Pursuit of Safe and Effective Imaging and Radiation Therapy/Planning Products

Monday, 7/30/2018, 4:30 PM - 6:00 PM
Room: Room 209

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Imaging and Radiation Therapy Devices circa 2018

- High technical complexity
  - Multiple systems (software and hardware)
  - A few parameters to several hundred parameters compounded by interconnectivity and interoperability challenges
- Limited to non-existent guidance/standards when technologies are introduced
  - Pressure to bring new technologies into clinics as soon as possible
- Stressful and high pressure work environment
  - Decreased resources and increased workload
- Complex clinical workflow
  - Potential for failures

Challenges

1. Safety
   - Complex and intricate information flow and handoffs. Poor hardware/software integration, inadequate QA, inadequate training of healthcare professionals, poorly-defined clinical workflow, non-adherence to established clinical practice standards, and ambiguities in decision making process

2. Lack of interoperable and interconnected devices
   - Complex, inconsistent interfaces, and non-uniform implementation of DICOM and HL7 standards by vendors.

3. Paucity of efficacy and effectiveness data
   - Complex treatment and imaging techniques have become the standard of care without systematic collection of high-quality evidence of improved efficacy and effectiveness.
IOM Recommendations*

• The FDA should seek information to develop an integrated premarket and postmarket regulatory process that can provide reasonable assurance of safety and effectiveness throughout the device life cycle. The attributes of such a process are:
  – be based on sound science
  – be clear, predictable, straightforward, and fair
  – be self-sustaining and self-improving
  – be risk-based
  – facilitate innovation that improves safety and effectiveness of devices throughout their life cycle
  – Apply relevant and appropriate regulatory authorities and standards throughout the life cycle of devices to ensure safety and effectiveness

* Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years, July 29, 2011

IOM Recommendations*

• The FDA should develop and implement a comprehensive strategy to collect, analyze, and act on medical-device postmarket performance information. Such a strategy should meet the following objectives:
  – provide performance information for use in the premarket review process
  – manage the risk-benefit ratio throughout the life cycle of devices better
  – inform the design of a new regulatory framework
  – Evaluate unacceptable risks to consumers, try to remedy the situation, and to sanction the violators

* Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years, July 29, 2011

IOM Recommendations*

• The FDA should develop and implement a program of continuous quality improvement to track regulatory decisions, identify potential process improvements in the regulatory framework, and address emerging issues that affect decision making.
• The FDA should develop procedures that ensure the safety and effectiveness of software used in devices, software used as devices, and software used as a tool for producing devices.
  – Develop guidance on software validation

* Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years, July 29, 2011
Session Speakers

1. Radiotherapy Product Development; from Concept to a Clinical Device: C. Zankowski*
2. Imaging Product Development; From Concept to a Clinical Device: E. Angel*
3. Quality Assurance Product Development; From Concept to a Clinical Device: W. Simon
4. MITA’s Role in the Development of Safe and Effective Imaging and Radiation Planning and Delivery Products: P. Hope*
5. FDA’s Role in the Regulatory Clearance of Safe and Effective Imaging and Radiation Planning and Delivery Products: W. Jung*
6. RO-SSI’s Role in Facilitating Safety Improvements in Radiotherapy: R. Siochi*