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

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

C Zankowski, E Angel, W Simon, P Hope, W Jung, & R Siochi
J Palta (Moderator)

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*