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Inside this issue: Blood, cell and tissue transplant surveillance

Although Canada has one of the safest blood as well as cell and tissue transplant systems in the world, errors and infections can occur. In this issue, read about the surveillance systems in place to monitor these systems. Also to mark the upcoming World AIDS Day on December 1, 2014, read about two developing surveillance systems of high-risk groups that include biological markers and a systematic review assessing rapid HIV tests.

Surveillance

Systematic review

Upcoming conference

December 2 - 4, 2014: Canadian Immunization Conference, Ottawa, Ontario, Canadian Public Health Association, the Public Health Agency of Canada, Canadian Association for Immunization Research and Evaluation and Canadian Paediatric Society
http://www.phac-aspc.gc.ca/cnic-ccni/index-eng.php

Useful link

Public Health Agency of Canada. Interim Biosafety Guidelines for Laboratories Handling Specimens from Patients Under Investigation for Ebola Virus Disease http://www.phac-aspc.gc.ca/id-mi/vhf-fvh/ebola-biosafety-biosecurite-eng.php

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Canada

A summary of the Transfusion Error Surveillance System: 2008 - 2011

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Abstract

Background: Although Canada has one of the safest blood systems in the world, transfusion errors can occur at any time from the moment of collection through to the transfusion of blood and blood products. The Transfusion Error Surveillance System (TESS) was initiated by the Public Health Agency of Canada (the Agency) to monitor transfusion-related errors occurring at any point in the transfusion chain.

Objective: To offer an analysis of the TESS data reported from 2008 to 2011.

Methods: Between 2008 and 2011, 12 to 15 hospitals from four provinces participated in the TESS. Reports on all transfusion-related errors were sent electronically on a quarterly basis to the Agency where they were consolidated, cleaned, validated and analyzed. Different types of transfusion errors were categorized by time of discovery (pre- or post-transfusion) and their potential impact on the patient's health. The occurrence rates of different types of errors were calculated using corresponding denominator data. Results were grouped by the transfusion capacity of reporting hospitals.

Results: Between 2008 and 2011, a total of 34,088 transfusion-related errors were reported. Of these, 33,622 (98.6%) were detected prior to transfusion. The most commonly reported were errors related to the collection (40.1%) and handling (10.4%) of blood samples. Of the remaining 466 (1.4%) that were detected after transfusion, 66 were of high potential severity and 16 of them resulted in adverse reactions in recipients. Inappropriate / incorrect / no product order accounted for over 56% (n=9) of these errors and the most common adverse reaction was transfusion-associated circulatory overload which occurred in eight (50%) of the patients that developed adverse reactions.

Conclusion: The TESS data from 2008 to 2011 demonstrates that blood transfusions are both safe and efficient in Canadian hospitals participating in the surveillance and also highlights the most common and most harmful errors that may be targeted for corrective actions.

Introduction

Blood transfusions are one of the key components of Canada's healthcare system. Each year in Canada, blood transfusions are used to treat people suffering from blood loss, anemia and cancer. Errors that can occur along the blood transfusion chain either before or after the actual transfusion may result in blood type (ABO) incompatibilities, administrative delays, product wastage and even inappropriate transfusions. These errors have the potential to impact patient safety and increase costs incurred by the healthcare system. In 2005, in recognition of the importance of transfusion safety in Canada, the Public Health Agency of Canada (the Agency) developed the Transfusion Error Surveillance System (TESS) to monitor unexpected, unplanned deviations from standard operating procedures or applicable laws and regulations, usually attributable to a human or system problem that could adversely affect the safety, efficacy or quality of blood, blood products and/or the safety of recipients. Outputs of the TESS are valuable at more than one level as they not only identify where and when most high potential severity errors occur in the transfusion chain, they also provide a benchmark for national and international comparisons. Most importantly, they assist in the development and assessment of transfusion safety measures. This is a summary of the 2008 - 2011 TESS Report (1).

Methods

Between 2008 and 2011, data on various types of transfusion-related errors were reported by a number of hospitals from four Canadian provinces / territories: 12 in 2008, 14 in 2009 and 15 in 2010 and 2011. Transfusion errors were detected within participating hospitals using various methods such as systematic quality control (chart audit, record review, real-time prospective transfusion audit), scheduled quality assurance control, supervisory reports and reporting by any other individual. However, due to the lack of standardization and systematic implementation across participating hospitals, errors detected through scheduled quality control or supervisory reports were excluded from the analysis.

The reporting process began with the individuals who discovered the event, whether or not they were involved. Following detection of a transfusion-related error at a hospital participating in the TESS, non-nominal data about the error and the patient involved were collected by the hospital using an online reporting form. The point in the transfusion chain at which the error occurred was also recorded together with the point at which the error was detected. Given the level of details recorded, a classification system was used to differentiate reported errors by types and sub-types and, to ensure high consistency in the classification across provinces and territories participating in the TESS, the Agency organized regular monthly error coding exercises where the provincial and territorial blood coordinating offices' staff submitted and discussed complex cases encountered in hospitals within their respective jurisdictions.

Data received from the provincial and territorial blood coordinating offices was consolidated into one Excel file, reviewed, validated and exported into the statistical package, Stata, for further statistical analysis. The occurrence rate of each type of error was calculated separately by dividing the total number of errors by its corresponding denominator and converting the result into 100,000 units of products received, requested, prepared, issued or per 100,000 samples received depending on the error type. Also, dividing the denominator (total number of units of products requested / received / issued / prepared or samples received) by the number of reported errors allowed the computation of the risk of a single case of individual type of errors.

Results were categorized by the size of hospitals which was determined based on the volume of blood transfusions performed annually. Hospitals that transfused less than 2,000 units of products were considered small capacity hospitals; whereas those transfusing between 2,000 and 10,000 or more were considered medium or large capacity hospitals.

Results

From 2008 to 2011, 34,088 transfusion errors that met the surveillance criteria were captured by the TESS (**Table 1**). The total annual errors reported ranged from a minimum of 8,253 to a maximum of 8,917 recorded respectively in 2009 and 2010. Only about 7.1% (n=2,430) were from hospitals of small transfusion capacity compared to 19.4% (n=6,617) and 73.5% (25,041) respectively for hospitals of medium and large capacity.

Table 1: Transfusion errors reported by hospitals of various transfusion capacities, TESS[1] 2008- 2011.

Type of Transfusion error	Small (less than 2,000 transfusions per year)		Medium (2,000 to 10,000 transfusions per year)		Large (more than 10,000 transfusions per year)		Overall	
	Freq.	%	Freq.	%	Freq.	%	Freq.	%
Distributor codes	42	1.7%	631	9.5%	1,069	4.3%	1,742	5.1%
Inventory management	14	0.6%	52	0.8%	94	0.4%	160	0.5%
Product check-in	62	2.6%	390	5.9%	1,030	4.1%	1,482	4.3%
Product request	32	1.3%	652	9.9%	1,989	7.9%	2,673	7.8%
Product selection	7	0.3%	32	0.5%	74	0.3%	113	0.3%

Request for pick-up	32	1.3%	254	3.8%	628	2.5%	914	2.7%
Sample collection	225	9.3%	1,338	20.2%	12,117	48.4%	13,680	40.1%
Sample handling	331	13.6%	606	9.2%	2,610	10.4%	3,547	10.4%
Sample receipt	945	38.9%	137	2.1%	1,042	4.2%	2,124	6.2%
Sample testing	587	24.2%	481	7.3%	1,408	5.6%	2,476	7.3%
Unit issue	29	1.2%	167	2.5%	249	1.0%	445	1.3%
Unit manipulation	53	2.2%	129	1.9%	340	1.4%	522	1.5%
Unit storage	3	0.1%	16	0.2%	51	0.2%	70	0.2%
Unit transfusion	40	1.6%	928	14.0%	2,045	8.2%	3,013	8.8%
Miscellaneous	28	1.2%	804	12.2%	295	1.2%	1,127	3.3%
Total	**2,430**	**100%**	**6,617**	**100%**	**25,041**	**100%**	**34,088**	**100%**

[1]TESS=Transfusion Error Surveillance System

Approximately 98.6% (n=33,622) of all the errors were discovered before the actual blood transfusion, including all those related to sample collection (n=13,680). The vast majority (97.6%) of the 466 errors detected after the actual transfusion were from medium (n=227) and large (n=228) capacity hospitals. Hospitals transfusing less than 2,000 units annually accounted for only 11 cases (**Table 2**) which were errors related to inventory management (n=2), request (n=3) issuance (n=2) and transfusion of prescribed products (n=4).

Overall, the most frequently reported errors detected after transfusion were related to unit transfusions of which more than 69% (n=192) were from hospitals transfusing between 2,000 and 10,000 units annually (**Table 2**). Large capacity hospitals accounted for 29.5% (n=82) and the remaining 1.4% (n=4) originated from hospitals with smaller transfusion capacity (**Table 2**).

The least common of the transfusion errors detected after the actual transfusion were primarily errors related to product storage, distribution and the request for pick-up, which occurred only once or twice during the period between 2008 to 2011 (**Table 2**).

Table 2: Errors discovered AFTER (n=466) blood transfusion by type of hospitals, TESS[1] 2008 – 2011

Type of Transfusion error	Small (less than 2,000 transfusions per year)		Medium (2,000 to 10,000 transfusions per year)		Large (more than 10,000 transfusions per year)		Overall	
	Freq.	Rate	Freq.	Rate	Freq.	Rate	Freq.	Rate
Distributor codes	0	-	2	1: 117,432	0	-	2	1: 439,663
Product check-in	0	-	0	-	3	1:206,374	3	1: 293,109
Unit storage	0	-	0	-	1	1:619,123	1	1: 879,326
Inventory management	2	1: 12,670	3	1: 78,288	2	1: 309,562	7	1: 125,618
Product request	3	1: 6,642	5	1: 47,934	56	1: 11,103	64	1: 13,771
Request for pick-up	0	-	0	-	1	1:621,772	1	1: 881,366
Product selection	0	-	3	1: 94,614	10	1: 65,484	13	1: 73,786
Unit manipulation	0	-	4	1: 70,961	2	1: 327,418	6	1: 159,870
Unit issue	2	1: 9,264	11	1: 21,308	30	1: 20,224	43	1: 19,991
Unit transfusion	4	1: 4,632	192	1: 1,221	82	1: 7,399	278	1: 3,092

Sample handling	0	-	0	-	7	1: 52,289	7	1: 89,415
Sample receipt	0	-	4	1: 51,917	18	1: 20,335	22	1: 28,450
Sample testing	0	-	3	1: 112,172	14	1: 58,353	17	1: 70,731
Miscellaneous	0	-	0	N/A	2	N/A	2	N/A
Total	**11**	**N/A**	**227**	**N/A**	**228**	**N/A**	**466**	**N/A**

[1]TESS= Transfusion Error Surveillance System

Since 2008, the total number of transfusion-related errors detected after the actual transfusion has changed significantly ($p<0.05$). This number initially increased by almost 29% in 2009 and for the two following years, it decreased by 16% and 33% respectively (**Table 3**). Sixty-six (14.2%) of these errors were deemed to be of high severity potential and of these,16 resulted in adverse reactions which included eight cases of transfusion-associated circulatory overload, two cases of febrile non-hemolytic reaction, one case of mild transfusion reaction and five cases of unusual transfusion reactions (**Table 4**). None of these adverse reactions resulted in death.

Table 3: Errors discovered AFTER (n=466) blood transfusion by surveillance year, TESS[1] 2008 – 2011

Type of Transfusion error	2008		2009		2010		2011		Overall	
	Freq.	Rate	Freq.	Rate	Freq.	Rate	Freq.	Rate	Freq.	Rate
Distributor codes	0	-	0	-	2	1: 105,423	0	-	2	1: 439,663
Product check-in	2	1: 115,521	0	-	0	-	1	1: 206,866	3	1: 293,109
Unit storage	0	-	1	1: 230,572	0	-	0	-	1	1: 879,326
Inventory management	2	1: 115,521	0	-	2	1: 105,423	3	1: 68,955	7	1: 125,618
Product request	18	1: 12,290	12	1: 19,068	16	1: 13,680	18	1: 11,802	64	1: 13,771
Request for pick-up	1	1: 221,226	0	-	0	-	0	-	1	1: 881,366
Product selection	1	1: 233,142	7	1: 34,177	4	1: 59,301	1	1: 249,635	13	1: 73,786
Unit manipulation	1	1: 233,142	0	-	4	1: 59,301	1	1: 249,635	6	1: 159,870
Unit issue	10	1: 21,485	14	1: 15,937	11	1: 19,621	8	1: 25,728	43	1: 19,991
Unit transfusion	63	1: 3,410	95	1: 2,349	78	1: 2,767	42	1: 4,901	278	1: 3,092
Sample handling	1	1: 166,703	2	1: 84,971	3	1: 49,982	1	1: 139,317	7	1: 89,415
Sample receipt	4	1: 41,676	5	1: 33,988	7	1: 21,421	6	1: 23,220	22	1: 28,450
Sample testing	5	1: 33,341	3	1: 56,647	5	1: 29,989	4	1: 34,829	17	1: 70,731
Miscellaneous	0	N/A	0	N/A	0	N/A	2	N/A	2	N/A
Total	**108**	**N/A**	**139**	**N/A**	**132**	**N/A**	**87**	**N/A**	**466**	**N/A**

[1]TESS= Transfusion Error Surveillance System

Table 4: Specific errors that resulted in adverse reactions, TESS[1] 2008 – 2011

Transfusion Error	Transfusion-associated circulatory overload	Febrile non-hemolytic	Mild transfusion reaction	Transfusion reaction of unspecified nature	Total
Incorrect/No product order	1	0	0	0	1
Inappropriate product order	5	1	0	2	8

Incorrect/No historical review	0	0	0	1	1
Wrong product issued to a patient	0	0	0	2	2
Transfusion of product with incompatible fluid	0	1	0	0	1
Guidelines for infusion time not followed	2	0	1	0	3
Total	**8**	**2**	**1**	**5**	**16**

[1]TESS= Transfusion Error Surveillance System

Conclusion

The TESS has demonstrated that participating hospitals have a very robust transfusion safety system in place as evidenced by data collected over a four-year period which showed that only a tiny proportion of transfusion-related errors go undetected prior to the actual blood transfusion. Moreover, the frequency of these errors has been decreasing since 2010. Continued monitoring of transfusion errors will support transfusion and patient safety and will also allow for the identification of points in the transfusion chain where targeted quality improvement initiatives would enable continuous decrease of the frequency of transfusion errors, particularly those escaping detection before the actual transfusion.

Acknowledgements

The development of the Transfusion Error Surveillance System (TESS) would not have been possible without the collaborative support and continued commitment of many transfusion safety officers, medical laboratory technologists and other healthcare professionals in hospitals and blood transfusion services. Their dedication to reducing errors and increasing patient safety has led to the collection and analysis of the 2008 - 2011 TESS data.

Conflict of interest

None

Funding

This work was supported by the Public Health Agency of Canada.

Reference

(1) Public Health Agency of Canada. Transfusion Error Surveillance System (TESS) – 2008-2011 Report. Ottawa: Centre for Communicable Diseases and Infection Control, PHAC; 2014. http://www.phac-aspc.gc.ca/hcai-iamss/tess-sset/results-resultats-2008-2011-eng.php

A summary of the Transfusion Transmitted Injuries Surveillance System: 2006 - 2012

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Abstract

Background: The Transfusion Transmitted Injuries Surveillance System (TTISS) is a pan-Canadian surveillance system established by the Public Health Agency of Canada (the Agency) in partnership with the provinces and territories to capture non-nominal data on adverse transfusion reactions in Canadian hospitals providing transfusion services with the overarching goal of improving patient safety.

Objective: To summarize transfusion-related adverse reactions reported to the TTISS between 2006 and 2012.

Methods: Hospitals from 10 provinces and two territories participated in the TTISS by collecting and submitting data on all transfusion-related reactions or injuries to the provincial / territorial blood coordinating offices. This data was sent to the Agency where it was consolidated, cleaned, validated and analyzed by type of reactions or outcome. Corresponding rates were also calculated using the total number of units of blood components transfused as a denominator.

Results: From 2006 to 2012, a total of 3,957 adverse reactions were reported to the TTISS, excluding minor allergic reactions. Of these, 2,920 (73.8%) were related to transfusion of blood components and 1,036 (26.2%) were from the transfusion of blood products. Among reactions related to the transfusion of blood components, the most common were: transfusion-associated circulatory overload (n = 1,242, 42.5%), severe allergic / anaphylactic / anaphylactoid reactions (n=411; 14.1%) and hypotensive reactions (n=298; 10.2%). Among those related to transfusion of blood products, close to one-half were intravenous immunoglobulin (IVIG) headache (n=295; 28.5%) or delayed hemolytic reaction (n=175; 16.9%). Death definitely attributable to transfusion was extremely rare: only one case diagnosed with transfusion-related acute lung injury was identified between 2006 and 2012.

Conclusion: The majority of reactions attributable to transfusion resulted in minor or no sequelae. Strengthening the TTISS will improve the monitoring of adverse transfusion reactions which is one of the key components of an overall patient safety strategy. Current initiatives to improve data quality include the development of transfusion-associated circulatory overload / transfusion-related acute lung injury recognition algorithm and the collection of appropriate denominators for the calculation of the rates of adverse reactions from the transfusion of blood products.

Introduction

The Transfusion Transmitted Injuries Surveillance System (TTISS) is a voluntary nationwide ongoing surveillance system established in 2001 by the Public Health Agency of Canada (the Agency) to monitor serious, moderate and selected minor transfusion-related adverse reactions occurring in Canadian healthcare settings. The TTISS collaborates with both the Canadian blood manufacturers (Canadian Blood Services and Héma-Québec) and Health Canada's Marketed Health Products Directorate to reconcile the data collected and to ensure comprehensiveness and accuracy in reporting.

The TTISS collects data on adverse transfusion reactions related to the transfusion of blood components (red blood cells, granulocytes, platelets, plasma and cryoprecipitates) and blood products (plasma derivatives such as

albumin, immune globulin, coagulation factors, etc.). Reactions are reported by an extensive network of hospitals throughout the country, covering all provinces and two territories. Hospitals in most provinces and territories are also mandated to report transfusion-related adverse events to their respective provincial / territorial blood coordinating offices, blood manufacturers (Canadian Blood Services and Héma-Québec) and the Marketed Health Products Directorate at Health Canada. The program is governed by the national TTISS Working Group and the National Working Party for Data Review which is composed of provincial and territorial members (mainly the provincial / territorial blood coordinating offices), as well as experts in public health, hematology, infectious diseases and transfusion medicine including front-line healthcare workers. This is a summary of a recent TTISS Report 2006 - 2012 (1).

Methods

Adverse transfusion reactions are defined as undesirable and unintended occurrences during or after the administration of blood, blood components or blood products (plasma derivatives) whether or not they are considered to be related to the administration of these products. The TTISS utilizes standardized case definitions outlined in the *TTISS User's Manual* and a standardized data collection form used by field surveillance staff. It should be noted that frequent minor reactions such as febrile non-hemolytic transfusion reactions, minor allergic reactions and delayed serological transfusion reactions are not reportable to the TTISS. Adverse reactions considered by the TTISS included severe allergic / anaphylactic / anaphylactoid reactions, transfusion-associated circulatory overload, transfusion-related acute lung injury, hypotensive reactions, post-intravenous immunoglobulin (IVIG) headache, acute and delayed hemolytic reactions.

Cases of adverse transfusion reactions were investigated and categorized by their level of severity (non-severe, severe and life-threatening) and their impact on the recipient's health which ranged from minor / no sequelae to death. Severe cases were defined as cases where prolonged hospitalization was directly attributed to the adverse reaction; or cases that resulted in persistent or significant disability / incapacity; or the adverse event necessitated medical or surgical intervention to preclude permanent / significant damage or impairment of body function. Life-threatening cases referred to cases requiring major intervention (i.e., vasopressors, intubation and transfer to intensive care) following the transfusion. Cases resulting in death were fully investigated at the hospital site to determine whether transfusion played a role and if so, to what degree.

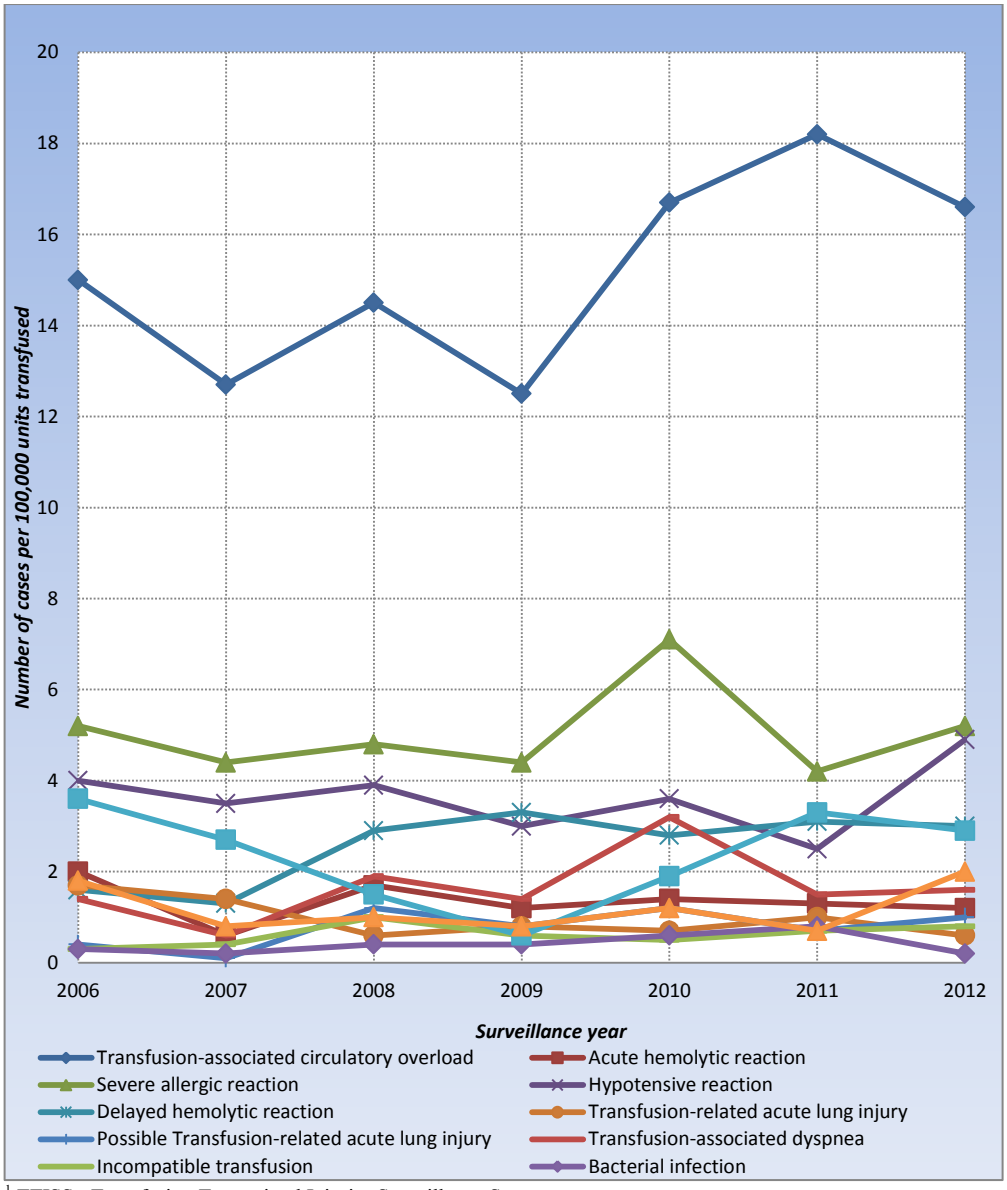
All the cases identified at participating hospitals were compiled and sent to the provincial / territorial blood coordinating offices where non-nominal data on serious, moderate and selected minor adverse transfusion reactions were extracted and transferred electronically to the Agency as per provincial / territorial / federal agreement. This transfer occurred on a quarterly basis where three-month data were sent to the Agency with a maximum delay of six months. The data from all the participating provinces / territories was reviewed, validated and consolidated into one file for analysis. In addition to cases of adverse transfusion reactions, provinces / territories provided the number of hospitals that participate in the TTISS for each surveillance year as well as the total number of units of blood components transfused.

Results

Between 2006 and 2012, the TTISS recorded 3,957 adverse transfusion reactions of which 2,920 (73.8%) were from the transfusion of blood components. The most common reactions from the transfusion of blood components were transfusion-associated circulatory overload (n=1,242) which occurred at a rate of about 15 cases for every 100,000 units of blood components transfused (**Figure 1**). Among those that resulted from the transfusion of plasma derivatives, the most common were post IVIG headache (n=295) and delayed hemolytic reactions (n=175) which accounted for approximately 28.5% and 16.9%, respectively.

Overall, 1,835 reactions were severe or life-threatening (1,505 related to transfusion of blood components and 329 related to transfusion of blood products).

Figure 1: Annual rate of adverse reactions from transfusion of blood components, TTISS[1] 2006 – 2012

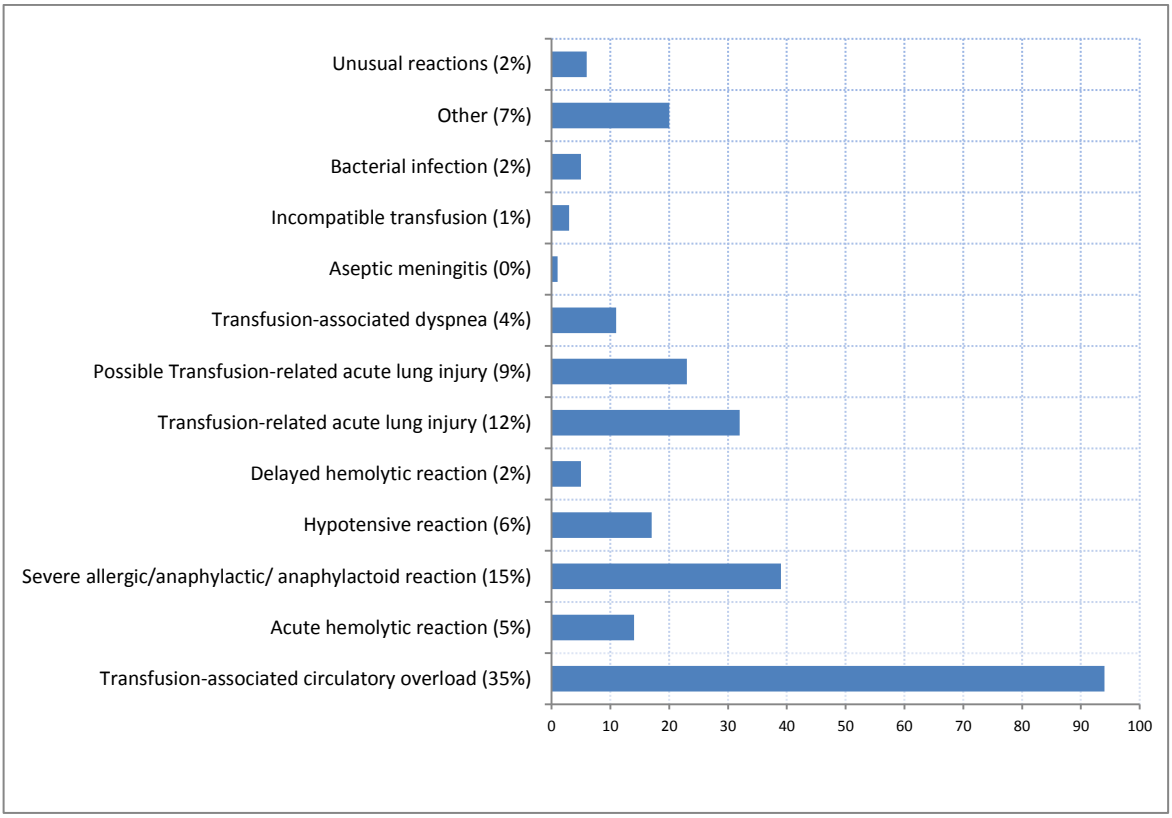


[1] TTISS= Transfusion Transmitted Injuries Surveillance System

Among the 1,693 severe or life-threatening cases where patient outcome data were available, the majority (1,573; 92.9%) resulted in minor or no sequelae and 79 (4.7%) resulted in major or long term sequelae. From 2006 to 2012, a total of 41 deaths were reported as definitely (n=1), probably (n=11) or possibly (n=29) related to transfusion. One-half of these were classified as transfusion-associated circulatory overload (n=13) or possible transfusion-related acute lung injury (n=12).

Life-threatening adverse reactions represented 7% (n=270) of adverse reactions recorded from 2006 to 2012 and the majority of these (92.2%) resulted from the transfusion of blood components. The most commonly reported adverse transfusion reactions were transfusion-associated circulatory overload (n=94) and severe allergic / anaphylactic / anaphylactoid reactions (n=39) (**Figure 2**).

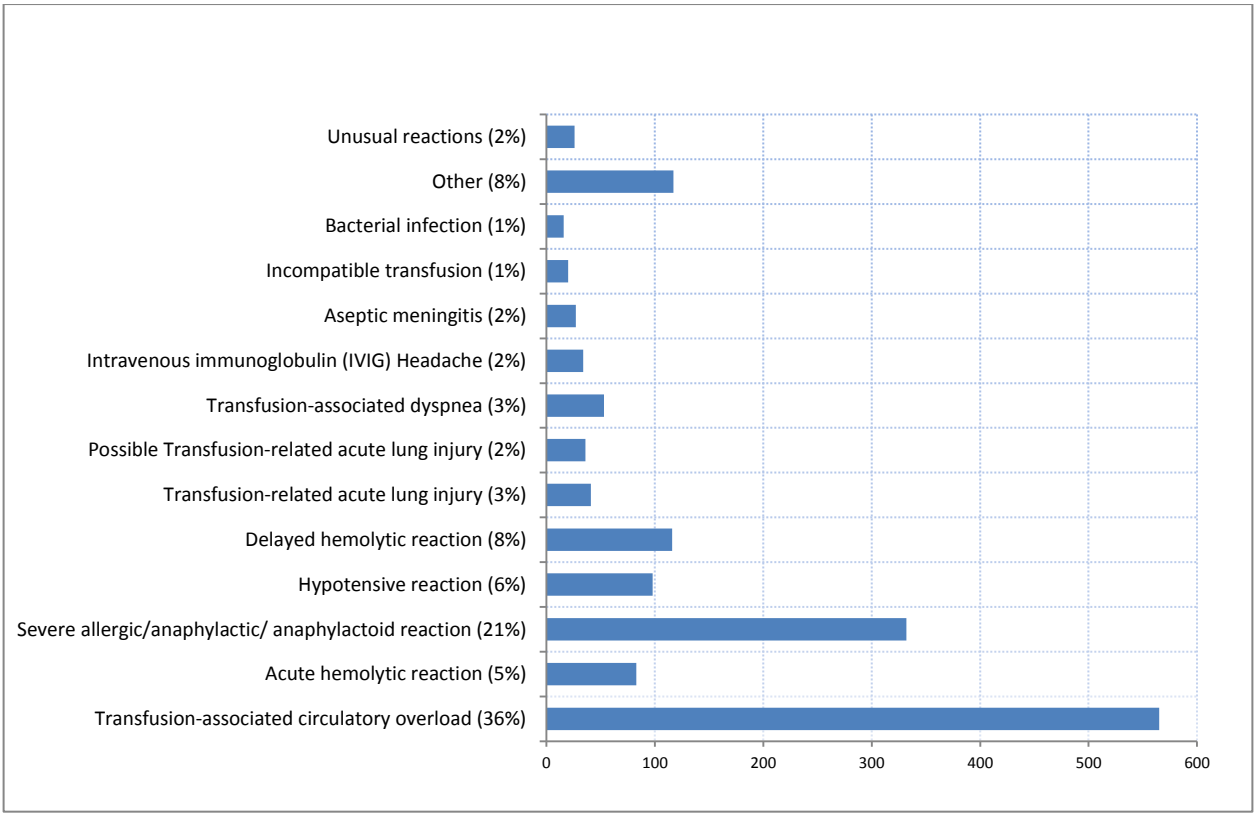
Figure 2: Life-threatening adverse transfusion reactions, TTISS[1] 2006 – 2012



[1] TTISS= Transfusion Transmitted Injuries Surveillance System

The large majority (96%) of transfusion-related adverse reactions captured by the TTISS between 2006 and 2012 resulted in minor or no sequelae. Blood transfusion was reported to have contributed to the death of 41 individuals for the 2006 - 2012 periods, but definitive evidence was established only for one case that developed transfusion-related acute lung injury. The evidence of the relationship between death and transfusion for the other cases was deemed at best to be probable (n=12) or possible (n=28). With over one-million units of blood components transfused annually, the case fatality rate amounted to about five per million (**Figure 3**).

Figure 3: Severe adverse transfusion reactions, TTISS[1] 2006 – 2012



[1] TTISS= Transfusion Transmitted Injuries Surveillance System

Conclusion

The TTISS is a truly pan-Canadian system that captures the bulk of adverse transfusion reactions that occur in Canadian hospitals. Several initiatives are currently being carried out by the Agency-led National TTISS Working Group to improve not only the reporting system, but also the quality of the data reported. Efforts include the development of an algorithm to help differentiate between transfusion-associated circulatory overload and transfusion-related acute lung injury and to determine a way to standardize the denominator data for blood products. Continued partnership between the Agency, the blood manufacturers (Canadian Blood Services and Héma-Québec) and the provinces / territories and Health Canada is vital to ensure timely reporting of accurate surveillance data that will help the development of better policies and procedures for transfusion safety and ultimately enhance patient safety in all Canadian hospitals.

Acknowledgements

The development of the Transfusion Transmitted Injuries Surveillance System (TTISS) would not have been possible without the collaborative support and continued commitment of the provincial / territorial blood coordinating offices, transfusion medicine staff at participating hospitals, the Canadian Blood Services and Héma-Québec. Their dedication to reducing adverse transfusion reactions / injuries and increasing patient safety has led to the collection and analysis of the 2006 - 2012 TTISS data.

Conflict of interest

None

Funding

This work was supported by the Public Health Agency of Canada.

Reference

(1) Public Health Agency of Canada. Transfusion Transmitted Injuries Surveillance System (TTISS): 2006-2012 Report. Ottawa: Centre for Communicabable Diseases and Infection Control, PHAC; 2014. http://www.phac-aspc.gc.ca/hcai-iamss/ttiss-ssit/index-eng.php

Developing a cells, tissue and organ surveillance system

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Abstract

Background: An increasing number of cell, tissue and organ transplant procedures take place each year in Canada, including procedures in clinics, physician and dental offices. The Public Health Agency of Canada (the Agency) is leading the development of a Cell, Tissue and Organ Surveillance System (CTOSS).

Objective: To create timely, useful and relevant national-level transplantation adverse event data by supporting the development and / or enhancement of provincial and territorial data collection systems.

Methods: Minimum data elements and definitions were established for tissues based on definitions established in the European Union and the United States. Data collection on adverse events related to human allograft tissue transplants began in April 2011 at pilot sites in Alberta, Ontario, Quebec, New Brunswick and Nova Scotia.

Results: By December 2013, eight tissue transplantation adverse events were reported. Seven involved corneal tissue and one involved cardiovascular tissue.

Conclusion: A fully developed CTOSS could increase Canadian capacity to improve patient safety. Data collection and analysis could increase the potential for a better understanding of transplantation adverse events, subsequently inform the development of strategies for overall prevention and reduce the severity of such events. The next steps in developing CTOSS will be to establish data elements and definitions for the cell and organ transplant components of the system and increase the number of pilot sites.

Introduction

An increasing number of cell, tissue and organ transplant procedures take place each year in Canada, including procedures in clinics, physician and dental offices (1). Over 90,000 tissue allografts are distributed for transplantation, including musculoskeletal, vascular, skin, cardiac and corneal tissues (2). Canadian Blood Services predicts that the need for organ transplants will increase significantly over the next two decades (3). The Public Health Agency of Canada (the Agency) is leading the development of a Cell, Tissue and Organ Surveillance System (CTOSS) that will aim to improve transplantation safety for Canadians by capturing and analyzing adverse event data and disseminating the resulting knowledge. Transplantation adverse event surveillance data is critical to our ability to improve patient safety through the development of appropriate programs and policies. Once fully developed, the system will collect data on moderate and severe adverse events in order to monitor trends in known and emerging risks and reduce the transmission of infectious diseases due to transplantation. The objective of this article is to summarize progress toward the development of the three component transplantation adverse event surveillance systems (4).

Methods

Minimum data elements and definitions of serious adverse events were developed in conjunction with definitions established in the European Union and the United States. For grading of severity related to the adverse event, the spectrum of nil, non-serious, serious, life-threatening and death were defined and applied to the case report. The grading system for imputability was applied to assess the probability that an adverse event in a recipient may be attributed to the process of donation or clinical application of the tissue applied. Data collection on adverse events

related to human allograft tissue transplants began in April 2011 at pilot sites in Alberta, Ontario, Quebec, New Brunswick and Nova Scotia. The mechanisms used to gather transplantation adverse event reports vary among the participating pilot sites.

Results

By December 2013, eight tissue transplantation adverse events were reported and the majority involved corneal tissue (**Table 1**). There were five corneal tissue transplantation adverse events (AEs) reported to the Agency from the Alberta pilot site since April 1 of 2011 and one corneal tissue-related adverse event was reported to the Agency from the Nova Scotia pilot site in 2011. One cardiovascular tissue-related serious adverse event was reported to the Agency from the Quebec pilot site in 2012 as well as a corneal tissue-related adverse event in 2013. Overall, most surveillance sites delivered complete transplantation AE reports and annual reports. It generally took three to six months for the site and tissue establishment to conduct a complete investigation of a suspected transplantation AE. There were several factors which affected the reporting of transplantation AEs including the expertise and experience of the treating physician in the detection of transplantation AEs in recipients, the effectiveness of coordination between procurement organizations and the hospitals as well as the workload of the coordinators.

Table 1: Overview of tissue transplantation adverse events by CTOSS[1] sites from April 2011 to December 2013

Year	Site 1	Site 2	Site 3	Site 4	Site 5
2011	0	0	0	0	1
2012	4	0	1	0	0
2013	1	0	1	0	0
Total	**5**	**0**	**2**	**0**	**1**

[1]CTOSS = Cell, Tissue and Organ Surveillance System

Conclusion

Canada's Cell, Tissue and Organ Surveillance System increases our capacity to identify common adverse events associated with transplantation. Improved data collection and analysis will increase our understanding of transplantation adverse events and inform the development of strategies to prevent or minimize these events. The next step in developing CTOSS will be to establish data elements and definitions for the cell and organ transplant components of the system and expand the number of sites participating in CTOSS.

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Conflict of interest

None

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A pilot behavioural and biological surveillance survey for HIV and other bloodborne infections among Aboriginal people in Regina, Saskatchewan

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Abstract

Background: Aboriginal people in Canada are disproportionately affected by HIV and other blood-borne infections. A-Track is a national public health surveillance system designed to monitor HIV and related infections, behaviours and socio-demographic factors among Aboriginal populations in Canada. The pilot survey for the A-Track surveillance system, the first of its kind in Canada, was conducted in Regina, Saskatchewan and implemented via a community and public health partnership.

Objective: To assess the prevalence of HIV, hepatitis C, syphilis and associated risk behaviours and socio-demographic factors among Aboriginal people in Regina, Saskatchewan. This focus of the pilot survey was to provide this surveillance information for public health action and to determine whether this type of public health surveillance activity could be conducted in an urban setting across Canada.

Methods: Survey participants were self-identified Aboriginal people (First Nations, Inuit or Métis) or those who claimed Aboriginal ancestry and between the ages of 16 and 60 years. These individuals were also asked to provide a blood sample for HIV, hepatitis C and syphilis antibody testing. Descriptive analyses were performed with sex-based comparisons.

Results: There were 1064 people who participated in the survey. Their average age was 33 years and 51% were male. The majority of participants (93%) lived in urban Regina at the time of the survey. Just over half (53.2%) of all participants had been removed from their families during childhood; 29.9% had lived in a residential or boarding school during childhood; and 57.7% had lived at some point in a correctional facility. Among the 1,045 participants who provided a blood sample of sufficient quantity for testing, 5.2% were HIV seropositive and 55.8% of these were aware of their HIV status. The lifetime exposure to hepatitis C was 41.6%, with significantly higher proportions of males than females testing positive for hepatitis C exposure. Syphilis seroprevalence was very low (<1%). Almost three-quarters (71.5%) of participants reported being tested for HIV at least once in their lifetime and among those ever tested, 67.6% had been tested during the 12 months prior to the interview.

Conclusion: Aboriginal people are disproportionately affected by the HIV/AIDS epidemic in Canada. The findings from the A-Track pilot survey can be used to inform and evaluate prevention and treatment services for HIV and other related infections among Aboriginal people. Lessons learned from the pilot survey could also be used to guide the possible implementation of A-Track in other urban and/or reserve locations in Canada.

Introduction

In Canada, Aboriginal people remain disproportionately affected by HIV/AIDS. It is estimated that in 2011, Aboriginal people made up 12.2% of new HIV infections (1). At the end of 2011, 8.9% of those living with HIV in Canada were Aboriginal people (1). By comparison, Aboriginal people represented 4.3% of the Canadian population in the 2011 census (2).

A-Track is a behavioural and biological surveillance system developed to monitor the prevalence of HIV and other related infections as well as associated risk behaviours and socio-demographics among Aboriginal populations in Canada. The A-Track system was piloted in Regina, Saskatchewan from 2011 to 2012. The focus of the pilot survey was to provide important surveillance information and determine whether this type of public health surveillance activity could be conducted in urban settings in Canada.

This report provides selected findings from the A-Track pilot survey and is a summary of a more in-depth report entitled *Summary of key finding from the A-Track pilot survey, 2011 - 2012* (3).

Methods

A-Track is a behavioural and biological surveillance system that monitors the prevalence of HIV and other related infections as well as the associated risk behaviours and socio-demographics among Aboriginal populations in Canada. A pilot survey was launched in Regina, Saskatchewan, from December 5, 2011 to June 15, 2012.

The A-Track pilot survey was developed and implemented via a community and public health partnership. The partners included: a Community Advisory Group, All Nations Hope Network, Regina Qu'Appelle Health Region, the Canadian Aboriginal AIDS Network, First Nations University of Canada and the Public Health Agency of Canada.

The A-Track surveillance system recognizes Aboriginal peoples' shared control over data, respects Aboriginal customs and is based on the tenants of mutual respect between all stakeholders, the recognition of shared responsibility, Aboriginal community involvement and the utilization of existing local expertise. The surveillance system protocol recognizes First Nations, Inuit and Métis communities-specific culturally competent ethical research practices including the principles of data ownership, control, access and possession and protection (4) and follows the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (5) and the Canadian Institutes of Health Research *Guidelines for Health Research Involving Aboriginal People* (6). The data from the Regina pilot survey is managed collaboratively by the All Nations Hope Network, the Regina Qu'Appelle Health Region and the Public Health Agency of Canada.

The target population for the pilot survey was people who self-identified as Aboriginal (First Nations, Inuit or Métis) or claimed Aboriginal ancestry and were between the ages of 16 and 60 years. Participation was voluntary, completely anonymous and based on informed verbal consent. Participants were recruited from community-based organizations, Friendship Centres, healthcare service points and other relevant venues in Regina.

Consenting participants were asked to complete a questionnaire covering demographics, sexual behaviour, drug use, HIV and hepatitis C testing / treatment history, access to health services and HIV-related knowledge. Participants were also asked to provide a finger prick blood sample which was tested for HIV, hepatitis C and syphilis antibodies.

The data in this report are descriptive results shown for the overall sample (as well as by sex) allowing for comparisons between male and female participants for demographics, antibody laboratory results, sexual and drug use behaviours and HIV testing, care and treatment. Findings for self-reported HIV, sexually transmitted infection and tuberculosis infection status, access to health services and HIV-related knowledge are not presented here and can be obtained from the full report (3). Where data in the table contain small cell counts, results should be interpreted with caution.

Results

A total of 1,064 individuals participated in the A-Track pilot survey, two of whom claimed Aboriginal ancestry and 1,062 of whom self-identified as Aboriginal. (**Table 1**) Of these 1,062, the majority (90.1%) self-identified as First Nations. Just over half (50.7%) of the participants were male and just under half (44.8%) of the participants were between the ages of 30 and 49 years, with a slightly lower proportion (42.2%) under the age of 29 years and over the age of 50 (13.0%). While the majority of participants (95.5%) self-reported their sexual orientation as heterosexual or straight, a significantly higher proportion of females than males self-identified as gay, lesbian, bisexual or other (6.9% versus 2.2%).

Table 1: Demographic characteristics of A-Track pilot survey participants

Demographic characteristic and past experiences	Total (n=1064)	Male (n=539)	Female (n=525)	p-value
Aboriginal subgroup (n=1062)				
First Nations	90.1% (957)	88.8% (477)	91.4% (480)	0.357
Métis	9.7% (103)	11.0% (59)	8.4% (44)	
Inuit	<1%	<1%	<1%	
Age in years (n=1064)				
29 and less	42.2% (449)	37.5% (202)	47.1% (247)	0.007
30 to 49	44.8% (477)	48.2% (260)	41.3% (217)	
50 and over	13.0% (138)	14.3% (77)	11.6% (61)	
Sexual orientation (n=1064)				
Gay, lesbian, bisexual and other	4.5% (48)	2.2% (12)	6.9% (36)	<0.001
Heterosexual or straight	95.5% (1016)	97.8% (527)	93.1% (489)	
Highest completed level of education (n=1064)				
Completed some high school or less	60.2% (640)	60.3% (325)	60.0% (315)	0.733
Completed high school	19.5% (208)	20.2% (109)	18.9% (99)	
Completed more than high school	20.2% (214)	19.3% (104)	21.0% (110)	
Total household income (n=738)[1]				
Up to $9,999	27.1% (200)	27.7% (100)	26.5% (100)	0.011
$10,000 to $39,999	51.1% (377)	46.3% (167)	55.7% (210)	
$40,000 or more	21.8% (161)	26.0% (94)	17.8% (67)	
Proportion who were ever removed or separated from family during childhood by child welfare agencies, church or government officials (n=1063)	53.2% (565)	53.0% (285)	53.3% (280)	0.907
Proportion who ever attended residential or boarding school for Aboriginal children during childhood (n=1061)	29.9% (317)	32.1% (172)	27.6% (145)	0.112
Proportion who were ever placed in a foster home or in foster care during childhood (n=1060)	43.4% (460)	41.7% (223)	45.1% (237)	0.256

Housing status during the 12 months prior to interview (n=1064) [2]				
Stable housing	73.5% (782)	68.8% (371)	78.3% (411)	
Unstable housing	6.4% (68)	8.2% (44)	4.6% (24)	0.001
Mix of stable and unstable housing	20.1% (214)	23.0% (124)	17.1% (90)	
Proportion who moved during the 12 months prior to interview for any reason (n=1064)	33.3% (354)	33.2% (179)	33.3% (175)	0.966
Proportion who had ever lived in a correctional facility (n=1061)	57.7% (612)	70.2% (376)	45.0% (236)	<0.001
Proportion who had lived in a correctional facility during the 12 months prior to interview (n=1064)	5.2% (55)	7.2% (39)	3.1% (16)	0.002

[1] Income was measured as the total household income, before taxes and other deductions, from all sources for the year ending December 31, 2010.
[2] Participants were asked to indicate all of the types of places where they had continuously or occasionally lived during the 12 months prior to interview. Responses were categorized as stable housing, unstable housing and mix of stable and unstable housing. Stable housing included: living in an apartment or house or a relative's apartment or house during the 12 months prior to interview. Unstable housing included: living in a friend's place, hotel or motel room, rooming or boarding house, shelter or hostel, transition or halfway house, drug treatment facility, correctional facility, public place (e.g., street, squats), psychiatric institution, hospital or any other responses that were considered unstable (e.g., vehicle, tent, anywhere outdoors) within the 12 months prior to interview.

Just over half (51.1%) of all participants who provided responses when asked about household income reported that their total household income was between $10,000 and $39,000. Significant differences were noted between the self-reported household incomes of males and females. Over half (60.2%) of the participants had less than a high school education, 19.5% had completed high school and 20.3% had some post-secondary education.

Just over half (53.2%) of all participants had been removed from their families during childhood; almost one-third (29.9%) had at some time during childhood lived in a residential or boarding school; and 43.4% had been placed in foster care at some time during childhood. No significant differences were noted between males and females.

While only 6.4% of all participants reported living exclusively in unstable housing during the 12 months prior to interview, 20.1% reported a mix of unstable and stable housing. A significantly higher proportion of male than female participants reported unstable housing as well as a mix of unstable and stable housing during the 12 months prior to interview. One-third of participants (33.3%) reported that they had moved for some reason within the 12 months prior to interview; no significant differences were noted between males and females.

Over half of all participants (57.7%) had, at some time in their lives, lived in a correctional facility; for male participants, this proportion was significantly higher as compared to female participants. The proportion of male participants who had lived in a correctional facility in the 12 months prior to interview was significantly higher than the proportion of female participants (7.2% versus 3.1%).

Table 2: HIV, hepatitis C and syphilis testing results for A-Track pilot survey participants

Laboratory results	Total	Male	Female	p-value
HIV seroprevalence (among participants who provided a blood sample, n=1045)[1]				
HIV seropositive	5.2% (54)	6.0% (32)	4.3% (22)	0.213
Proportion of HIV seropositive participants who reported a history of injection drug use (n=54)	92.6% (50)	90.6% (29)	95.5% (21)	0.506[5]
Proportion of HIV seropositive participants who were aware of their HIV positive status (n=52)[2]	55.8% (29)	50.0% (15)	63.6% (14)	0.328
Lifetime exposure to hepatitis C (among participants who provided a blood sample, n=1044)[3]				

Hepatitis C seropositive	41.6% (434)	46.1% (245)	36.9% (189)	0.003
HIV and hepatitis C serostatus (among participants who provided a blood sample of sufficient quantity for testing of both HIV and hepatitis C antibodies, n=1044)				
Seropositive for HIV only	0.0% (0)	0.0% (0)	0.0% (0)	0.011
Seropositive for hepatitis C only	36.5% (381)	40.2% (214)	32.6% (167)	
Seropositive for both HIV and hepatitis C	5.1% (53)	5.8% (31)	4.3% (22)	
Seronegative for both HIV and hepatitis C	58.4% (610)	54.0% (287)	63.1% (323)	
Lifetime exposure to syphilis (among participants who provided a blood sample, n=1045)[4]				
Syphilis seropositive	0.2% (2)	0.2% (1)	0.2% (1)	0.977[5]

[1] HIV testing of dried blood spot (DBS) specimens was performed using the AVIOQ HIV-1 EIA assay. Confirmatory testing was subsequently performed using the Bio-Rad GS HIV-1 Western Blot assay. A positive result indicated a current HIV infection.
[2] Participants who reported that their last HIV test result was positive and who were found to be HIV seropositive based on testing of the biological specimen provided at the time of interview were classified as being aware of their HIV positive status.
[3] Hepatitis C testing of DBS specimens was performed using the Ortho HCV version 3.0 EIA. Confirmatory testing was not performed for samples that tested positive. A positive result indicated past or present hepatitis C infection and did not discriminate acute from chronic or resolved infections.
[4] Syphilis testing was performed using the Serodia® Treponema pallidum particle agglutination assay (TP-PA). Confirmatory testing was not performed for samples that tested positive. A positive result was due either to false positivity or the presence of antibodies against syphilis, which indicated either past or present syphilis infection but did not distinguish acute from chronic or resolved infections.
[5] Please note that due to small cell counts, Chi-squared results should be interpreted with caution.

Among the 1,045 participants who provided a blood sample of sufficient quantity for HIV testing, 54 participants (5.2%) were found to be HIV positive and no significant differences were found between males and females **(Table 2)**. Of the 54 participants who tested positive for HIV, the majority of both males and females had a history of injection drug use; overall, 92.6% of all HIV seropositive participants reported that they had, at some time in their lives, used injection drugs. Just over half (55.8%) of the participants who were found to be HIV seropositive were aware of their HIV positive status and no significant differences were noted between males and females.

It is interesting to note that unawareness of HIV infection status was highest among participants who were HIV positive and who did not have a history of injection drug use. Among the 54 participants who tested positive for HIV, four had never injected and all of these participants (4/4; 100%) were unaware of their HIV positive status (data not shown). By contrast, among the 50 participants who tested positive for HIV and had a history of injection drug use, 42% (21/50) were unaware of their HIV positive status (data not shown).

Among the 1,044 participants who provided a sample of sufficient quantity for hepatitis C antibody testing, 41.6% were seropositive, with significantly higher proportions of males than females testing positive for hepatitis C exposure. A positive hepatitis C result indicates past or present hepatitis C infection and does not discriminate acute from chronic or resolved infections. Syphilis seroprevalence was very low among both males and females; overall, only 0.2% of participants were seropositive for syphilis. A positive syphilis result indicates past or present syphilis infection.

Although it is not possible to determine the proportion of participants that were co-infected with HIV and hepatitis C at the time of the survey due to the laboratory test used (i.e., it was not possible to distinguish present from past hepatitis C infection), 5.1% of participants were found to be seropositive for both HIV and hepatitis C. A significantly higher proportion of males than females tested positive for both HIV and hepatitis C antibodies.

Table 3: Injecting behaviours of the A-Track pilot survey participants

Injecting behaviour	Total	Male	Female	p-value
Proportion who had ever injected drugs (n=1063)	50.0% (532)	53.4% (287)	46.7% (245)	0.029
Proportion that were identified as HIV seropositive based on testing of biological sample among those who reported ever injecting drugs (n=528)	9.5% (50)	10.2% (29)	8.6% (21)	0.549

Proportion who first injected before the age of 16 (n=531)	19.4% (103)	19.5% (56)	19.3% (47)	0.942
Proportion who had injected drugs in the six months prior to interview (n=1064)	30.3% (322)	32.5% (175)	28.0% (147)	0.113
Injecting behaviours among participants who reported injecting drugs in the six months prior to interview (n=322)				
Proportion who used sterile needles and/or syringes at last injection (n=321)[1]	98.8% (317)	97.7% (170)	100% (147)	0.064
Proportion who injected with a used needle and/or syringe in the six months prior to interview (n=319)	9.1% (29)	8.7% (15)	9.6% (14)	0.776
Most commonly reported injection drugs used in the six months prior to interview[2]				
Cocaine	56.7% (181)	59.5% (103)	53.4% (78)	0.272
Non-prescribed morphine	51.1% (163)	54.9% (95)	46.6% (68)	0.138
Ritalin	49.8% (159)	49.1% (89)	50.7% (74)	0.782
Non-prescribed Talwin and Ritalin	17.2% (55)	16.2% (28)	18.5% (27)	0.587
Dilaudid (hydromorphone)	15.7% (50)	15.6% (27)	15.8% (23)	0.971
Most commonly reported person with whom participants injected in the six months prior to interview[2]				
Friend(s) or people you know well	53.3% (171)	55.2% (96)	51.0% (75)	0.458
Regular sex partner(s)	47.7% (153)	47.7% (83)	47.6% (70)	0.988
No one: you injected by yourself	40.2% (129)	42.0% (73)	38.1% (56)	0.482
Most commonly reported location of injection in the six months prior to interview[2]				
Your own apartment or house	72.6% (233)	77.0% (134)	67.4% (99)	0.053
Friend's place	44.2% (142)	46.6% (81)	41.5% (61)	0.364
Other family member's house or place	20.9% (67)	20.7% (36)	21.1% (31)	0.930

[1] Based on international reporting requirements through the *Global AIDS Response Progress Report* (GARPR), though the GARPR indicator is based on respondents who report injecting drugs in the last month rather than the last six months.
[2] Participants were provided with a list of responses and were asked to check all those that applied to them. As participants could select more than one response, the total denominator is not shown.

Half of all participants (50.0%) reported that they had, at some time in their lives, used injection drugs, with a significantly higher proportion of male participants reporting a history of injection drug use **(Table 3)**. Among participants that reported having injected drugs at some time, 9.5% were found to be HIV seropositive based on testing of biological samples at the time of interview. Just under one-fifth (19.4%) of participants who had ever injected drugs reported that they had first done so before the age of 16; no significant differences were found between male and female participants. Overall, almost one-third of all participants (30.3%) had used injection drugs during the six months prior to interview, with no significant differences observed between males and females.

Of the 322 individuals who reported injection drug use in the six months prior to interview, the majority (98.8%) had used a clean needle and/or syringe during their last injection, with similar proportions observed among male and female participants. However, almost one-tenth (9.1%) had used a contaminated needle and/or syringe in the six months prior to interview and no significant differences were noted between males and females. With respect to the drugs or substances most commonly reported as being injected in the six months prior to interview, no significant differences were noted between males and females; cocaine, non-prescribed morphine and Ritalin were the three most commonly reported drugs used by both males and females. No significant differences were noted between males and females with respect to the people with whom they most often injected; among both males and females, friend(s) or people they knew well, followed by regular sex partner(s) were the most

commonly reported persons with whom injection occurred. Among both males and females, their own apartment or house was the most commonly reported location of injection in the six months prior to interview.

Several of the sexual behaviour indicators listed in the table below are consistent with those required for international reporting, namely the *Global AIDS Response Progress Report* (GARPR). Refer to the footnotes for specification of which indicators are consistent with GARPR.

Table 4: Sexual behaviours of A-Track pilot survey participants

Sexual behaviour	Total	Male	Female	p-value
Proportion who first had sexual intercourse before the age of 15 (among participants 16 to 24 years old, n=266)[1]	41.0% (109)	50.0% (58)	34.0% (51)	0.009
Proportion who had more than one sexual partner in the 12 months prior to interview (n=926)[1,2]	42.7% (395)	45.5% (210)	39.9% (185)	0.086
Proportion who had used a condom at last sexual intercourse (among participants aged 16 to 49 who reported having had more than one sexual partner in the 12 months prior to interview, n=393)[1]	52.7% (207)	57.7% (120)	47.0% (87)	0.035
Proportion who had a client sex partner in the 12 months prior to interview, n=876) [3]	7.2% (63)	3.1% (14)	11.4% (49)	<0.001
Proportion who used a condom at last sexual intercourse with a client sex partner (among participants who reported having had a client sex partner in the 12 months prior to interview, n=62)	82.3% (51)	78.6% (11)	83.3% (40)	0.682[4]

[1] Indicator for the *Global AIDS Response Progress Report*.
[2] This measure was derived from participants' responses to a series of questions related to the number of regular male sex partners, casual male sex partners, regular female sex partners, casual female sex partners, client sex partners and paid sex partners; only those participants that provided valid responses to at least one question in the series were included in the denominator.
[3] A client sex partner is defined as someone who has given the participant money, drugs, goods or anything else in exchange for sex. [4] Please note that due to small cell counts, Chi-squared results should be interpreted with caution.

It was found that a significantly higher proportion of male than female participants between the ages of 16 and 24 years had their first sexual intercourse prior to the age of 15 years (50.0% of males versus 34.0% of females) **(Table 4)**. Just under half (42.7%) of all participants reported having had more than one sexual partner in the 12 months prior to interview, with similar proportions observed among males and females. Among those participants between the ages of 16 and 49 years who reported having more than one sexual partner in the 12 months prior to interview, a significantly higher proportion of male participants had used a condom at last sexual intercourse (57.7% of males versus 47.0% of females). Among those participants who reported having had a client sex partner in the 12 months prior to interview, 82.3% reported using a condom at last sexual intercourse and no significant differences were noted between males and females.

Table 5: HIV testing, care and treatment of A-Track pilot survey participants

HIV testing, care and treatment	Total	Male	Female	p-value
Proportion who had ever tested for HIV (n=1049)	71.5% (750)	67.7% (360)	75.4% (390)	0.005
Proportion who had tested for HIV in the 12 months prior to interview (among participants who had ever tested for HIV, n=750)	67.6% (507)	68.9% (248)	66.4% (259)	0.469
Proportion who reported that they were currently under the care of a doctor for HIV (among participants who self-reported being HIV positive,	86.7% (26)	80.0% (12)	93.3% (14)	0.283[2]

n=30)[1]				
Proportion who had ever taken prescribed drugs for HIV (among participants who self-reported being HIV positive, n=30)	66.7% (20)	73.3% (11)	60.0% (9)	0.439

[1] Defined as a single visit or more to a doctor or other health professional in the six months prior to interview for HIV testing, treatment, counselling, etc.
[2] Please note that due to small cell counts, Chi-squared results should be interpreted with caution.

Just under three-quarters (71.5%) of participants reported that they had been tested for HIV at least once during their lifetime, and history of HIV testing was significantly higher among female than male participants **(Table 5)**. Of the 750 individuals who had ever been tested for HIV, 67.6% had been tested during the 12 months prior to the interview, with similar proportions among males and females. Among participants who reported being HIV positive, 86.7% reported that they were under the care of a doctor at the time of the interview and 66.7% reported that they had, at some time, taken prescription drugs for HIV. No significant differences were found between males and females.

Conclusion

Findings from the A-Track pilot survey are consistent with other findings that suggest Aboriginal populations in Canada are disproportionately affected by HIV (7-15). These findings also suggest that numerous risk behaviours may be contributing to the transmission of HIV and other blood-borne infections among Aboriginal populations and therefore underscore the continued need for health and social support services, as well as testing for HIV and other blood-borne infections. An analysis of the Aboriginal Social Determinants of Health would further inform service development and delivery by contextualizing the environments of risk and resilience that influence behaviours.

There are however limitations to the findings. The pilot survey only included Aboriginal people recruited at community and healthcare venues in Regina and thus, findings cannot be said to be representative of all Aboriginal people in Regina or of all Aboriginal people in Canada. In addition, the A-Track pilot survey findings are based on self-reported data and it is therefore possible that certain risk behaviours were over or underrepresented. These limitations notwithstanding, findings from the A-Track pilot survey – the first of its kind in Canada – provide valuable information for treatment and prevention services and programs at local, provincial and national levels. This surveillance data can be used to inform existing interventions and to design new strategies aimed at decreasing the risk of HIV and related infections among Aboriginal people in Canada.

In conclusion, this assessment of the pilot survey design and implementation processes and outputs has demonstrated the feasibility of such a behavioural and surveillance system for urban settings in Canada and provide lessons for use in future surveys of its kind.

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Conflict of interest

None

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Key findings from a national enhanced HIV surveillance system: 2010 - 2012

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Abstract

Background: People who inject drugs represent an important risk group in Canada's HIV epidemic. I-Track is a national public health surveillance system designed to monitor HIV and hepatitis C prevalence and associated risk behaviour factors among people who inject drugs in Canada. Information is collected through cross-sectional surveys conducted periodically at sentinel sites across Canada. I-Track Phase 3 was conducted between April 26, 2010 and August 7, 2012 across 11 participating sentinel sites.

Objective: To assess the prevalence of HIV, lifetime exposure to hepatitis C and associated risk behaviours among people who inject drugs in Canada to guide and help evaluate HIV and hepatitis C prevention, treatment and control activities.

Methods: People who had injected drugs in the six months prior to the interview and who met the minimum age of consent participated in an interviewer administered survey and provided a blood sample for HIV and hepatitis C antibody testing. Descriptive analyses were performed with sex-based comparisons.

Results: There were 2,687 people who participated in the survey. 68.2% were male, 60.9% were between the ages of 30 and 49 years and 36.2% self-identified as Aboriginal. Among the participants who provided a blood sample of sufficient quantity for testing, 11.2% were HIV seropositive and their lifetime exposure to hepatitis C infection was 68.0%. Drugs commonly injected included cocaine (64.3%), hydromorphone (47.2%), non-prescribed morphine (47.0%), oxycodone (37.7%) and heroin (26.7%). Injecting with previously used needles and/or other injection equipment was reported by 15.5% and 34.5% of participants, respectively. Just over one-third reported having two or more sex partners in the six months prior to the interview (34.4%) and using a condom at last sex (36.6%). The majority of participants had tested at least once in their lifetime for HIV or hepatitis C (92.9% and 91.4%, respectively). A large proportion of the participants who reported being HIV positive were under the care of a doctor (95.0%) and nearly two-thirds were taking medications prescribed for their HIV infection at the time of the interview (66.0%).

Conclusion: HIV seroprevalence and lifetime exposure to hepatitis C infection were high among I-Track Phase 3 participants. Although many participants reported safe injection and safe sexual practices, a high proportion of participants reported risk behaviours associated with acquisition and transmission of HIV and hepatitis C. People who inject drugs continue to represent an important risk group in Canada's HIV epidemic and the I-Track Phase 3 survey findings highlight the need for continued treatment and prevention services, as well as routine and integrated testing among people who inject drugs.

Introduction

Certain risk behaviours among people who inject drugs, such as the sharing of needles and other injecting equipment as well as unprotected sex, are associated with the transmission of blood-borne infections including HIV and hepatitis C. It is estimated that in 2011, people who inject drugs made up 13.7% of new HIV infections

and 16.9% of those living with HIV in Canada (1). Hepatitis C among people who inject drugs in Canada also continues to be a major public health concern with injection drug use accounting for 61% of newly acquired hepatitis C infections in Canada each year (2).

A behavioural and biological national surveillance system, called I-Track, was developed to monitor the prevalence of HIV and hepatitis C as well as associated risk behaviours among people who inject drugs in Canada. The I-Track pilot was conducted from 2002 - 2003 in four sites, followed by three phases of data collection: Phase 1 from 2003 - 2005 in seven sites, Phase 2 from 2005 - 2008 in 10 sites and Phase 3 from 2010 to 2012 in 11 sites.

The ongoing monitoring of risk behaviours among persons who inject drugs serves as an early warning system for the spread of blood-borne infections in Canada. In addition, the I-Track survey results can help inform and evaluate existing public health responses to HIV and hepatitis C among persons who inject drugs in Canada.

This report provides selected findings from I-Track Phase 3 and is a summary of the more in-depth report (3).

Methods

I-Track is a behavioural and biological surveillance system that monitors the prevalence of HIV and hepatitis C as well as the associated risk behaviours among people who inject drugs in Canada. Information is collected through cross-sectional surveys conducted periodically at sentinel sites across Canada. I-Track Phase 3 surveys were conducted between April 26, 2010 and August 7, 2012 across 11 participating sentinel sites.

The target population was people who had injected drugs in the six months prior to recruitment and who met the minimum age of consent as per provincial requirements. Participation was voluntary, completely anonymous and based on informed verbal consent. Consenting participants were asked to complete an interviewer administered questionnaire covering demographics, drug use and injecting behaviours, sexual behaviours, HIV and hepatitis C testing and treatment history, use of health services and HIV-related knowledge. Participants were also asked to provide a biological sample which was tested for HIV and hepatitis C antibodies. Testing was first performed for HIV followed by testing for hepatitis C providing there was sufficient sample volume.

The data in this report are descriptive results shown for the overall sample, as well as by sex, allowing for comparisons between male and female participants for demographics; antibody laboratory results; drug use and injecting behaviours; sexual risk behaviours; HIV and hepatitis C testing, care and treatment; and use of health services. Findings for HIV-related knowledge are not presented here and can be obtained from the full report (3). Where data in the table contain small cell counts, the results should be interpreted with caution.

Results

A total of 2,687 individuals participated in I-Track Phase 3 across 11 sentinel sites in Canada: Whitehorse YK (n=55), Prince George BC (n=150), Edmonton AB (n=183), Regina SK (n=251), Thunder Bay ON (n=138), Sudbury ON (n=148), London ON (n=204), Toronto ON (n=260), Kingston ON (n=200), the SurvUDI network (sites in the province of Québec* and Ottawa, ON) (n=937) and Halifax NS (n=161). SurvUDI network sites in the province of Québec include Abitibi-Témiscamingue, Outaouais, Montréal, Montérégie, Québec City, Saguenay-Lac St-Jean, Mauricie-Central Québec and Eastern Townships.

Table 1: Demographic characteristics of I-Track Phase 3 participants

Demographic characteristic and incarceration history	Total[1] (n=2687)	Male (n=1832)	Female (n=855)	p-value
Age in years (n=2687)				
Under 30	20.9% (561)	16.8% (307)	29.7% (254)	<0.001
30-49	60.8% (1635)	62.3% (1142)	57.7% (493)	
50 and over	18.3% (491)	20.9% (383)	12.6% (108)	
Self-reported Aboriginal ethnicity (First Nations, Métis or Inuit) (n=2678)	36.2% (968)	29.4 % (537)	50.6% (431)	<0.001
Sexual orientation (n=2673)				
Heterosexual or straight	88.3% (2359)	91.9% (1679)	80.3% (680)	<0.001
Gay, lesbian, bisexual, two-spirit or other	11.7% (314)	8.1% (147)	19.7% (167)	
Level of education (n=2679)				
Completed some high school or less	55.7% (1492)	53.4% (974)	60.6% (518)	0.002
Completed high school	20.9% (560)	22.1% (403)	18.4% (157)	
Completed more than high school	23.4% (627)	24.5% (447)	21.2% (180)	
Monthly income (n=2641)[2]				
Less than $500	14.4% (379)	12.3% (222)	18.7% (157)	
Between $500-$999	39.7% (1049)	40.3% (726)	38.4% (323)	<0.001
Between $1000-$1999	29.3% (775)	28.8% (518)	30.6% (257)	
$2000 and more	16.6% (438)	18.6% (334)	12.4% (104)	
Housing status at the time of interview (n=2669)[3]				
Stable housing	61.3% (1637)	57.6% (1049)	69.3% (588)	<0.001
Unstable housing	38.7% (1032)	42.4% (772)	30.7% (260)	
Proportion who had been incarcerated in the six months prior to interview (n=2683)[4]	11.5% (308)	12.5% (229)	9.3% (79)	<0.014
Proportion who had ever lived in a correctional facility (n=2678)	82.5% (2210)	88.5% (1618)	69.7% (592)	<0.001

[1] I-Track Phase 3 participants who indicated a sex at birth other than male or female (n=3) were excluded from the analyses presented in this report.
[2] This included all sources of income, both legal and illegal, during a one month period.
[3] Participants were asked to indicate where they were living at the time of the interview and responses were categorized as stable housing or unstable housing. Stable housing included: living in an apartment or house or a relative's apartment or house at the time of the interview. Unstable housing included: living in a friend's place, hotel or motel room, rooming or boarding house, shelter or hostel, transition or halfway house, drug treatment facility, correctional facility, public place (e.g., street, squats), psychiatric institution, hospital or any other responses that were considered unstable (e.g., vehicle, tent, anywhere outdoors).
[4] Participants were provided with a list of housing options and asked to select all the places where they had lived in the six months prior to interview. Participants who selected a correctional facility (jail, corrections, prison) are presented here.

Table 1 identifies the socio-demographic characteristics of Phase 3 participants were similar to those of previous I-Track phases; a large proportion of participants were male (68.2%) and the largest proportion of participants were between the ages of 30 and 49 years (60.9%), with a significantly higher proportion of male participants than female participants in this age group (62.3% versus 57.7%) and in the 50 and over age group (20.9% versus 12.6%). Although a large proportion of I-Track participants self-reported their sexual orientation as heterosexual or straight (88.3%), a significantly higher proportion of females than males self-identified as gay, lesbian, bisexual, two-spirit or other (19.7% versus 8.1%).

Over one-third (36.2%) of participants self-identified as Aboriginal (First Nation, Métis or Inuit), which is well above the proportion of self-identified Aboriginal persons among the general Canadian population. According to 2011 data from the *National Household Survey*, 4.3% of the total Canadian population self-identify as Aboriginal (4).

There was substantial variation across sites with respect to the proportion of participants that self-reported their ethnicity as Aboriginal. For example, 89.6% of participants in Regina and 84.7% of participants in Edmonton self-identified as Aboriginal while only 19.1% of participants in London and 13.7% of participants in the SurvUDI network self-identified as Aboriginal (data not shown). In addition, a significantly higher proportion of female participants across all sites self-identified as Aboriginal (50.6% of females versus 29.4% of males).

Over half (55.7%) of participants reported having less than a high school education, with a significantly higher proportion of female participants reporting a lower level of education as compared to their male counterparts. Over one-third (39.7%) of participants reported that their monthly income was in the range of $500 and $999, though there was considerable variation across participants and significant differences were noted between males and females.

Over one-third (38.7%) of all participants reported living in unstable housing at the time of the interview, with a significantly higher proportion of males reporting unstable housing. More than one-tenth (11.5%) reported having lived in a correctional facility in the six months prior to the interview; among males, this proportion (12.5%) was significantly higher as compared to females (9.3%). A large proportion of all participants (82.5%) reported that they had, at some time in their lives, been incarcerated; the proportion of males that reported a history of incarceration was significantly higher as compared to the proportion of females (88.5% versus 69.7%). Both unstable housing and incarceration present challenges to the prevention and control of HIV and other blood-borne infections among persons who inject drugs in Canada as both are known as high-risk injecting environments (5,6).

Table 2: HIV and hepatitis C laboratory results of I-Track Phase 3 survey participants

Laboratory results	Total	Male	Female	p-value
HIV seroprevalence (among participants who provided a blood sample, n=2593)[1]				
HIV seropositive	11.2% (291)	11.6% (205)	10.4% (86)	0.387
Proportion of HIV seropositive participants who were aware of their HIV positive status (n=281)[2]	78.6% (221)	78.7% (155)	78.6% (66)	0.984
Lifetime exposure to hepatitis C (among participants who provided a blood sample, n=2575)[3]				
Hepatitis C seropositive	68.0% (1750)	67.9% (1192)	68.1% (558)	0.899
HIV and hepatitis C serostatus (among participants who provided a biological sample of sufficient quantity for testing of both HIV and hepatitis C antibodies, n=2575)				
Seropositive for HIV only[1]	1.7% (43)	2.0% (35)	1.0% (8)	0.312
Seropositive for hepatitis C only[3]	58.5% (1505)	58.4% (1025)	58.6% (480)	
Seropositive for both HIV and hepatitis C[1,3]	9.5% (245)	9.5 % (167)	9.5% (78)	
Seronegative for both HIV and hepatitis C	30.4% (782)	30.1 % (529)	30.9% (253)	

[1] HIV testing of dried blood spot (DBS) specimens was performed using the AVIOQ HIV-1 EIA assay. Confirmatory testing was subsequently performed using the Bio-Rad GS HIV-1 Western Blot assay. A positive result indicated a current HIV infection.
[2] Participants who reported that their last HIV test result was positive and who were found to be HIV seropositive based on testing of the biological specimen provided at the time of interview were classified as being aware of their HIV positive status.
[3] Hepatitis C testing of DBS specimens was performed using the Ortho HCV version 3.0 EIA. Confirmatory testing was not performed for samples that tested positive. A positive result indicated past or present hepatitis C infection and did not discriminate acute from chronic or resolved infection.

Overall, HIV seroprevalence and lifetime exposure to hepatitis C infection were high **(Table 2)**. 11.2% of the survey participants who provided a biological sample of sufficient quantity for testing were HIV positive and 68.0% were seropositive for hepatitis C. No significant differences in HIV and hepatitis C seroprevalence were found between males and females. Although it is not possible to determine the proportion of participants that were co-infected with HIV and hepatitis C at the time of interview due to the nature of the laboratory test used (i.e., it was not possible to distinguish present from past hepatitis C infection), the proportion of participants who were seropositive for both HIV and hepatitis C (9.5%) nevertheless highlights the potential for multiple infections to complicate treatment responses as well as health outcomes among people who inject drugs in Canada.

The necessity of routine and integrated HIV and hepatitis C testing among people who inject drugs cannot be overstated. It was found that only 78.6% of I-Track Phase 3 participants who tested positive for HIV based on the biological sample provided at the time of interview were aware of their infection or alternatively, that 21.4% of seropositive participants were unaware of their HIV positive status. Individuals who are unaware of their infection status are not able to benefit from treatment and counselling services and, moreover, cannot take measures to reduce their risk of HIV transmission to others. Furthermore, testing provides an opportunity to increase awareness of safe injection and sexual practices among people who inject drugs, as well as an opportunity to link individuals to available health and social support services.

Table 3: Drug use and injecting behaviours of I-Track Phase 3 survey participants

Drug use behaviour	Total	Male	Female	p-value
Proportion who first injected before the age of 16 years (n=2669)	15.4% (412)	14.0% (255)	18.5% (157)	0.003
Most commonly reported injection drugs used in the six months prior to interview[1]				
Cocaine	64.3% (1724)	66.0% (1206)	60.8% (518)	0.009
Hydromorphone	47.2% (1265)	47.1% (861)	47.4% (404)	0.890
Morphine (non-prescribed)	47.0% (1259)	45.0% (822)	51.3% (437)	0.002
Oxycodone	37.7% (1012)	36.8% (673)	39.7% (339)	0.143
Heroin	26.7% (716)	27.5% (503)	25.0% (213)	0.170
Most commonly reported person with whom participants injected in the six months prior to interview[2]				
No one (i.e., injected alone)	59.3% (1588)	60.2% (1101)	57.2% (487)	0.145
Friend(s) or people they knew well	50.5% (1354)	49.0% (896)	53.8% (458)	0.020
Regular sex partner(s)[3]	31.0% (831)	24.8% (453)	44.4% (378)	<0.001
People they didn't know well	17.8% (478)	18.1% (331)	17.3% (147)	0.604
Family member(s)	10.6% (285)	8.0% (147)	16.2% (138)	<0.001
Proportion who had used a sterile needle and/or syringe at last injection (n=2663)[4]	94.5% (2516)	94.7% (1721)	94.0% (795)	0.433
Proportion who had injected with a used needle and/or syringe in the six months prior to the interview (n=2671)	15.5% (415)	13.7% (249)	19.6% (166)	<0.001
Proportion who reported that their used needle and/or syringe had been subsequently used by someone else for injection in the six months prior to interview (n=2646)	15.5% (409)	12.7% (229)	21.4% (180)	<0.001
Proportion who had injected with other used injection equipment in the six months prior to interview (n=2672)[5]	34.5% (922)	31.6% (576)	40.9% (346)	<0.001
Proportion who reported that their other used injection equipment had been subsequently used by someone else in the six months prior to the interview (n=2659)[5]	33.1% (880)	29.7% (540)	40.3% (340)	<0.001

Most commonly reported location of injection in the six months prior to interview[6]				
Own apartment / house	61.1% (1642)	59.0% (1081)	65.6% (561)	<0.001
Friend's place	42.1% (1131)	40.4% (740)	45.7% (391)	0.007
Public place[7]	39.4% (1059)	41.8% (766)	34.3% (293)	<0.001
Hotel / motel room	15.6% (419)	14.6% (267)	17.8% (152)	0.080
Vehicle[8]	15.6% (419)	14.4% (263)	18.3% (156)	0.009
Rooming / boarding house	8.2% (220)	8.9% (163)	6.7% (57)	0.052

[1] Participants recorded all drugs that they had injected for non-medicinal purposes in the six months prior to interview. The most commonly reported drugs among all participants are presented. As participants could select more than one response, the total denominator is not shown.
[2] Participants indicated all types of persons with whom they had injected in the six months prior to interview. The most commonly reported persons are presented. As participants could select more than one response, the total denominator is not shown.
[3] A regular sex partner was defined as someone with whom the participant had a relationship and with whom the participant was emotionally involved.
[4] This measure is also used to contribute to the *Global AIDS Response Progress Reporting Indicator* 2.3 (7).
[5] Other used injection equipment included water, filters, cookers, spoons, tourniquets, ties, swabs and acidifiers.
[6] Participants indicated all locations where they had injected drugs in the six months prior to interview. The most commonly reported locations among all participants are presented. As participants could select more than one response, the total denominator is not shown.
[7] Public place included street, park, squat, subway, etc.
[8] Vehicle included car, van, recreational vehicle, etc.

Several differences were noted between the drug use and injecting behaviours of males and females (**Table 3**). Overall, 15.4% of all participants reported that they had injected drugs for the first time prior to the age of 16 years, with a significantly higher proportion of females than males reporting early use of injection drugs (18.5% versus 14.0%). Participants reported a variety of substances that they had injected in the six months prior to interview, though cocaine was the most commonly reported among all participants (64.3%). A significantly higher proportion of male than female participants reported injecting cocaine (66.0% versus 60.8%), while a significantly higher proportion of female than male participants reported injecting non-prescribed morphine (51.3% versus 45.0%).

With respect to the persons with whom participants injected in the six months prior to interview, a significantly higher proportion of females reported injecting with friend(s) or people they knew well, regular sex partner(s) or family member(s). The high proportion of participants (59.3%) who reported injecting alone is of particular concern as injecting alone is a significant risk factor for overdose and death (8).

While a large proportion (94.5%) of both male and female participants reported using a sterile needle at their last injection, a significantly higher proportion of female participants reported a history of high-risk injecting behaviours, including use of contaminated needles, syringes and/or other injection equipment, as well as passing on used needles, syringes and/or other used injection equipment to others. These findings, coupled with data from national routine surveillance which demonstrate that a higher proportion of female adults as compared to their male counterparts acquire HIV through injection drug use, suggest that females who inject drugs are particularly vulnerable to HIV infection (9).

Participants reported a range of locations where they had injected drugs in the six months prior to interview. The most common location was their own apartment or house and this location was reported by a significantly higher proportion of female than male participants (65.6% versus 59.0%). A significantly higher proportion of female than male participants also reported injecting drugs at a friend's place and in a vehicle. In contrast, a significantly higher proportion of male than female participants reported injecting drugs in a public place. Overall, 39.4% of all participants reported injecting in a public place which is of notable concern as public injection drug use is associated with high-risk injection practices and, in turn, increased risk of transmission of HIV and other blood-borne pathogens (10).

Table 4: Sexual risk behaviours of I-Track Phase 3 survey participants

BehaviourSexual behaviour	Total	Male	Female	p-value
Proportion who had two or more sex partners in the six months prior to interview (n=2676) [1]	34.4% (920)	31.3% (572)	40.9% (348)	<0.001
Proportion who had used a condom at last sex (among participants who reported sex in the previous month, n=2124) [1]	36.6% (777)	37.2% (505)	35.4% (272)	0.401
Proportion who had a client sex partner in the six months prior to interview (n= 2687) [1]	12.8% (343)	4.7% (86)	30.1% (257)	<0.001
Proportion who had used a condom at last sex with a client sex partner (n=306)	77.1% (236)	57.4% (35)	82.0% (201)	<0.001
Proportion who had been previously diagnosed with a sexually transmitted infection (n=1732) [2,3]	39.3% (680)	32.7% (355)	50.2% (325)	<0.001

[1] A client sex partner was defined as someone who has given the participant money, drugs, goods or anything else in exchange for sex.
[2] Defined as ever being told by a health professional (e.g., doctor or nurse) as having had chlamydia, gonorrhoea, human papillomavirus, genital herpes, oral herpes or another sexually transmitted infection.
[3] Data on the history of diagnosis with a sexually transmitted infection was not collected in the SurvUDI network.

Use of drugs has been shown to influence sexual behaviour by increasing risk taking (**Table 4**). Therefore understanding the high-risk sexual behaviours (e.g., inconsistent condom use, multiple sex partners, sex trade work) of people who inject drugs in Canada is therefore of great public health importance (11). Among I-Track Phase 3 participants who reported being sexually active, female and male participants differed in their sexual behaviours. A significantly higher proportion of female than male participants reported two or more sex partners in the six months prior to interview. Among participants who reported sex in the month prior to interview, reported condom use at last sex was similar between male and female participants, albeit quite low across all participants (36.6%). It should be noted that condom use at last sex was measured across all sex partner types. In comparison, reported condom use at last sex with a client partner was substantially higher (77.1%) and a significantly higher proportion of female than male participants reported this behaviour (82.0% versus 57.4%). A significantly higher proportion of female than male participants reported having a client sex partner in the six months prior to interview (30.1% versus 4.7%). History of a diagnosis of a sexually transmitted infection was significantly higher among female than male participants (50.2% versus 32.7%).

Table 5: Testing and follow up for HIV and hepatitis C of I-Track Phase 3 survey participants

HIV and hepatitis C tTesting, care and treatment and follow up	Total	Male	Female	p-value
HIV				
Proportion who had ever tested for HIV (n=2657)	92.9% (2468)	91.9% (1668)	95.1% (800)	0.002
Proportion who had tested for HIV within the two years prior to interview (among participants who self-reported being HIV negative, n=2010)	85.0% (1709)	83.6% (1133)	88.1% (576)	0.008
Proportion who reported that they were under the care of a doctor for HIV at the time of interview (among participants who self-reported being HIV positive, n=95) [1]	95.0% (95)	94.2% (49)	95.8% (46)	0.713[2]
Proportion who had ever taken prescribed drugs for HIV (among participants who self-reported being HIV positive, n=77)	77.0% (77)	80.8% (42)	72.9% (35)	0.351
Proportion who were taking prescribed drugs for HIV at the time of interview (among participants who self-reported being HIV positive, n=100)	66.0% (66)	75.0% (39)	56.3% (27)	0.048
Hepatitis C				
Proportion who had ever tested for hepatitis C (n=2646)	91.4% (2417)	90.3% (1625)	93.6% (792)	0.004
Proportion who reported that they were under the care of a doctor for hepatitis C at the time of interview (among participants who self-reported being infected with hepatitis C at the time of the interview, n=1063) [3]	48.4% (514)	49.3% (358)	46.3% (156)	0.359
Proportion who had ever taken prescribed drugs for hepatitis C (among participants who self-reported being infected with hepatitis C at the time of the interview, n=1060)	9.5% (101)	10.8% (78)	6.9% (23)	0.045
Proportion who were taking prescribed drugs for hepatitis C at the time of interview (among participants who self-reported being infected with hepatitis C at the time of the interview, n=1063)	2.4% (25)	2.6% (19)	1.8% (6)	0.402

[1] Defined as a single visit or more to a doctor for HIV treatment, counselling, testing, etc. in the six months prior to interview.
[2] Please note that due to small cell counts, results should be interpreted with caution.
[3] Defined as a single visit or more to a doctor for hepatitis C treatment, counselling, follow-up testing, etc. in the year prior to interview.

Most participants reported that they had ever tested for HIV and hepatitis C at some point in their lives (92.9% and 91.4% respectively) and history of testing was significantly higher among female participants for both infections **(Table 5)**. No

significant differences were found between male and female participants with respect to care and treatment for HIV, except that a significantly higher proportion of self-reported HIV positive male than self-reported HIV positive female participants reported that they were taking prescribed drugs for HIV at the time of the interview (75.0% versus 56.3%, respectively). Among participants who reported being infected with hepatitis C at the time of the interview, low proportions reported being under the care of a doctor and taking prescribed drugs either at the time of the interview or in the past. No statistically significant differences were found between male and female participants in terms of care and treatment for hepatitis C, except that a significantly higher proportion of male than female participants reported that they had, at some time in their lives, taken prescribed drugs for hepatitis C (10.8% versus 6.9%, respectively).

Table 6: Use of health services and level of difficulty accessing clean needles

Access to Health services use and access	Total	Male	Female	p-value
Proportion who reported use of the following healthcare services in the 12 months prior to interview				
Needle exchange / harm reduction facilities (n=1732)	89.0% (1541)	87.4% (948)	91.7% (593)	0.006
Hospitals (n=1732)	59.4% (1029)	57.9% (628)	61.9% (401)	0.105
Community drop-in centres (n=1733)	54.5% (945)	55.2% (599)	53.4% (346)	0.464
Medical clinics (n=1730)	47.1% (815)	42.7% (462)	54.6% (353)	<0.001
Community health centres (n=1735)	44.9% (779)	42.7% (464)	48.5% (315)	0.019
Detox or drug treatment facilities (n=1731)	32.2% (557)	31.9% (346)	32.6% (211)	0.765
Mental health and addictions centres (n=1729)	23.7% (409)	21.6% (234)	27.1% (175)	0.009
Culturally-based services (n=1729)	10.0% (173)	9.4% (102)	11.0% (71)	0.284
Sexual health centres (n=1727)	9.6% (165)	7.3% (79)	13.4% (86)	<0.001
Self-reported level of difficulty accessing clean needles (n=2663)				
Very easy	81.0% (2158)	82.2% (1493)	78.6% (665)	0.006
Somewhat easy	15.5% (413)	15.0% (272)	16.7% (141)	
Somewhat difficult	3.1% (83)	2.4% (44)	4.6% (39)	
Very difficult	0.3% (9)	0.4% (8)	0.1% (1)	

The provision of health and social support services to priority populations, including people who inject drugs, is an important component of Canada's response to HIV/AIDS and other blood-borne and sexually transmitted infections. Therefore, understanding health service use among people who inject drugs in Canada is of critical importance (12). Use of healthcare services in the 12 months prior to interview varied depending on the health service in question, and, overall needle exchange or harm reduction facilities were most commonly used among all participants (89.0%) (**Table 6**)**.** Health services use was higher among female participants with a significantly higher proportion reporting that they accessed needle exchange or harm reduction facilities, medical clinics, community health centres, mental health and addictions centres and sexual health centres. A large proportion of participants (96.5%) reported that their level of difficulty accessing clean needles was either very easy or somewhat easy and significant differences were noted between male and female participants.

Conclusion

Overall, HIV seroprevalence and lifetime exposure to hepatitis C infection were high among I-Track Phase 3 participants. Although many participants reported safe injection and safe sexual practices (e.g., abstaining from using or sharing contaminated equipment, condom use, etc.), a high proportion of participants reported risk behaviours associated with acquisition and transmission of HIV and other sexually transmitted and blood-borne infections. These findings suggest that people who inject drugs continue to represent an important risk group in Canada's HIV epidemic and highlight the need for continued treatment and prevention services, as well as routine and integrated testing among people who inject drugs.

This enhanced HIV surveillance system is unique in Canada. I-Track data are collected by repeated cross-sectional surveys at selected sentinel sites across Canada using consistent sampling and recruitment strategies over time. While it is not possible to examine causality directly, these surveillance data offer a valuable source of information for treatment and prevention services and programs at local, provincial and national levels. I-Track uses non-random, convenience sampling methods to overcome some of the inherent difficulties in accessing this hard-to-reach population. Given this, the surveillance findings may not be representative of all people who inject drugs in Canada. With the exception of the laboratory results, this report's findings are based on self-reported data that are subject to social desirability bias and it is therefore possible that certain risk behaviours were over or underrepresented.

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Conflict of interest

None

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A review of Human Immunodeficiency Virus (HIV) rapid testing

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Abstract

Background: In Canada, it is estimated that 71,300 persons were living with HIV at the end of 2011. Approximately 25% (14,500 to 21,500) of prevalent cases were unaware of their HIV infection. Expanded use of HIV rapid tests may increase the detection of undiagnosed infections, enable earlier treatment and support services and prevent the onward transmission of HIV.

Objective: To examine patient acceptability, impact (defined as receipt of test results and linkage to care) and cost-effectiveness of HIV rapid tests.

Methods: A search was conducted for systematic reviews on HIV rapid testing, with studies from both developed and developing countries, published in English and between 2000 and 2013. The *Assessment of Multiple Systematic Review* (AMSTAR) tool was used to assess the included systematic reviews for methodological quality. Results were summarized narratively for each of the outcomes.

Results: Eight systematic reviews were included. Acceptability of HIV rapid tests was generally high in medical settings (69% to 98%) especially among pregnant women and youth attending emergency rooms but was lower in non-medical settings (14% to 46%). The percentage of people who obtained their test results was variable. It was high (83% to 93%) in emergency rooms but was low in a rapid care setting with regular business hours (27%). Impact on linkage to care was limited. Only one systematic review examined cost-effectiveness of rapid testing and concluded that HIV rapid tests were cost-effective in comparison to traditional methods; however, results were all based on static models.

Conclusion: Overall, HIV rapid tests demonstrated generally high acceptability, variability in receiving test results and limited impact on linkage to care. While these findings suggest that HIV rapid tests may be useful, further research is needed to confirm in whom, when and where they are best used and how to ensure better linkage to care.

Introduction

At the end of 2011, an estimated 71,300 persons were living with Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) in Canada and an estimated 25% were unaware of their HIV status (1). Those unaware of their status are unable to take advantage of available support services and care, are at increased risk of transmitting HIV and are at increased risk of acquiring other sexually transmitted and blood-borne infections. Effective screening strategies that lead to earlier diagnosis and treatment can contribute to improved individual and population health outcomes (2).

With the emergence of new diagnostic technologies, there are increasing options for HIV testing. Rapid tests for HIV are available worldwide including oral fluid tests and finger prick tests using whole blood or plasma. HIV rapid tests can be either self-administered or administered by trained staff. In Canada, HIV rapid tests can only be carried out by trained staff in point-of-care (POC) settings (e.g., doctors' offices, clinics, emergency departments) (3-5). In addition, the Public Health Agency of Canada recommends that HIV rapid tests be administered in conjunction with pre- and post-test counselling (5).

Only one HIV rapid test is licensed for use in Canada (6). In October 2005, Health Canada approved the INSTI™ HIV-1 Antibody Test (a single use rapid test for HIV) for use in POC settings. In 2008, the license was amended to include the INSTI™ HIV-1/HIV-2 Antibody Test (6). This test is a preliminary antibody screening test that can be performed on site where the patient can receive their results immediately (< 1hr) (7-10). If the patient receives a preliminary reactive result, a confirmatory test using traditional laboratory-based testing is required. If the test result is negative (non-reactive), no further testing is necessary (3,5).

Previous studies suggest POC testing has the potential to improve the management of infectious diseases by identifying new infections, reducing the numbers of those who are unaware and facilitating linkage to care (11,12). To ensure HIV rapid tests are feasible, they should also be cost-effective. The objective of this rapid review was to examine the most current evidence on patient acceptability, impact (defined as receipt of test results and linkage to care) and cost-effectiveness of HIV rapid tests.

Methods

We followed the Ottawa Hospital Research Institute's methods for conducting rapid reviews (13). This method is designed to provide decision-makers with a synthesis of an extensive literature in a timely manner (13). A protocol was developed for the rapid review a priori that included: question development and refinement; a systematic literature search; screening and selection of systematic reviews; assessing the quality of the evidence; and a narrative synthesis of included studies. (13).

Search strategy

The following databases were searched: Medline, Embase, Scopus, Social Policy and Practice, Proquest Public Health and Google Scholar. Articles were included if they were published between January 2000 and September 2013; included studies from developed or developing countries; and/or published in English. The search strategy included the following key words: ("human immunodeficiency virus" OR "HIV") AND ("Point of care" OR "point-of-care", "rapid test" OR "home-based test" OR "screen*") AND ("linkage to care" OR "follow-up" OR "barrier*", "intervention*" OR "access*" OR "diagnos*") OR ("acceptab*", "willing*", "satisf*", "preference*") OR ("feasib*", "economic*", "financ*", "cost*"). Articles that reported results on HIV prevalence or studies with no mention of HIV rapid testing were excluded from the review.

Quality assessment of the studies

Each systematic review was evaluated using the *Assessment of Multiple Systematic Review* (AMSTAR) tool for methodological quality (14). The AMSTAR tool consists of an 11-item questionnaire that assesses the following criteria: use of an a priori design; duplicate study selection and data extraction process; comprehensive literature search; use of publication status as an inclusion criterion; characteristics of included studies; list of included / excluded studies; assessment of the quality of studies; appropriate use of scientific quality in forming conclusions; appropriate methods used to combine study findings; assessment for publication bias; and acknowledgement of conflict of interest. To ensure reliability of the assessment, two of the authors (SH, SF) evaluated the systematic reviews using the AMSTAR tool. Where there was discrepancy, a third person (DP) was invited to assess the criterion in question.

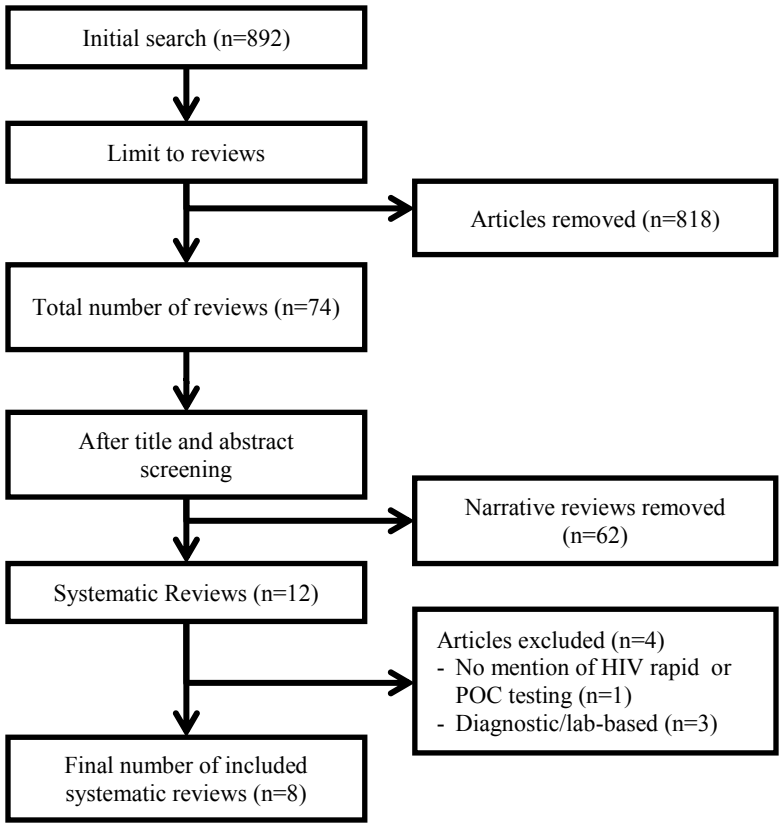
Data extraction

For each of the included systematic reviews, two authors (SH, SF) extracted data on population; search years; number of included studies; locations of included studies; study objective; type of intervention; and outcomes. Outcomes of interest included: acceptability, receipt of HIV test results, linkage to care and cost-effectiveness. After data extraction, both authors compared their findings to ensure consistency.

Results

The initial search yielded a total of 892 articles on rapid testing for HIV. After limiting to systematic reviews (n=12), eight review articles met the inclusion criteria (**Figure 1**).

Figure 1: Algorithm of literature search and study selection of systematic reviews on rapid HIV testing



A description of the included reviews and the respective AMSTAR score out of 11, are presented in **Table 1**. Three had perfect AMSTAR scores and another was of high quality (with a score of 8). Reasons for a systematic review having a score less than eight included: it did not specify a duplicate study selection and data extraction process; assessment and documentation of the quality of the studies; or assessment of publication bias.

Table 1: Description of included systematic reviews with the AMSTAR[1] scores

Reference	Objective(s)	Population and location	Search period, intervention and number of included studies	AMSTAR score (out of 11)
Bateganya (2007) (17)	To identify and critically appraise studies addressing the implementation of home-based HIV voluntary counselling and testing; to assess the effect of this intervention compared to facility-based HIV counselling and testing.	**Population:** Adults (>15 years) **Location(s):** Uganda and Zambia	**Search period:** 1980 - 2007 **Intervention:** Voluntary counselling and testing for HIV **No. included studies:** 2	11
Bateganya (2010) (8)	To establish the effect of home-based HIV voluntary counselling and testing on uptake of HIV testing.	**Population:** Adults (>15 years) **Location(s):** Zambia	**Search period:** 2007 - 2008 **Intervention:** Voluntary counselling and testing for HIV **No. included studies:** 1 [1]	11
Dibosa-Osadolor (2010) (21)	To review evidence used to derive estimates of cost-effectiveness of HIV screening and to appraise the methodologies of economic studies of HIV screening.	**Population:** Various **Location(s):** Not stated	**Search period:** 1993 - 2008 **Intervention:** Economic modelling of HIV screening and testing programs **No. included studies:** 17	7
Napierala Mavedzenge (2013) (18)	To conduct a review of policy and research on HIV self-testing.	**Population:** Various **Location(s):** Kenya, Zambia, United States, Singapore, South Africa, Germany, Malawi, Netherlands, United Kingdom, France	**Search period:** 1980 - May 2012 **Intervention:** HIV self-testing **No. included studies:** 24	6
Pant Pai (2007) (15)	To summarize the overall diagnostic accuracy of rapid HIV tests in pregnancy; evaluate outcomes and impact of testing; and identify practical challenges related to the implementation of voluntary HIV testing and counselling in pregnant women.	**Population:** Pregnant women (18 to 44 years) **Location(s):** South Africa, United States, Latin America, South-East Asia, Jamaica	**Search period:** 1991 - July 2005 **Intervention:** HIV POC testing in pregnancy **No. included studies:** 17	8
Pant Pai (2013) (9)	To review supervised and unsupervised self-testing strategies for HIV.	**Population:** Various **Location(s):** United States, Canada, Singapore, India, Malawi, Spain, Kenya, Netherlands	**Search period:** January 2000 - October 2012 **Intervention:** Supervised and unsupervised HIV POC testing **No. included studies:** 21	11

Roberts (2007) (16)	To review the outcomes of blood and oral fluid rapid HIV testing.	**Population:** Various **Location(s):** United States, Kenya, Brazil, Zimbabwe, Burkina Faso, Mexico	**Search period:** January 2000 - June 2006 **Intervention:** HIV rapid testing **No. included studies:** 26	4
Turner (2013) (19)	To review preferences and acceptability of rapid POC testing in youth, to document notification rates and to identify socio-demographic factors associated with youth choosing rapid HIV POC testing over traditional testing.	**Population:** Youth (<25 years) **Location(s):** United States	**Search period:** January 1990 - March 2013 **Intervention:** HIV POC testing **No. included studies:** 14	7

[1]AMSTAR= *Assessment of Multiple Systematic Review* (AMSTAR) is a tool used to assess the methodological quality of systematic reviews.
[2] This review included one study as it was an update to the Bateganya (2007) Cochrane review.

Acceptability

Almost all of the reviews (7/8) examined acceptability. Acceptability was defined in these reviews as the population's uptake of a rapid test (8, 9, 15-17) or as the patient's preference for a rapid test when offered the choice of a rapid test or traditional laboratory-based test (18, 19).

In the Roberts et al. review, the overall acceptability of rapid tests administered in both medical and community settings ranged from 14% to 98 % (16). Acceptability of rapid testing was lower (14% to 46%) in alternative testing sites (e.g., bathhouses, needle exchange programs, jails and emergency departments) compared to medical settings (69% to 98%) (e.g., sexually transmitted infection clinics, labour and delivery units and hospitals) (16). The wide range of acceptance rates may have been affected by differences in the definition of acceptability and in the data collection methods.

In two reviews, acceptability for HIV rapid tests was high among pregnant women (15,16). In the Pant Pai et al. review, acceptability among pregnant women ranged from 83% to 97% (15). Similarly, in the Roberts et al. review, acceptability among pregnant women ranged from 74% to 86% in American studies and from 93% to 98% in international studies (16). Among pregnant women, the following factors were associated with high acceptability of HIV rapid testing: age (<21 years), higher education and lack of appropriate prenatal care during pregnancy (15).

Among the youth, Turner et al. found that 35% to 93% accepted HIV rapid tests when offered. The 35% acceptance rate was found in an adolescent outpatient clinic (19). However, when given the option of rapid or traditional methods, youth from the adolescent outpatient clinic selected rapid methods 70% of the time (19). The highest acceptance rates (83% to 93%) were found in emergency rooms suggesting that there is high acceptability for rapid testing among youth attending emergency departments (19).

In the Mavedzenge et al. review, acceptability was defined as the interest to self-test. Among key populations such as men who have sex with men (MSM) and emergency department attendees, the authors found that acceptability of self-testing was moderate to high (62% to 92%) (18). Reasons for preferring self-testing included privacy, autonomy, confidentiality, anonymity, convenience and speed.

Pant Pai et al. demonstrated that acceptability (choosing self-testing over the traditional laboratory-based tests) was high in supervised and unsupervised settings (9). In supervised settings, there was high acceptability (74% to 96%) among emergency department attendees, urban MSM, university students and the general urban population. Of note, an older study from 2001 reported an acceptance rate of 24% among HIV clinic attendees. In unsupervised settings, the high acceptability (74% to 84%) was only based on two studies, which focused on healthcare professionals and HIV negative MSM (9).

Acceptability of HIV rapid tests was variable across different populations, but was generally high among pregnant women, youth attending emergency rooms and in medical settings. More research is needed to explore self-testing in unsupervised settings and reasons for low acceptance rates in non-medical settings.

Receipt of HIV test results

Four of the eight (4/8) systematic reviews examined the impact of HIV rapid testing on patients' receipt of test results. One systematic review by Roberts et al. noted that 27% to 100% of clients who attended medical and community settings for rapid testing received their HIV test results (16). The low rate of 27% was when same day results were available in an urgent care clinic with regular business hours and most participants left before the results were available (20). In the remaining studies, more than 70% of participants who underwent rapid testing at hospitals, sexually transmitted infection clinics, homeless shelters and bathhouses received their test results (16).

In a review by Bateganya et al., those who received voluntary counselling and testing (with rapid tests) at home were approximately five times more likely to receive their test results compared with those who received voluntary counselling and rapid testing at a clinic (17). The authors conducted an updated review that included one additional study, and found that 56% of individuals who had the home-based testing received their test results compared to 12% who had clinic-based testing (8). Based on these findings, receipt of rapid test results tended to be moderate to high except in urgent care clinics with regular business hours.

Linkage to care

Six of the eight (6/8) systematic reviews assessed linkage to care although the definition of linkage to care varied among the reviews. Roberts et al. defined linkage to care as entry into medical care and found this occurred in 47% to 100% of those who were diagnosed with HIV from rapid tests (16). Mavedzenge et al. defined linkage to care as linkage to prevention, treatment and care services and concluded that data are insufficient to determine whether self-testing leads to timely linkage to care (18). Dibosa-Osadolor et al. found that rapid HIV testing resulted in a higher percentage of patients being appropriately linked to care compared to traditional HIV testing (21); however, exact percentages were not listed. Bateganya et al. did not provide a clear definition for linkage to care, but included studies that offered voluntary pre- and post-test counselling at home. Compared to those offered testing and counselling in a clinic, those tested at home were more likely to accept post-test counselling (17). In the updated review by Bateganya et al., 12% received post-test counselling from a clinic and 56% received post-test counselling at home (8). Most reviews acknowledged that information on linkage to care was sparse (9, 15, 16).

See **Table 2** for a summary of the acceptability, receipt of test results and linkage to care data.

Table 2: Summary of acceptability, receipt of HIV test results and linkage to care with primary references

Reference	Acceptability	Receipt of HIV test results	Linkage to care
Bateganya (2007) (17)	Those randomized in optional testing locations (including home-based testing) were 4.6 times more likely to accept voluntary counselling and testing than those in the facility arm (RR 4.6 95% CI 3.6-6.2) (26).	In the year where participants were given the option to receive their HIV test results at home, participants were 5.23 times more likely to receive their results than during the year when results were available only at the facility (OR 5.23 95%CI 4.02-6.8) (27).	The definition for linkage to care was unclear. It appears that those who received their results also received post-test counselling.
Bateganya (2010) (8)	Acceptability of pre-test counselling and HIV test was 12% vs. 57% (optional group) (26)	12% received post-test counselling and their test results from the local clinic; 56% received results and counselling at home (RR 4.7 95%CI 3.62-6.21) (26).	The definition for linkage to care was unclear. It appears that those who received their results also received post-test counselling.
Dibosa-Osadolor (2010) (21)	N/A	N/A	Antibody rapid testing also resulted in a higher percentage of patients being appropriately linked to care (28-31).
Napierala Mavedzenge (2013)	Health workers from African countries had high interest in self-testing 73% to 79% (32-34).	N/A	Insufficient data.

(18) In US studies, emergency department patients and MSM[2] had high acceptability ranging from 83% to 89% (35-37).			
Pant Pai (2007) (15)	Overall acceptability: 83% to 97% (38-42). No clear consensus on patient preference for method of rapid tests (e.g., blood-based over oral fluid based).	N/A	Details of linkages to care and prevention were not reported.
Pant Pai (2013) (9)	Overall acceptability: 74% to 96% for both supervised and unsupervised settings (7, 35, 43-49). Supervised settings: 24% to 95% (7,35,43-47) - Urban MSM: 74% (35) - Emergency department: 85% (7) - Rapid HIV testing site: 78% (45) - General urban population: 92% (46,47) - Educated students: 95% (44) - HIV Clinic attendees: 24% (43) Unsupervised settings: 78% to 84% (48,49) - Non-monogamous MSM: 84% (49) - Healthcare professionals: 78% (48)	N/A	Only one study in a US unsupervised setting was reported → 96% of those who test positive for HIV *would* seek post-test counselling (50).
Roberts (2007) (16)	Overall acceptability: 14% to 98% (10, 39,51-64). - Pregnant women (US): 74% to 84% to 86% (39,52,53) - Women in labour: 95% (62) - Pregnant women in international prenatal settings: 93% to 98% (57,62,64) - Pregnant women in prenatal medical care (18% and 26%) (59,60) - Urgent care: 40% (20) - Hospitals: 60% (63) - Emergency: 29% (54) - Government Health centre (Kenya): 93% (51) - STI[1] clinics: 65% to 87% (54-56) - County jail: 46% (54) - Bathhouse: 21% (10) - Needle exchange: 14% (10)	Overall receipt of HIV test results: 27% to 100% (10, 20, 51,54-56,59,63-69). - Hospital: 95% to 100% (63,65) - STI[1] clinic: 89% to 99% (55,56,66) - Urgent care: 27% (20) - Labour / delivery unit: 68% to 94% (67) - Prenatal care: 74% and 98% (59,64) - Mobile site: 99% (68) - Community settings (e.g., homeless shelters, jail, bathhouse, needle exchange): 83% to 100% (10,54,69)	Overall: 47% to 100% (all US studies) (20, 54, 55, 65). Few studies examined entry rates into medical care in those who were found to be HIV+ from rapid tests.
Turner (2013) (19)	Overall acceptability: 35% to 93% (70-80). Lowest acceptance rate was found in an adolescent outpatient clinic (35%) (73). Highest acceptance rates found in emergency departments (83% and 93%) (74, 77). When given the options of rapid and traditional testing, youth selected rapid tests 70% of the time (73).	Participants who chose a rapid test were more likely to receive their test results within the follow-up period, compared with those who chose traditional test (91.3% vs. 46.7%; OR 12 95%CI 3.98-36.14) (73). 100% of youth aged 13-17 years who accepted rapid testing received their results (77).	N/A

[1] STI = sexually transmitted infections
[2] MSM= men who have sex with men

Cost-effectiveness

Of the 17 modelling studies reviewed by Dibosa-Osadolor et al., seven studies addressed diagnostic testing for HIV detection. Four modelling studies specifically assessed rapid testing with immediate patient notification in a clinical setting. The authors concluded that HIV rapid testing was more cost-effective than traditional laboratory-based testing with immediate patient notification (21). However, the majority of the modelling studies of rapid testing reviewed were based on static models, which do not include time dependencies. This can potentially result in an overestimation of the cost-effectiveness of infectious diseases (21, 22). In this review, there was no information on the direct and indirect costs of rapid testing or on the cost per the quality-adjusted life-year gained.

Discussion and conclusion

Our rapid review of eight systematic reviews found that HIV rapid tests demonstrated generally high acceptability, especially among pregnant women; variability in receiving test results; and limited impact on linkage to care. One review found that rapid testing was cost-effective, but the studies were based on a static versus a dynamic model; therefore, further studies are warranted to determine the impact of rapid tests on linkage to care and its cost-effectiveness.

The rapid review methodology is a fairly novel approach that has its strengths and limitations. The strength is that it is a rapid way to summarize evidence for decision-makers. In addition, the evidence is presented transparently, allowing users to assess the evidence and make informed decisions. However, there are a few limitations to consider when reviewing these results. The shortened timeframe of the rapid review process may miss studies that were not included in the reviews and therefore, may introduce bias through the absence of some relevant information. It may exclude recently published systematic reviews or those currently in press (23, 24). Moreover, data from some individual studies were cited more than once across the systematic reviews, which may inflate the confidence in the results presented in this rapid review (24, 25). Finally, the systematic reviews included studies from different countries and different types of HIV rapid tests; therefore, the results from this review may not be generalizable to other rapid tests or to the Canadian setting.

It appears that offering HIV rapid tests in settings is highly effective when test results can be readily obtained. This suggests that rapid HIV tests could decrease the proportion of individuals who are unaware of their HIV status and merits further study. Future research should compare effectiveness among different populations and settings, as well as explore ways to improve linkage to care. It would be useful to have a cost-effectiveness study based on a dynamic model.

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Conflict of interest

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