.3)		
Southlake Regional Health Centre	401	2.7 (1.4, 4.9)	2.6 (1.2, 4.0)	5.5 (3.4, 8.3)	5.3 (3.1, 7.5)		
Trillium Health Centre	72	4.2 (0.9, 12.2)	3.8 (0.5, 7.1)	6.9 (2.3, 16.2)	6.6 (1.4, 11.8)		
Sunnybrook Health Sciences Centre	298	3.7 (1.8, 6.6)	3.5 (1.9, 5.2)	7.7 (4.9, 11.6)	7.6 (5.0, 10.2)		
Kingston General Hospital	279	4.3 (2.2, 7.5)	4.4 (2.6, 6.2)**	7.2 (4.4, 11.1)	7.3 (4.6, 10.1)		
University of Ottawa Heart Institute	333	2.4 (1.0, 4.7)	2.5 (0.8, 4.1)	3.9 (2.1, 6.7)	4.0 (1.5, 6.5)		
Ontario	3,254	2.3 (1.8, 2.9)	2.3	5.7(4.9, 6.5)	5.7		

Data source: Ontario ICD Database results valid to September 30, 2009

© Institute for Clinical Evaluative Sciences

<sup>\*</sup> Adjusted by age, sex and ICD implant type

<sup>&</sup>lt;sup>†</sup> Significantly lower than Ontario rate

<sup>\*\*</sup> Significantly higher than Ontario rate

#### 4.4 Appropriate therapy rates for secondary prevention patients by site

Table 2d shows appropriate therapy rates for secondary prevention patients by site. St. Michael's Hospital's 45-day risk-adjusted rate of 16.8% was significantly higher than the Ontario rate of 7.6%.

St. Michael's Hospital had a 6-month risk-adjusted rate of appropriate therapy for secondary prevention patients of 23.6%, which was significantly higher than the Ontario rate of 13.7%.

Table 2d. Appropriate therapy rates for secondary prevention patients by site							
		45 days of i	herapy within mplant date 00 persons)	Appropriate the 6 months of in a crates per 10	mplant date		
Site	No. of Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*		
Toronto General Hospital	155	6.5 (3.1, 11.9)	6.7 (2.4, 10.9)	13.5 (8.4, 20.7)	13.9 (8.5, 19.4)		
Hamilton Health Sciences Centre	220	5.5 (2.8, 9.5)	5.6 (2.1, 9.2)	12.3 (8.1, 17.9)	12.4 (7.9, 16.9)		
St. Michael's Hospital	174	17.2 (11.6, 24.6)**	16.8 (12.9, 20.6)**	24.1 (17.4, 32.6)**	23.6 (18.6, 28.6)**		
London Health Sciences Centre	279	4.3 (2.2, 7.5) <sup>†</sup>	4.5 (1.3, 7.7)	9.7 (6.4, 14.1)	10.0 (5.9, 14.1)		
Rouge Valley Health System	53	3.8 (0.5, 13.6)	3.5 (0.0, 10.3)	7.5 (2.1, 19.3)	7.0 (0.0, 15.8)		
Southlake Regional Health Centre	119	8.4 (4.0, 15.5)	7.9 (3.3, 12.5)	14.3 (8.3, 22.9)	14.0 (8.0, 20.1)		
Trillium Health Centre	58	8.6 (2.8, 20.1)	7.6 (1.3, 14.0)	17.2 (8.3, 31.7)	15.4 (7.2, 23.7)		
Sunnybrook Health Sciences Centre	89	3.4 (0.7, 9.9)	3.3 (0.0, 8.6)	10.1 (4.6, 19.2)	10.3 (3.1, 17.4)		
Kingston General Hospital	97	8.2 (3.6, 16.3)	7.9 (2.8, 13.0)	16.5 (9.4, 26.8)	16.3 (9.5, 23.0)		
University of Ottawa Heart Institute	140	9.3 (4.9, 15.9)	9.8 (5.3, 14.3)	11.4 (6.5, 18.6)	11.6 (5.9, 17.3)		
Ontario	1,384	7.6 (6.2, 9.2)	7.6	13.7 (11.8, 15.7)	13.7		

Data source: Ontario ICD Database results valid to September 30, 2009 © Institute for Clinical Evaluative Sciences

<sup>\*</sup> Adjusted by age, sex and ICD implant type

<sup>\*\*</sup> Significantly higher than Ontario rate † Significantly lower than Ontario rate

## 5.0 Inappropriate Shock Rates from February 15, 2007 to September 30, 2009

#### 5.1 Inappropriate shock rates by implant indication

Table 3a shows inappropriate shock rates by implant indication. The overall risk-adjusted rate of inappropriate shock at 45 days was 1.9%. There was no significant difference in this rate for primary and secondary prevention indications.

The overall risk-adjusted rate of inappropriate shock increased at 6 months to 3.5%. Again, there was no significant difference in this rate between primary prevention and secondary prevention indications.

Table 3a. Inappropriate shock rates by implant indication										
		45 days of	e shock within implant date 00 persons)	6 months of	e shock within implant date 100 persons)	Inappropriate shock within 6 months of implant date (ICD recipients)				
Implant indication	No. of Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*	MADIT II	SCD-HeFT			
Primary prevention	3,254	1.9 (1.5, 2.4)	2.0 (1.5, 2.4)	3.0 (2.4, 3.7)	3.1 (2.5, 3.8)	~ 8%	~ 1–2%			
Secondary prevention	1,384	2.0 (1.3, 2.8)	1.8 (1.1, 2.5)	4.7 (3.6, 6.0)**	4.3 (3.3, 5.2)					
Total	4,638	1.9 (1.5, 2.4)	1.9	3.5 (3.0, 4.1)	3.5					

Data source: Ontario ICD Database results valid to September 30, 2009

© Institute for Clinical Evaluative Sciences

<sup>\*</sup> Adjusted by age, sex and ICD implant type

<sup>\*\*</sup> Significantly higher than Ontario rate

#### 5.2 Inappropriate shock rates by site

Table 3b shows inappropriate shock rates by site. Trillium Health Centre and Sunnybrook Health Sciences Centre had 45-day, risk-adjusted rates of 4.5% and 4.8%, respectively. These were significantly higher than the Ontario rate of 1.9%.

Hamilton Health Sciences Centre and the University of Ottawa Heart Institute had significantly lower 45-day risk-adjusted rates of inappropriate shock at 0.5% and 0.4%, respectively, than the Ontario rate of 1.9%.

Sunnybrook Health Sciences Centre's 6-month risk-adjusted rate of 7.1% was significantly higher than the Ontario rate of 3.5%.

Hamilton Health Sciences Centre and the University of Ottawa Heart Institute had a significantly lower 6-month risk-adjusted rate for inappropriate shock than the Ontario rate (1.5% vs. 3.5%).

Table 3b. Inappropriate shock rates by site							
			shock within mplant date 00 persons)	6 months of	e shock within implant date 00 persons)		
Site	No. of Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*		
Toronto General Hospital	557	2.0 (1.0, 3.5)	1.8 (0.7, 2.8)	3.6 (2.2, 5.5)	3.2 (1.8, 4.6)		
Hamilton Health Sciences Centre	771	0.5 (0.1, 1.3) <sup>†</sup>	0.5 (0.0, 1.5) <sup>†</sup>	1.4 (0.7, 2.6) <sup>†</sup>	1.5 (0.2, 2.8) <sup>†</sup>		
St. Michael's Hospital	496	2.4 (1.3, 4.2)	2.4 (1.2, 3.6)	5.0 (3.3, 7.4)	4.9 (3.3, 6.5)		
London Health Sciences Centre	772	1.8 (1.0, 3.0)	1.8 (0.8, 2.7)	3.2 (2.1, 4.8)	3.0 (1.8, 4.3)		
Rouge Valley Health System	156	1.3 (0.2, 4.6)	1.3 (0.0, 3.5)	4.5 (1.8, 9.2)	4.6 (1.7, 7.6)		
Southlake Regional Health Centre	520	2.5 (1.3, 4.3)	2.4 (1.2, 3.6)	4.2 (2.7, 6.4)	4.4 (2.8, 6.0)		
Trillium Health Centre	130	4.6 (1.7, 10.0)	4.5 (2.1, 6.8)**	5.4 (2.2, 11.1)	5.0 (1.9, 8.0)		
Sunnybrook Health Sciences Centre	387	4.4 (2.6, 7.0)**	4.8 (3.3, 6.2)**	6.2 (4.0, 9.2)**	7.1 (5.2, 9.1)**		
Kingston General Hospital	376	2.1 (0.9, 4.2)	2.3 (0.9, 3.8)	4.0 (2.2, 6.6)	4.5 (2.5, 6.5)		
University of Ottawa Heart Institute	473	0.4 (0.1, 1.5) <sup>†</sup>	0.4 (0.0, 1.7) <sup>†</sup>	1.5 (0.6, 3.0) <sup>†</sup>	1.5 (0.0, 3.2) <sup>†</sup>		
Ontario	4,638	1.9 (1.5, 2.4)	1.9	3.5 (3.0, 4.1)	3.5		

 $<sup>^{*}</sup>_{\scriptscriptstyle \perp}$  Adjusted by age, sex and ICD implant type

<sup>†</sup> Significantly lower than Ontario rate

<sup>\*\*</sup> Significantly higher than Ontario rate

#### 5.3 Inappropriate shock rates for primary prevention by site

Table 3c shows inappropriate shock rates for primary prevention by site. Sunnybrook Health Sciences Centre's 45-day risk-adjusted rate of 5.1% was significantly higher than the Ontario rate of 1.9%.

Hamilton Health Sciences Centre had a significantly lower 45-day risk-adjusted rate of inappropriate shock for primary prevention (0.6%) than the Ontario rate (1.9%).

Sunnybrook Health Sciences Centre's risk-adjusted rate of inappropriate shock for primary prevention within 6 months was significantly higher than the Ontario rate (6.0% vs. 3.0%).

Hamilton Health Sciences Centre's 6-month risk-adjusted rate of inappropriate shock for primary prevention was significantly lower than the Ontario rate (1.3% vs. 3.0%).

Table 3c. Inappropriate shock rates for primary prevention patients by site						
	No. of	45 days of i	Inappropriate shock within 45 days of implant date (rates per 100 persons)		Inappropriate shock within 6 months of implant date (rates per 100 persons)	
Site	Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*	
Toronto General Hospital	402	2.2 (1.0, 4.2)	2.0 (0.8, 3.3)	3.0 (1.5, 5.2)	2.6 (1.1, 4.2)	
Hamilton Health Sciences Centre	551	0.5 (0.1, 1.6) <sup>†</sup>	0.6 (0.0, 1.7) <sup>†</sup>	1.3 (0.5, 2.6) <sup>†</sup>	1.3 (0.0, 2.7) <sup>†</sup>	
St. Michael's Hospital	322	1.9 (0.7, 4.1)	1.9 (0.4, 3.4)	4.3 (2.4, 7.3)	4.4 (2.5, 6.3)	
London Health Sciences Centre	493	1.8 (0.8, 3.5)	1.8 (0.6, 3.0)	2.6 (1.4, 4.5)	2.5 (1.1, 4.0)	
Rouge Valley Health System	103	1.9 (0.2, 7.0)	2.0 (0.0, 4.7)	3.9 (1.1, 9.9)	4.0 (0.6, 7.3)	
Southlake Regional Health Centre	401	2.5 (1.2, 4.6)	2.5 (1.2, 3.9)	4.0 (2.3, 6.5)	4.1 (2.4, 5.8)	
Trillium Health Centre	72	4.2 (0.9, 12.2)	4.0 (0.9, 7.1)	5.6 (1.5, 14.2)	5.2 (1.4, 9.0)	
Sunnybrook Health Sciences Centre	298	4.7 (2.6, 7.9)**	5.1 (3.5, 6.7)**	5.4 (3.1, 8.7)**	6.0 (4.0, 8.1)**	
Kingston General Hospital	279	1.4 (0.4, 3.7)	1.5 (0.0, 3.2)	2.2 (0.8, 4.7)	2.4 (0.3, 4.5)	
University of Ottawa Heart Institute	333	0.6 (0.1, 2.2)	0.6 (0.0, 2.1)	1.8 (0.7, 3.9)	1.8 (0.0, 3.6)	
Ontario	3,254	1.9 (1.5, 2.4)	1.9	3.0 (2.4, 3.7)	3.0	

<sup>\*</sup> Adjusted by age, sex and ICD implant type

<sup>†</sup> Significantly lower than Ontario rate

<sup>\*\*</sup> Significantly higher than Ontario rate

#### 5.4 Inappropriate shock rates for secondary prevention by site

Table 3d shows inappropriate shock rates for secondary prevention by site. Sunnybrook Health Sciences Centre and Kingston General Hospital had risk-adjusted rates within 6 months of 9.8% and 10.2% respectively, significantly higher than the Ontario rate of 4.7%.

The University of Ottawa Heart Institute had a significantly lower risk-adjusted rate of inappropriate shock for secondary prevention within 6 months than the Ontario rate (0.8% vs. 4.7%).

Table 3d. Inappropriate shock rates for secondary prevention patients by site						
	No. of	45 days of	Inappropriate shock within 45 days of implant date (rates per 100 persons)		Inappropriate shock within 6 months of implant date (rates per 100 persons)	
Site	No. of Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*	
Toronto General Hospital	155	1.3 (0.2, 4.7)	1.1 (0.0, 3.1)	5.2 (2.2, 10.2)	4.6 (1.5, 7.8)	
Hamilton Health Sciences Centre	220	0.5 (0.0, 2.5)	0.5 (0.0, 2.4)	1.8 (0.5, 4.7) <sup>†</sup>	1.9 (0.0, 4.7)	
St. Michael's Hospital	174	3.4 (1.3, 7.5)	3.4 (1.4, 5.5)	6.3 (3.2, 11.3)	6.3 (3.2, 9.4)	
London Health Sciences Centre	279	1.8 (0.6, 4.2)	1.8 (0.2, 3.4)	4.3 (2.2, 7.5)	4.1 (1.7, 6.5)	
Rouge Valley Health System	53	0.0 (0.0, 0.0)	0.0 (0.0, 3.8)	5.7 (1.2, 16.5)	6.1 (0.2, 12.0)	
Southlake Regional Health Centre	119	2.5 (0.5, 7.4)	2.1 (0.0, 4.3)	5.0 (1.9, 11.0)	4.7 (1.0, 8.3)	
Trillium Health Centre	58	5.2 (1.1, 15.1)	5.0 (1.5, 8.5)	5.2 (1.1, 15.1)	5.4 (0.0, 11.0)	
Sunnybrook Health Sciences Centre	89	3.4 (0.7, 9.9)	3.5 (0.6, 6.4)	9.0 (3.9, 17.7)	9.8 (5.2, 14.4)**	
Kingston General Hospital	97	4.1 (1.1, 10.6)	4.5 (1.6, 7.4)	9.3 (4.2, 17.6)	10.2 (5.8, 14.6)**	
University of Ottawa Heart Institute	140	0.0 (0.0, 0.0)	0.0 (0.0, 2.5)	0.7 (0.0, 4.0) <sup>†</sup>	0.8 (0.0, 4.4) <sup>†</sup>	
Ontario	1,384	2.0 (1.3, 2.8)	2.0	4.7 (3.6, 6.0)	4.7	

<sup>\*</sup> Adjusted by age, sex and ICD implant type

<sup>&</sup>lt;sup>†</sup> Significantly lower than Ontario rate

<sup>\*\*</sup> Significantly higher than Ontario rate

# 6.0 Inappropriate Therapy Rates from February 15, 2007 to September 30, 2009

#### 6.1 Inappropriate therapy rates by implant indication

Table 4a shows inappropriate therapy rates by implant indication. The overall risk-adjusted rate of inappropriate therapy at 45 days was 1.8%. There was no significant difference in this rate for primary and secondary prevention indications.

As expected, risk-adjusted rates of inappropriate therapy increased within 6 months for primary, secondary and overall indications, to 3.0%, 3.8% and 3.3%, respectively. Again, there was no significant difference in this rate for primary and secondary prevention indications.

	Table 4a. Inappropriate therapy rates by implant indication								
		45 days of i	therapy within mplant date 00 persons)	Inappropriate 6 months of (rates per 1	Inappropriate shock within 6 months of implant date (ICD recipients)				
Implant indication	No. of Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*	MADIT II			
Primary prevention	3,254	1.6 (1.2, 2.1)	1.6 (1.2, 2.1)	2.9 (2.3, 3.5)	3.0 (2.4, 3.6)	~ 8%			
Secondary prevention	1,384	2.3 (1.6, 3.3)	2.1 (1.4, 2.8)	4.1 (3.1, 5.3)	3.8 (2.9, 4.7)				
Total	4,638	1.8 (1.4, 2.2)	1.8	3.3 (2.8, 3.8)	3.3				

<sup>\*</sup> Adjusted by age, sex and ICD implant type

#### 6.2 Inappropriate therapy rates by site

Table 4b shows inappropriate therapy rates by site. The overall risk-adjusted rate of inappropriate therapy at 45 days was 1.8%. Trillium Health Centre and Sunnybrook Health Sciences Centre had 45-day risk-adjusted rates of 3.9% and 3.5% respectively, significantly higher than the Ontario rate of 1.8%.

Hamilton Health Sciences Centre had a significantly lower 45-day risk-adjusted rate of inappropriate shock than the Ontario rate (0.7% vs. 1.8%).

Trillium Health Centre, Sunnybrook Health Sciences Centre and St. Michael's Hospital, at 6.2%, 6.8% and 5.3%, respectively, all had risk-adjusted rates of inappropriate therapy within 6 months that were significantly higher than the Ontario rate of 3.3%.

Hamilton Health Sciences Centre had a significantly lower risk-adjusted rate of inappropriate shock within 6 months than the Ontario rate (1.9% vs. 3.3%).

Table 4b. Inappropriate therapy rates by site							
	No. of	Inappropriate therapy within 45 days of implant date (rates per 100 persons)		Inappropriate therapy within 6 months of implant date (rates per 100 persons)			
Site	Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*		
Toronto General Hospital	557	1.3 (0.5, 2.6)	1.2 (0.1, 2.3)	2.0 (1.0, 3.5)	1.9 (0.4, 3.3)		
Hamilton Health Sciences Centre	771	0.6 (0.2, 1.5) <sup>†</sup>	0.7 (0.0, 1.6) <sup>†</sup>	1.8 (1.0, 3.0) <sup>†</sup>	1.9 (0.6, 3.1) <sup>†</sup>		
St. Michael's Hospital	496	2.6 (1.4, 4.5)	2.5 (1.4, 3.6)	5.4 (3.6, 7.9)**	5.3 (3.8, 6.8)**		
London Health Sciences Centre	772	1.6 (0.8, 2.7)	1.5 (0.6, 2.5)	2.8 (1.8, 4.3)	2.8 (1.6, 4.0)		
Rouge Valley Health System	156	0.6 (0.0, 3.6)	0.6 (0.0, 2.6)	1.9 (0.4, 5.6)	1.9 (0.0, 4.7)		
Southlake Regional Health Centre	520	2.5 (1.3, 4.3)	2.4 (1.3, 3.6)	4.0 (2.5, 6.2)	4.0 (2.5, 5.5)		
Trillium Health Centre	130	4.6 (1.7, 10.0)	3.9 (1.8, 6.0)**	6.9 (3.2, 13.1)	6.2 (3.3, 9.1)**		
Sunnybrook Health Sciences Centre	387	3.4 (1.8, 5.7)	3.5 (2.2, 4.8)**	6.5 (4.2, 9.5)**	6.8 (5.0, 8.6)**		
Kingston General Hospital	376	2.7 (1.3, 4.9)	2.8 (1.5, 4.2)	4.3 (2.4, 6.9)	4.5 (2.7, 6.4)		
University of Ottawa Heart Institute	473	0.6 (0.1, 1.9)	0.7 (0.0, 1.9)	0.6 (0.1, 1.9) <sup>†</sup>	0.7 (0.0, 2.3) <sup>†</sup>		
Ontario	4,638	1.8 (1.4, 2.2)	1.8	3.3 (2.8, 3.8)	3.3		

<sup>\*</sup> Adjusted by age, sex and ICD implant type

<sup>†</sup> Significantly lower than Ontario rate

<sup>\*\*</sup> Significantly higher than Ontario rate

#### 6.3 Inappropriate therapy rates for primary prevention patients by site

Table 4c shows inappropriate therapy rates for primary prevention patients by site. Sunnybrook Health Sciences Centre's 45-day risk-adjusted rate of 3.8% was significantly higher than the Ontario rate of 1.6%.

St. Michael's Hospital and Sunnybrook Health Sciences Centre had 6-month risk-adjusted rates of inappropriate therapy for primary prevention patients of 5.0% and 6.8%, respectively. These rates were significantly higher than the 6-month Ontario rate of 2.9%.

Toronto General Hospital had a significantly lower risk-adjusted rate of inappropriate shock for primary prevention within 6 months than the Ontario rate (0.9% vs. 2.9%).

Table 4c. Inappropriate therapy rates for primary prevention patients by site							
	No. of	45 days of	therapy within implant date 00 persons)	Inappropriate therapy within 6 months of implant date (rates per 100 persons)			
Site	No. of Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*		
Toronto General Hospital	402	0.5 (0.1,1.8)	0.5 (0.0,1.7)	1.0 (0.3,2.5) <sup>†</sup>	0.9 (0.0,2.5) <sup>†</sup>		
Hamilton Health Sciences Centre	551	0.7 (0.2,1.9)	0.7 (0.0,1.7)	1.6 (0.7,3.1)	1.7 (0.3,3.1)		
St. Michael's Hospital	322	2.2 (0.9,4.5)	2.1 (0.8,3.4)	5.0 (2.8,8.1)	5.0 (3.2,6.8)**		
London Health Sciences Centre	493	1.4 (0.6,2.9)	1.4 (0.3,2.5)	2.6 (1.4,4.5)	2.6 (1.1,4.1)		
Rouge Valley Health System	103	0.0 (0.0,0.0)	0.0 (0.0,2.3)	1.9 (0.2,7.0)	2.0 (0.0,5.2)		
Southlake Regional Health Centre	401	2.0 (0.9,3.9)	2.2 (0.9,3.4)	3.7 (2.1,6.2)	3.8 (2.1,5.4)		
Trillium Health Centre	72	4.2 (0.9,12.2)	3.7 (1.0,6.4)	6.9 (2.3,16.2)	6.5 (2.8,10.3)		
Sunnybrook Health Sciences Centre	298	3.7 (1.8,6.6)**	3.8 (2.4,5.2)**	6.4 (3.8,10.0)**	6.8 (4.8,8.8)**		
Kingston General Hospital	279	2.2 (0.8,4.7)	2.2 (0.8,3.7)	2.9 (1.2,5.6)	3.0 (1.0,5.1)		
University of Ottawa Heart Institute	333	0.9 (0.2,2.6)	0.9 (0.0,2.2)	0.9 (0.2,2.6) <sup>†</sup>	0.9 (0.0,2.7) <sup>†</sup>		
Ontario	3,254	1.6 (1.2,2.1)	1.6	2.9 (2.3,3.5)	2.9		

Data source: Ontario ICD Database results valid to September 30, 2009

<sup>\*</sup> Adjusted by age, sex and ICD implant type

<sup>&</sup>lt;sup>†</sup> Significantly lower than Ontario rate

<sup>\*\*</sup> Significantly higher than Ontario rate

#### 6.4 Inappropriate therapy rates for secondary prevention patients by site

Table 4d shows inappropriate therapy rates for secondary prevention patients by site. When we examined 45-day rates, there was no significant difference in inappropriate therapy rates for secondary prevention patients between sites.

When we examined the inappropriate therapy rates for secondary prevention patients within 6 months, Kingston General Hospital had a significantly higher rate of inappropriate therapy than the Ontario rate (8.4% vs. 4.1%).

Table 4d. Inappropriate therapy rates for secondary prevention patients by site							
	No. of	45 days of i	Inappropriate therapy within 45 days of implant date (rates per 100 persons)		Inappropriate therapy within 6 months of implant date (rates per 100 persons)		
Site	No. of Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*		
Toronto General Hospital	155	3.2 (1.0, 7.5)	2.9 (0.7, 5.1)	4.5 (1.8, 9.3)	4.3 (1.3, 7.4)		
Hamilton Health Sciences Centre	220	0.5 (0.0, 2.5)	0.5 (0.0, 2.6)	2.3 (0.7, 5.3)	2.4 (0.0, 5.1)		
St. Michael's Hospital	174	3.4 (1.3, 7.5)	3.4 (1.2, 5.6)	6.3 (3.2, 11.3)	6.2 (3.3, 9.1)		
London Health Sciences Centre	279	1.8 (0.6, 4.2)	1.9 (0.1, 3.7)	3.2 (1.5, 6.1)	3.3 (0.9, 5.7)		
Rouge Valley Health System	53	1.9 (0.0, 10.5)	1.8 (0.0, 5.8)	1.9 (0.0, 10.5)	1.9 (0.0, 7.1)		
Southlake Regional Health Centre	119	4.2 (1.4, 9.8)	3.2 (0.9, 5.6)	5.0 (1.9, 11.0)	4.5 (1.2, 7.9)		
Trillium Health Centre	58	5.2 (1.1, 15.1)	4.4 (0.9, 8.0)	6.9 (1.9, 17.7)	6.4 (1.5, 11.4)		
Sunnybrook Health Sciences Centre	89	2.2 (0.3, 8.1)	2.2 (0.0, 5.2)	6.7 (2.5, 14.7)	6.6 (2.5, 10.7)		
Kingston General Hospital	97	4.1 (1.1, 10.6)	4.4 (1.3, 7.4)	8.2 (3.6, 16.3)	8.4 (4.4, 12.4)**		
University of Ottawa Heart Institute	140	0.0 (0.0, 0.0)	0.0 (0.0, 2.8)	0.0 (0.0, 0.0)	0.0 (0.0, 3.4) <sup>†</sup>		
Ontario	1,384	2.3 (1.6, 3.3)	2.3	4.1 (3.1, 5.3)	4.1		

Data source: Ontario ICD Database results valid to September 30, 2009 © Institute for Clinical Evaluative Sciences

<sup>\*</sup> Adjusted by age, sex and ICD implant type

<sup>\*\*</sup> Significantly higher than Ontario rate

<sup>†</sup> Significantly lower than Ontario rate

#### 7.0 Death Rates from February 15, 2007 to September 30, 2009

#### 7.1 Death rates by implant indication

Table 5a shows the death rates by implant indication. The overall risk-adjusted rate of death at 45 days was 0.7%. For secondary prevention patients, the risk-adjusted rate was significantly higher at 1.2%. Primary prevention patients had a risk-adjusted rate of death of 0.5% at 45 days.

As expected, the risk-adjusted rates of death increased within 6 months for primary, secondary and overall indications, to 2.5%, 4.2% and 3.0%, respectively. Secondary prevention patients continued to have a significantly higher risk-adjusted rate of appropriate shock within the 6-month period.

Table 5a. Death rates by implant indication								
Implem	No. of	Death with of impla (rates per 1	ant date	of impl	in 6 months ant date  00 persons)	Death within 6 months of implant date (ICD recipients)		
Implant indication	Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*	MADIT II	SCD-HeFT	
Primary prevention	3,254	0.6 (0.3, 0.9)	0.5 (0.2, 0.8)	2.6 (2.0, 3.2)	2.5 (1.9, 3.1)	~ 4.0%	~ 3.5%	
Secondary prevention	1,384	1.2 (0.7, 1.9)	1.2 (0.7, 1.6)**	4.0 (3.0, 5.2)**	4.2 (3.3, 5.1)**			
Total	4,638	0.7 (0.5, 1.0)	0.7	3.0 (2.5, 3.5)	3.0			

<sup>\*</sup>Adjusted by age, sex and ICD implant type

<sup>\*\*</sup> Significantly higher than Ontario rate

#### 7.2 Death rates for primary prevention patients by site

Table 5b shows death rates for primary prevention patients by site. When we examined primary prevention patients only, there was no significant difference in death rates among sites.

Table 5b. Death rates for primary prevention patients by site						
	No. of	of imp	hin 45 days lant date 100 persons)	Death within 6 months of implant date (rates per 100 persons)		
Site	Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*	
Toronto General Hospital	402	0.2 (0.0, 1.4)	0.3 (0.0, 1.1)	2.2 (1.0, 4.2)	2.7 (1.0, 4.4)	
Hamilton Health Sciences Centre	551	0.5 (0.1, 1.6)	0.5 (0.0, 1.2)	3.3 (1.9, 5.2)	3.1 (1.8, 4.4)	
St. Michael's Hospital	322	1.2 (0.3, 3.2)	1.2 (0.4, 2.1)	2.8 (1.3, 5.3)	2.8 (1.1, 4.5)	
London Health Sciences Centre	493	0.8 (0.2, 2.1)	1.0 (0.2, 1.7)	2.0 (1.0, 3.7)	2.3 (0.8, 3.7)	
Rouge Valley Health System	103	1.0 (0.0, 5.4)	0.9 (0.0, 2.3)	1.9 (0.2, 7.0)	1.7 (0.0, 4.6)	
Southlake Regional Health Centre	401	0.5 (0.1, 1.8)	0.4 (0.0, 1.1)	3.5 (1.9, 5.9)	3.5 (1.9, 5.0)	
Trillium Health Centre	72	0.0 (0.0, 0.0)	0.0 (0.0, 1.7)	2.8 (0.3, 10.0)	2.8 (0.0, 6.5)	
Sunnybrook Health Sciences Centre	298	0.7 (0.1, 2.4)	0.5 (0.0, 1.3)	2.3 (0.9, 4.8)	2.0 (0.3, 3.6)	
Kingston General Hospital	279	0.4 (0.0, 2.0)	0.3 (0.0, 1.2)	1.8 (0.6, 4.2)	1.6 (0.0, 3.3)	
University of Ottawa Heart Institute	333	0.0 (0.0, 0.0)	0.0 (0.0, 0.9)	2.1 (0.8, 4.3)	2.2 (0.5, 4.0)	
Ontario	3,254	0.6 (0.3, 0.9)	0.6	2.6 (2.0, 3.2)	2.6	

<sup>\*</sup>Adjusted by age, sex and ICD implant type

#### 7.3 Death rates for secondary prevention patients by site

Table 5c shows death rates for secondary prevention patients by site. When we examined secondary prevention patients only, there was no significant difference in death rates among sites.

Table 5c. Death rates for secondary prevention patients by site						
	No. of	of imp	thin 45 days lant date 100 persons)	Death within 6 months of implant date (rates per 100 persons)		
Site	No. of Implants	Crude	Risk-adjusted*	Crude	Risk-adjusted*	
Toronto General Hospital	155	0.0 (0.0, 0.0)	0.0 (0.0, 1.7)	4.5 (1.8, 9.3)	5.0 (1.8, 8.3)	
Hamilton Health Sciences Centre	220	1.4 (0.3, 4.0)	1.5 (0.0, 3.0)	4.1 (1.9, 7.8)	4.1 (1.5, 6.7)	
St. Michael's Hospital	174	1.1 (0.1, 4.2)	1.2 (0.0, 2.8)	4.6 (2.0, 9.1)	4.6 (1.7, 7.4)	
London Health Sciences Centre	279	0.7 (0.1, 2.6)	0.7 (0.0, 2.0)	3.9 (2.0, 7.1)	4.1 (1.8, 6.4)	
Rouge Valley Health System	53	1.9 (0.0, 10.5)	1.7 (0.0, 4.4)	3.8 (0.5, 13.6)	3.5 (0.0, 8.6)	
Southlake Regional Health Centre	119	2.5 (0.5, 7.4)	2.0 (0.3, 3.7)	5.0 (1.9, 11.0)	4.9 (1.5, 8.3)	
Trillium Health Centre	58	3.4 (0.4, 12.5)	3.5 (0.8, 6.3)	5.2 (1.1, 15.1)	5.0 (0.1, 9.9)	
Sunnybrook Health Sciences Centre	89	0.0 (0.0, 0.0)	0.0 (0.0, 2.1)	3.4 (0.7, 9.9)	3.1 (0.0, 7.0)	
Kingston General Hospital	97	0.0 (0.0, 0.0)	0.0 (0.0, 1.9)	2.1 (0.2, 7.4)	1.8 (0.0, 5.4)	
University of Ottawa Heart Institute	140	2.1 (0.4, 6.3)	2.7 (0.7, 4.6)	2.9 (0.8, 7.3)	3.0 (0.0, 6.3)	
Ontario	1,384	1.2 (0.7, 1.9)	1.2	4.0 (3.0, 5.2)	4.0	

<sup>\*</sup> Adjusted by age, sex and ICD implant type

#### 8.0 Comments

The implantable cardioverter defibrillator is a useful mode of therapy to prevent sudden cardiac death and is particularly beneficial when used in patients who could most benefit from the device. One of the ways that the defibrillator's benefit to the patient may be appreciated is when the ICD provides a life-saving appropriate shock. In contrast, an inappropriate shock provides a therapy to the patient that may result in a painful shock without any potentially life-saving benefit.

In this report, we examined rates of appropriate and inappropriate shocks and therapies to patients who had been implanted with an ICD in Ontario. We found that while the rates of these events were in line with expectations based on randomized trials, there was variation in the rates depending on the hospital where the ICD was implanted. This may speak to differences in the ways that hospitals select their patients for an ICD.

We also examined rates of early death in patients who have been implanted with an ICD. An early death is an undesired outcome after having been implanted with an ICD. While the overall rates were comparable to those published in randomized trials, there was some variation in the rates of early death in patients who had been implanted with an ICD.

We also observed that patients who had an ICD implanted for primary prevention had consistently far lower rates of appropriate shock than those implanted for a secondary prevention indication. Secondary prevention patients had higher rates of appropriate shock, but they also had higher mortality rates than those who were implanted with a primary prevention device. These findings suggest that better ways are needed to identify primary prevention patients who would be more likely to benefit from an ICD. Strategies to reduce death despite an ICD are needed, particularly in secondary prevention patients.

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