

ECRI Institute Statement

Clinical Operations Working Group

Health IT Standards Committee

March 28, 2011

I am Vice President for Health Technology Evaluation and Safety at ECRI Institute. ECRI Institute is a nonprofit health technology, patient safety, and research organization that is dedicated to bringing the discipline of applied scientific research to discover which medical procedures, devices, drugs, and processes are best for enabling improved patient care. We appreciate the opportunity to provide our perspectives in the UDI portion of today's meeting.

ECRI Institute has a tremendous amount of experience with medical technology. Next month we will be publishing the fortieth anniversary issue of our *Health Devices* journal. *Health Devices* is known for its comparative evaluations of medical devices. Our evaluations are often compared to those published in *Consumer Reports*. Recent evaluations have begun to assess the interoperability-related performance and features of medical devices. *Health Devices* also includes guidance articles on a wide range of health technology planning, management, use, and safety topics. We are currently developing an "interoperability resource center" on the member section of our Health Devices System website with a variety of tools and information intended to help healthcare organizations better plan for and manage interoperability. *Health Devices* has recently received national attention for its article on our Top Ten List of Health Technology Hazards. Item 5 on our list which covers data loss, system incompatibilities, and other health IT complications, is directly related to today's meeting.

A major part of the mission for ECRI Institute has been to create and maintain the Universal Medical Device Nomenclature System or UMDNS. UMDNS is now over 40 years old. Our UMDNS efforts also support our work for international organizations like World Health Organization, for which we are a Collaborating Center for Patient Safety, Risk Management and Healthcare Technology. We license UMDNS free of charge to regulatory agencies, hospitals and health systems, manufacturers, and distributors worldwide. Our nomenclature is, by far, the most used medical device nomenclature system "on the ground" in the U.S. healthcare system. It has been honed over the decades to be useful in practice, not just in theory. UMDNS is relied on by thousands of hospitals to support procurement, asset management, hazard and recall tracking, other patient safety purposes, indexing of literature, spend analysis, quality improvement, and systems-level benchmarking. Currently, there are more than 2,300 licensee organizations in more than 100 countries. One license agreement can represent individual users or entire hospital systems. For example, the US Veterans Health Administration recently signed a VA wide license for all of its facilities.

Applications utilizing UMDNS have been developed by group purchasing organizations like Premier, and by the Department of Defense (DOD) for its Defense Medical Logistics Standard Support (DMLSS) system, which is deployed worldwide. UMDNS is also being incorporated into the Veterans Health Administration asset management system. ECRI Institute has recently begun to work with most of the capital medical equipment maintenance management systems (CMMS) vendors to integrate UMDNS into their applications. These vendors include EQ2 Inc., Four Rivers, IBM, Maintenance Connection, Phoenix Data Systems, St. Croix Systems, TMA Systems, and Vision Facilities Management. One of the functions enabled by the CMMS vendors is an automated look-up of their customers' inventories matched against UMDNS to identify product recalls.

From an informatics perspective, UMDNS is an ISO-designated standard taxonomy and coding system, and has been in the Unified Medical Language System (UMLS) for nearly 20 years. It was recommended by the Institute of Medicine Committee on Data Standards for Patient Safety. ECRI utilizes UMDNS as a central organizing concept for all of our device-related information products and databases, including our many patient safety applications. As a contractor to the Agency for Healthcare Research and Quality (AHRQ), we use UMDNS to encode device-related concepts in the National Guideline Clearinghouse and the National Quality Measures Clearinghouse.

In addition to its coverage of medical devices and supplies, clinical laboratory equipment and in vitro diagnostics, genetic tests and selected hospital furniture, systems and test equipment, UMDNS has had significant growth in the healthcare IT area. There are over 560 preferred terms tagged with the Healthcare Information Technology specialty attribute. These cover clinical devices ranging from workstations, transmitter/receiver systems, computer-aided detection systems, monitors and the software required for their varied uses to various types of information systems used throughout hospital systems to more general computer equipment such as network devices, and printers.

Internationally, UMDNS is used by manufacturers for product registration, by ministries of health for many purposes, by WHO in its tool for resource allocation in developing countries, and in Asia as the foundation for the Asian Medical Device Nomenclature System.

ECRI believes that with so many healthcare organizations and other stakeholders relying on UMDNS to maintain the accuracy and consistency of device terminology, within their organizations, across systems, and beyond, it is critical that UMDNS be an integral part of future technology-related standards efforts like UDI. Otherwise healthcare organizations will take

years to adapt their various databases to other conventions at an extreme cost in dollars and to patient safety.

Thank you very much.