Eliciting Clinical Requirements for the Medical Device Plug-and-Play (MD PnP) Interoperability Program

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In early 2004, a multidisciplinary, geographically distributed team initiated a program to lead the development of medical device interoperability standards. Participants in the May 2004 kick-off meeting concluded that identifying clinical requirements for improving safety and healthcare efficiency is essential to enable development of technical specifications for connectivity/interoperability standards.

An open session at the 2005 annual meeting of the Society for Technology in Anesthesia (STA) was organized to elicit requirements from meeting participants. Guidelines for participation were developed by a team that included the authors and 4 medical industry experts: R. Clark, J. Robinson, R. Tham, and A. Abramovitch:

> *"Assume that there are no technical, economic, legal, or regulatory obstacles to deploying a comprehensive PnP system:*
>
> 1. What clinical challenges exist today that could be solved by the proposed system?
> 2. Which obstacles to safety, efficiency, and teamwork could be reduced or eliminated by the proposed system?
> 3. How would this approach affect the practice environment?
> 4. What risks may be introduced by a PnP system, and how could they be mitigated?"

Approximately 50 clinicians, engineers, and other domain experts participated. The interactive session generated 80 high-level clinical requirements that were condensed post-hoc into 30 unique requirements. Subsequently, the requirements were incorporated into a specification template with the following headings: Clinical Scenario, Current Hazards, Desired State, and Future Hazards. A report-back of the original requirements expanded into the template is planned for the MD PnP working group session at the 2006 STA annual meeting.

STA annual meeting program: http://www.anestech.org/meetings_staannual.htm
MD PnP program information: http://www.mdpnp.org