Design Sprint

www.SafeMedicationUse.ca
October 3 & 4, 2019
Toronto, ON

Hosted by Institute for Safe Medication Practices Canada

Facilitated by:

Special thank you to the Canadian Patient Safety Institute for financial support and collaboration. Thank you also to Patients for Patient Safety Canada for partnering on the development of this work!

DESIGN SPRINT ARTIFACT

CONTEXT

The Institute for Safe Medication Practices Canada (ISMP Canada) medication incident consumer reporting and learning website "SafeMedicationUse.ca" was launched in 2010. The goal of the website was to reduce or prevent medication incidents, which falls within the mandate of ISMP Canada.

The number of reports submitted to the website have decreased over time and most reports are coming from 8 provinces.

On October 3 & 4 – a group of passionate patients, pharmacists and representatives from national patient safety organizations from across the country came together to tackle the challenge: "How might we engage the public to share medication incidents in order to prevent others from having similar events" using a 2-day design sprint facilitated by The Pivot Group.

In this report we will outline what was discovered in the steps of a sprint: understand, define, ideate, decide, prototype and test.

SPRINT TEAM

The advisory committee members (called Sprint Team in this report), formed by ISMP Canada, was made up of 15 patient advisors and representatives of partner organizations.

Annette McKinnon (co-chair), Patients for Patient Safety Canada
Carolyn Hoffman (co-chair), ISMP Canada
Bernadette St. Croix, Patient and Family Advisor, Patient Experience Advisory Council of Central Health
Diana Ermel, representative, Best Medicines Coalition
Jordan Hunt, representative, Canadian Institute for Health Information
Kathy Mazza, CBI Home Health-Ontario/representative from Canadian Home Care Association
Kimberly Strain, Patient and Family Partner, Patient Voices Network, British Columbia
Marissa Lennox, representative, Canadian Association of Retired Persons
Pierre Dessureault, Patient Partner, Quebec
Stephen Routledge, representative, Canadian Patient Safety Institute
Susan Halliday Mahar, representative, Canadian Pharmacists Association
Michael Hamilton, Gary Lee, Pierrette Leonard, Dorothy Tscheng, ISMP Canada

UNDERSTAND

All Sprint Team members were asked to interview 5 people (family members, friends or neighbors) in their communities, before the design sprint, with the following questions:

- If you had a medication incident – who would you tell?
- Why would you want to share your report?

- What would prevent you from reporting?
- What do you think of this website (www.safemedicationuse.ca)?
- Any other open ended questions that come to mind.

The feedback received from the Sprint Team questions is summarized below.

- People report to their doctor or pharmacist or people close to them.
- There is an assumption that there are safety checks in place already with medications.
- Reporting website is unknown.
- Reporting will probably not change anything.
- Website is too professional (not plain language) and "not pretty" .

The Sprint Team spent time trying to understand the problem better. Here were the elements thought to be important.

- Low reporting
- We have a lot of med errors/incidents
- Fear of reporting
- Low level of involvement with the public (zero conversations)
- People don't have the power!
- Lack of action from reporting
- People think the medical system is right

Experts were invited to the workshop to give short presentations (via zoom or in person) that were called "lightning talks" and "comparable solutions" (A copy of the PPTs are enclosed in Appendix A).

Michael Hamilton, Medical Director, ISMP Canada & *Dorothy Tscheng*, Director, Practitioner & Consumer Reporting & Learning, ISMP Canada

Jessica Leung, Regional Coordinator (Ontario), Canada Vigilance Program

Saul Weingart, Chief Medical Officer, Tufts Medical Center, Boston

Marianne Bjørnø Banke, Administrative Officer, Danish Patient Safety Authority,
Knowledge and Learning, Denmark

Stephanie Callan, Communications Specialist, Choosing Wisely Canada, Toronto

Richard Liebrecht, Product Manager, Jobber/The Pivot Group, Edmonton

DEFINE & DECIDE

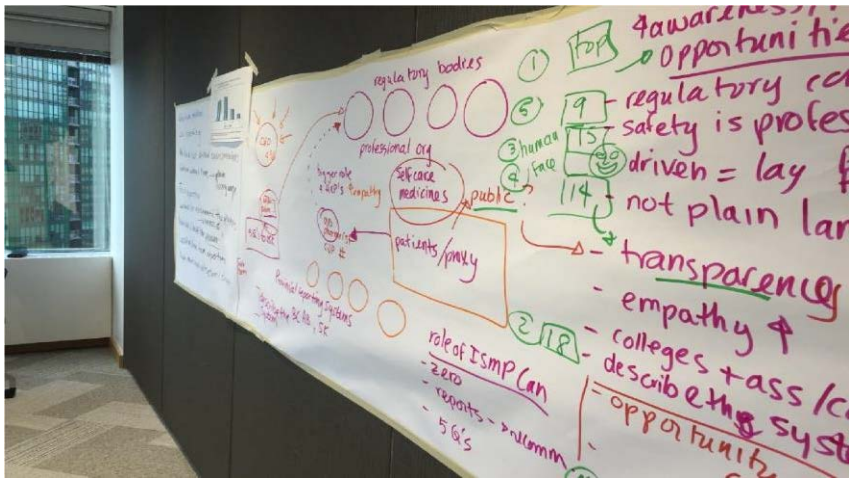
A comprehensive system map was completed to identify pain points and opportunities (image below). Each Sprint Team member then presented their top three "How Might We's" (HMW)as a result of the lightning talks and system map. HMW's are a generative way to frame questions or curiosities. All the HMWs from

the Sprint Team were compiled into an affinity map (image below) to organize the ideas. Each member was then given 3 dots to vote on their favorite HMW.

The top three HMWs are listed below. There was a recognition that both the "system" and "reporting" HMWs would likely overlap. Initially the "engagement and awareness" HMWs did not receive many votes – but the group then agreed that this was an integral piece of the puzzle – hence it was added to be developed into a prototype.

Top three prototypes

1) **System.** Question: How can we have a true med safety system that gives value to customers?
2) **Reporting.** Question: How might we streamline reporting of adverse reactions, incidents and near misses?
3) **Awareness & Engagement**. Question: How might we engage people and get them to come to us? How might we encourage people to share the learnings with others?

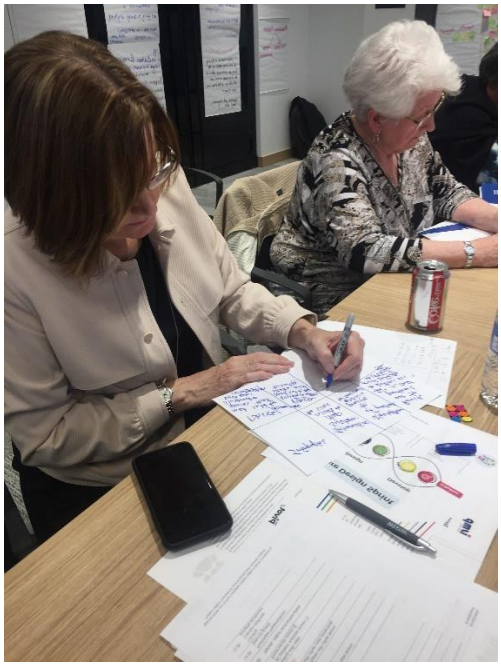


System map to identify pain points and opportunities

HMW's were clustered into categories on this affinity map

IDEATE

Sprint Team members were asked to self-select an area of interest in one of the three prototype areas. We had 3 – 8 individuals per group. Each person was then asked ideate (using Crazy 8's) and build storyboards for their ideas before sharing it with their team mates.



Crazy 8 (8 ideas in 8 minutes) and storyboarding the details.

PROTOTYPE & TEST

Each team spent the morning of day two to build a façade of their service or product. Some teams called in special favors from friends and colleagues across the country for advice. Most of the materials were created using pen and paper (and craft supplies) – but one team used an hour of a graphic designer to whip up an early prototype for testing.

After the teams built their prototypes, they spent the afternoon of day two testing their ideas with users. Users were patients, pharmacists or people working in the building. The users were asked questions like:

- What is the first impression of this idea?
- What do you like - what don't you like?
- What would you rate this service (1 – 10)?
- What would make it a 10?
- If we were to offer this tomorrow – what advice do you have for us? What are some red flags?

In the next few pages, each prototype is described with the user feedback.

SYSTEM Prototype

Question the group wanted to answer: How can we have a true med safety system that gives value to customers?

The team focused most of their prototype on designing a new digital interface for reporting the medication problem. They agreed to stay broad initially to appeal to as many people as possible. They based the digital interface on an algorithm where they first asked the user what type of problem they had (before any reporting occurs) in three categories:

1) Medication side effect
2) Medication error
3) Medication problem

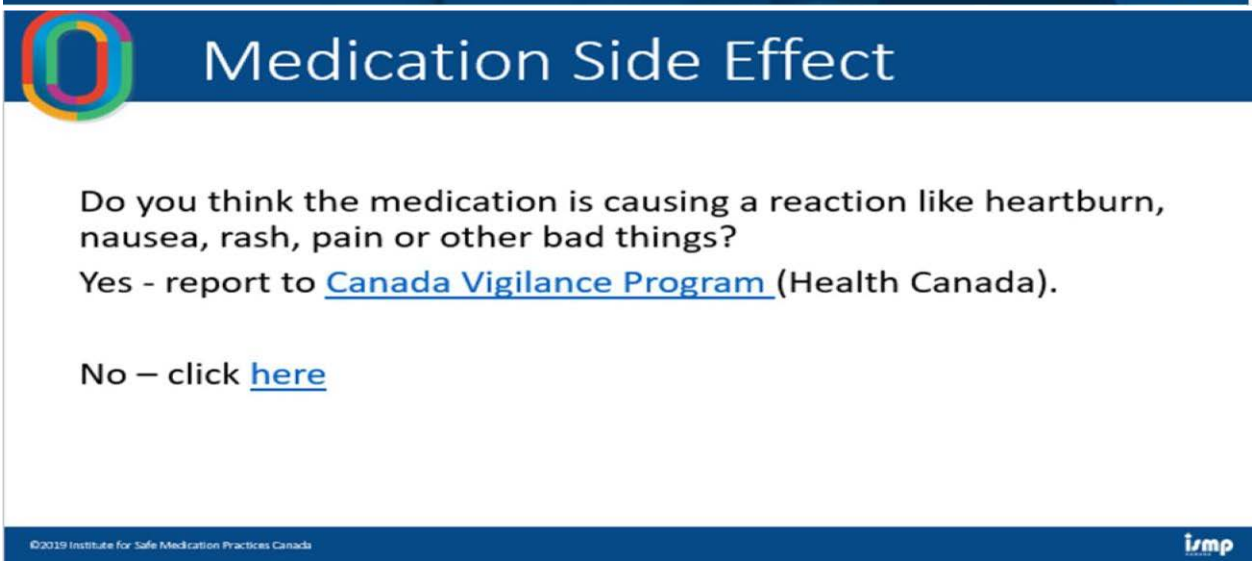
Each of these decision points for the user would direct them to different websites. [1)
medication *side effects* would direct them to the Canada Vigilance Program (Health Canada); 2) medication *error;* and, 3) medication problem, to www.safemedicationuse.ca. The mocked-up web pages (see last PPT in Appendix A) used lay language and tried to get the user to identify where they should be directed for their report.

User testing:

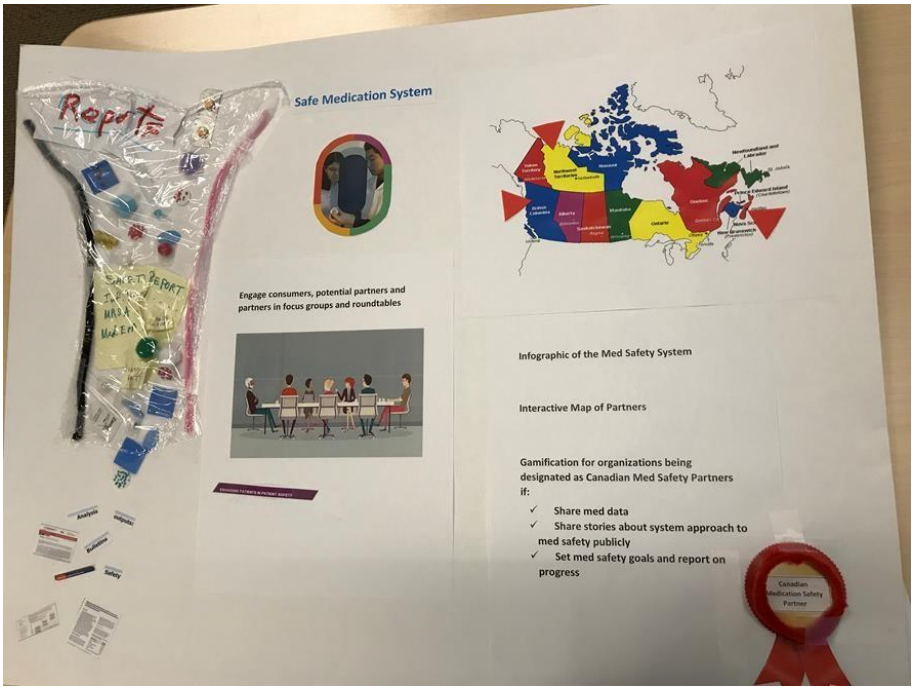
This team tested the mocked-up webpages with a few members of the general public and pharmacists with positive feedback. More user testing is needed to ensure the language is clearly understood; but this early mock-up would likely be considered a flawed success (met user needs but not fully tested to know if they met all their needs). The team learned something and can now iterate and test again.

This team also presented a bigger picture (Safe Medication System image at the end of this section) of how they believe the system should be coordinated for the users/community. This included:

- Engaging consumers, potential partners and focus groups/roundtables;
- Create a system infographic for the medication safety system in Canada (similar to the Danish lightning talk);
- Interactive map of partners; and,
- Gamification for organizations to be designated as Med Safety Partners
    - Share medication safety date
    - Share stories about system approach to medication safety publicly
    - Set med safety goals and report on progress.



Mock-up of the full System Prototype is the last PPT in Appendix A



Visual image of a Safe Medication System

REPORTING prototype

Question the group wanted to answer: HMW streamline reporting of adverse reactions, incidents and near misses?

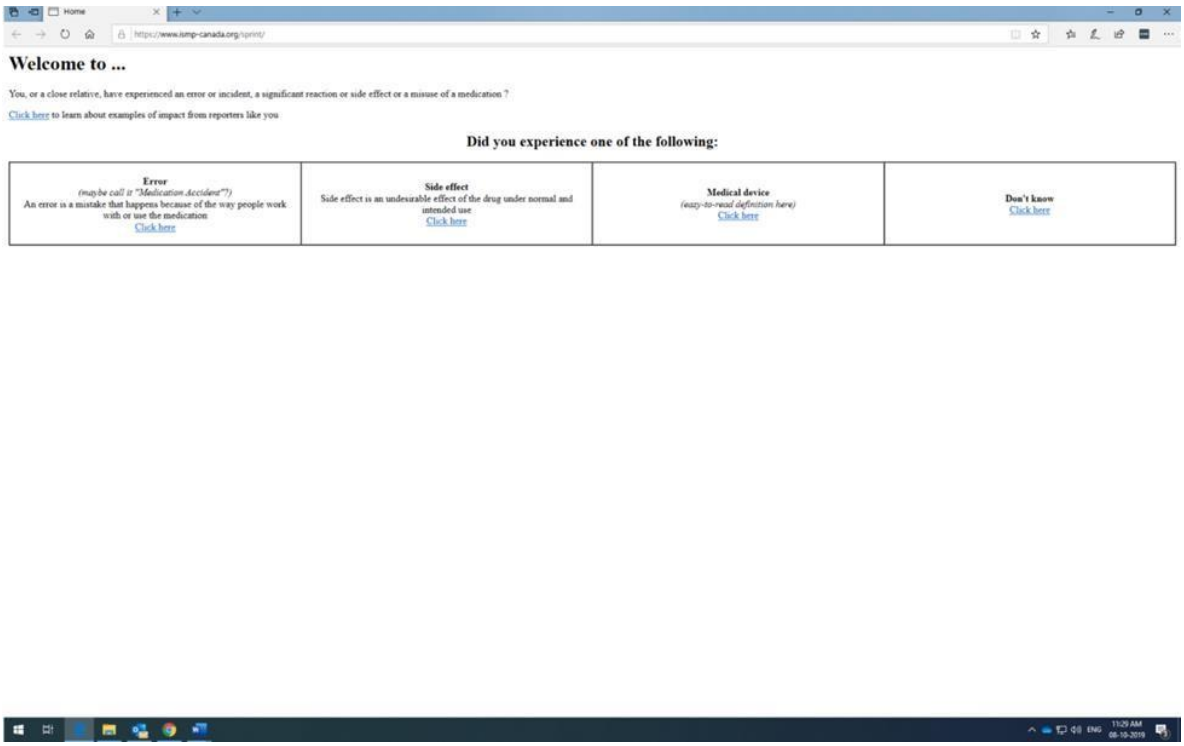
The prototype that was developed for the reporting of medical incidents came in 3 different formats. The first format is the online program that consumers would use when they experience an incident, an adverse drug reaction or a problem with their medical device. The team decided to also give a reporting page for "other" medical related incidents that a consumer may have and that does not fit with any of the other categories. When consumers look online to report an incident, they will find www.safemedicationuse.ca. They wanted to create a home page that would encompass all types of incidents so that the consumer could easily find what they are looking for. On the home page there is a link to "error", "side effect", "medical device" and "I don't know". All four options will have a plain language description for the consumer to decide which choice to click. When they click on either the "error" or "I don't know" choice, the consumer will be instantly directed to a page where they tell what happened and complete other information, that which is necessary to data collection. If they click on "side effect" or "medical device", the site will redirect them immediately to the Health Canada consumer reporting site. The goal is to make reporting as easy and seamless as possible for the consumer.

This team wanted an option for consumers to share their experience/story so that others can see that reporting is important to improving safety. ISMP Canada could share anecdotes of how patient reporting made a tangible improvement.

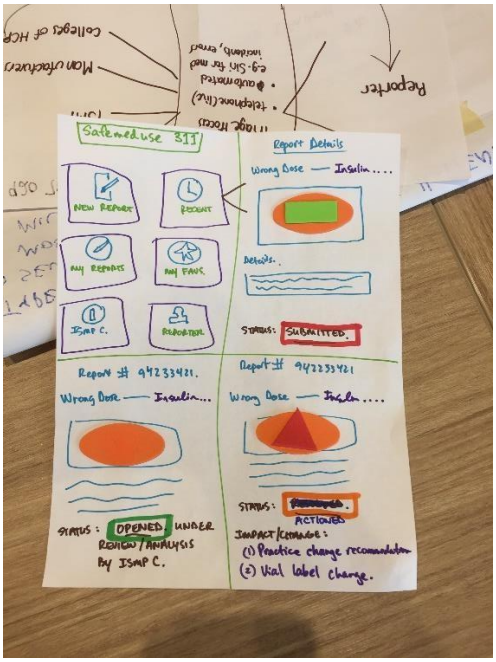
After a lightning talk from Richard Liebrecht on digital experience they were encouraged to create a good experience for the consumer, not just a data entry site. In that respect, they would embed links to ISMP Canada, Patients for Patient Safety Canada and Canadian Patient Safety Institute so that if the consumer is interested in learning more, then they can engage with these sites as well.

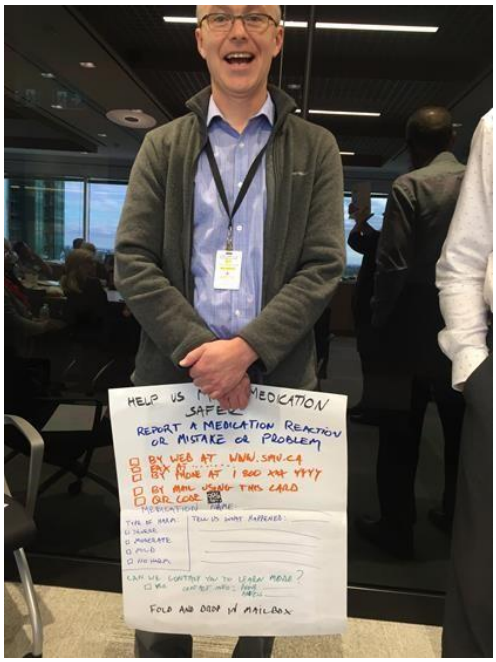
For the population who does not have the ability to be online, or who chooses not to be online, the team created a paper document that patients would complete and mail to ISMP Canada. It would be a prepaid, opaque paper that folded in half and sealed so that it could be dropped into the mailbox easily and confidentially. They envision that those forms would be widely available in pharmacies, hospitals, long term care centres, clinics, doctor's offices, etc.

User testing:
The Reporting Prototype team tested the mocked-up webpages with a few members of the general public and pharmacists with positive feedback. More user testing is needed to ensure the language is clearly understood; but this early mock-up would likely be considered a flawed success (met user needs but not fully tested to know if they met all their needs). The team learned something and can now iterate and test again.



Mock-up of the home page where reporters decide if it is an error, side effect, medical device issue or do not know.





Story boards to describe each step of the prototype

ENGAGEMENT AND AWARENESS prototype
Question the group wanted to answer: How might we engage people and get them to come to us?

This team was made up of mostly the patient and family advisors from the Sprint Team. They were inspired by the presentation from Stephanie Callan, Choosing Wisely. They were impressed with the simple and engaging messaging (both visuals and text).

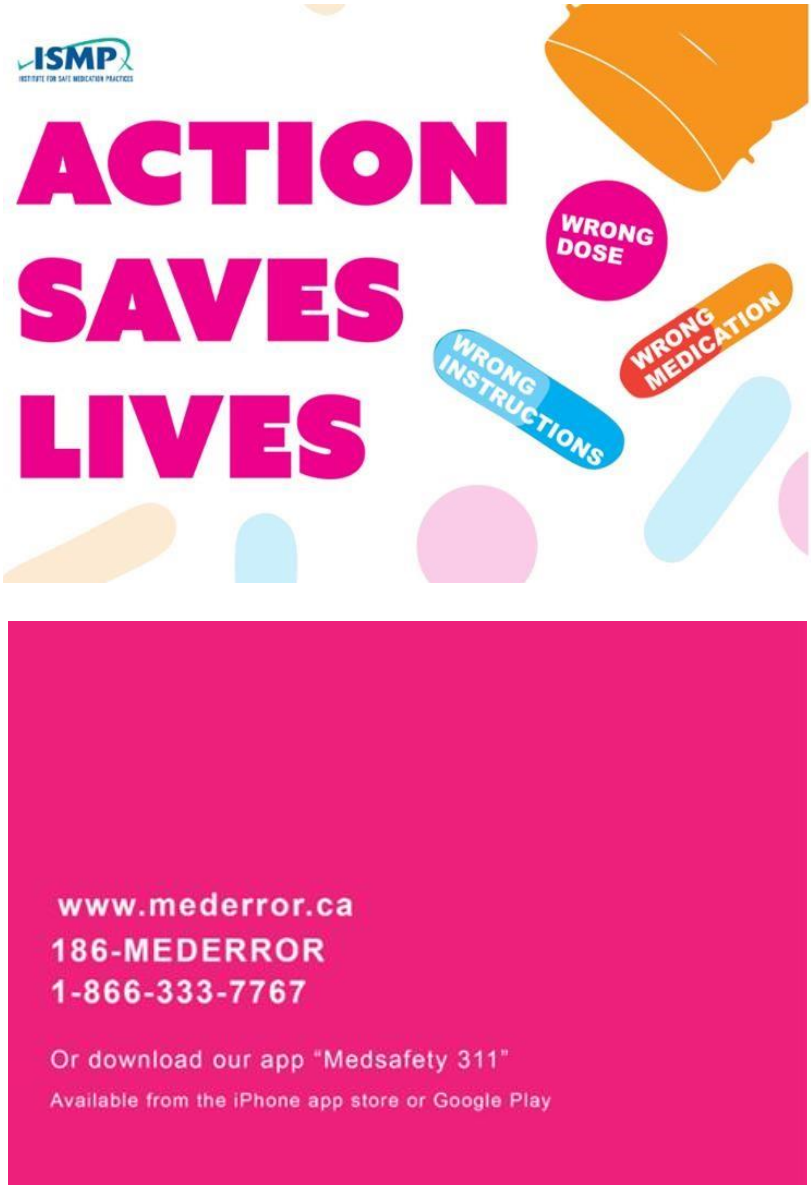
They settled on a campaign title of "Action Saves Lives". In a consult with Stephanie Callan they were encouraged to pick a positive slogan that would be inviting for people (vs. something negative).

The team initially thought about a way to include a "sticker" or message on "how to report medication errors" on all the prescription instructions from dispensing pharmacies. However, once they consulted with a community pharmacist they were told that the pharmacist would like to be the first point of contact if there is a mistake/error/problem vs. going to a reporting website. The team then realized that they needed another avenue to reach consumers. They created a card that has a simple image of medication errors (pills falling down the page). They thought the URL www.mederror.ca would be more descriptive. Included in the reporting options are a phone number and a med safety app (called 311). The campaign would focus on disseminating this card and awareness campaign far and wide; including pharmacies, hospitals, doctors' offices and walk in clinics.

User testing

They tested the campaign card with pharmacists with initial positive feedback. Graphic design was a very early draft. More user testing is needed to ensure that consumers know how to join the campaign. This early mock-up would likely be considered a flawed success (met user needs but not fully tested to know if they met all their needs). The team learned something and can now iterate and test again.

This team also liked the idea of gamifying the campaign with badges and levels of engagement (like prototype no. 1). However, they ran out of time to prototype these elements of the campaign.



Mock-up of the campaign cards

The Sprint Team and Facilitator

Presentations

At the end of the Sprint each prototype team gave a presentation of their work to all sprint team members, additional ISMP Canada Staff and consultants, ISMP Canada Board Members, and ISMP USA.

Thank you!

ISMP Canada would like to thank the Sprint Team and the Sprint Workshop Facilitator, Marlies van Dijk, The Pivot Group, for making this extraordinary event possible. We are also grateful for the presentations from the various experts from around the world and for the patient/family, public and professional individuals that contributed your time in the development and testing of the three prototypes.

A Special thank you to the Canadian Patient Safety Institute for financial support and collaboration. Thank you also to Patients for Patient Safety Canada for partnering on the development of this work!

APPENDIX A

Lightning Talks

And

System Team Prototype

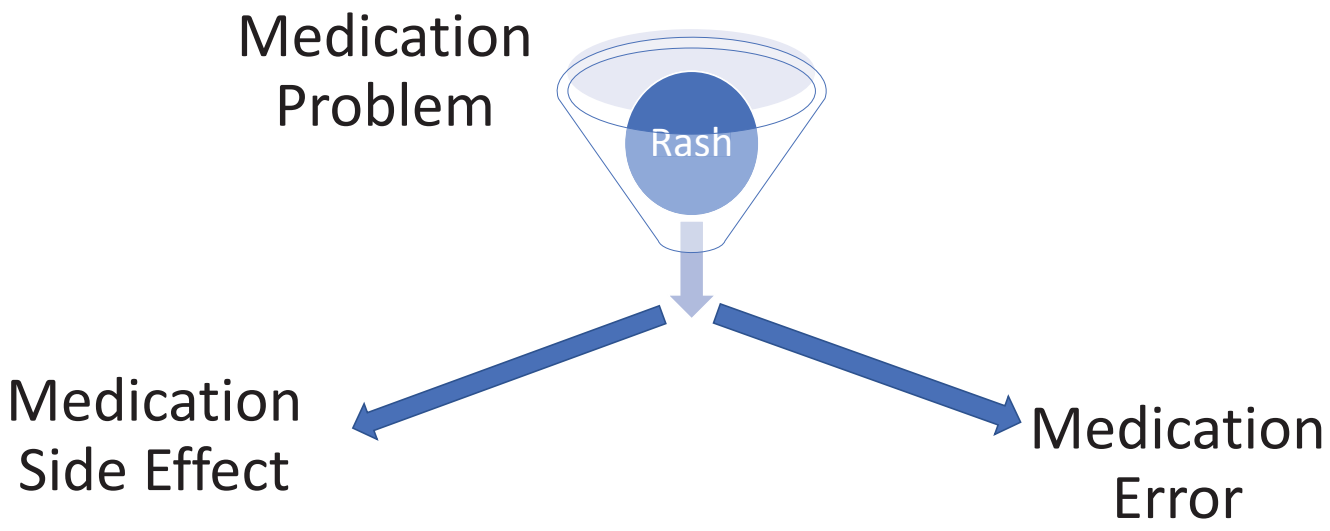
PowerPoint Presentations


ZERO
PREVENTABLE HARM
FROM MEDICATIONS
SafeMedicationUse.ca
ismp
CANADA


ENABLE
EDUCATE
DELIVER
INNOVATE
ENGAGE
ismp
CANADA

I have a medication problem to report…….

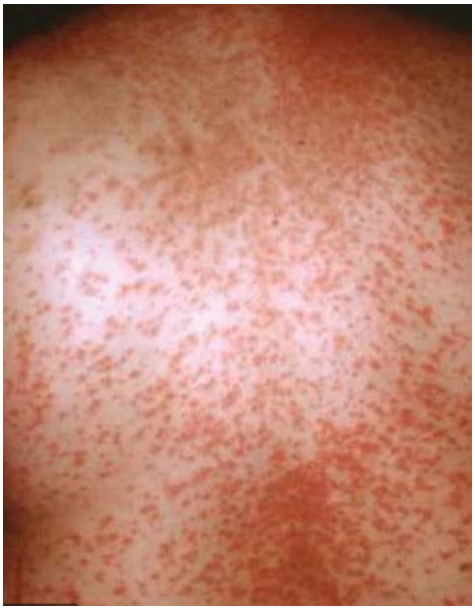
My Medication Problem



My Medication Problem

I have a rash all over my body after taking the antibiotic penicillin.

This is the first time I have taken this medication.



Medication Side Effect

A problem because of the way the medication works in the body; an undesirable effect of the drug under normal and intended use of the drug is a **SIDE EFFECT (adverse effect, adverse reaction)**.

Side effects like nausea, rash, sleepiness, cough, aches, but can be more serious like stroke.

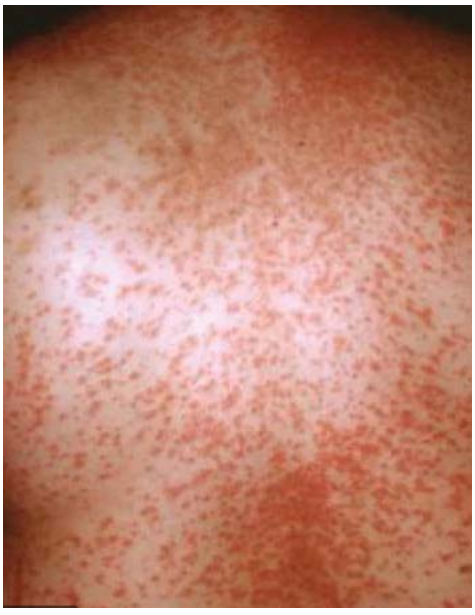
Report to Canada Vigilance Program (Health Canada).

Side Effect to Canada Vigilance Program

My Medication Problem

I have a rash all over my body after taking my antibiotic. I told my doctor that I was allergic to penicillin many years ago.

I just found out the antibiotic is a penicillin.



Medication Error

A **MEDICATION ERROR** or **INCIDENT** is a mistake that happens because of the way you or others, including health care professionals, work with or use the medication. A medication error is preventable.

Mistakes like wrong dose, wrong person, missed allergy, confusing packaging

Report to SafeMedicationUse.ca

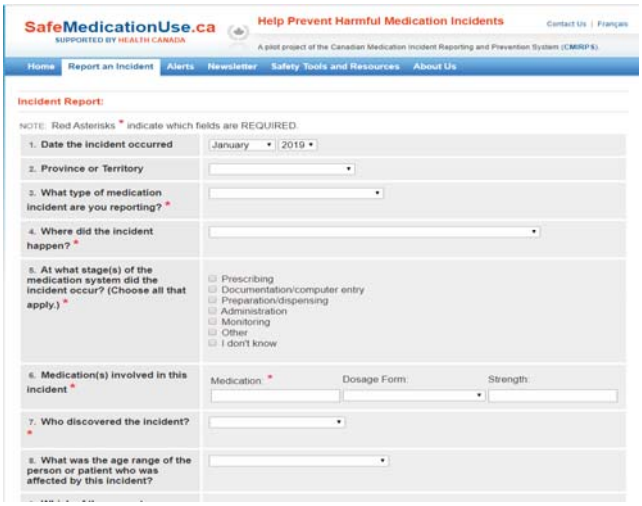
Medication Error to SafeMedicationUse.ca

Report to SafeMedicationUse.ca or Canada Vigilance Program (Health Canada).

Both are related to drug safety and we will ensure that any report reaches the correct organization.

Side Effect or Medication Error?

SafeMedicationUse.ca



https://safemedicationuse.ca/Reporting/form/report_form.php

Alright! I've reported.
What happens next?

SafeMedicationUse.ca

SafeMedicationUse.ca

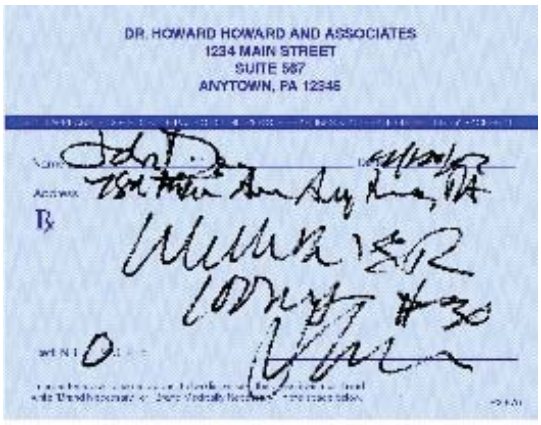
Reasons like

- Confusing packaging

SafeMedicationUse.ca

Reasons like

- Illegible or difficult to interpret prescriptions



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SafeMedicationUse.ca

Reasons like

- Problems with the work environment

SafeMedicationUse.ca

In general, the more we know about the problem, the richer our analysis can be, and the better our recommendations can become.

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Does my report have any impact?

Government of Canada / Gouvernement du Canada

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We believe in the value of patient and consumer experiences and stories in making healthcare safer.

We believe in the value of working together.

ismp

ZERO
PREVENTABLE HARM
FROM MEDICATIONS

A Key Partner in the Canadian Medication Incident Reporting and Prevention System

ismp CANADA

Health Canada Santé Canada

Canada

Health Canada

Adverse Reaction Reporting

Your Role in Patient Safety

Jessica Leung

Regional Canada Vigilance Program Coordinator (ON)

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Canada Vigilance Program

Learning Objectives

1. Learn about the Canada Vigilance Program (CVP)
2. Understand the role of consumers and Health Canada in the process of reporting suspected adverse reactions (ARs) to health products to help minimize risks
3. Recognize the importance of monitoring and reporting suspected ARs to health products
4. Consumer-focused statistics on reporting habits

Canada Vigilance Program
Then…

- Spontaneous Adverse Reaction Reporting Program exists since 1965
- One of 10 founding countries of the World Health Organization (WHO) International Program for Adverse Reaction Monitoring in 1968

The Canadian Adverse Drug Reaction Reporting Program 1965 (colour-coded pigeon-hole system)

THALIDOMIDE AND CONGENITAL ABNORMALITIES

SIR,—Congenital abnormalities are present in approximately 1·5% of babies. In recent months I have observed that the incidence of multiple severe abnormalities in babies delivered of women who were given the drug thalidomide ('Distaval') during pregnancy, as an antiemetic or as a sedative, to be almost 20%.

These abnormalities are present in structures developed from mesenchyme—i.e., the bones and musculature of the gut. Bony development seems to be affected in a very striking manner, resulting in polydactyly, syndactyly, and failure of development of long bones (abnormally short femora and radii).

Have any of your readers seen similar abnormalities in babies delivered of women who have taken this drug during pregnancy?

Hurstville, New South Wales. W. G. MCBRIDE.

*** In our issue of Dec. 2 we included a statement from the Distillers Company (Biochemicals) Ltd. referring to "reports from two overseas sources possibly associating thalidomide ('Distaval') with harmful effects on the fœtus in early pregnancy". Pending further investigation, the company decided to withdraw from the market all its preparations containing thalidomide.—ED.L.

McBride, W.G. *Lancet* . 1961; 2: 1358

Canada Vigilance Program
…and Now

- One of 127 official member countries and 29 associate members (September 2017) that contributes to the WHO Pharmacovigilance Program
- Mandatory reporting for Market Authorization Holders **& Hospitals (as of December 16, 2019)**
- Voluntary reporting for Health Professionals and Consumers
- Legislative Framework (e.g., *Food and Drugs Act and Regulations*, *Access to Information and Privacy Act*)
- The Canada Vigilance Program is supported by seven regional offices who provide a regional point-of-contact for health professionals and consumers

Canada Vigilance Program

Definitions…

» **Adverse Drug Reaction (ADR)**

"a noxious and unintended response to a drug, which occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease or the modification of an organic function"

» **Serious ADR**

"a noxious and unintended response to a drug that occurs at any dose and requires in-patient **hospitalization** or prolongation of existing hospitalization, causes **congenital malformation**, results in persistent or significant **disability** or **incapacity**, is **life-threatening** or results in **death**"

ARs that require significant medical intervention to prevent one of the outcomes listed above are also considered serious.

Food and Drug Regulations, Part C, Division 1, C.R.C., c. 870

Canada Vigilance Program

Definitions: CVP vs Various Patient Safety Programs

What is a medication incident?

» *A medication incident is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/ packaging/ nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.*

In simpler terms, a medication incident is a mistake with medicine, or a problem that could cause a mistake with medicine.

Canada Vigilance Program

CVP vs Various Patient Safety Programs

Canadian Medication Incident Reporting Program System (CMIRPS)

» CMIRPS is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.

» Reporting, sharing and learning about medication incidents will help to reduce their reoccurrence and help create a safer healthcare system.

Each of the CMIRPS collaborating organizations contributes information, tools and/or expertise in the prevention of harmful medication incidents.

Canada Vigilance Program

Why is Reporting ARs So Important?

What Patients Want to Know About Their Medications

During face-to-face interviews, patients were asked what information they desired at the time of receiving both new and refill prescriptions.

» **70.7% wanted risk information about adverse effects and or drug interactions.**

Table 2. Content analysis results: Information desired from the pharmacist when receiving a new prescription[a]

Category	No. (%)
Adverse effects (ADRs and allergic reactions)	349 (58.2)
Basic directions/instructions	196 (32.6)
Drug interactions with prescriptions or unspecified	180 (30.0)
Drug indication	112 (18.7)
Complex instructions (includes special instructions and precautions unique to prescription or person)	91 (15.2)
General information (vague statements from patient)	42 (7.0)
Cost, payment, insurance information	39 (6.5)
Alternative therapies/other treatment options	34 (5.7)
Monitoring (what to watch for: therapeutic and adverse)	32 (5.3)
Written or Internet information adequate	32 (5.3)
None	21 (3.5)
Other (statements regarding pharmacist using his/her judgment to give needed information)	17 (2.8)
Refill information	10 (1.7)
Drug interactions with nonprescription medications	10 (1.7)
Appearance of drug product	6 (1.0)
Don't know	2 (0.3)

Krueger JL, *et al. J Am Pharm Assoc.* 2011;51:510–519

Canada Vigilance Program

Why is Reporting ARs So Important?...

Table 1. Patient Characteristics and Motivations for Reporting per Stratum

Motivations for Reporting per Stratum	ATC code J01 (antibiotics)		ATC code C10 (statins)		ATC code C0 (cardiovascular drugs	
	Male	Female	Male	Female	Male	Female
Total pts., n	3	2	4	4	4	4
Pts. with serious ADRs, n[a]	2	0	1	2	0	1
Mean age, y (range)	63 (62–64)	37 (20–54)	51.8 (39–63)	63 (52–70)	53.8 (42–60)	57.8 (42–80)
Altruistic motives, number of times mentioned						
Feeling that reporting will lead to more research and knowledge about drugs	1	2	2	3	4	2
Making ADR publicly known for other patients	1	2	3	4	1	1
Withdrawal of drug from market in case of danger for other patients	1					
Less prescriptions of a drug when it has a lot of ADRs						1
Sparing other patients trouble			2	2		1
Feedback to marketing authorization holder through pharmacovigilance center			1			
Change in patient information leaflet needed			1	1	2	
Personal motives, number of times mentioned						
Wanting more information about own ADR	2	1	2	2		1
Wanting to know if complaints are caused by drug (confirmation)	3	1		1		
Concern about own ADR	1			2		1
Severity of the reaction	2		2	2	2	1
Being unsatisfied with information or care provided by health-care professional	1			2	1	
Feeling anger towards marketing authorization holder	1			2		
Wanting to be heard	1			1		
Knowing that health-care professional does not report ADRs		2				
Because the possibility of reporting just exists		1			1	
Unexpectedness of reaction			2			
Reaction occurring after substitution of drug brand					1	
No recognition of ADR by health-care professional/not being taken seriously				1		1

ADR = adverse drug reaction; ATC = Anatomical Therapeutic Chemical; CIOMS = Council for International Organizations of Medical Sciences.
[a]Number of patients with an ADR that was serious according to the criteria of the CIOMS Working Group IV (1998, Geneva).

van Hunsel F P et al. *Ann Pharmacother.* 2010;44:936-937

Canada Vigilance Program

Why Report

Reporting an AR may contribute to:

- The identification of previously unrecognized rare, or serious ARs;
- Changes in product safety information (e.g., through an update to the Canadian product monograph);
- Other regulatory actions such as the issuance of a health product advisory or the withdrawal of a product from the Canadian market;
- International data regarding benefits and risks of health products; and
- Increasing the safe use of health products by Canadians

Canada Vigilance Program

Who Should Report

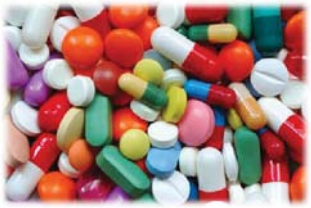
Key Partners

- Government
- Industry
- Hospitals and academia
- Medical and pharmaceutical associations
- Poison and medicines information centres
- Health professionals
- **Patients / consumers**
- World Health Organization (WHO)

Canada Vigilance Program

Scope of Regulated Products in Canada

- ~ 11,700* human drug products and biologics
- 11,092 are Pharmaceutical drugs
  - 7,653 are prescription drugs
  - 3,439 are non-prescription drugs
- 609 are Biological drugs
  - 293 are prescription drugs
  - 316 are non-prescription drugs



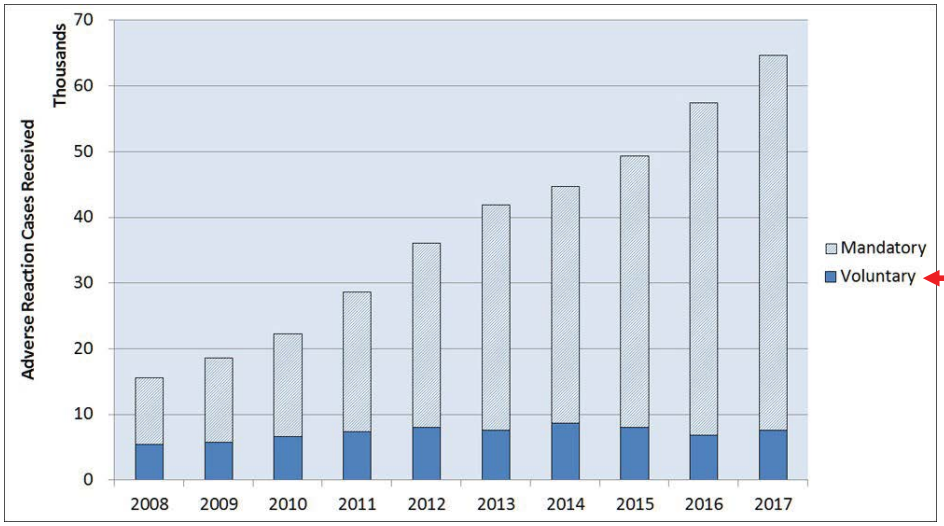
- ~ 50,000 natural health products on the Canadian market (most are over the counter and self-care products and available in pharmacies and health food stores) 36,431 licenses have been issued representing 52,378 products (as of the end of June 2012)

- Approximately 81,000 licensed medical devices

Canada Vigilance Program

Annual Trends (2008-2017)

Domestic mandatory and voluntary adverse reaction case reporting from 2008 to 2017

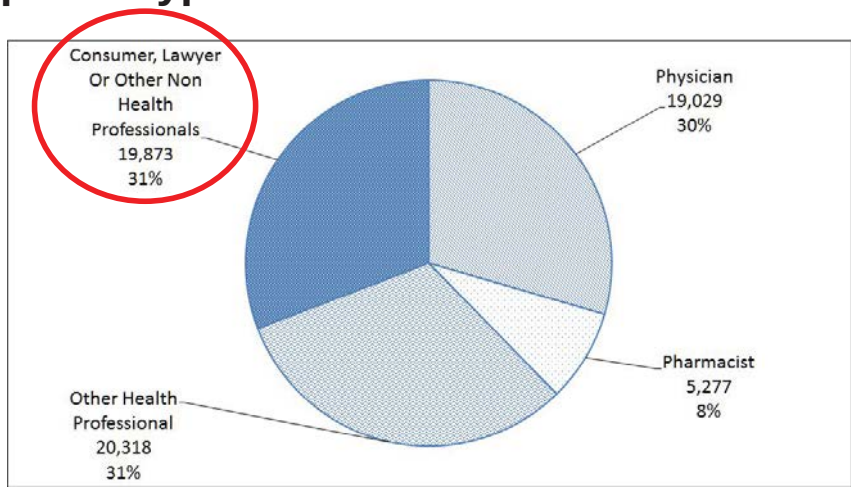


https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/annual-trends-adverse-reaction-case-reports-health-products-medical-device-problem-incidents.html

Canada Vigilance Program

Annual Trends (2008-2017)

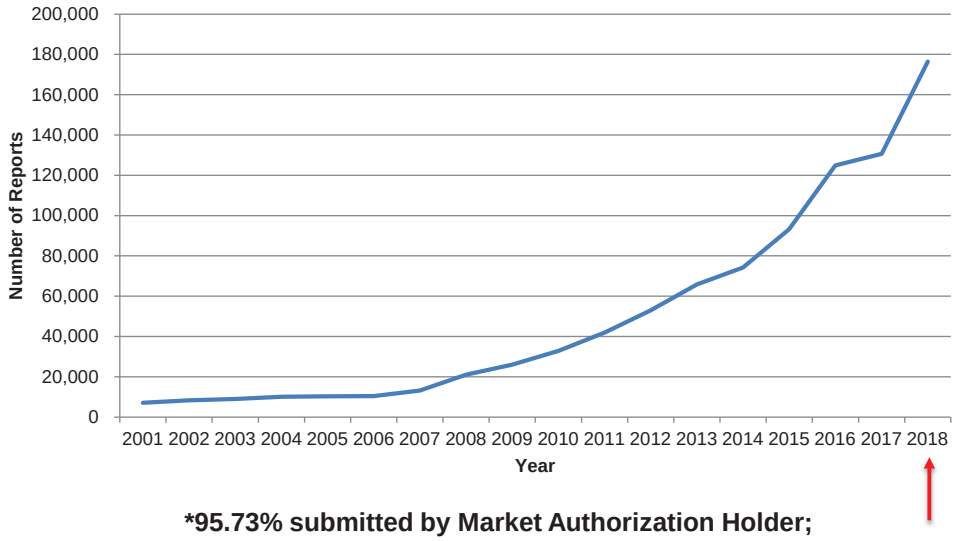
Domestic adverse reactions case reports by reporter type received for 2017



https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/annual-trends-adverse-reaction-case-reports-health-products-medical-device-problem-incidents.html

Canada Vigilance: Reporting Statistics 2001-2018

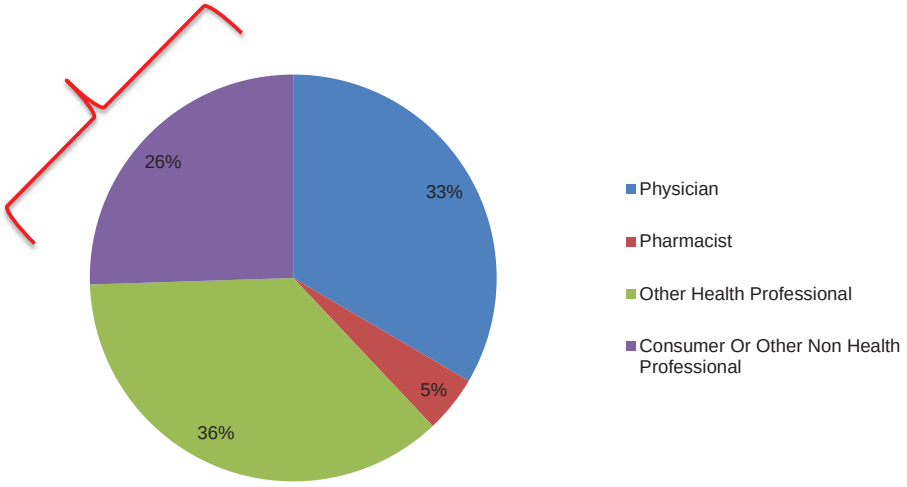
Number of Reports* Received (2018): 176,435



***95.73% submitted by Market Authorization Holder;**
4.09% submitted via voluntary reporting program

Canada Vigilance: Reporting Statistics (2018)

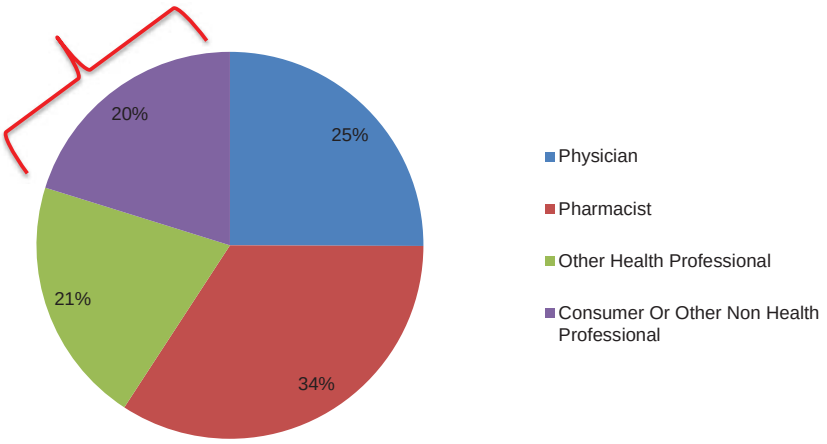
Number of Reports* Received by Reporter Type: 176,283



*** Canada Vigilance receives reports for both initial and follow-up information concerning suspected adverse reactions.**

**** Represents the number of domestic reports received from Market Authorization Holders (MAHs) mandatory reporting and voluntary reports received directly from the community and hospitals.**

Canada Vigilance: Reporting Statistics 2018
Voluntary Reports Received by Reporter Type Specialization: 7,129

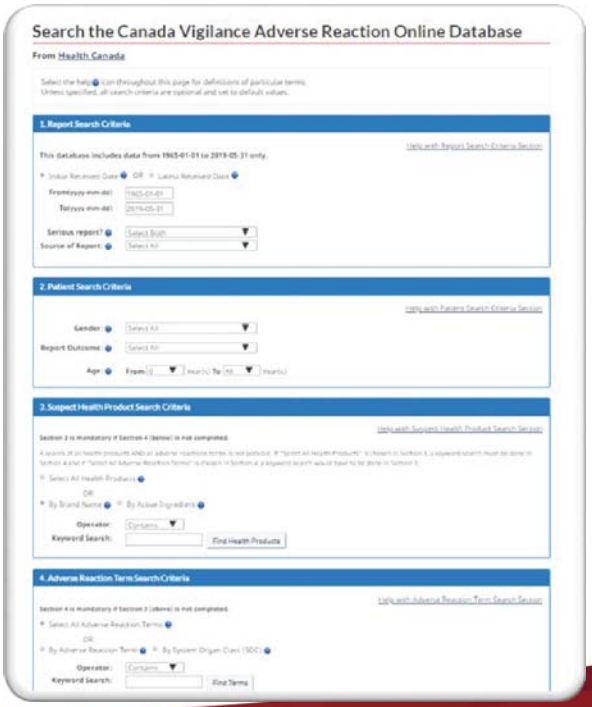


*** Canada Vigilance receives reports for both initial and follow-up information concerning suspected adverse reactions.**

Canada Vigilance Program
Feedback Provided to Reporters…

Adverse Reaction Database

- Database of information concerning suspected adverse reactions to Canadian marketed health products reported to Canada Vigilance
- Search by date, patient age/gender, product and/or adverse reaction
- Updated monthly – For more recent data contact regional office



https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html

Canada Vigilance Program

Feedback Provided to Reporters…

MedEffect™ Canada website

Centralized access to :

- » Reliable & relevant health product safety information
- » Advisories & Health Product InfoWatch
- » Safety Reviews
- » Information on how to report ARs & other reporting initiatives
- » Adverse Reaction Database
- » **Subscribe to health and safety updates**

https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html

Canada Vigilance Program

Contact Information

Mail
Canada Vigilance Program
Marketed Health Products Directorate
Health Canada
Address Locator: 1908C
Ottawa ON
K1A 0K9

Phone

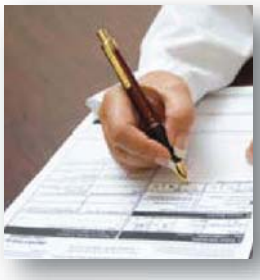
Toll Free 1-866-234-2345

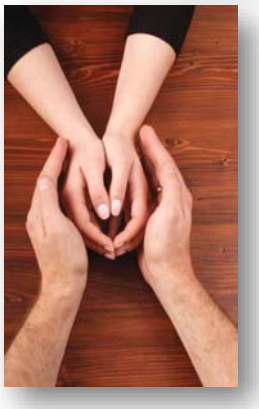
Fax

Toll Free 1-866-678-6789

E-Mail

hc.canada.vigilance.sc@canada.ca





Canada Vigilance Program

Health Canada Resources

Drug and Health Product Register (DHPR):

- https://hpr-rps.hres.ca/

Drug Product Database (DPD):

- https://health-products.canada.ca/dpd-bdpp/index-eng.jsp

Natural and Non-prescription Health Products:

- http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php

Licensed Natural Health Products Database (LNHPD):

- https://health-products.canada.ca/lnhpd-bdpsnh/index-eng.jsp

Medical Devices:

- http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php

Patients for Patient Safety Canada (PFPSC):

- https://www.patientsafetyinstitute.ca/en/toolsResources/Vanessas-Law/Pages/Public-Vanessas-Law.aspx

Health Care Safety Hotline

Consumer Medication Incident Reporting Advisory Committee

Saul N. Weingart, MD
Tufts Medical Center and
Tufts University School of Medicine

Aims, Methods, and Design Challenges

Health Care Safety Hotline Project

- **Objective:** Design and implement a standardized approach to collecting patient, family and caregiver reports about safety-related issues (prototype)

- **Evaluation Goal**: To assess prototype's feasibility, yield, and scalability and recommend modifications that could enable expansion of the prototype nationwide

Pilot Project Timeline

- Design (2011-2013)
  - Environmental scan
  - Focus groups and cognitive interviews
  - Expert panel review
  - OMB review (public comment period)
- Implementation (2013-2014)
  - Prototype development & testing
  - Community deployment
- Evaluation (2014-2016)

Desirable Features

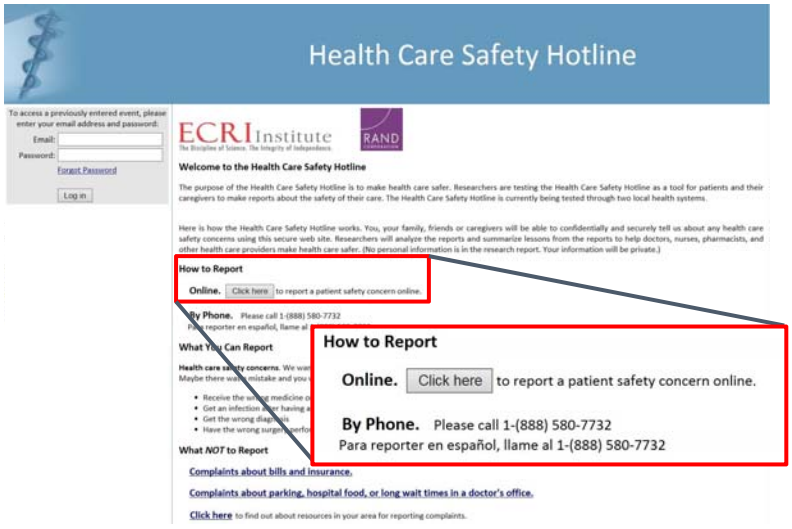
- Patient and consumer friendly
- Standardized
- Engage relevant care delivery organizations
- Community-based and scalable
- Employ a legal framework that:
  - Allows integration of provider and patient information to promote learning
  - Appropriately minimizes risks for both patients and providers (privacy, confidentiality, reputation, etc.)

It's Complicated

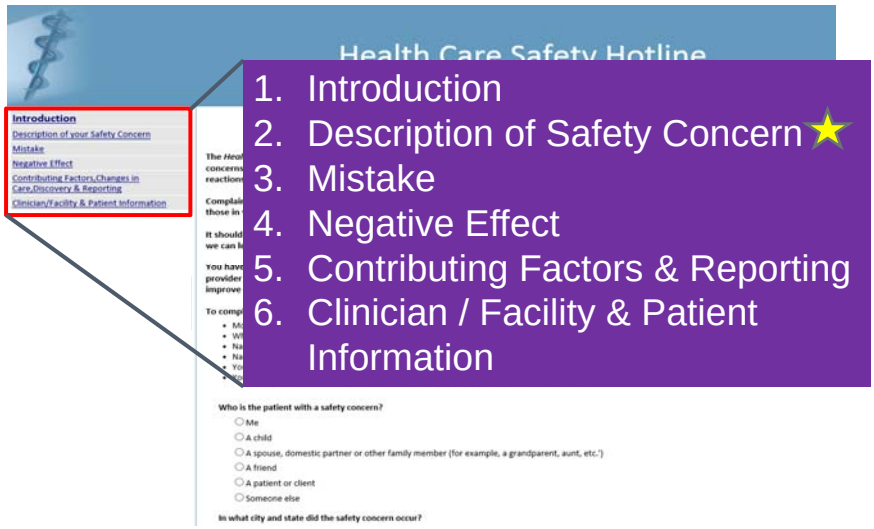
- Many interested parties
- Research vs. peer review protections
  - Consumer reports are not peer-review protected
- Intake process
  - Complex eligibility evaluation and research disclaimer
  - Eliciting information without burdening reporters
- Workflow processes are more complicated than expected
  - Clarifying and classifying reports
  - Relaying information to partner organizations

Design

Home Page

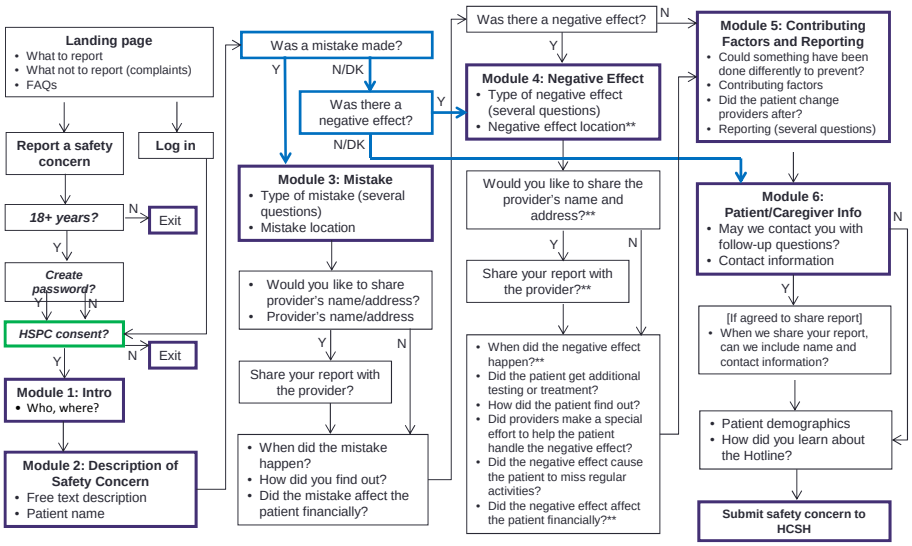


Modular Construction



1. Introduction
2. Description of Safety Concern ★
3. Mistake
4. Negative Effect
5. Contributing Factors & Reporting
6. Clinician / Facility & Patient Information

Health Care Safety Hotline Intake



**Respondent only asked this question if she did not complete Module 3

Community Partners and Outreach

Summary of Web Metrics, Reported Events, and Provider Responses

Only 34 Completed Reports in 13 months

Table 1 Patient Safety Hotline website and telephone contacts

Activity	*N*
Total visitors with unique IP address	1530
Source of access	
Search engine	382
Other	166
FAQ page	647
Event reporting form page 1—welcome and introduction	405
Event reporting form page 2—screening and consent	396
Completed online reports	20
Complete telephone Hotline reports	17
Total completed reports	37
Consented to clarification call	34
Completed clarification call*	22
Agreed to share report and patient identification with clinician or facility	34

*The remaining 34–22 = 12 reports did not require clarification.

Source: Weingart et al. IJQHC 2017; 29: 521.

Hotline Information Allowed Community Partners to Take Action on Behalf of Patients

- Case re-evaluated (n=17)
- Staff members educated (n=4)
- Patient relations spoke to reporter/patient (n=3)
- Improvement project initiated (n=1), follow-up with MD (n=1), policy changed (n=1), reported to Joint Commission (n=1), reviewed by legal team (n=1)

Lessons Learned

Lessons Learned: Bottom Line

- The Hotline is a tool that can be used to collect reports from patients and families on a variety of patient safety events
- It provides new information on known and unknown events
  - The majority of reporters consented to having information shared with health care delivery organizations
- However, passive data collection is not a robust means of generating reports!

Thank you

Project Team

- RAND Corporation
  - M. Susan Ridgely (PI)
  - Eric Schneider (Original PI)
  - Denise Quigley
  - Lauren Hunter
  - Shaela Moen
- Tufts Medical Center
  - Saul Weingart (Chair, TEP)
- ECRI Institute
  - Robert Giannini (ECRI Project Lead)
  - Gregory Lee
  - Karen Zimmer
- Brigham and Women's Hospital
  - Joel Weissman

AHRQ
Jim Battles (Project Officer)
Farah Englert and Alison Hunt

Funded by AHRQ ACTION II Task Order #14

Technical Expert Panel Members

NAME	POSITION
Troy Brennan	Executive Vice President and Chief Medical Officer, CVS Caremark Corporation and CVS Pharmacy, Inc.
John Clarke	Professor of Surgery, Drexel University; Clinical Director, Patient Safety and Quality Initiatives at ECRI Institute
Jim Conway	Principal, Governance and Executive Leadership at Pascal Metrics; Senior Fellow, Institute for Healthcare Improvement
Jack Fowler	Senior Research Fellow, Center for Survey Research at University of Massachusetts, Boston
Helen Haskell	Founder and President, Mothers Against Medical Error
Lisa McGiffert	Campaign Director, Consumer Union's Safe Patient Project
Tejal Gandhi	President, National Patient Safety Foundation
Richard Roberts	President, World Organization of Family Doctors; Professor of Family Medicine, University of Wisconsin School of Medicine & Public Health

DANISH PATIENT SAFETY AUTHORITY

The Danish Experience with a Patient Safety Incident Reporting and Learning System

Marianne Banke, MSc. Public Health
Administrative officer, The Danish Patient Safety Authority

11 November 2019

DANISH PATIENT SAFETY AUTHORITY

The Danish Health Care System in Short

5 Regions

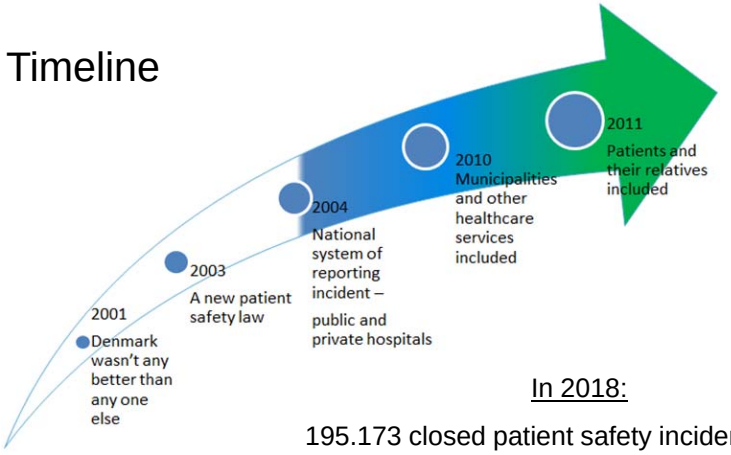
Hospitals, general practitioners, specialist doctors, therapists and chiropractors, midwives, dentists and dental hygienists, pychologists, pharmacies, doctor on call, regional housing, pre-hospital og ambulances

98 Municipalities

Nursing homes, home nurse, home care, the public dental, housing for citizens with disabilities, social housing, addiction treatment, care centers, prevention centre, rehabilitation, others

DANISH PATIENT SAFETY AUTHORITY

Timeline



In 2018:

195.173 closed patient safety incidents in total

3.430 closed patient safety incidents reported by patients or relatives (1,75 %)

DANISH PATIENT SAFETY AUTHORITY

Characterisation of the Danish Reporting and Learning System

- **Sanction-free**

A health professional can not on the basis of a reported patient safety incident be subjected to disciplinary investigations or measures by the employer, supervisory reaction (inspection) by the Danish Patient Safety Authority or criminal sanctions by the courts.

- **Mandatory**

A health care professional who becomes aware of a patient safety incident **must** report the incident. Patients and relatives **may** report.

- **Confidential**

Information about the reporting patient, relative or health care professional's identity can not be disclosed.

Information about the identy of the patient, relative or health care professionals involved in the reported patient safety incident can not be disclosed.

DANISH PATIENT SAFETY AUTHORITY

The reporting form for patients and relatives

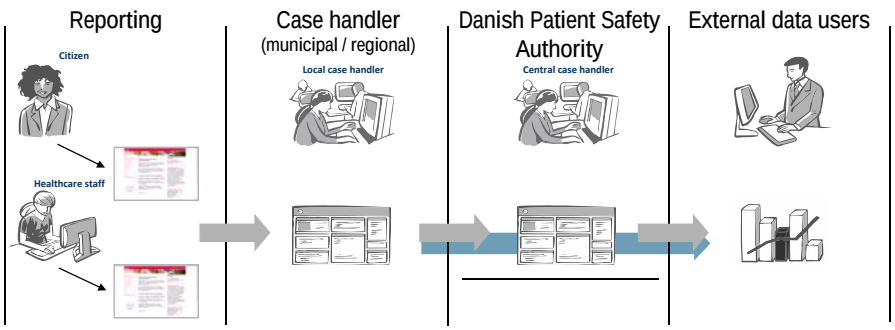
1. Are you a patient or a relative?
2. Patient information (name and social security number)
3. Where did the incident happen? (location lookup) *
4. When did it happen?
5. Headline of the incident description *
6. What happened – incident description? *
7. Contact information on reporter (name, email, phone number)
8. File attachment

Link: Patients' and relatives' reporting form

Link: Reporting form for health care staff

DANISH PATIENT SAFETY AUTHORITY

The Flow of a Reported Patient Safety Incident



DANISH PATIENT SAFETY AUTHORITY

Our experience + the feedback from the patients

- Difficult for patients/relatives to distinguise between the parallel systems for complaints, compensation and incident reporting.
- The patients miss information about what happens with the report and any potential actions being taken based on the report – only possible at the local level.
- Difficult to extract aggregated learning from patient and relative reporting – should be done locally for each individual incident[1]
- A need for collaboration with the Danish Medicines Agency regarding adverse reactions (different laws, different requirements)

1: *"Patients Own Safety Incidents Reports to the Danish Patient Safety Database Possess a Unique but Underused Learning Potential in Patient Safety".* By: Christiansen, Anders Bech; Simonsen, Simon; Nielsen, Gert Allan

DANISH PATIENT SAFETY AUTHORITY

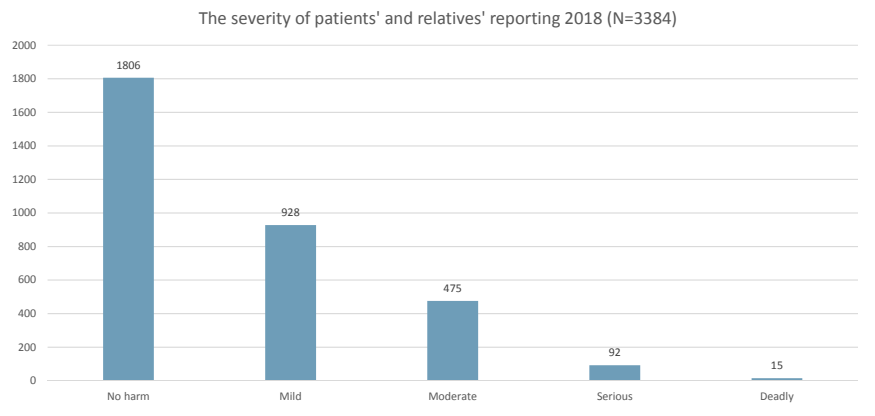
Actions taken based on (all) medicin incidents

- Invitation to pharmaceutical companies to read anonymised incidents – increases understanding.
- Dialogue meetings with pharmaceutical companies and Patient Organisations: what kind of incidents do we see.
- Letters to pharmaceutical companies regarding trends in the incidents and suggestions for solutions.
- Collaboration with the Association of Phamacies to reach the citizens

DANISH PATIENT SAFETY AUTHORITY

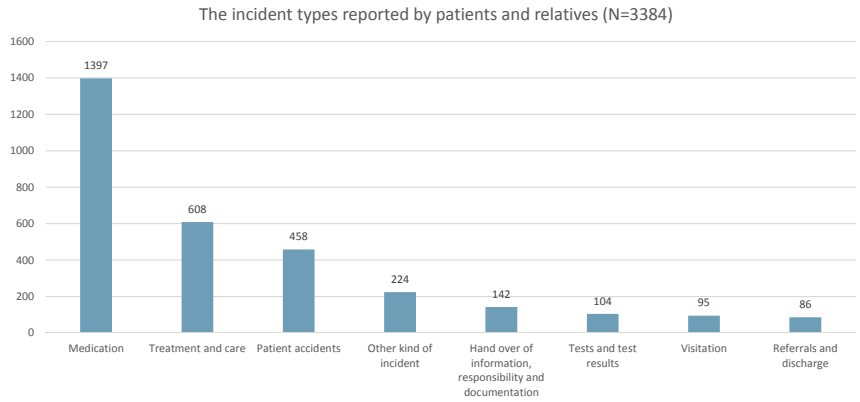
DANISH PATIENT SAFETY AUTHORITY

Severity of patients' and relatives' reporting



DANISH PATIENT SAFETY AUTHORITY

Types of incidents reported by patients and relatives



DANISH PATIENT SAFETY AUTHORITY

Length of incident description

Study*: "Patients Own Safety Incidents Reports to the Danish Patient Safety Database Possess a Unique but Underused Learning Potential in Patient Safety"*

By: Christiansen, Anders Bech; Simonsen, Simon; Nielsen, Gert Allan

Patients' and relatives' descriptions are, on average, longer than descriptions by health professionals, regardless of severity.

Average of relatives' descriptions: 1447 words

Average of nurses' descriptions: 426 words.

DANISH PATIENT SAFETY AUTHORITY

Content of patients' and relatives' reporting

Study*: "Patients Own Safety Incidents Reports to the Danish Patient Safety Database Possess a Unique but Underused Learning Potential in Patient Safety"*

By: Christiansen, Anders Bech; Simonsen, Simon; Nielsen, Gert Allan

(and supported by our experience)

The descriptions by patients and relatives are more focused on:

- The consequences of the incident
- The circumstances surrounding the incident
- The interpersonal communication
- The emotions that the incident gave rise to in the patient

Choosing Wisely Canada – Communications

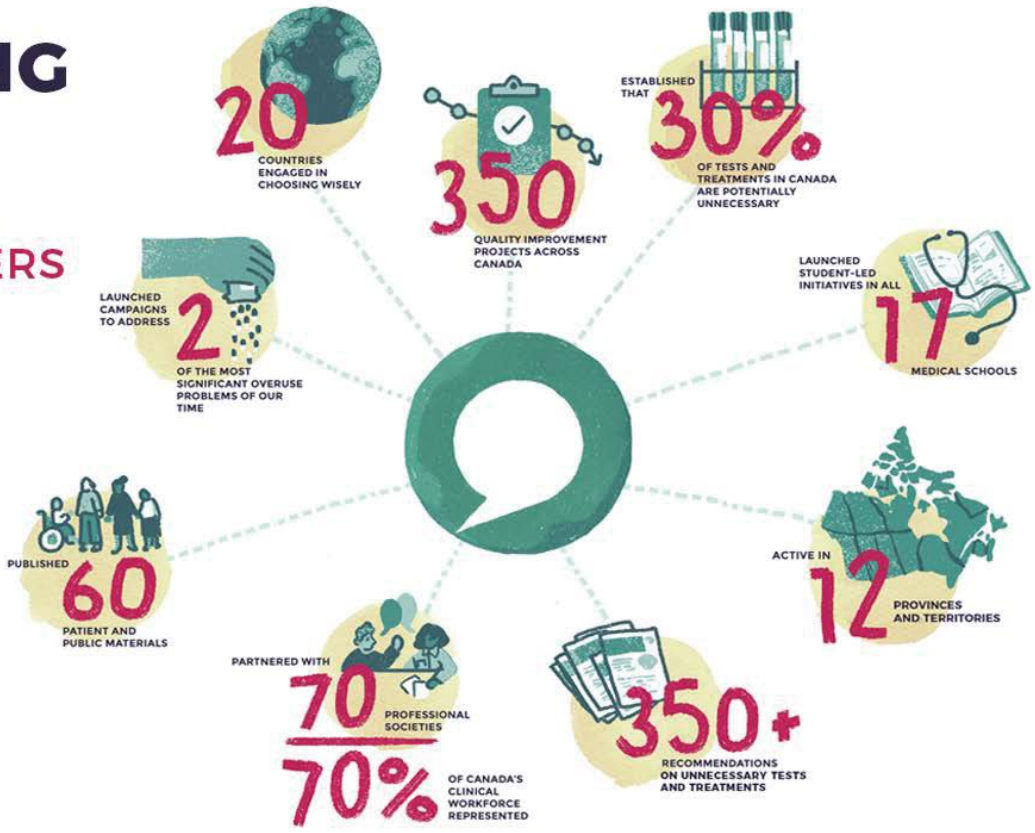
Stephanie Callan | Communications Specialist

October 3, 2019

Choosing Wisely Canada is the national voice for reducing unnecessary tests and treatments in health care.

CHOOSING WISELY CANADA

BY THE NUMBERS



COMMUNICATIONS

Our Goals

→ **Build Awareness**

Provide information on the harms of overuse in health care.

→ **Education**

Develop resources that encourage conversations between clinicians and patients.

→ **Support others**

Highlight others working on Choosing Wisely Canada in their own settings.

FOUR QUESTIONS

TO ASK YOUR HEALTH CARE PROVIDER

1. **Do I really need this test, treatment or procedure?**
2. **What are the downsides?**
3. **Are there simpler, safer options?**
4. **What happens if I do nothing?**

Talk about what you need, and what you don't.
To learn more, visit www.choosingwiselycanada.org.

Choosing Wisely Canada™

ANTIBIOTICS CAMPAIGN

Using Antibiotics Wisely

A national campaign that encourages conversations between clinicians and patients about unnecessary antibiotic use.

www.choosingwiselycanada.org/antibiotics

Using Antibiotics Wisely

01

Content

Working group identifies area of overuse to build campaign as it aligns with Choosing Wisely Canada

02

Branding

Choosing Wisely Canada's team align any resources with campaign branding.

03

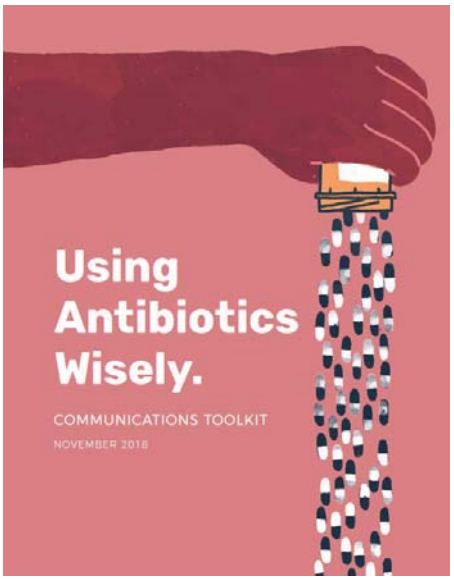
Consultation

Choosing Wisely Canada sends to relevant stakeholders for feedback.

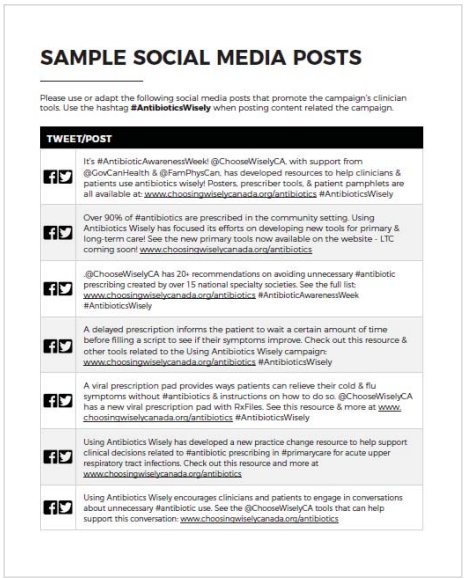
04

Launch

Communications takes final products and prepares for public launch.



About the Initiative

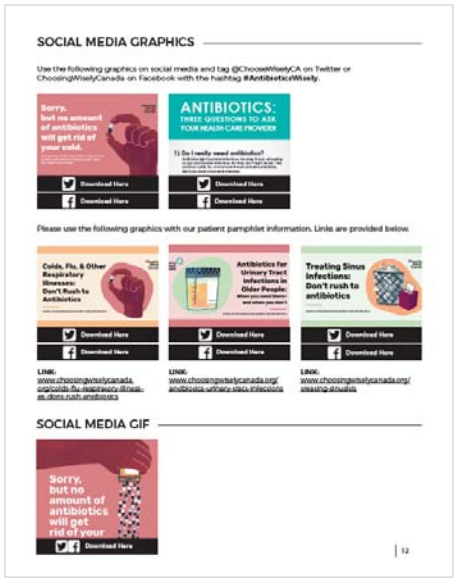


SAMPLE SOCIAL MEDIA POSTS

Please use or adapt the following social media posts that promote the campaign's clinician tools. Use the hashtag **#AntibioticsWisely** when posting content related the campaign.

TWEET/POST
It's #AntibioticAwarenessWeek! @ChooseWiselyCA, with support from @GovCanHealth & @FamPhysCan, has developed resources to help clinicians & patients use antibiotics wisely! Posters, prescriber tools, & patient pamphlets are all available at: www.choosingwiselycanada.org/antibiotics #AntibioticsWisely
Over 90% of #antibiotics are prescribed in the community setting. Using Antibiotics Wisely has focused its efforts on developing new tools for primary & long-term care! See the new primary tools now available on the website - LTC coming soon! www.choosingwiselycanada.org/antibiotics
@ChooseWiselyCA has 20+ recommendations on avoiding unnecessary #antibiotic prescribing created by over 15 national specialty societies. See the full list: www.choosingwiselycanada.org/antibiotics #AntibioticAwarenessWeek #AntibioticsWisely
A delayed prescription informs the patient to wait a certain amount of time before filling a script to see if their symptoms improve. Check out this resource & other tools related to the Using Antibiotics Wisely campaign: www.choosingwiselycanada.org/antibiotics #AntibioticsWisely
A viral prescription pad provides ways patients can relieve their cold & flu symptoms without #antibiotics & instructions on how to do so. @ChooseWiselyCA has a new viral prescription pad with RxFiles. See this resource & more at www.choosingwiselycanada.org/antibiotics #AntibioticsWisely
Using Antibiotics Wisely has developed a new practice change resource to help support clinical decisions related to #antibiotic prescribing in #primarycare for acute upper respiratory tract infections. Check out this resource and more at www.choosingwiselycanada.org/antibiotics
Using Antibiotics Wisely encourages clinicians and patients to engage in conversations about unnecessary #antibiotic use. See the @ChooseWiselyCA tools that can help support this conversation: www.choosingwiselycanada.org/antibiotics

Provide Sample Content



SOCIAL MEDIA GRAPHICS

Use the following graphics on social media and tag @ChooseWiselyCA on Twitter or ChoosingWiselyCanada on Facebook with the hashtag **#AntibioticsWisely**.

Please use the following graphics with our patient pamphlet information. Links are provided below.

SOCIAL MEDIA GIF

Easy to Access Materials

HOSPITAL CAMPAIGN

Diving into Overuse in Hospitals

A campaign to reduce unnecessary tests and treatments in hospitals settings.

www.choosingwiselycanada.org/hospitals

01

Digital Campaign

Digital campaign began three months prior to release of campaign to raise awareness.

02

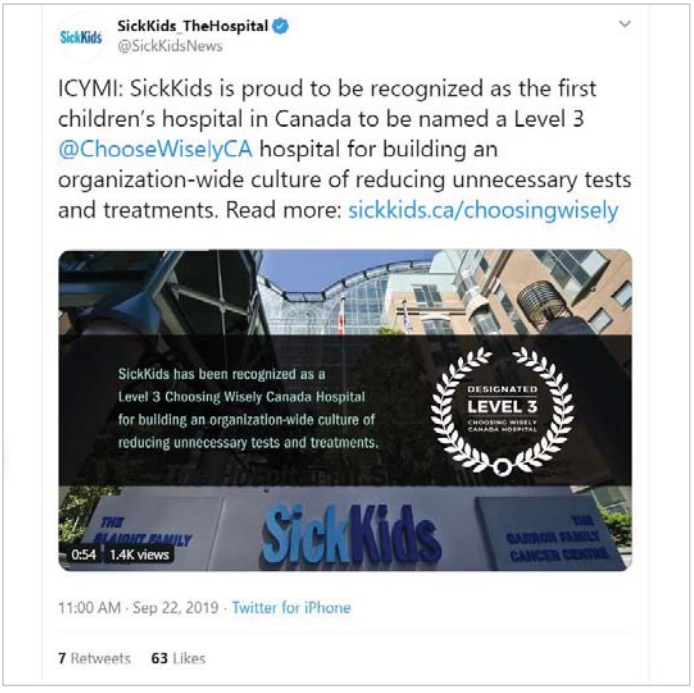
Launch Materials

Webinar was used as a launch and to introduce a starter kit – a key resource for the campaign.

03

Spreading the Message

A digital package was created to help other communication teams communicate this initiative.



Questions & Comments

Digital Experience

Richard Liebrecht

Oct. 4, 2019

the Pivot group

thepivotgroup.ca

How is the
Library
still a thing?

Programming **up** twice as much as circulation is **down!**

People don't just want to be **informed anymore.** They want to:

Be entertained

Make a difference

Reflect their values

Try something new

Do stuff!

The User Story:

As a (type of user), I want to (take an action) so that I can (meet a goal).

The User Story:

As a person who has recovered from a medication incident, **I want to** share my complication story **so** I don’t feel alone.

We live in an **ecosystem** of digital devices and spaces.

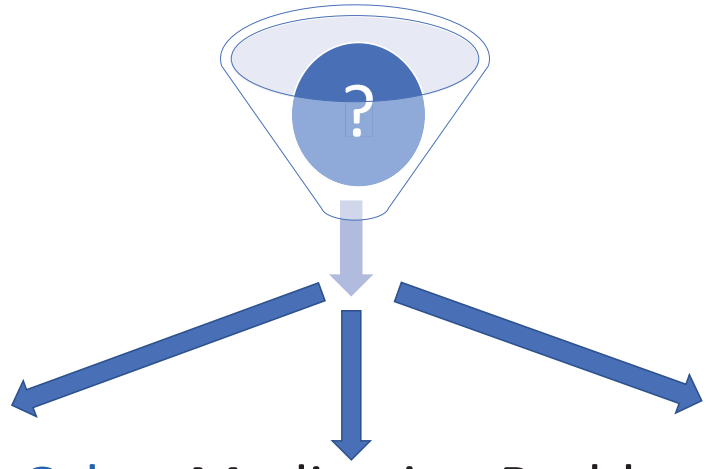
Don’t get hung up on just rebuilding the same website.

Please!

I have a problem with a medication* to report…….

* or an over-the-counter product, cannabis, e-vaping and/or other

My Medication Problem



Medication Side Effect

Other Medication Problem

Medication Error

Unsure – we're here to help.

Medication Side Effect

Do you think the medication is causing a reaction like heartburn, nausea, rash, pain or other bad things?

Yes - report to Canada Vigilance Program (Health Canada).

No – click here

Medication Error

Do you think that there was a mistake with the medication like:

- you received the wrong medication;
- or the wrong dose of medication; or
- Some other mistake?

Report to SafeMedicationUse.ca

No – click here

So your medication problem is not a side effect or mistake. Please share what your medication problem is here.

Other Medication Problem?

SafeMedicationUse.ca