Patient safety and optimal performance: a holistic framework for medical devices

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WHO publication (Ref. 1) available on the Internet
Key points

focus: regulated products; users = professionals, patients and public

- differences between medical devices and drugs
- 3 essential steps to ensure device patient safety
- 3-stage framework for optimal performance reflecting World Health Assembly Resolution WHA 60.29

- 3-stage framework as simple reference to facilitate education and communication among stakeholders
- design and functioning of complex holistic system for best outcome
## Medical Devices and Drugs

### The Twin with Different Nature

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<tr>
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<th>Medical devices</th>
<th>Drugs</th>
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<tr>
<td>User interface</td>
<td>Device-user-patient</td>
<td>Drug-patient</td>
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<td>Effecting Outcome</td>
<td>User knowledge and <strong>skills</strong></td>
<td>Active ingredients</td>
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<td>Maintenance</td>
<td>Essential</td>
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<td>Facility Planning</td>
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<td>Technical support</td>
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<td>Recurrent Operation</td>
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<td>Operation Budget</td>
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Three essential steps to ensure medical device patient safety

Step 1: Government Product Safety Assessment (medical device regulation)
(Health Canada medical device license for classes 2, 3 and 4)

Step 2: User Contextual Safety Assessment
- Environmental
- Human factor
- etc...

Step 3: User Safe Use and Management
- User training
- Maintenance
- Performance surveillance
Provocative thoughts

- Majority of the public, including healthcare professionals, may not know the scope and limitation of medical device regulations; often they have unrealistic expectations of the regulators’ ability to protect their safety.

- The Government could update the public perception of medical device safety and define user responsibilities.
Three essential steps to ensure medical device patient safety

**Step 1**
Government Product Safety Assessment (medical device regulation)
(Health Canada medical device license for classes 2, 3 and 4)

**Step 2**
User Contextual Safety Assessment
- Environmental
- Human factor
- etc…

**Step 3**
User Safe Use and Management
Cultivate culture
- Informed acquisition
- Responsibility
- Accountability

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Overall Instructions for Use (user responsibility)
Global calls for rational use of medical technology

- To curb soaring global healthcare cost, in 2007, World Health Assembly Resolution (WHA 60.29) calls for rational use of medical technologies highlighting HTA.

- The 3-step diagram can be enriched to guide national or individual policies in safe and optimal utilization of medical devices in line with WHA 60.29.
Handy Policy Framework for Optimal Utilization of Medical Devices

1. Device Market Regulation
   - General assessment with globally harmonized criteria
   - Good Manufacturing Practices

2. Adoption / Selection
   - Focused assessment with user needs and contexts
   - (health policy, safety costs...HTA etc.)

3. Utilization / Disposal
   - Safe effective use Performance surveillance
   - Good Planning and Management Practices

policy equally applicable at national or individual levels
holistic system needs collaboration for best outcome

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interaction and collaboration needed
Stakeholders for Medical Devices
(WHO Ref 1, Figure 3, Page 8)
active ingredients for medical devices

? by linking the isolated stakeholders to collaborate
Active ingredients for medical devices

Manufacturers

Vendor

Government

User

Public/Patient

active COLLABORATION
some suggestions

- Health Canada could explicitly disclose limitation of the device regulations and define user responsibilities.

- Government and industry could encourage informed medical device users and empower them with evidence-based benefits and risk information.

- CADTH could consider including user contextualized environmental and human factors in assessing device safety in HTA projects involving medical devices.

- The public should encourage active collaboration among all stakeholders on the holistic system design and operation for best outcome.
References

   www.who.int/medical_devices/publications/en/MD_Regulations.pdf

   www.regulatoryaffairsmedtech.com

   P49-56, Human Factor Horizons 2010

4. WHO: The World Health Assembly Resolution WHA60.29, 2007  
   http://www.who.int/medical_devices/resolution_wha60_29-en1.pdf