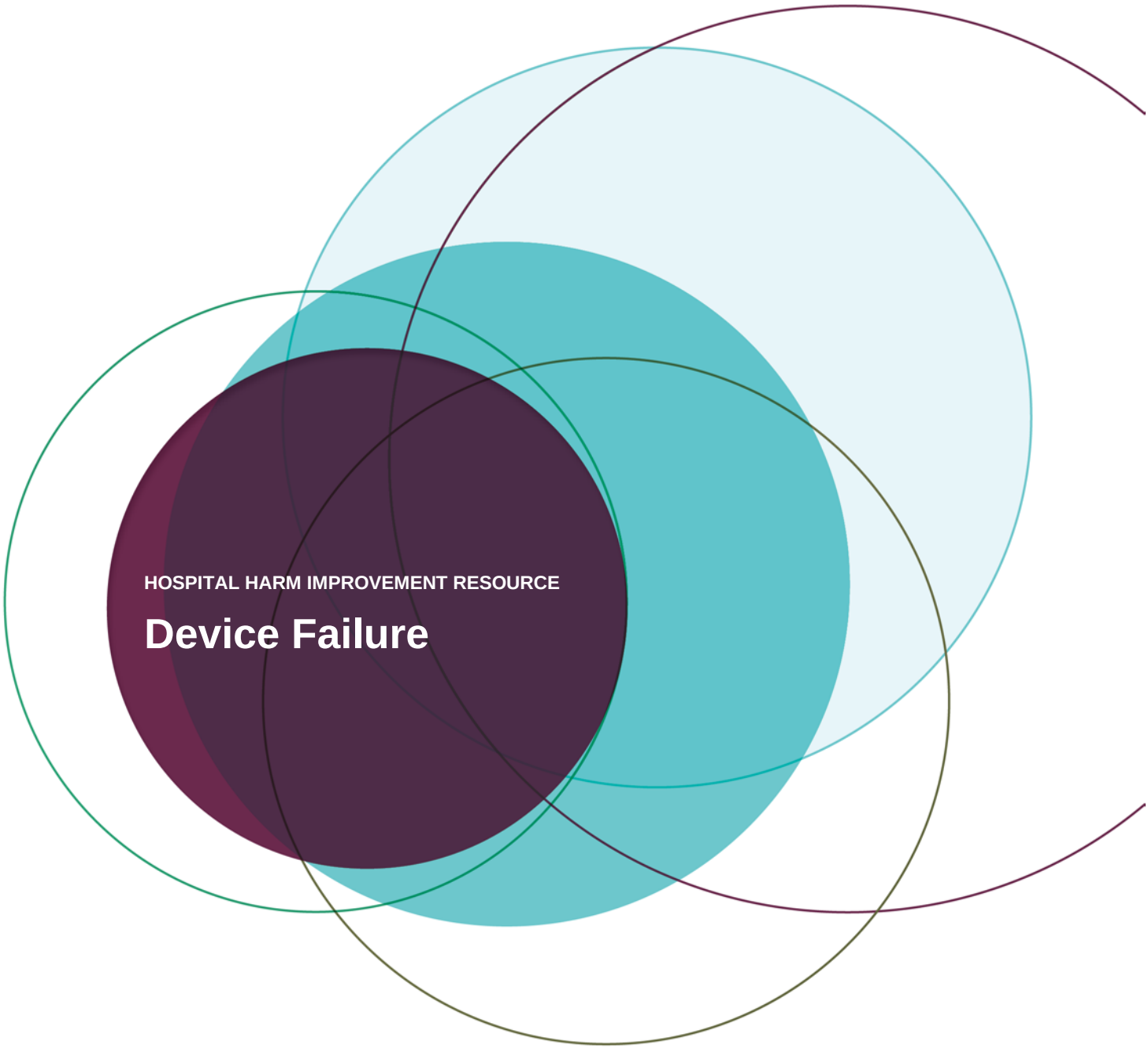

HOSPITAL HARM IMPROVEMENT RESOURCE

Device Failure

cpsi icsp
Canadian Patient Safety Institute
Institut canadien pour la sécurité des patients

ACKNOWLEDGEMENTS

The Canadian Institute for Health Information and the Canadian Patient Safety Institute have collaborated on a body of work to address gaps in measuring harm and to support patient safety improvement efforts in Canadian hospitals.

The Hospital Harm Improvement Resource was developed by the Canadian Patient Safety Institute to complement the Hospital Harm measure developed by the Canadian Institute for Health Information. It links measurement and improvement by providing resources that will support patient safety improvement efforts.

DISCHARGE ABSTRACT DATABASE (DAD) CODES INCLUDED IN THIS CLINICAL CATEGORY:

D20: Device Failure

Concept	Mechanical complications of devices, catheters, grafts, implants, or prostheses associated with a medical or surgical procedure.
Notes	This clinical group includes mechanical failure and complications of devices: breakdown, displacement, leakage, malposition, obstruction, perforation or protrusion of devices, catheters, grafts, implants, or prostheses associated with a medical or surgical procedure.
Selection criteria	
Codes	**Code descriptions**
T82.0–T82.5 T83.0–T83.4 T84.0–T84.4 T85.0–T85.6	Identified as diagnosis type (2) AND Y60–Y84 in the same diagnosis cluster
Codes	**Code descriptions**
T82.0	Mechanical complication of heart valve prosthesis
T82.1	Mechanical complication of cardiac electronic device
T82.2	Mechanical complication of coronary artery bypass and valve grafts
T82.3	Mechanical complication of other vascular grafts
T82.4	Mechanical complication of vascular dialysis catheter
T82.5	Mechanical complication of other cardiac and vascular devices and implants
T83.0	Mechanical complication of urinary (indwelling) catheter
T83.1	Mechanical complication of other urinary devices and implants
T83.2	Mechanical complication of graft of urinary organ
T83.3	Mechanical complication of intrauterine contraceptive device
T83.4	Mechanical complication of other prosthetic devices, implants, and grafts in genital tract
T84.0-	Mechanical complication of internal joint prosthesis
T84.1-	Mechanical complication of internal fixation device of bones of limb
T84.2-	Mechanical complication of internal fixation device of other bones
T84.3	Mechanical complication of other bone devices, implants, and grafts
T84.4	Mechanical complication of other internal orthopaedic devices, implants, and grafts
T85.0	Mechanical complication of ventricular intracranial (communicating) shunt
T85.1	Mechanical complication of implanted electronic stimulator of nervous system
T85.2	Mechanical complication of intraocular lens
T85.3	Mechanical complication of other ocular prosthetic devices, implants, and grafts

Device Failure

T85.4	Mechanical complication of breast prosthesis and implant
T85.5	Mechanical complication of gastrointestinal prosthetic devices, implants, and grafts
T85.6	Mechanical complication of other specified internal prosthetic devices, implants, and grafts
Additional codes	**Inclusions**
Y60–Y84	Complications of medical and surgical care (refer to Appendix A) of the Hospital Harm Indicator General Methodology Notes

Overview and Implications

A medical device is any instrument or component used to treat, diagnose, or prevent a human disease or abnormal physical condition. In this context, medical devices used on animals are not included. All medical devices pose some level of risk based on their use in diagnosis or treatment, or due to malfunction. In Canada, medical devices are grouped into four classes based on the expected level of risk to a person's health and safety with Class I offering the lowest risk.

Medical devices range from adhesive bandages, toothbrushes and contact lenses to complex devices, such as x-ray units, insulin pumps and pacemakers. They also include in vitro diagnostic devices, such as cancer screening tests, blood glucose monitors, and pregnancy test kits. (Health Canada, 2020).

A medical device problem is related to:

- inadequate labelling or instructions for use
- a failure of the device or a deterioration in its effectiveness
- an actual or potential deficiency that may affect product performance or safety
- a serious deterioration in the patient's health (possibly related to a medical device)
- death, or has the potential to lead to death if the device is used again
- (Health Canada, 2020)

Canada's monitoring of therapeutic products plays an important role in public health and patient safety. Hospitals help make health products safer by reporting serious medical device incidents in order to:

- promote the safe use of health products by Canadians
- may be the first sign of previously unrecognized rare or serious ADRs or MDIs
- help Canada take action against products that may pose a risk to health and safety

Medical device incidents refer to medical device failures that take place in a hospital. As of December 16, 2019, hospitals are required to report medical device incidents. Canadian hospitals are required to report all serious medical device incidents (MDIs), according to the Medical Devices Regulations (SOR/98-282) for medical device incidents. By law, a medical device is defined as:

- **Active device:** a medical device that depends on a source of energy for its operation, other than energy generated by the human body or gravity. A medical device that transmits or withdraws energy or a substance to or from a patient without substantially altering the energy or the substance is not an active device.
- **Active diagnostic device:** an active device that, whether used alone or in combination with another medical device, is intended to supply information for the purpose of detecting, monitoring, or treating a physiological condition, state of health, illness, or congenital deformity.

- **Active therapeutic device**: an active device that, whether used alone or in combination with another medical device, is intended to support, modify, replace, or restore a biological function or structure for the purpose of treating or mitigating an illness or injury, or a symptom of an illness or injury (Medical Devices Regulations).

Health Canada's system designed to track incidents where devices may have harmed patients is so hobbled by under-reporting, the toll on Canadians is unknown. Never-before-released federal data shows at least 1,400 Canadians have died since 2008 in incidents involving devices that were designed to help them. During those 10 years, another 14,000 Canadians were injured (McLean & Cribb, 2018).

In August 2020 and for the first time, the Canadian Institute for Health Information (CIHI) released an analysis focused on the 12-high volume, high-cost implantable medical device (IMD) procedures provided in hospitals across the country each year. The top12 IMD procedures include (in order of frequency):

- Cataract lens insertion;
- Knee replacement;
- Hip replacement;
- Coronary stent;
- Ear tube;
- Pacemaker;
- IUD;
- Spinal fusion and fixation hardware;
- Transvaginal mesh implant and Tension Free Vaginal Tape (TVT) procedure;
- Breast implant prosthesis;
- Shoulder replacement;
- Defibrillator (CIHI, 2020a).

The incidence of in-hospital device failures reported for the HHIR ranged from 3,802 in fiscal 2014-2015 to 4,109 in fiscal 2019-2020 (CIHI, 2020b).

The Medicines & Healthcare products Regulatory Agency (MHRA) recommends that an integral part of system management for medical devices, is that healthcare organizations should appoint a director or board member with overall responsibility for medical device management. In addition, Medical Device Safety Officers (MDSO) and a Medical Devices Management Group should be appointed to review and report adverse incidents to the MHRA and other official agencies.

Reporting of Medical Device Incidents

Reporting of an adverse incident or near miss which has the potential to cause, unexpected or unwanted effects involving the safety of patients, users or other persons is critical and should include any known problems associated with product design, documentation, and common use related issues should also be reported for follow-up. Reporting is essential to ensure that lessons are learnt, and adverse events are not repeated. National reporting is essential to

ensure that trends are spotted, and appropriate action is taken across the country to help ensure the safe and effective use of medical devices, for example through safety messages. Unless all adverse events are reported, emerging problems cannot be identified, continuing the risk of repeat events and patient harm (MRHA, 2021).

The results of a systematic review of 30 studies suggested four main barriers to error reporting as follows: fear of punishment or censure, uncertainty regarding what should be reported, uncertainty as to how incident reports will be used, and lack of time. Potential strategies to improve incident reporting include accessible electronic error reporting systems, training about what to report and how, and feedback on actions taken based on error reported (Polisena et al., 2015a).

The results of another study by the same author, in two large Canadian tertiary hospitals, revealed that the knowledge and experience of hospital staff, as well as the patient's clinical characteristics and device performance were important factors in incident recognition. Incident severity, awareness, and ease of use of reporting systems and processes, as well as organizational culture, and personal attitudes and perceptions of responses contributed to the frequency of reporting device incidents. The discontinued use of a medical device or equipment was the most common resolution to prevent the reoccurrence of a similar error. Suggested strategies for improvement involved education and training, institutional and professional cultures, and improved reporting systems and processes (Polisena et al., 2015b).

Medical device problems may surface years after they have been used or implanted in thousands of patients. Health Canada is responsible for the surveillance and reporting of device advisories, warnings, or recalls and posts this information in the Advisories, Warnings and Recall Database and Drug and Medical Device Recall Listing available on their website (Polisena et al., 2014). The Protecting Canadians from Unsafe Drugs Act, also known as Vanessa's Law, is intended to increase drug and medical device safety in Canada by strengthening Health Canada's ability to collect information and to take quick and appropriate action when a serious health risk is identified. As of December 16, 2019, it became mandatory for hospitals to report serious adverse drug reactions (serious ADRs) and medical device incidents (MDIs) to Health Canada (Health Canada et al., n.d.).

Risk Factors

An audit conducted by the UK National Patient Safety Agency reported that device-related incidents are caused by device failure (43.8 per cent), inappropriate use (29.3 per cent), lack of training (12.3 per cent), and poor maintenance (1.5 per cent) (Polisena et al., 2014).

GOAL

Reduce the incidence of mechanical complications or failures of devices including: breakdown, displacement, leakage, malposition, obstruction, perforation or protrusion of devices, catheters, grafts, implants, or prostheses associated with a medical or surgical procedure.

Importance to Patients and Families

Medical device incidents are problems with any type of medical product or equipment that led to or could have led to a serious health concern. A medical device incident can occur shortly after beginning treatment or much later. Harm from a medical device can be mistaken for a symptom of a disease (PFPSC et al., n.d.).

Everyone who witnesses or experiences a problem with a medical device is strongly encouraged to report it. A patient or their care provider can also work with their healthcare provider to submit a report . Medical devices range from adhesive bandages, toothbrushes, and contact lenses to complex devices such as x-ray units, insulin pumps, and pacemakers. They also include in vitro diagnostic devices, such as cancer screening tests, blood glucose monitors, and pregnancy test kits (Health Canada, 2020).

Examples of Medical Device Incidents are:

- An infusion pump stopped working and did not give an alarm. The patient needed a longer stay in hospital.
- A defibrillator used to treat a cardiac arrest did not work properly. The patient was not revived.
- A prosthetic knee replacement failed due to damaged material.
- A breast implant was suspected of causing a rare cancer.

Awareness and conversation with health care providers are key components in identifying a serious adverse drug reaction or medical device incident (PFPSC et al., n.d.).

Patient Story – CPSI-PFPSC

If something doesn't feel right, you have to ask the question

Two weeks after his brush with death, Nicholas Bravi stepped out of his shower with the steri-strips washed away and the angry red scar on his chest fully visible for the first time (CPSI, 2014).

Clinical and System Reviews, Incident Analyses

Given the broad range of potential causes of device failure, in addition clinical and system reviews to identify latent causes and determine appropriate recommendations.

Occurrences of harm are often complex with many contributing factors. Organizations need to:

1. Measure and monitor the types and frequency of these occurrences.
2. Use appropriate analytical methods to understand the contributing factors.
3. Identify and implement solutions or interventions that are designed to prevent recurrence and reduce risk of harm.

4. Have mechanisms in place to mitigate consequences of harm when it occurs.

To develop a more in-depth understanding of the care delivered to patients, chart audits, incident analyses and prospective analyses can be helpful in identifying quality improvement opportunities. Links to key resources for conducting chart audits and analysis methods are included in the Hospital Harm Improvement Resource Introduction.

If your review reveals that your cases of device failure are linked to specific processes or procedures, you may find these resources helpful:

- Canadian Agency for Drugs and Technologies in Health (CADTH) https://www.cadth.ca/
- Canadian Patient Safety Institute www.patientsafetyinstitute.ca
    - Health Canada, Institute for Safe Medication Practices Canada, Health Standards Organization, Canadian Patient Safety Institute. Educational Support for Mandatory Reporting of Serious ADRs and MDIs by Hospitals. CPSI. https://www.patientsafetyinstitute.ca:443/en/toolsResources/Vanessas-Law/Pages/default.aspx

- Government of Canada www.Canada.ca
    - Health Canada. About medical device problems. Government of Canada. Published January 24, 2020. https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/medical-device-problems.html
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    - Health Canada. Canadian Medical Devices Sentinel Network. Government of Canada. Published June 26, 2019. https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/medeffect-canada-canadian-medical-devices-sentinel-network-pilot-project.html
    - Health Canada. Medical device incidents. In: Adverse reactions, medical device incidents and health product recalls in Canada: 2019 summary report. Government of Canada. Published December 11, 2020. https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/adverse-reactions-incidents-recalls-2019-summary.html#a3
    - Health Canada. Adverse reactions, medical device incidents and health product recalls in Canada: 2019 summary report. Government of Canada. Published December 11, 2020. https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/adverse-reactions-incidents-recalls-2019-summary.html

- Medicines & Healthcare Products Regulatory Agency (MRHA) Medicines and Healthcare products Regulatory Agency - GOV.UK www.gov.uk

    - Medicines & Healthcare products Regulatory Agency (MHRA). *Managing Medical Devices: Guidance for Health and Social Care Organisations*. MHRA; 2021. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/965010/Managing_medical_devices022021.pdf
    - Medicines & Healthcare products Regulatory Agency (MHRA). *Devices in Practice: Checklists for Using Medical Devices*. MHRA; 2014. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/403401/Devices_in_practice.pdf

- National Institute for Health and Care Excellence (NICE) www.nice.org.uk
    - National Institute for Health and Care Excellence. Published guidance and advice. NICE Guidance. https://www.nice.org.uk/guidance/published?type=apg,csg,cg,cov,mpg,ph,sg,sc,dg,hst,ipg,mtg,qs,ta
    - National Institute for Health and Care Excellence. Introducing techniques and medical devices. NICE Guidance: Local Practice. Published January 2013. https://www.nice.org.uk/sharedlearning/introducing-techniques-and-medical-devices
    - National Institute for Health and Care Excellence. Medical Technologies Evaluation Programme. NICE guidelines. https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-medical-technologies-evaluation-programme
- World Health Organization (WHO) www.who.int
    - World Health Organization. Medical devices. WHO Health Topics. https://www.who.int/health-topics/medical-devices#tab=tab_1

MEASURES

Vital to quality improvement is measurement, and this applies specifically to implementation of interventions. The chosen measures will help to determine whether an impact is being made (primary outcome), whether the intervention is being carried out (process measures), and whether any unintended consequences ensue (balancing measures).

In selecting your measures, consider the following:

- Whenever possible, use measures you are already collecting for other programs.
- Evaluate your choice of measures in terms of the usefulness of the final results and the resources required to obtain them; try to maximize the former while minimizing the latter.
- Try to include both process and outcome measures in your measurement scheme.

- You may use different measures or modify the measures described below to make them more appropriate and/or useful to your particular setting. However, be aware that modifying measures may limit the comparability of your results to others.
- Posting your measure results within your hospital is a great way to keep your teams motivated and aware of progress. Try to include measures that your team will find meaningful and exciting (IHI, 2012).

Global Patient Safety Alerts

Global Patient Safety Alerts provides access and the opportunity to learn from other organizations about specific patient safety incidents including alerts, advisories, recommendations, and solutions for improving care and preventing incidents. Learning from the experience of other organizations can accelerate improvement (CPSI, n.d.).

Recommended search terms:

- Device failure
- Medical device

You may also search Medical Device Incidents on the Government of Canada website.
https://hpr-rps.hres.ca/mdi_landing.php?lang=en

Success Stories

One important success factor that will enhance the safety of medical devices is to gain trust from the frontline healthcare providers and ensure that their incident reports will be reviewed to resolve the errors and prevent future similar errors. These individuals, therefore, should be kept abreast of any relevant developments and receive timely feedback (Polisena, 2014).

HSO – Leading Practices

Reporting of Adverse Events in Reprocessing of Medical Devices
Hôpital Charles LeMoyne, Quebec. 2011

https://healthstandards.org/leading-practice/reporting-of-adverse-events-in-reprocessing-of-medical-devices/

This a system for identifying risks in reprocessing medical devices and analysing the underlying causes. It is used to develop a profile of the risks inherent in the process for reprocessing reusable medical devices. Using this practice, information on reprocessing is also disseminated throughout the organization, primarily to the risk manager and management. Each adverse event is identified either by the clinicians who notice errors in their trays during use or by computer searches in the organization's tracking software. These events are recorded in a database, Access, and the underlying causes are analysed to develop and implement measures to prevent recurrence (HSO, 2011).

The Development of an Interdisciplinary Smart Pump Working Group reporting to Safe Medication Practices for the Management of Parenteral Administration using Smart Pump Technology

Royal Victoria Regional Health Centre, 2019

https://healthstandards.org/leading-practice/development-interdisciplinary-smart-pump-working-group-reporting-safe-medication-practices-management-parenteral-administration-using-smart-pump-technology/

The Smart Pump Working Group is an inter-professional group (clinical educators, front-line pharmacists, Professional Practice Manager, Pharmacy Manager, Biomedical Engineering representative, Network Administrator from Information Technology Services) that reports to Safe Medication Practices Committee. Its primary mandates are to review current practices of smart pump devices within the organization and to develop recommendations to the Safe Medication Practices Committee by utilizing the data from smart pumps to improve safety and develop an on-going process for smart pump updates and continued data analysis. It is also mandated to review, on an on-going basis, any required additions/changes to ensure consistent, scheduled drug library (DL) updates occur, aligning with medication safety standards and recommendations from organizations such as ISMP Canada.

The Working Group meets monthly, and the work accomplished has led to a drug library compliance rate of greater than 98 per cent for over one year and the almost elimination of medication errors related to I.V. administration of medications due to over-riding parameters.

We feel that this is innovative and transformative because, in a meeting with ICUMedical, when we were reviewing next steps in report development for presentation to our hospital executives, ICUMedical (the manufacturers for the Plum 360 Smart Pumps) had indicated that there were not aware of any other institution in Canada that had an efficient and effective Working Group, and who are using the actual data for on-going quality improvements. They were the ones who had indicated that we should be putting this initiative forward as a Leading Practice (HSO, 2019).

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