Health Canada
Outreach, Education and Feedback – Mandatory Reporting of Serious Adverse Drug Reaction (ADR) and Medical Device Incident (MDI) by Health Care Institutions

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Current Reporting Landscape

- **Drugs**
  - Mandatory for manufacturers to report within 15 days after receiving or becoming aware of:
    - Any serious adverse drug reaction (expected and unexpected) that has occurred in Canada with respect to the drug
    - Unusual failure in efficacy that has occurred in Canada for new drugs
    - Any serious unexpected adverse drug reaction that has occurred outside Canada with respect to the drug
  - All adverse drug reaction reports from the public or health care professionals are considered voluntary
- **Medical Devices**
  - Manufacturers and importers are required to report serious incidents related to a medical device:
    - Within 10 days: if an incident leads to a death or a serious deterioration of health.
    - Within 30 days: if an incident were to reoccur, could end in death or serious deterioration of health.
  - All other types of reports from industry and public or health care professionals are considered voluntary

Introduction to Vanessa's Law (Bill C-17)

- Bill C-17: Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) amends the *Food and Drugs Act* to improve Health Canada's ability to:
  - Collect post-market safety information;
  - Take appropriate action when a serious risk to health is identified;
  - Promote greater confidence in the oversight of therapeutic products by increasing transparency
- Named after Vanessa Young (daughter of Terence Young)
- Vanessa's Law received Royal Assent in November 2014

Overview of Changes to the Act

- The amendments to the *Food and Drugs Act* include:
  1. Power to compel information, tests/studies and reassessments
  2. Power to compel a label change
  3. Power to recall unsafe therapeutic products
  4. Tougher measures for those that do not comply
  5. Ability to incorporate by reference
  6. **Mandatory reporting by healthcare institutions**
     - **Once regulations are developed, *Vanessa's Law* will require healthcare institutions to report:**
       - **Serious adverse drug reactions (ADRs) and medical device incidents (MDIs)**

Multi-pronged Approach to Improve the Reporting of Serious ADRs and MDIs

Consultations and Regulatory Process for Mandatory Reporting

- **May 2016**: Issue Identification Paper – what we heard during early consultation process
- **July 2017**: Discussion Paper – for consultation and Webinar
- **December 2017**: 'What We Heard Report' in response to 2017 consultation
- **Winter 2017-18:** Development of Regulatory Proposals and Supporting Documents
    - Draft Regulations
    - Regulatory Impact Analysis Statement
    - Cost Benefit Analysis – Hospitals and associations participation in Technical Briefings
- **June 2018**: Pre-Publication in Canada Gazette 1 (75 day consultation period)
    - Accompanying draft guidance document
- **Fall/Winter 2018:** Analyze stakeholder comments and revise Regulatory Proposal and Draft Guidance
- **June 2019:** Publication of final Regulations in Canada Gazette 2
- **June to Dec 2019:** 6 month coming into force period (per CG1 proposal)

Outreach, Education and Feedback - Partnership

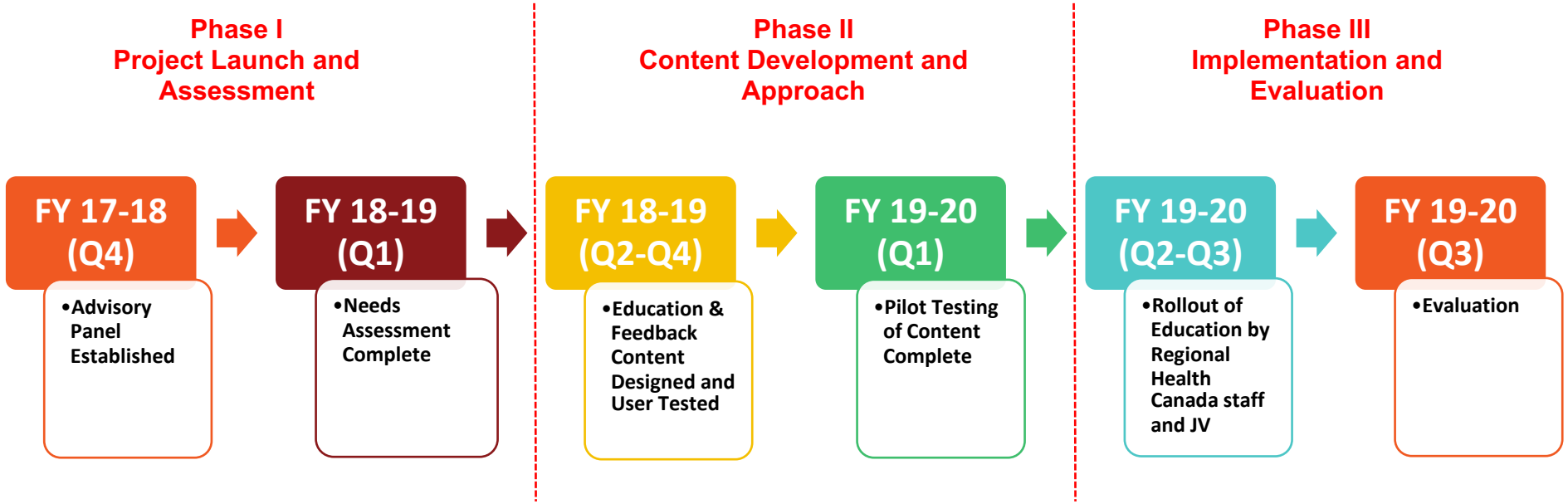
- Outreach, education and meaningful feedback required to address reporting barriers that are beyond the reach of regulations
- Health Canada awarded a contract on December 1, 2017 to the Institute for Safe Medication Practices Canada (**ISMP Canada**) in a Joint Venture with the Health Standards Organization (**HSO**), and the Canadian Patient Safety Institute (**CPSI**)
- The Joint Venture will work with Health Canada to develop and implement an educational approach and content to motivate and support the reporting of serious ADRs and MDIs
- Health Canada staff in Regional offices will deliver outreach and education, in partnership with the Joint Venture, prior to the coming into force of the regulatory requirement

ismp CANADA

HSO

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

Key Milestones for Outreach, Education and Feedback



Project start date: December 1, 2017
Project end date: November 1, 2019

** Following the project, Health Canada intends to continue to support outreach, education and feedback

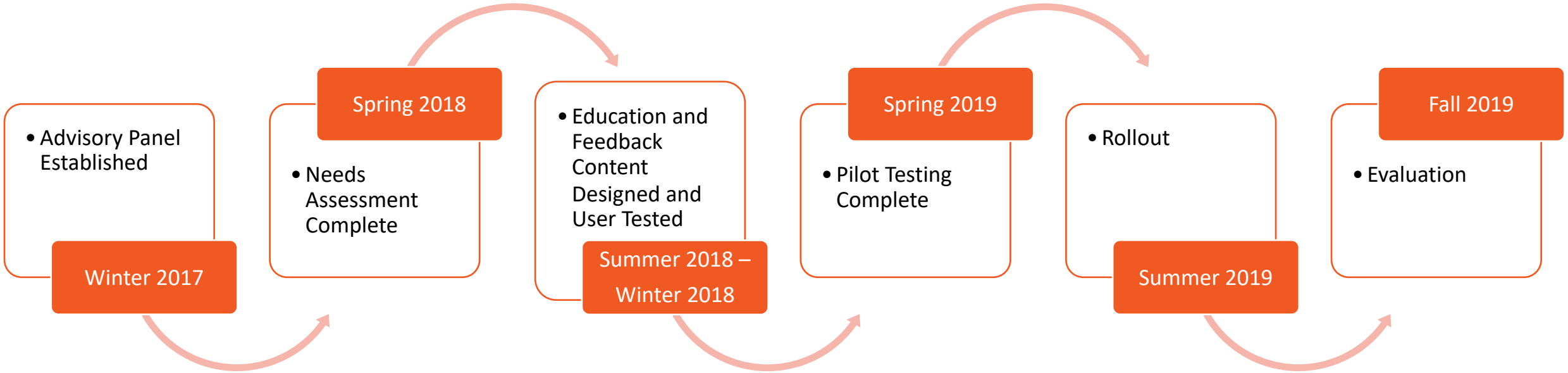
Logic Model

PROJECT LOGIC MODEL – OUTREACH, EDUCATION AND FEEDBACK - MANDATORY ADR/MDI REPORTING FOR HOSPITALS

VISION	OBJECTIVES	INPUTS	OUTPUTS	SHORT-TERM OUTCOMES	INTERMEDIATE OUTCOMES	LONG-TERM OUTCOMES	ULTIMATE AIM
Support healthcare professionals, patients and hospitals in ADR and MDI awareness, identification and reporting	1. Assess type of outreach, education and feedback needed to motivate and support ADR and MDI reporting 2. Develop and deliver outreach, education and feedback	**Project Team** • ISMP, HSO, CPSI team • Health Canada team **Collaborators/ Partners** • Health care providers • Hospitals • Patients • Associations • Regulators • Policy Makers • Accreditation bodies • Standard setting orgs • Universities • National orgs (e.g. CIHI, CADTH, CHI) • Intl. organizations **Technology** • Teleconference, WebEx platform, email and MS tools **Knowledge & Practice** • Advisory panel • Health Canada resources, regulations • PM resources and tools, evaluation, engagement, education and change methodologies **Funding** • Contract per RFP	**Joint Venture Team** • Project Charter • Project Plan • Logic Model • Engagement Plan • Communications Plan • Steering Committee • Advisory Committee • Needs Assessment and Gap Analysis • Implementation Plan • Preliminary Outreach and Education Content • Preliminary Feedback Reporting Content • User Testing Results • Evaluation Plan and Tools • Pilot Testing Results • Final Outreach, Education and Reporting Content • Final Evaluation Plan and Report	• Advisory Panel established • Target audiences participate in needs assessment • Awareness of gaps that can be addressed with education	• Guidance provided by Advisory Panel • Consensus on education content • Outreach to target audience on education and feedback achieved • Potential reporters are engaged in the education program	• Improved understanding of the value and accountability of ADR/MDI reporting • Availability of an evaluation framework to support continuous improvement • Provision of meaningful feedback	**Improved quality and increased quantity of ADR and MDI reports to ensure sufficient data to detect safety problems**

Problem: Under-reporting of Adverse Drug Reactions and Medical Device Incidents

Engagement Plan



Stakeholder Preliminary Analysis Mapping

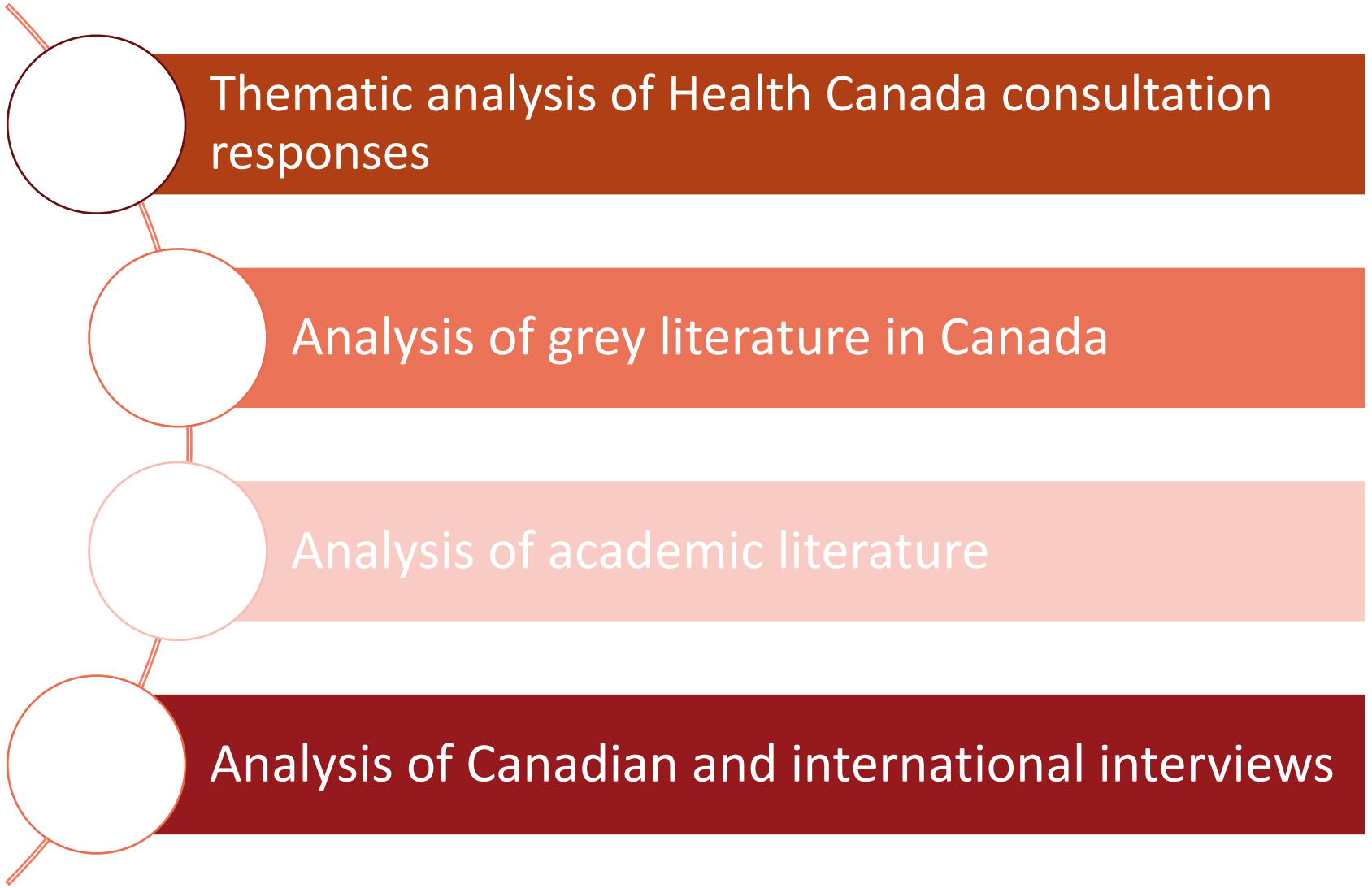
Stakeholders	Contribution	Legitimacy	Willingness**	Influence	Necessity
Patients	High	High	High	High	High
Hospitals	High	High	High	High	High
Health Care Providers Working in Hospitals	High	High	Medium	High	High
Other Hospital Staff	High	High	Medium	High	High
Ministries of Health*	Medium	Medium	Medium	High	High
Patient Safety and Health Quality Councils	High	High	High	High	High
Universities/Colleges and Regulatory Bodies	High	High	Medium	High	High
Advisory Panel	High	High	High	High	High

* May vary depending on Ministry reporting structure
** TBD; will be monitored

Needs Assessment

- To determine what is needed to improve quality and quantity of ADR/MDI reporting
- Focused on:
  - facilitators (and ways to overcome barriers) for reporting, and
  - understanding the feedback required to motivate and support reporting. [NOTE: feedback is a facilitator]
- The needs assessment served to:
  - **Raise awareness of the gaps that can be addressed by education**
  - Inform the content and approach for outreach, education and feedback

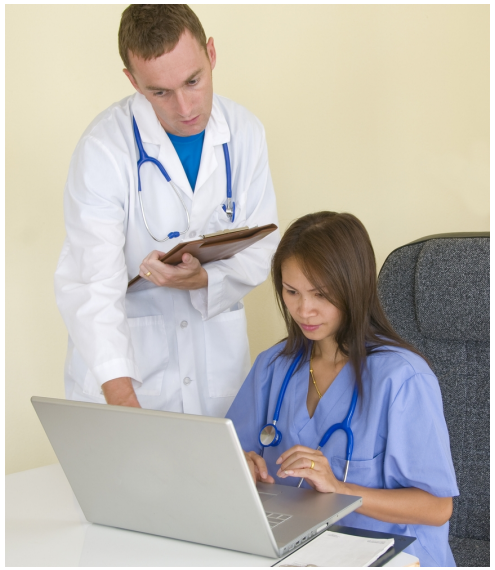
Needs Assessment Framework



Consistent Themes

Theme: Reporting system and process opportunities

- Integrate reporting systems into existing electronic health records (EHR)
- Simplify reporting forms, with a two-tier process to follow-up for additional details
- Clarify reporting processes for users, including what and how to report



Theme: Resource allocation

- Additional staff needed to support reporting on-site (i.e., ‘champions’, sentinel groups)
- Compensation for reporting is controversial;
- Healthcare students need more resources for early learning about reporting

Theme: Health Canada feedback opportunities

- Increase awareness of existing feedback mechanisms
- Life-cycle of a report, from receipt to dissemination of findings, made apparent
- Reporter follow-up and dissemination of findings done as soon as possible
- Drug/device-specific statistics readily available (i.e., number of reports, harm, strategies)

Theme: Culture of safety

- A culture of safety is important to encourage reporting without the fear of blame/retribution
- Peer support can help remind practitioners that reporting is their collective duty of care
- Benefits of reporting need to be publicized (i.e., safer drug/device use, reduced patient harm)

Implementation Plan

1. The educational content will address the knowledge gaps identified in the Needs Assessment.
2. The strategy for education will result in downloadable educational materials/product, hosted by Health Canada, to enable incorporation into various educational modalities/platforms.
3. Any stakeholder interested in incorporating the materials into their educational/training programs/platforms will be encouraged to utilize the materials with acknowledgement of Health Canada as the source.
4. The strategies for outreach and communications will maximize the reach, dissemination, and uptake of the educational materials/product. The Stakeholder Engagement Plan will inform the outreach, and includes the Advisory Panel.
5. Communications will reflect key messages from the educational materials/product and the expected outcomes regarding ADR/MDI reporting as outlined in the Project Logic Model.
6. The Joint Venture partners will utilize their networks to support outreach and communications.

Outreach and Communications

- Outreach and communications from [updated] Stakeholder Engagement Plan
  - Collaboration with patients and patient organizations
  - Collaboration with hospitals
  - Collaboration with regulatory bodies and professional associations
  - Collaboration with provincial/territorial ministries of health and patient safety and health quality councils
  - Collaboration with academic faculties
  - Communication with pharmaceutical/medical device companies
- Reach and dissemination of materials to end-users
- Incentivization of educational product