BRIEF HISTORY OF MEDICAL DEVICE INTEROPERABILITY ACTIVITIES

Medical Information Bus ("MIB") 1982-1984
- First well-known effort to develop medical device-specific communication standard and supporting hardware.
- Focused on intravenous infusion devices and RS-232 hardware.
- Not adopted by medical device manufacturers due to low clinical demand, complexity, and proprietary hardware requirements.
- Main institutional proponents were:
  > LDS Hospital (Salt Lake City, UT; ongoing)
  > Mayo Clinic (Rochester, MN; abandoned)
  > MGH (Boston, MA)

IEEE 1073 (1991-present)
- Family of standards formed to build on MIB concepts.
  > Technically, non-standardized MIB focused on "lower layers" of the networking stack.
  > IEEE 1073 initiated efforts to standardize and improve "lower layers" while adding work on "upper layers" (referring to a 7 layer ISO communication model).
  > "Black boxes" to convert RS-232 to new standard hardware and protocols.
  > While officially designated 1073, the historical but imprecise MIB moniker persists.
- ISO 11073: Transition of 1073 to an ISO (international) standard mainly due to broader European involvement and government requirements.
  > Reflects further harmonization with ISO/CEN standards.
  > Work continues in IEEE 1073 committees, then "elevated" for international ISO approval as 11073.
- Recently, work continues on 1073 and has accelerated.
  > Early lower layers have been superseded, new "lower layer" transports have been defined, and new proposals are under consideration.
  > Still no motivating Supply-Demand Market
- Adoption and promotion of 1073 by medical device manufacturers has been slow.
- User knowledge and demand are almost nonexistent.

HL7 (Health Layer 7)
- HL7 is a standards developing organization that is best known for standards that are used to communicate patient data between clinical information systems at the application level, the "top layer" of the 7 layer ISO model. (see www.HL7.org)
- Lacking device connectivity
  > Never intended for Point-of-Care devices and monitors
  > To fill that need, IEEE 1073 meetings have been scheduled concurrently for cooperation since 1999.

ASA 1994 Scientific Exhibit
- An automatic anesthesia record keeper (Bicker and Gage, SUNY Stony Brook)
  > Standard device interfaces (unique, medical device only cable connector)
  > Manufacturer independence
- Live demonstration of Plug-and-Play
  > An "Aha!" experience for a few hundred viewers.

Medical Device Plug-and-Play Program (MD PnP)
The MD PnP program is a multi-disciplinary, multi-institutional program started in early 2004 (initially as ORF PnP for "OR of the Future" plug-and-play) to support the development and adoption of clinically grounded solutions for medical device interoperability. Clinical scenarios are being elicited from clinicians and clinical engineers to identify settings in which patient safety and healthcare efficiency could be improved by seamlessly integrating medical devices. MD PnP connectivity will support comprehensive data acquisition by the EMR and safety interlocks to reduce errors. The MD PnP lab opened in May 2006 to evaluate technical solutions to clinical scenarios. (see www.mdpnp.org)

ICEMan
The MD PnP program has defined functional elements of an “ecosystem” to support the safe implementation of medical device integration. The proposed ICEMan (Integrated Clinical Environment Manager) standard includes requirements for “black box” recording of data, security and authentication, and a “plug-and-play” architecture.

IHE
The Integrating the Healthcare Enterprise initiative (IHE) has been defining data transmission requirements to support clinical and enterprise workflow. IHE identifies existing standards, but does not create new standards. In 2005, IHE started work on point-of-care devices to EMR connectivity. Initial work is concentrating on transfer of patient ID and physiological data (not including waveforms). See www.ihe.net.