Software Regulation:
The Transfusion Medicine Experience

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Founded 60 Years Ago, BloodCenter of Wisconsin seeks to advance patient care by delivering life-saving solutions grounded in unparalleled medical and scientific expertise.
Blood Center of Wisconsin

Rodeina Davis – Sept. 10, 2009
Relevant Background

- 20 years experience as Chief Information Officer at 3 large blood centers
- Member of IT Executive Council of International Society for Blood Transfusion (ISBT)
- Participated in creating and adoption of an international consensus standard for blood banking data definition and data structure
- Worked with regulatory agencies and industry to develop & improve IT use in transfusion medicine
- Chaired 2 task forces to develop international industry guidelines for security and RFID
- Member of Biovigilance Working Party to develop national surveillance system for transfusion medicine
- Developed systems with 510(k) premarket approval from FDA
Transfusion Medicine

Transfusion medicine is a segment of healthcare comprised of blood centers and hospital transfusion services.

- Blood centers collect, process, and distribute blood products to hospitals
- Transfusion services cross match, issue, and transfuse blood products to patients

Both function under direction of transfusion medicine physicians.
Software as a Medical Device

- Software used in both blood centers and transfusion services is highly regulated.
- The software is considered a Class II medical device requiring 510(k) premarket notification.
- No other software used in healthcare or pharma requires 510(k).
Regulation of Medical Devices

Is it a medical device?

- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article including any component, part, or accessory which is … intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease … *

- Is it in interstate commerce/commercial distribution?

- Is the data transmitted or accessed across state lines?

*Section 201(h) of the FD&C Act
Medical Device Classification (by risk)

**Class I** - General controls alone are sufficient to provide reasonable assurance of safety and effectiveness

**Class II** – General controls alone are insufficient to provide reasonable assurance of safety and effectiveness and there is sufficient information to establish special controls – 510(k) applies

**Class III** – Insufficient information that general or special controls will provide reasonable assurance of safety and effectiveness, i.e., there is no predicate
Questions to Ask

- Why and how did our software become highly regulated?
- What are the benefits?
- What are the unintended consequences?
- Are the benefits of 510(k) worth the risk of unintended consequences?
- Are there alternative ways to ensure both the confidence of the regulators and the needs of our industry?
Why and how did our software become highly regulated?

- Major recall & several major incidents in early 1990s involved poorly designed and unvalidated software
- In response, FDA issued memo ascribing responsibility to transfusion medicine establishments
- Our industry had little understanding of or investment in IT, depended on software vendors, and was unable to enforce vendor software quality
- Industry leadership requested that the FDA regulate blood banking software as a medical device
- March 31, 1994 – FDA issued memo that software used in blood establishments is a medical device and will require 510(k) premarket notification
What are the benefits?

- Gives FDA authority to intervene to correct problems
- Moves system error responsibility from users to vendors
- Early identification of defects in software products
- Substandard software/vendors no longer in market
- Safety of software on the market improved (80% survey response from industry members – July 2008)
Unintended Consequences

- Introduced market barriers
- Slowed down time to market for improvements and upgrades
- Inhibited introduction of new technology
- Created misconception of intent
- Increased costs for the vendor and industry
- Placed boundaries on vendors and products
- Made integration of systems difficult or almost impossible
The “Worth” Question

State of our industry has changed since regulation was requested 14 years ago
- Quality systems in place
- Clear understanding of verification & validation
- IT leadership is part of best practices
- Automation has improved but complicates what we do
- Business decisions and patient care rely on shared information from multiple systems

Are the benefits of 510(k) worth the risk of unintended consequences?
The “Worth” Question

This question was examined at a conference July 10-11, 2008 with FDA, software vendors, blood centers, hospital transfusion services, etc.

- Benefits in first 10 years of regulation outweighed unintended consequences
- Lack of integrated solutions in the last 4 years have promoted adoption of suboptimal alternative solutions that are:
  - more error prone
  - less cost-effective
- Our industry has not seen the benefits of widely adopted technologies in other industries in the last 4 years

Are the benefits of 510(k) worth the risk of unintended consequences?
Alternatives

- Refine definitions of portions of software that must be regulated
- Streamline 510(k) submission process
- Standardize interfaces between systems so 510(k) amendment not required
- Establish discussion forums: FDA, vendors, and industry
- Reconsider classification of software as Medical Device Class I, not requiring 510(k)
Conclusion

- While our industry benefitted from regulation for a period of time, the same regulation is a deterrent to adoption of new technology and innovation.
- At this point our industry would benefit more from regulation oversight without the 510(k) process:
  - No adverse impact on safety and effectiveness
  - Reduced risk of work-arounds
  - Improved availability of software solutions and technology
  - No impact on patient safety
- Be careful what you ask for; it is almost impossible to remain agile in a regulated environment
Links

Deciding When to Submit a 510(k) for a Change to an Existing Device
http://www.fda.gov/cdrh/ode/510kmod.html

Premarket Notification (510(k))
http://www.fda.gov/CDRH/DEVADVICE/314.html

510(k) Blood Establishment Computer Software (list)
http://www.fda.gov/cber/products/510ksoft.htm

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
http://www.fda.gov/cdrh/ode/guidance/337.html