Robotics in Healthcare: What the Future Holds in Standards

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Agenda

- Background on the workshop and its objectives
- Highlights from the breakout sessions
- Conclusions and next steps
Background on the workshop and its objectives

- Standards in the FDA Regulatory Framework
- Definition of a Medical Device
- Workshop Goals and Objectives

Medical Device Regulatory Framework is Based on Risk

Medical Device Classes:

Class I
- General Controls
- Most exempt from premarket submission

Class II
- Special Controls
- Premarket Notification [510(k)]

Class III
- Premarket Approval [PMA]

Additional Classification:

Evaluation of Automatic Class III Designation (De Novo)
- Device "types" that have never been marketed in the U.S., but whose safety profile and technology are now reasonably well understood

Humanitarian Device Exemption (HDE)
- Devices for orphan diseases intended to benefit patients in diagnosis and/or treatment of disease or condition affecting or manifested in fewer than 4,000 patients per year in the United States
FDA and Consensus Standards

• FDA is authorized to recognize all or part of national and international standards through publication of a notice in the Federal Register. Manufacturers may be able to declare conformance to recognized standards and not be required to be submitted in the 510(k).

• FDA has recognized approximately 900 standards. A current list of FDA recognized standards and guidance on the recognition and use of consensus standards can be found on CDRH's Standards website.

FDA and Consensus Standards

• Conformance with recognized consensus standards may not always be a sufficient basis for regulatory decisions.
  – A specific device may raise a safety or effectiveness issue not addressed by any recognized consensus standard.
  – A specific FDA regulation may require additional information beyond what conformity to the recognized consensus standards provides.
Medical Device Definition

• The term "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:
  – (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
  – (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  – (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

ISO robot standardization activities

Gurvinder S. Virk
Chairman of ISO TC 184/SC 2/WG 7 (Personal care robot safety)
Professor of Robotics, School of Engineering and Advanced Technology, Massey University, WGN, NZ
Chairman, CLAWAR Association Ltd, UK
New service robots

Passenger Robots
- i-foot (TOYOTA)
- Swing (Waseda Univ.)

Surgery Robots
- Regina-JR (Japan Logic Machine)
- GUIDO (Haptica)

Care Robots
- CARE-O-BOT (Fraunhofer-IPA)

Domestic Robots
- Roomba (iRobot)
- Automower (Electrolux)

Changing face of ISO robot standardization

ISO 9946 — Presentation of Characteristics
ISO 10218 — Safety
ISO 9409-1 — Mechanical Interfaces

ISO 10218 — Safety of industrial robots
ISO 8373 — Updated Vocabulary
ISO xxxx — Safety of robots in personal care
So what is a robot?

- **Robot**: First used by Czech writer Karel Capek in a play entitled Rossum’s Universal Robots in 1921. Capek’s robots were hard-working humanoid machines. The word derives from robota, the Czech word for slave labourer.
- **Robotics**: The term robotics, meaning the technical field encompassing robot technology, was first used by Isaac Asimov in 1942 in a short story entitled Runaround.
- **No “official ISO” definition of robot**
- **Official ISO definition (ISO 8373)**: An industrial robot is an automatically controlled, reprogrammable, multipurpose manipulator, programmable in three or more axes which may be either fixed in place or mobile for use in industrial automation applications.
- **Current trends**: Term “robot” is now being used for systems that have “motion” and “intelligence” rather than being “multi-purpose” as defined in ISO 8373.

### Industrial/ Service robots

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<tr>
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<th>Industrial Robots</th>
<th>Service Robots</th>
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<td><strong>Working environments</strong></td>
<td>Controlled and defined environments</td>
<td>Information structured/ unstructured environments</td>
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<td><strong>Users</strong></td>
<td>Training for specified tasks in defined environments</td>
<td>Training to cover wide range of tasks in info structured/ unstructured environments</td>
</tr>
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<td><strong>Safety</strong></td>
<td>Machine dependant</td>
<td>Dependent on the robot and the user</td>
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<tr>
<td><strong>Working philosophy</strong></td>
<td>To keep robots and humans separated (see ISO10218-1)</td>
<td>Robots and humans must share workspace for providing/ receiving the services</td>
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<tr>
<td><strong>Machine design</strong></td>
<td>Flexible on commissioning</td>
<td>Flexible on demand</td>
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Translated from Czech:

- **Robot**: První použití českým spisovatelem Karlem Capekem v hře Rossumův Univerzální Robotic v roce 1921. Capekův robot byl tvrdokraký člověkem, ktorý učí programovateľný, všestranný manipulátor, programmovateľný v tri alebo ďalšie osi, ktorý môže byť pevný v mieste alebo mobilný, ktorý je používateľom v průmyslovej automatickej aplikácii.
- **Robotika**: Term robotika, znamenajúce technickú oblast robota, bol prvýkrát použitý Isaacom Asimovom v roce 1942 v novine Runaround.
- **Nie existuje oficiálna ISO definícia robota**
- **Oficiálna ISO definícia (ISO 8373)**: Prúdový robota je automaticky ovládaný, určite reprogramovateľný, všestranný manipulátor, programmovateľný v tri alebo ďalšie osi, ktorý môže byť pevný v mieste alebo mobilný, ktorý je používateľom v průmyslovej automatickej aplikácii.
- **aktuálna tendencia**: Term “robot” je dnes používaný pre systémy, ktoré mali “pohyb” a “inteligencia” až údajne “všestranný” podľa definície ISO 8373.
Latest ISO robot definitions

- **robot**: actuated mechanism programmable in more than one axis with a degree of autonomy, moving within its environment, to perform intended tasks
- **service robot**: robot that performs useful tasks for humans, society or equipment excluding industrial automation applications
- **autonomy**: ability to control movement and communication to perform intended tasks without human intervention
- **personal care robot**: service robot with the purpose of aiding actions or performing actions that contribute directly towards improvement of the quality of life of individuals
- **medical robot**: a robot or a robotic device intended to be used as a medical device

Workshop Goals and Objectives

- **Definitions and Boundaries**
- **Identification of Gaps**
- **Future Directions**
Highlights from the breakout sessions

- What are the boundaries between medical and non-medical applications as well as within the categories of surgical, transport and personal care?
- What aspects of medical care robots are amenable to standardization and what are the priorities and the timeframe for this work?
- What other areas of robotics are still emerging but poised to soon move into clinical trials?
- Surgical robots: What is a surgical robot within the definition and boundaries set earlier? What are the most significant standards needs – necessary and achievable to fill the gaps?
- Transport robots and Personal care robots: What are transport and personal care robots within the definition and boundaries set earlier? What are the most significant standards needs – necessary and achievable to fill the gaps?
- What risk paradigm is appropriate for a medical care robot and what are the risks that need to be managed?

What are the boundaries between medical and non-medical applications?

- The boundaries between medical and non-medical applications really depends on three things:
  - The intended use, the intended use, and the intended use.
What risk paradigm is appropriate for a medical care robot?

- **Factor to consider:**
  - **Motion** – actuated mechanism programmable in more than one axis and moving within its environment.
  - **Autonomy** – Level of human involvement in overseeing the operation of the robot or robotic device both in normal operation and particularly when there is a problem or fault in the system.
  - **Intelligence** – Built in expert knowledge or skill to allow an operator (or perhaps no operator at all) to perform tasks with less skill/knowledge than would be required of a human performing the same task on their own.

- **These considerations are not unique to medical care robots. They are seen in other applications such as systems employing physiologic closed-loop control*. However, robots and robotic devices bring them all together in one environment.**

*See IEC 60601-1-10:2007, Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers.

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What risk paradigm is appropriate for a medical care robot?

- **The breakout session briefly examined three risk paradigms currently available in accepted international standards:**
  - **ISO 14971, Medical devices – Application of risk management to medical devices:** Standard already in wide use in the medical device sector and recognized by FDA and harmonized in the EU.
  - **ISO 31000, Risk management – Principles and guidelines:** A 2009 standard describing a life-cycle process applicable to a wide range of activities, including strategies and decisions, operations, processes, functions, projects, products, services and assets.
  - **IEC 61508 Series, Functional safety of electrical/electronic/ programmable electronic safety-related systems:** Family of standards dealing with industrial process measurement and control and IT applications in industry including design automation.

- **The breakout session concluded that ISO 14971 is an appropriate paradigm for medical care robots.** Manufacturers have already successfully applied this paradigm to medical robotic devices including surgical robots currently on the market.
What other areas of robotics are still emerging?

- Broad taxonomy of systems, e.g.,
  - Hospital Logistic Systems
  - Assist Devices
  - Therapy Augmentation Devices (Surgeon; Other caregivers)
  - Patient-Augmentation Devices
  - Decision-Support Devices
  - Autonomous-Action Devices (Surgical; Care-giving)

- Some themes
  - Some products in all these areas already, but new technology and capabilities emerging in each area
  - Common to all: Increasing levels of autonomy
  - Common to all: Increasing complexity / role of information
    - Need for integration of “robot” into complex systems environment
    - Need for standards & practices for information capture
  - Common to all: Validation of advantage from technology
  - Common to all: Training standards

Integration: Information-Intensive Interventional Suite

Data Logging & Summary
Logistics & Scheduling
PACS, other patient data bases

Imaging systems
- X-ray, US, CT, MRI, etc.

Assistant Workstation

Surgeon Interfaces

Anesthesia, vital signs, logistics, back table, etc.

OR video

Robots

1) Breakout Session C: Report by M. H. Taylor, Engineering Research Center for Computer Integrated Surgical Systems and Technology
What aspects of medical care robots are amenable to standardization?

• **Safety**
  – Concerns
    • Injury to patients
    • Injury to medical personnel
    • Damage to itself or other equipment
  – Emergency Procedures / Risk Control Measures *
  – Risk Assessment

• **Security and Privacy**
  – Unauthorized tampering / Security of the interface
  – Security of personal information

• **Performance / Effectiveness**
  – Common framework for accuracy (coordinate systems) *
  – Reliability *
  – Versioning
  – Validation / Verification *
  – Reusability / sharing

* Unique (or most relevant) to medical care robots.

What aspects of medical care robots are amenable to standardization?

• **Environment**
  – Classification of the environment
  – Compatibility with the environment / Sterilization *

• **Training and Certification**
  – Certification of the human operator *
  – “Mental Models” of the state of operation of the system *

• **Control / Control Methods**
  – Software *
  – Hardware *
  – User programmability/customization *
  – Autonomous adaptation *

* Unique (or most relevant) to medical care robots.
What aspects of medical care robots are amenable to standardization?

- **Interoperability / Integration**
  - Interface with other devices and external data *
    - Real-time quality of service (QoS) requirements
    - External (non-real-time) information
  - User Interfaces *
  - Management/integration of components of the system *
  - Sources of information, what is recorded, what is archived and how it is accessed (black box) – event correlation (for distributed devices) *
  - Health maintenance (device self-awareness/self-diagnostics/prognostics) *
  - Common ontology *

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- **Conclusions and next steps**
  - Robotics is moving to a new era: Service Robots aimed at mass markets
  - New technologies need to be developed to meet the requirements of this new sector where close human-robot interaction is needed
  - Safety standards are needed urgently to assist rapid development:
    - ISO non-medical personal care robot safety standard due to be published in 2011
    - Medical care robot safety standards: work started in 2009, due to progress approximately 2 years behind non-medical robot work
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- Presentations, breakout sessions reports, and other documents from the workshop are available to the public at:
  http://mdpnp.org/FDA_Workshop_on_Robots.html

* The website is sponsored by the Medical Device "Plug-and-Play" Interoperability Program (MD PnP™), Julian M. Goldman, MD, Director. For more information on MD PnP™ see: http://mdpnp.org/Home_Page.php

Thank you for your attention!

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