Introducing Medical Technology into the Clinical Setting: Case Study of the Process

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Background

Definitions
- What is a new **"medical technology"**
  - Drug, device, technique, process of care
- What defines a **medical device**
  - Used for: diagnosis, treatment, prevention of disease
  - Does **not** achieve purpose through chemical actions

FDA Role
- Ensures safety and efficacy
  - 500,000 different devices
- Monitoring adverse events
  - Annually receives: 80,000-120,000 reports

Financial considerations
- Medical device industry market: $130 billion
- 2/3 of academic institutions hold equity interests in companies that sponsor research at that institution

Goals

- Examine **patient safety and outcomes** during the introduction of HIPEC into a physician's practice
  - *Investigate*:
    - **Approval** process of a device
    - **Training** provided by a medical technology company
    - **Monitoring** of outcomes and adverse events

Methods

- Literature review
- Internet research
- Interviews
- Observing HIPEC usage
- IRB submission for retrospective chart review at RIH for patients who received HIPEC in past 2 years
  - Demographics, overall morbidity and mortality, survival rates

Results

Device Approval
- ThermaSolutions submitted a 510(k) application for its Thermo-Chem-HT system
  - Demonstrated "**substantial equivalence**" to previously FDA approved devices
  - Stated **intended use** of device
  - Classified as Class II Device

Training
- ThermaSolutions training support
  - RIH training sessions
    - To: perfusion staff, nurses
    - Topics
      - Equipment set-up, usage and monitoring
      - Chemo handling and disposal
    - Length: 30-60 minutes
  - Availability for cases
    - Guarantees coverage for initial 3-5 cases
    - Available for additional cases upon request
    - Additional consultation and service support

Monitoring
- Patient outcomes
  - Overall morbidity, mortality, survival rates
    - National averages as basis of comparison
    - RIH site example reports favorable outcome data compared to national averages
      - IRB submission for site specific example will allow more detailed examination
- FDA adverse event reporting
  - MedSun and MAUDE Reports
    - Screen froze
    - "Potential for patient harm"

Discussion

Approval
- "**Least burdensome**" approach to provide data necessary to demonstrate safety and efficacy
  - 510(k) applications/yr: 4000
  - Premarket Approval applications/yr: 100
  - **Benefits**: 510(k) process costs less and faster
  - **Concerns**: Less rigorous data on safety and efficacy required via 510(k) process

Discussion

Training
- Important and potentially preventable risk factor
  - Insufficient training on using a new technology can lead to poor patient outcomes
  - System issues
    - Lack of standardization
    - Lack of accreditation
- Company provided training
  - **Benefits**: Specialized knowledge
  - **Concerns**: Quality of training
  - Possible solution: 3rd party instructor

Monitoring

Patient outcomes
- Appropriate comparison
- Patient selection criteria
- **Concern**: Lack of large scale randomized control trials before widespread use of new technology

FDA post-market surveillance
- Relies on: manufacturers, medical facilities, patients
- **Benefits**: identify uncommon but serious adverse events
- **Concerns**: Passive, no standard threshold for intervention

Conclusions

- The "**least burdensome"** approach for **approval** may not always provide robust pre-market data for device safety and efficacy
- Industry is in a unique position to provide **training** for its devices
- **No** standardization or **accreditation** of training programs
- Monitoring patient **outcomes** and reporting **adverse events** are not standardized and can be inadequate
- Potential for bias, conflicts of interest exist at diverse levels.

Limitations and Future Directions

- **Generalization**: One experience of one doctor
- **Complexity** of problem: Not extensive review of process
- Outcome assessment: size of case load used for basis of comparison to detect meaningful differences
- Health care provider **surveys**
  - Training provided by device companies
  - Post-market surveillance reporting adherence
  - Consultant contracts with companies