Medical device use and adverse event reporting

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Disclosures

I have no actual or potential conflict of interest in relation to this topic or presentation
Overview of my research

Guideline implementation
• Framework of guideline implementability
• Criteria/considerations for developing guideline implementation tools
• How best to identify, incorporate and report patient preferences in guidelines

Patient engagement / Patient-centred care
• Parkinson’s Disease (MJFF 2017-2018), Ductal carcinoma in situ (CCSRI 2017-18)
• Hospital planning, evaluation and improvement (CIHR 2018-20)
• Implementing patient-centred care for women across the lifespan (MOHLTC 2017-21)

Quality improvement / Patient safety
• Determinants and impact of multidisciplinary teamwork on service delivery (wait times, # visits) in cancer diagnostic assessment programs (CBCF 2012-15)
• Determinants of trauma triage and transfer in higher- and lower-performing hospitals
• Quality indicators for cancer (multiple types), trauma care, public health emergency preparedness
Medical devices research team

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Ariel Ducey, PhD, University of Calgary
Anthony (Tony) Easty, PhD, University of Toronto
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Special thanks to Julie Takata, MSc, University Health Network
Learning objectives

• Define medical devices and adverse medical device events (AMDEs)
• Examine the number of device recalls in Canada
• Review factors that influence:
  • Clinical decision-making for devices
  • AMDE reporting
• Discuss the role of industry representatives
• Assess the implications from the perspective of stakeholders
• Consider next steps for policy, practice, and research
Medical devices

Non-drug technologies or instruments vital to the prevention, diagnosis, cure or treatment of a disease or abnormal physical condition

Class I. Lowest risk

Class II. Low risk

Class III. Moderate risk

Class IV. High risk
Top 3 patient safety incidents in hospitals

1. Active failures, defined as mistakes or deviations from policy (18%)
2. Individual factors such as skill, experience, and attitudes (11%)
3. Design, availability and functioning of medical devices (10%)


Device factors involved in AMDEs

37% to 47% of adverse medical device events (AMDEs) in the United States and United Kingdom attributed to device design, manufacturing, quality control, labeling or packaging

Post-market surveillance

- CIHR 2010-11
- Interviewed 37 stakeholders and held meeting with 47 stakeholders
- No single or multifaceted strategy superior or suitable
- Recommended further exploratory research to describe the context of device use and AMDEs (BMJ Qual Saf 2013)

Identifying optimal postmarket surveillance strategies for medical and surgical devices: implications for policy, practice and research

Anna R Gagliardi,¹ Muriah Umoquit,¹ Pascale Lehoux,² Sue Ross,³ Ariel Ducey,⁴ David R Urbach¹
Informing policy on post-market surveillance

• CIHR 2013-16

• Multi-component study:
  • Describe evidence available to support decision-making
  • Describe device recalls in Canada
  • Describe factors influencing device use and AMDE-reporting
1. Assessment of evidence on devices

RESEARCH ARTICLE

Meta-Review of the Quantity and Quality of Evidence for Knee Arthroplasty Devices

Anna R. Gagliardi¹, Ariel Ducey², Pascale Lehoux³, Sue Ross⁴, Patricia Trbovich¹, Anthony Easty⁵, Chaim Bell⁶, Julie Takata¹, Christof Pabinger⁷, David R. Urbach¹
1. Assessment of evidence on devices

- Systematic review of 265 studies evaluating knee implants published from 1986 to 2014 and involving 59,217 patients found:
  - Many devices were evaluated in only one study
  - Most studies single cohorts, <100 patients, <2 years follow-up
- Patients, physicians, hospitals and payers rely on poor-quality evidence to support decisions about knee implants
# 2. Device recalls in Canada

MEDICAL DEVICE RECALLS IN CANADA FROM 2005 TO 2015

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<tr>
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2. Device recalls in Canada

- Data from Health Canada + data from Medical Devices Active License Listing (MDALL) and Recall and Safety Alerts Database (RSAD)
- 24,849 new devices were licensed from 2005 to 2015
- 5% of 7,226 recalls were judged to have a reasonable probability of serious consequences or death

<table>
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<tr>
<th>Hazard Priority Classification</th>
<th>Class I (N, %)</th>
<th>Class II (N, %)</th>
<th>Class III (N, %)</th>
<th>Class IV (N, %)</th>
<th>Total (N, %)</th>
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<tbody>
<tr>
<td>Priority I (Serious)</td>
<td>34 (3)</td>
<td>123 (4)</td>
<td>143 (5)</td>
<td>54 (12)</td>
<td>354 (5)</td>
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<tr>
<td>Priority II (Temporary)</td>
<td>622 (59)</td>
<td>1598 (55)</td>
<td>1829 (66)</td>
<td>299 (63)</td>
<td>4348 (60)</td>
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<tr>
<td>Priority III (Unlikely)</td>
<td>410 (38)</td>
<td>1175 (40)</td>
<td>822 (29)</td>
<td>117 (25)</td>
<td>2524 (35)</td>
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<tr>
<td>Total</td>
<td>1066 (100)</td>
<td>2896 (100)</td>
<td>2794 (100)</td>
<td>470 (100)</td>
<td>7226 (100)</td>
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Context of device use and AMDEs

- Qualitative interviews with 22 physicians who implanted devices
- 5 provinces; early, mid and later career; community/academic
- Cardiovascular (n=10): accessories (screws, leads), artificial hearts, cannulae, implantable cardiac defibrillators, pacemakers, stents and valves (tissue, mechanical)
- Orthopedic (n=12): accessories (nails, screws, aiming devices), elbow prostheses, hip prostheses (hemi, total), locking plates, knee prostheses (unicompartmental, total), resurfacing caps or cups (hip, knee) and rods (femur, spine)
3. Factors influencing clinical decision-making

Multiple constraints compromise decision-making about implantable medical devices for individual patients: qualitative interviews with physicians

Anna R. Gagliardi¹, Ariel Ducey², Pascale Lehoux³, Thomas Turgeon⁴, Jeremy Kolbusik⁵, Sue Ross⁶, Patricia Trbovich⁷, Anthony Easty⁷, Chaim Bell⁸ and David R. Urbach¹
3. Factors influencing clinical decision-making

- **COMPlexity**
  - Consideration of multiple factors

- **Patient**
  - Lack of patient engagement in device decision-making

- **Evidence**
  - Lack of data on device safety, effectiveness and performance

- **Health System**
  - Limits on devices in stock or specified in purchasing contracts

- **Physician**
  - Lack of physician proficiency on a range of devices; or access to colleagues to discuss devices

- **Market**
  - Few comparable devices on market; reliability of industry representatives

- **Patient Outcomes**
3. Factors influencing clinical decision-making

There is really nothing in the literature that is helpful on this. Everything we do in orthopedics is a beta test. You know how drugs go through phases of testing? There’s nothing equivalent to that in orthopedics. Someone just comes up with what they think is the latest and greatest idea and before long it’s a product and someone does a few [cases] and then it’s just on the market…. Maybe 10 years ago we started to see what are called locking plates and that’s where screws lock into the plate rather than just squeezing the plate against the bone…. So people started putting them in left, right and centre, which caused all sorts of problems because we actually really didn’t understand what they were doing at the biology level. It took 3 or 4 or 5 years to try and figure that out and figure out the modes of failure and what you should do or shouldn’t do. So it’s just one big running beta test
3. Factors influencing clinical decision-making

One of the biggest deciding factors will be cost and not necessarily surgeon comfort, patient anatomy and track record of implant. We’ve had experience that if you force surgeons to change implants based on a contract that your complication rate goes up for a while. That is problematic when it occurs. So it makes good business sense until you actually go and look at your revision costs over the next months to 2 years and then, all of a sudden, all of your cost-savings went into pain and suffering of patients and their subsequent care.

Sometimes the implant you put in is not what you think is the best for the patient because that’s the only thing available through the buying group.
4. Patient engagement in discussions/decisions

Factors constraining patient engagement in implantable medical device discussions and decisions: interviews with physicians

ANNA R. GAGLIARDI¹, PASCALE LEHOUX², ARIEL DUCEY³, ANTHONY EASTY⁴, SUE ROSS⁵, CHAIM M. BELL⁶, PATRICIA TRBOVICH¹, JULIE TAKATA¹, and DAVID R. URBACH¹
Model of person-centred care

- Fostering patient-physician relationship
- Exchanging information
- Responding to patient emotions
- Managing uncertainty
- Making decisions
- Enabling patient-self-management
It’s an important thing in our day and age. This is what’s going in them. They have the right to participate.

At a certain point it becomes absurd. Are we gonna have to discuss what suture material we use? And why we’re using that vendor? The average person is not interested. It’s just too heavy for them to grasp. Maybe I’m very paternalistic. I don’t think I am. An overarching policy of detailed descriptions of different technologies and why we might use one over the other—I’m really not sure that it’s relevant.
4. Patient engagement in discussions/decisions

<table>
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<th>Category</th>
<th>Constraining factors</th>
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| Patient              | • Best fit for physical and demographic characteristics  
                        • Prognosis (life or death scenario)  
                        • Age (device longevity greater than expected patient lifespan)  
                        • Individual desire for PE (most prefer to let physicians decide)  
                        • Capacity to understand complex, technical information  
                        • Well informed about manufacturers/devices |
| Physician            | • Familiarity/comfort with specific device due to training/experience  
                        • Time required to educate patients |
| Health system        | • Fulfilment of purchasing group contracts  
                        • Use of least costly device for same indication |
| Device or device     | • Comparative advantage of different devices for same indication  
                        • Number of different devices available for the same indication |
| market               |                                                        |
Nature of AMDEs

During Surgery
- Manufacturer instructions
- Failure implanting system
- Unexpected behaviour of device
- Broken/unuseable component
- Misaligned/mismatched components
- Poor fit with patient physiology

After Surgery
- Physiological response
  - Thrombosis, blockage, calcification, infection, swelling, muscle dissolution, osteolysis
- Device problems
  - Loosening, unhinging, fracture, breakage, decomposition
AMDE impact on patients

- Longer surgery, increased risk morbidity/mortality
- Revision surgery
- Cardiovascular:
  - Loss of organs or limbs (thrombosis/artery blockage)
  - Death (lack of/too much therapy from wiring/power failure)
- Orthopedic:
  - Impingement, corrosion, disarticulation of joints, fracture or breakage of joints or bones, muscle dissolution, osteolysis, non-malignant tumors, swelling, pain, suboptimal correction of original problem, poor quality of life
AMDE impact on providers

Individual
• Heightened awareness of potential for AMDEs (trial and error)
• Prompted self-reflection on their role in causing the AMDE
• Might switch products, companies
• Stress, annoyance

Hospital/health system
• Wasted/delayed operating room time, nursing time
• Cost of devices that were unuseable
• Effort of identifying patients in whom recalled devices were implanted
5. Factors influencing AMDE reporting

Factors influencing the reporting of adverse medical device events: qualitative interviews with physicians about higher risk implantable devices

Anna R Gagliardi, Ariel Ducey, Pascale Lehoux, Thomas Turgeon, Sue Ross, Patricia Trbovich, Anthony Easty, Chaim Bell, David Urbach
5. Factors influencing AMDE reporting

**Physician Beliefs and Behaviour**
- Perceived responsibility for reporting
- Physician beliefs about what constitutes an AMDE:
  - Expected or unavoidable
  - Occurrence after 2 years expected
  - Less frequent than in the past
  - Only concerning if catastrophic
  - Confounded by multiple factors
- Behaviour in response to AMDEs
  - Employ work around solutions for device limitations
  - Switch to similar devices on market

**Health Care System Capacity**
- Lack of systems for AMDE reporting
- Lack of patient monitoring to identify AMDEs
- Poor documentation of devices in patient records
- Purchasing contracts may stipulate use of AMDE-prone devices

**Motivation to report AMDEs**

**Reporting of AMDEs**

**Industry Responsiveness**
- No feedback from industry to physicians who report AMDEs
- Little impact of AMDE reporting on devices
5. Factors influencing AMDE reporting

Sometimes the implant you put in is not what you think is the best for the patient because that’s the only thing available through the buying group.

The only real monitoring that goes on is we put something in, we follow it up to see whether it healed and the problem went away, so they’re not followed specifically for the implant, they’re just followed by us for the patient in general.

It’s hard to know if it’s the device itself, the way the operator used it, or the way the patient’s anatomy might have changed over time.

Eventually the manufacturer paid attention and then changed the engineering of the device. But that took probably somewhere between two and three years. They’ve invested a huge amount of money in product development and then they’ve got a big back inventory. So if there’s a big cost associated with change, and people have figured out a work around, then there’s a lot less pressure on the company to change.
6. Role of industry representatives

"We can’t get along without each other": Qualitative interviews with physicians about device industry representatives, conflict of interest and patient safety

Anna R. Gagliardi, Pascale Lehoux, Ariel Ducey, Anthony Easty, Sue Ross, Chaim Bell, Patricia Trbovich, David R. Urbach
6. Role of industry representatives

Inform and support purchasing

Convey recalls or warnings

Support troubleshooting

Provide training for new devices

Financial support for R&D, meetings

Surgical support
- Present most cases
- Supply/stock devices
- Proper assembly/use
- Oversee nurses/free physicians
- Liability
- Improve quality of care
6. Role of industry representatives

My rep is there for my cases 95% of the time or more. Sometimes I have questions about a design issue with some of their implants. Other times there will be issues with supplies, we don't have enough of this or that. They're also there to cycle out implants that are reaching their expiry date, and they're there to teach the nurses how to use all the stuff.

I don't like having the reps in the room generally. I want the people who are using the equipment to know it and learn it and there's no encouragement to do that if the people are being spoon fed all the time.

The main thing is to disassociate any sense of obligation toward the rep. I don't take any money from them and, if they all have equal access, then there's no way you can be biased. So I have a good relationship with them. But it's definitely not at arms-length because when I have issues I want to be able to approach them and complain.

There are a number of other companies we use where the representation falls well below the standard and it's well-known. In relationships like that your guard is up, you're always double-checking everything, you're always verifying with other colleagues that have used that system to make sure that you're doing the best you can for the patient.
Limitations

- Generalizability to population of orthopedic/cardiovascular physicians
- Hospital sampling may have revealed additional organizational factors
- Transferrability to settings outside of Canada
Balancing access AND safety

Premarket evaluation
- Timely access to devices
- Reasonable assurance of safety/effectiveness

Regulatory approval

Postmarket evaluation
- AMDEs under-reported
- Patients exposed to unnecessary risk

Data
- AMDEs detected more quickly
- Physicians/hospitals/health systems can make better decisions
- Data is shared with patients so that they are engaged
- Industry more rapidly provided with information for design improvement
Balancing access AND safety

- CIHR 2016-17
- Held one-day national multisector meeting on Nov 3, 2017
- 49 patients with medical devices, researchers, nurses, physicians, and representatives of professional associations, a law firm, a medical-legal insurance agency, health technology assessment agencies, federal government device regulation, research and development hubs, supply chain management services and medical device manufacturers and distributors
- Identified pre- and post-market strategies needed to optimize medical device use and outcomes
Recommended policy and practice

- Mount an organized appeal for federal and provincial funding for R&D and health technology assessment
- Work with federal regulators to fortify regulatory standards based on human factors engineering
- Conduct an environmental scan to describe Canadian registries and other device-related activities/infrastructure
- Develop a strategic plan for a national device registry and reporting system
- Engage with professional colleges and associations to develop medical device continuing professional development opportunities for physicians
- Develop and implement a model of evidence-informed procurement
Recommended research

- Assess AMDE type, frequency, determinants and outcomes including health system and societal costs
- Describe the quantity and quality of evidence that is appropriate for devices in different stages of development (use IDEAL-D framework)
- Examine how to identify AMDEs in administrative data
- Explore patient engagement in device decision-making and reporting of AMDEs
- Investigate physician learning curves on various types of new medical devices to inform the design of continuing professional development programs
Many thanks for your kind attention

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