Welcome

Our webinar will begin shortly

Happy

Canadian Patient Safety Week 2019
Canadian Patient Safety Week Webinar:
Mandatory Reporting of Serious Adverse Drug Reactions
And Medical Device Incidents

November 1, 2019

ConquerSilence.ca
Today’s Moderator and Sponsors

Mr. Christopher Thrall
Canadian Patient Safety Institute
Communications Officer

A huge thank you to GOJO Industries, Inc. and HealthPRO for sponsoring CPSW this year!
Today’s Speakers

Mr. Marc Mes
MHPD Director General,
Health Canada

Ms. Maryann Murray
Patient Advocate,
Patients for Patients Safety Canada

Ms. Maryanne D’Arpino
CPSI Senior Director,
Patient Safety Improvement and Capability Building
Today’s Speakers (continued)

Ambika Sharma
Medication Safety Specialist,
ISMP Canada

Sylvia Hyland
VP Operations and Privacy Officer,
ISMP Canada

Nancy Louis
Manager, Medication Quality & Safety
Alberta Health Services

Holly Myer
Provincial Director, AHS
Product Quality & Safety
Alberta Health Services
Patient safety incidents are the third leading cause of death in Canada, behind cancer and heart disease.
Today in Canada every 17 minutes someone dies in a hospital from an adverse event.
Today’s Moderator

Let’s #ConquerSilence in healthcare together.
It’s time to speak up.

• Your inner voice can save lives.

• This campaign should move you to speak.

• Death is no match for your voice.
Participation in this presentation will enable you to:

1. Understand mandatory reporting of serious ADRs and MDIs in the context of patient safety
2. Describe the regulatory requirements for mandatory reporting of serious ADRs and MDIs by hospitals
3. Identify strategies and systems to support mandatory reporting of serious ADRs and MDIs
Mr. Marc Mes
MHPD Director General
Health Canada
Maryann Murray
Patients for Patient Safety Canada
Purpose of Vanessa’s Law
The Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) introduces amendments to the Food and Drugs Act to improve Health Canada's ability to:
Who was Vanessa?

Vanessa’s Law was enacted in 2014 and the mandatory reporting requirements come into effect December 16th, 2019.
Patients for Patient Safety Canada members are world leaders in patient safety improvement initiatives.

An active member of PFPSC, Maryann Murray, lost her daughter, Martha Murray, to an adverse drug reaction when Martha was 22 years old.

“People have given their lives, or they’ve suffered, and the least we can do for them is to report what happened and allow the analysis to occur so we can prevent it from happening again.”

Maryann Murray
We All Have a Role in Safety
Maryanne D’Arpino
Senior Director,
Canadian Patient Safety Institute (CPSI)
Health Canada is continuously looking for ways to strengthen its knowledge base on product safety in the interest of improving patient outcomes and public health.

What Are the Benefits of Serious ADR and MDI Reporting?

Serious ADR and MDI Reporting Contributes to:

- **IDENTIFICATION** of emerging safety issues related to drugs and medical devices
- **ASSESSMENT** of harm vs. benefit of drugs and medical devices
- **SHARING** of learning, including warnings and advisories for health care providers, patients, and stakeholders
- **IMPROVEMENT** of safety of products through risk mitigation such as a labelling change, a product information update, or a recall
Ambika Sharma
Medication Safety Specialist

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The educational materials provide core content about serious adverse drug reaction (serious ADR) and medical device incident (MDI) reporting.

There are 4 PowerPoint modules:

- **Module 1** – Overview of Vanessa’s Law and Reporting Requirements
- **Module 2** – Reporting Processes to Health Canada
- **Module 3** – Strategies to Promote and Support Mandatory Reporting
- **Module 4** – Health Canada’s Review and Communication of Safety Findings

More information is available from:

Conceptual Model of Serious ADR and MDI Reporting by Hospitals

Source: Serious ADR and MDI Action Cycle. ISMP Canada, HSO, CPSI; 2019.
Regulations for Mandatory Reporting
Who Is Required to Report?

The regulations apply to all hospitals.

The regulations define a hospital as a facility that:

- is licensed, approved or designated as a hospital by a province or territory, in accordance with the laws of the province or territory, to provide care or treatment to persons suffering from any form of disease or illness; or
- is operated by the Government of Canada and provides health services to in-patients.

Notes:

- Outpatient clinics are subject to the regulations if they are legally part of the hospital, even if they are physically separate from the hospital. On the other hand, clinics that may be physically located within a hospital, but that are not legally part of the hospital, will not be subject to the regulations.
- Health care institutions that are outside the scope of the definition of hospitals, such as private clinics or long-term care facilities (e.g., nursing homes), continue to be encouraged to report on a voluntary basis.

What are the Definitions of a Serious ADR and MDI?

A **serious adverse drug reaction (serious ADR)** is a noxious and unintended response to a drug that occurs at any dose and that

- 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.

A **medical device incident (MDI)** is an incident related to a failure of a medical device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use that has led to the death or a serious deterioration in the state of health of a patient, user, or other person, or could do so were it to recur.

Note: Hospitals are not required to establish causality; the information to be submitted by the hospital to Health Canada only needs to represent the suspicions of a health care professional that a serious ADR or MDI has been observed.

The mandatory reporting requirements for hospitals apply to therapeutic products, including:

- Pharmaceuticals (prescription and non-prescription drugs)
- Biologic drugs (biotechnology products, fractionated blood products, plasma proteins, and vaccines [excluding vaccines administered under a routine immunization program of a province or territory])
- Radiopharmaceutical drugs
- Disinfectants
- Medical devices
- Drugs for an urgent public health need

When in doubt, Health Canada encourages hospitals to report.

The term medical device covers a wide range of health and/or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition.

Medical devices are classified into Class I (lowest risk) to Class IV (highest risk). Examples are:

- Class I – hospital beds, wheelchairs, leg prostheses
- Class II – infusion sets, syringes, tracheostomy tubes, urethral catheters
- Class III – infusion pumps, anesthesia gas machines, intrauterine devices
- Class IV – pacemakers, defibrillators, breast implants, bone grafts

All classes of medical devices are included in mandatory reporting by hospitals.

When Must Hospitals Report?

The regulations require hospitals to report serious ADRs or MDIs in writing to Health Canada within 30 calendar days of first documentation of the serious ADR or MDI within the hospital.

The regulations require hospitals to report all documented serious ADRs and all documented MDIs, where the required information is **within the control of the hospital**.

- Information that is within the control of the hospital is information that would be reasonably accessible within the hospital.

- While it is encouraged for hospitals to take all reasonable steps to retrieve the required information to complete as thorough a report as possible, there is no requirement to do further investigation in order to obtain the pieces of information.

Examples of serious ADR or MDI documentation within the hospital include:

- a serious ADR or MDI that is identified in a patient’s clinical/medical record;
- a serious ADR or MDI that is identified in a separate report form (electronic or hard copy) that has been completed by a health care professional; and
- a serious ADR or MDI that has been documented in an ADR form or a product complaint form (e.g., an MDI form) as per internal hospital policy, a pathology report, an incident/patient safety learning database, or a computerized prescription recording system.

• Health Canada remains flexible and is able to receive reports in various formats via multiple secure submission methods, recognizing that hospital systems vary.
  – If interested in submitting reports electronically to Health Canada, please email the Canada Vigilance Program at hc.canada.vigilance.sc@canada.ca.
  – Health Canada supports report submissions using a secure File Transfer Protocol (sFTP) and continues to explore system-to-system options.

• The reporting forms for serious ADRs and MDIs, together with instructions, are available on the Health Canada website:
New Form for Mandatory Reporting of Serious ADRs

New Form for Mandatory Reporting of MDIs

The reporting form for medical device problems was created for multiple reporting uses:

- **Mandatory reporting for**
  - hospitals,
  - **Special Access Program** (SAP),
  - **Investigational Testing Authorization** (ITA)

- **Voluntary reporting to**
  - **Canadian Medical Devices Sentinel Network** (CMDSNet) by participating institutions

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Vice President Operations and Privacy Officer

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Strategies to Support Mandatory Reporting

Note: Health Canada does not endorse any particular strategy.
The following examples, in alphabetical order, are provided for information sharing only.
The following self-assessment questions may be helpful to identify opportunities to prepare for the implementation of mandatory reporting within your hospital:

- In what way is serious ADR and MDI documentation and reporting promoted?
- Are our hospital policies and procedures aligned with the mandatory reporting requirements?
- Can our hospital systems be leveraged to facilitate documentation and reporting?
- How can awareness and knowledge of serious ADR and MDI documentation and reporting be improved?
- Has our hospital leadership created an environment that supports serious ADR and MDI documentation and reporting?
- Are patients and families empowered to ask questions and be engaged in monitoring their treatments?
- Is serious ADR and MDI documentation and reporting included in orientation or education programs?
- Is the learning or feedback derived from serious ADR and MDI reports shared with health care providers?
Strategic and Operational Considerations for Teams

• **Create a multidisciplinary team (e.g., ‘Safety Team’) to support serious ADR and MDI documentation and reporting, and assist with:**
  - identifying serious ADRs and MDIs through proactive monitoring;
  - completing and submitting serious ADR and MDI reports;
  - disseminating learning from serious ADR and MDI reporting;
  - providing coaching and education;
  - enabling continuous quality improvement for serious ADR and MDI reporting processes; and
  - providing regular updates to senior leadership.

• **Identify individual ‘Champions’ to help lead serious ADR and MDI reporting efforts and/or provide support for identifying and submitting serious ADR or MDI reports to Health Canada.**

• **Identify networking opportunities to support collaboration and shared commitment to serious ADR and MDI documentation and reporting.**
• A centralized provincial approach has been developed for serious ADR reporting and for improved MDI reporting.
  ◦ Provincial Task Force is in place to coordinate the initiative
  ◦ Includes centralized process to receive, review and further report

• Alberta is implementing a province-wide clinical information system
  ◦ All sites will use a single electronic health record
  ◦ There is a phased roll out across the province over five years
  ◦ Serious ADR reporting will be integrated into the electronic health record
  ◦ MDI reporting will be linked from the electronic health record, as well as from the Alberta Health Services intranet

Source: Alberta Health Services; 2019.
The BC Patient Safety & Learning System (BCPSLS) has partnered with the BC Ministry of Health, health authorities, and Health Canada to create a provincial strategy for implementing the mandatory reporting requirements.

The provincial strategy includes:

- the use of an established, province-wide incident reporting system (BCPSLS) to report ADRs and MDIs;
- a steering committee and working groups to guide and implement the approach; and
- a communication and education campaign to promote reporting.

Members of the steering committee and working groups include representatives from BCPSLS, BC Ministry of Health, Health Canada, pharmacy, biomedical engineering, supply chain, and quality, safety and risk.

In Newfoundland and Labrador, the Department of Health and Community Services has partnered with the four regional health authorities in a steering committee to create a provincial strategy for implementing the mandatory reporting requirements.

The Provincial Steering Committee’s mandate includes:

- establishing the most effective and efficient method for mandatory reporting,
- promoting interdisciplinary collaboration in mandatory reporting, and
- implementing an educational approach.

Team members of the steering committee include representatives from quality, patient safety and risk management, pharmacy services, nursing, physicians, biomedical services, and information technology.

Source: Department of Health and Community Services, Newfoundland and Labrador; 2019.
EXAMPLE: Quebec (CHU Sainte-Justine)

- Goal: Collaboration between the pharmacist and medical archivist to lead implementation of mandatory serious ADR reporting.

- A pharmacovigilance coordinator (pharmacist)
  - manages the reporting of serious ADRs to Health Canada, and
  - reviews and disseminates risk communications from Health Canada.

- A medical archivist (i.e., medical records staff) codes serious ADRs from notes in the patient’s medical record and sends the information to the Pharmacovigilance Coordinator.

Notes:
- A serious ADR may be missed if it is not well documented in the medical record. Providing training to health care providers about documenting ADRs is useful.
- A process to document a serious ADR identified by the medical archivist after discharge is also helpful.

Source: CHU Sainte-Justine, Quebec; 2019.
Strategic and Operational Considerations for Technology

- **Integrate the reporting process into workflow and technology systems** to make reporting as effective and efficient as possible.
  - Explore opportunities to incorporate serious ADR and MDI reporting in **electronic health record** (or electronic medical record) systems
  - Explore opportunities to incorporate serious ADR and/or MDI reporting in **electronic incident reporting** systems
  - Explore opportunities to use the **pharmacy information system** to record serious ADRs and facilitate reporting to Health Canada
• To facilitate serious ADR and MDI **traceability to a specific product**, technology systems and documentation practices may need to accommodate product-specific identifiers:
  - Drug identification number (DIN) for drugs, disinfectants and biologics / biosimilars
  - Device identifier, catalogue number or model name for medical devices
  - Brand name for all health products
  - Manufacturer’s name for all health products

• Explore the feasibility of support from a designated team (e.g., health record team, patient safety team, or risk management team) to **track serious ADRs and MDIs** from the hospital’s documentation/coding system(s).
Facilities across Canada capture administrative, clinical, and demographic information on all hospital stays for reporting to the Canadian Institute for Health Information’s (CIHI) Discharge Abstract Database (DAD).

Upon a patient’s discharge, the health record is reviewed and coded, according to national standards, using ICD-10-CA. ICD-10-CA is the enhanced Canadian version of the 10th revision of the International Statistical Classification of Diseases and Related Health Problems. ICD-10-CA contains codes for diseases, signs and symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or diseases. ICD-10-CA coding can be leveraged to support serious ADR and MDI tracking.

Source: Canadian Institute for Health Information; 2019.
• Adverse effect categories in ICD-10-CA:

<table>
<thead>
<tr>
<th>Y40-Y59</th>
<th>Adverse effects during therapeutic use of a drug, medicament or biological substance</th>
<th>These external cause codes are assigned when the drug/substance is used as prescribed or intended in therapeutic use.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y70-Y82</td>
<td>Adverse events with medical devices</td>
<td>These external cause codes are assigned exclusively for unexpected malfunctioning or breakage of a device.</td>
</tr>
</tbody>
</table>

• There are some gaps in what is captured to meet DAD reporting requirements and what is needed to comply with mandatory reporting requirements:
  ◦ CIHI's DAD ICD-10-CA coding does not capture specific drug/device names, therefore this information would need to be obtained from the patient’s health record for mandatory reporting.
  ◦ CIHI’s DAD ICD-10-CA coding is based on physician*-documented adverse effects that cause harm.
  ◦ CIHI’s DAD ICD-10-CA coding is based on actual events and would not identify potential for serious harm in the case of medical device incidents.

*Mandatory reporting regulations do not require physician confirmation of a serious ADR or MDI.
Strategic and Operational Considerations for Education

• Refer to Health Canada’s resources:
  o Modules – Educational support for mandatory reporting
  o Posters to promote reporting

• Include education about serious ADR and MDI reporting in:
  o orientation programs,
  o student teaching programs and curricula, and
  o continuing education programs.

• Empower patients and families to ask questions and be engaged in monitoring their treatments

• Share tips for recognizing a serious ADR or MDI with health care providers
  o Consider if symptoms experienced by the patient might be due to a serious ADR or MDI

• Develop a process to regularly share within the hospital (e.g., newsletters, intranet) Health Canada’s safety findings related to serious ADRs and MDIs
Tips for Recognizing a Serious ADR or MDI

• Serious harm from a drug or from a medical device can be mistaken for a symptom of a disease.

• A high level of suspicion, clinical awareness, and patient dialogue are key components in identifying a serious ADR or MDI. The following can help:
  ◦ Ask about the patient’s medical history
  ◦ Consider a serious ADR or MDI if there is:
    ▪ an unexpected change in the patient’s clinical condition
    ▪ a new health problem for the patient
    ▪ a need for urgent additional therapies, procedures or surgeries
    ▪ a sudden need for a rescue drug (e.g., naloxone, epinephrine, glucagon)
    ▪ a medical order for an acute change to therapy (e.g., abrupt discontinuation)

• A serious ADR or MDI can occur shortly after beginning treatment or much later
Examples of Safety Information Sharing

Health Canada disseminates findings to health care providers and the public to **alert** and **educate** them about identified health risks related to health products.

**Multiple sources of safety information** are available to provide up-to-date information:

- **Adverse Reaction Online Database** (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-database.html)
- **Medical Device Incidents Database** (https://hpr-rps.hres.ca/mdi_landing.php)
- **Drug and Health Product Register (DHPR)** (https://hpr-rps.hres.ca/)
Alberta Health Services (AHS)

Nancy Louis
Manager, Medication Quality & Safety
Alberta Health Services

Holly Myer
Provincial Director, AHS Product Quality & Safety
Alberta Health Services
Vanessa’s Law
The Alberta Approach
Alberta Health Services: Get to Know Us

**HISTORY**

- Founded May 2008
- Brought together 9 regional health authorities and 3 agencies
- Largest, fully-integrated health system in Canada

**BY THE NUMBERS – OUR PEOPLE**

- 108,000 Employees
- Serving 4.2 million Albertans
- 650 Facilities across the province
- 8,968 Acute and sub-acute care beds/spaces
Connect Care
Who will we reach?

**POPULATION**
- 86,900 AHS
- 8,800 Covenant
- 8,000 Physicians
- 10,000 Students
- 2,100 Carewest / Capital Care / CLS

**BEDS**
- 8,940 Total Hospital Acute and Sub-Acute Care
- 25,323 Total Continuing Care
- 2,659 Total Addiction and Mental Health

**FACILITIES**
- **Community Ambulatory Care**
  - 6 Urgent Care Centres
  - 7 Ambulatory Care Centres
  - 3 Family Care Clinics
  - 139 Public Health Centres

- **Addiction and Mental Health**
  - 39 Addiction
  - 26 Community Mental Health
  - 5 Standalone Psychiatric

- **Acute Care**
  - 106 Total Designated Hospitals

- **Cancer Care**
  - 17 Cancer Centres

- **Community-Based Care**
  - 331 Long-Term Care and Supportive Living
  - 108 Additional Contracted Care Sites
  - 20 Community Hospice, Palliative & End-of-Life Care
Alberta Approach

• Centralized provincial approach
  • In development for Serious Adverse Drug Reaction (SADR) reporting
  • Existing process is under improvement for Medical Device Incident or Problem (MDIP) reporting
• AHS Vanessa’s Law Task Force
  • Multidisciplinary committee responsible for coordinating the initiative
• Will include a centralized process to receive, review, collate, and submit reports
Alberta Approach

• Communication plan in development
  • Goals: generate awareness, promote understanding of the importance of the legislation, convey the importance of reporting, engage audiences to make the necessary practice changes
  • AHS specific educational resources (e.g. memos, posters, videos, learning module)
  • Landing page on AHS intranet
  • Central email account for questions and follow up
Alberta is implementing a province wide electronic medical record
- All sites will use a single electronic health record after a staggered roll out across the province

- Timeline for Epic – first site goes live in November 2019
- SADR reporting will be integrated into Epic
- MDI reporting will be linked from within Epic, as well as from the AHS intranet
# SADR reporting process in AHS

<table>
<thead>
<tr>
<th>Sites that have implemented Epic</th>
<th>Sites that have not yet implemented Epic</th>
</tr>
</thead>
<tbody>
<tr>
<td>SADR reporting functionality will be fully integrated into the electronic health record</td>
<td>Existing online reporting system (AHS Reporting and Learning System – RLS) will be used</td>
</tr>
</tbody>
</table>
SADR reporting process in Epic

Criteria for a Reportable Serious Adverse Drug Reaction (SADR)

Adverse Effects Following Immunization (AEFI) and Blood Product reactions are reported HERE

Before continuing, please consider whether or not the current adverse drug reaction (ADR) meet both of the following criteria to be considered a serious adverse drug reaction.

The event is:

1. Related to current hospitalization encounter, and
2. Caused or potentially caused:
   a. Hospitalization or prolongation of existing hospitalization
   b. Congenital malformation
   c. Persistent or significant disability or incapacity
   d. Life threatening situation or death

If yes to both 1 and 2 above, please complete the mandatory documentation for Health Canada below. Document the allergy, then complete an ADR note for the patient's event. While nursing and or pharmacy can begin the note, the patient’s attending provider should complete and sign the note.
SADR reporting process in Epic
SADR reporting process in RLS

Reporting & Learning System for Patient Safety (RLS)

- Fall
- Medication or Other Substance
- Laboratory or Blood Products
- Venous Thromboembolism (VTE)
- Pressure Injury/Skin Wound
- Other Patient Safety Event
- Pharmacy Good Catch (Pharmacy Staff Use Only)
SADR reporting process in RLS

What was the medication problem?
- Adverse drug reaction
- Contraindicated
- Damaged product (e.g. faulty package)
- Drug or solution incompatible mixture
- Expired or deteriorated medication / product
- Extra dose

Was the adverse drug reaction serious?
- Yes
- No

A serious adverse drug reaction is a noxious and unintended response to a drug that occurs at any dose and that:
- requires in-patient hospitalization or prolongation of existing hospitalization;
- causes congenital malformation, results in persistent or significant disability or incapacity; or
- is life-threatening or results in death.

* Health Canada - Mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals

Selecting these options will open the serious adverse drug reaction specific questions.
**MDIP reporting process - Legacy**

### Two Teams – Two Streams

3+ forms, 2 teams, 1 Medical Device Hotline (1-888)

<table>
<thead>
<tr>
<th>“Equipment”</th>
<th>“Product”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintained devices</td>
<td>Consumable devices</td>
</tr>
<tr>
<td>• <em>Incidents (harm)</em> typically reported through RLS</td>
<td>• ~23% reported through RLS</td>
</tr>
<tr>
<td>• <em>Problems</em> typically reported by Clinical Engineering via Equipment Feedback form</td>
<td>• <em>Incidents and Problems</em> typically reported through Product Feedback form</td>
</tr>
</tbody>
</table>

*Equipment* and *Product* categories refer to different types of medical devices:
- **Equipment**: Devices that need regular maintenance and are typically owned by the hospital.
- **Product**: Consumables like syringes and catheters that are replaced regularly.

*Incidents (harm)* and *Problems* are generally reported through specific feedback forms.
Updated MDIP process

<table>
<thead>
<tr>
<th>New, Single MDIP Reporting Form (&amp; MDIP Hotline)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• InfoPath Form (eventually stand-alone Datix form)</td>
</tr>
<tr>
<td>• Feed into MDS Teams’ Sharepoint site</td>
</tr>
<tr>
<td>• MDS Teams validate, facilitate, investigate, report</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Epic Locations</th>
<th>Non-Epic Locations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Link on every Epic user’s ‘hyperspace’ to MDIP form</td>
<td>Link on intranet to same MDIP form, feeds same SP site</td>
</tr>
</tbody>
</table>
New MDIP form – four views

Frontline Clinicians

+ MDS Teams

= Health Canada & Vendor
Barcode scanning + UDIs

- Barcode scanning for implants, *to start*
- UDI eventually required all devices (USFDA & HC we hope)

Supply MDIP “Wasted Reason”

- Device problem before or during use
- Cue/double-check that we have not missed MDIP
Thank you!
Questions?
A huge thank you to **GOJO Industries, Inc.** and **HealthPRO** for sponsoring Canadian Patient Safety Week 2019.
#ConquerSilence

#ConquerSilence Campaign is here to stay

Donate your voice: [www.conquersilence.ca](http://www.conquersilence.ca)

Register for upcoming webinars, listen to the podcast and download resources at: [www.patientsafetyweek.ca](http://www.patientsafetyweek.ca)
The educational modules were developed by the collaborating parties:

Health Canada
Institute for Safe Medication Practices Canada (ISMP Canada)
Health Standards Organization (HSO)
Canadian Patient Safety Institute (CPSI)

The presentation provided today includes slides adapted from the educational modules:

More information is available from: