

NEWS

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September Plenary Meeting

to Feature HL7 Founding Chair Sam Schultz and Director of the Office of Interoperability and Standards Dr. John Loonsk

HL7's 20th Annual Plenary Meeting bears the theme: *HL7 Standards: Past, Present and Future.* This year's Plenary program commemorates the 20th anniversary of HL7 with an enlightening look at HL7 as an organization and its enduring relevance in healthcare IT. The Plenary session will take place on the morning of Monday, September 11, 2006 at the Boca Raton Resort and Club in Boca Raton, FL, and will kick-off the HL7 September Working Group Meeting.

We are pleased to welcome the founding chair of the HL7 Board of Directors, Sam Schultz, PhD, as our keynote speaker at the Plenary session. During his presentation, 2006: A Standards Odyssey—Somewhere in Time, he is



Sam Schulz

expected to share his reflections on the early years of HL7 as well as his thoughts on the qualities that have allowed the organization to have such a lasting impact in the health-care standards arena.

In addition, Director of the Office of Interoperability and Standards at the Office of the National Coordinator for Health Information Technology (ONCHIT) John Loonsk, MD, will be presenting an overview of



John Loosk

the HITSP use cases. He is expected to review the current status of the American Health Information Community (AHIC) breakthrough cases as defined for implementation by HITSP and the importance of standards to the viability of the use case solutions.

The Plenary session will once again include the HL7 State of the Union Address, to be delivered by Chair Chuck Meyer and International Representative Kai Heitmann, MD. In addition, there will be a panel discussion highlighting how HL7 supports international, national and regional interoperability. This panel will be moderated by John Loonsk, MD and will feature representatives from the four consortia developing prototypes for a National Health Information Network (NHIN). It will also highlight various international projects from Canada, France, the Netherlands and the UK.

Please see page 2 for a detailed agenda. We invite you to attend and look forward to another fantastic Plenary meeting. To register for the 20th Annual Plenary and Working Group Meeting, go to www.HL7.org and click on the Boca Raton icon at the top of the home page. Early Bird registration ends August 14, while online registration ends August 21, after which point registration is available onsite only.

HL7 Standards: Past, Present and Futur

HL7 Standards: Past, Present and Future Monday, September 11, 2006



8:30 - 8:35 am

Welcoming Comments

Mark McDougall, Executive Director, HL7

8:35 - 9:15 am

State of the Union Address

Chuck Meyer, Chair, HL7 Board of Directors *Kai Heitmann, MD*, International Representative, HL7 Board of Directors; Chair, HL7 Germany

9:15 - 9:45 am

Keynote Address:

2006: A Standards Odyssey - Somewhere in Time

Samuel Schultz, PhD, Founding Chair of the HL7 Board of Directors (1987); Principal and Co-Founder, Cardinal Consulting

9:45 - 10:30 am

HITSP Use Case Standard

John W. Loonsk, MD, Director, Office of Interoperability and Standards, Office of the National Coordinator for Health Information Technology

10:30 - 11:00 am

Break

11:00 am - 12:30 pm

Panel Session

HL7 and International, National and Regional Interoperability

Moderator: John W. Loonsk, MD

Jared Adair, Director, Healthcare Strategies, CSC

John Quinn, Technical Committee Chair, HL7; Senior Executive, Accenture

Dave "Casey" Webster, Chief Architect, NHIN

Robert Cothren, PhD, Chief Scientist, Health Solutions, Northrop Grumman

Robert A. Stegwee, PhD, Chair, HL7 The Netherlands

Ken Lunn, Head of Comms and Messaging, NHS National Program for IT

Dennis Giokas, CTO, Canada Health Infoway *François Macary*, Chair, HL7 France; Co-Chair, IHE Laboratory Committee

Schedule and speakers are subject to change. A final agenda will be printed in the HL7 Onsite Schedule in August.

Register Online Today! www.HL7.org



Strategic Initiatives: From Vision to Reality

By Chuck Meyer, Chair, Health Level Seven and Co-Chair, Strategic Initiatives Task Force

Chuck Meyer

In the April Newsletter, Cherri McGrew and I presented the Strategic Initiatives developed by a task force of your peers (SITF) under the guidance of a consulting team funded by the Robert Wood Johnson Foundation (RWJF). The stated purpose of the RWJ grant was to improve the efficiency of the HL7 standards development process. Such a task is not as straightforward as it sounds given that all facets of the organization came under scrutiny: structure, staffing, tooling, and funding. As is typical with such endeavors, change was inevitable. However, the changes recommended go far beyond what most thought the outcome would be.

As a touch point, let's quickly recap the seven strategic initiatives keeping in mind that there is no implied hierarchy or priority, given that we will be undertaking to implement these initiatives for the most part concurrently.

- HL7 will implement a new business model and organizational structure
- HL7 will adopt a formal product and services strategy to be reviewed annually by the Board of Directors
- HL7 will optimize the use of its volunteers and other resources
- HL7 will develop a brand hierarchy to help the marketplace better understand the relationship of its products to each other and the organization
- HL7 will develop consistent organizational messages and a communications strategy to disseminate those messages

- HL7 will implement a productoriented project management approach to ensure development of high quality standards and associated products in a committed timeframe
- HL7 will institute quality testing at key stages in the development process

The key to making these initiatives reality is the acceptance of HL7 the organization as a non-profit business entity and the adoption of business practices appropriate to the sustainability and viability of a \$5 to \$8 million operation. Like any business, HL7 must articulate its vision; develop and maintain a 3 to 5 year strategy; employ professional management to achieve its objectives; and, lacking stockholders, be responsive to the demands of the various stakeholder groups representing the health informatics standards domain. This will not happen overnight and requires significant planning.

The Strategic Initiatives Implementation Plan (SIIP) has been evolving since the May Working Group Meeting (WGM) and will be the focus of the Board of Directors Retreat in August. The 65 page draft SIIP has been circulated to the Affiliate chairs and the Technical Steering Committee (TSC) for feedback. At the WGM, the Board of Directors recognized the pivotal role envisioned for HL7's Chief Executive Officer (CEO). The Board approved the formation of a select CEO search committee with the intent of having the CEO in place by January 2007. The CEO search committee will look to professional recruiters for appropriate candidates.

One of the CEO's first responsibilities will be to work with the Board and staff to define a funding model appropriate to the new organization.

2007 is envisioned as a transition year during which HL7 will truly become an international standards development organization. Concurrently, the creation of the HL7 US Affiliate will provide a focal point for collaboration on the various national programs being promulgated by the HHS Office of the National Coordinator. It is hoped that through planning, much of the stress and trauma usually associated with such activities will be minimized, if not eliminated. Significant effort will be required to ensure a smooth transition of governance and the maintenance of the standard. Any one of you may be called upon to participate in one or more of the groups involved in some facet of the transition.

continued on next page

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Mark D. McDougall *Publisher*

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Strategic Initiatives, continued

What will HL7 look like in 2008? The draft SIIP calls for an organization focused on standards at the ISO level that directly coordinates with the European standards body CEN. Given that the majority of volunteers are represented by the US Affiliate, the HL7 standards will continue to be accredited through ANSI prior to submission to ISO. It is probable that the US Affiliate will also host two out of three WGMs each year. The HL7 Board will take on an international flavor with a number of seats allocated to Affiliate regions. These seats will consist of appointed positions as well as four Directors-at-Large that will be elected from among the general worldwide membership. The Board will continue to establish strategy and set priorities. The CEO will report to the Board and will have overall responsibility for the organization. The current secretariat is envisioned as continuing in an operational role with the Executive Director functioning as the Chief Operating Officer (COO).

The CEO will institute the Technical Directorate (TD) under the control of the Chief Technology Officer (CTO). The CTO will report directly to the CEO. The TD will be staffed to support project management; maintenance, ballot, and publication of the standard; and tooling. The TSC will

be composed of three subcommittees: Infrastructure, Semantics, and Domain Expertise. The chairs of the three subcommittees will represent the TSC in the TD. Volunteers will be focused on developing the standards with all ancillary activity being undertaken by the TD. The TD will report to the CTO. There has been discussion of adopting the project proposal model wherein a project, following TD review and approval, moves forward as it attracts resources from the matrix of volunteers. The project would have defined milestones and specific deliverables. Projects could be generated internally or externally and could involve funding to expedite completion.

We envision that there will be greater reliance on the Draft Standard for Trial Use (DSTU). Rather than relying on iterative committee and membership level ballots to provide a normative standard, HL7 will encourage implementation of the specification to provide real world experience. Once a specification has achieved successful implementation, it will be submitted to a normative ballot and subsequent accreditation. This approach may entail a closer relationship with organizations such as IHE or OMG, another aspect to be considered during transition. Throughout the process, from proposal to accreditation, there will be "quality gates" providing ongoing quality assurance. From a product management perspective, the process will include check points for marketing review to ensure appropriate branding and development of collaterals.

HL7 must also improve its public image. As with the CEO, the Board identified an improved web presence as a priority issue. The Electronic Services (ES) committee, with staff assistance, prepared a Request for Information (RFI) on web strategy, evaluation, and development. The results of the RFI produced an RFP for requirements gathering and web site framework development that should shortly produce a contract. This is one of the projects that the Board agreed to fund with operational reserves to kick-start certain facets of the transition. The SIIP also calls for enhanced outreach to stakeholder groups with the intent of enrolling new members and/or generating project proposals from currently disenfranchised groups.

As I stated earlier, the SIIP will be the focus of the August Board Retreat. There will be specific action recommended on some items, while other implementation issues may call for the formation of task forces to develop solutions. In any case, we are committed to recreating HL7 to be even better than it has been. I look forward to sharing more details with you during the September WGM in Boca Raton. Have a wonderful summer and safe travels.

Comey

Charles (Chuck) Meyer, HL7 Chair (2006-2007)

Upcoming Co-Chair Elections

The following HL7 Technical Committees and Special Interest Groups will conduct co-chair elections at the September Working Group Meeting in Boca Raton:

- Clinical Decision Support electing one co-chair
- Health Care Devices electing one co-chair
- Infrastructure & Messaging electing one co-chair
- Modeling & Methodology electing one co-chair
- Orders & Observations electing one co-chair
- Public Health Emergency Response electing two co-chairs
- Scheduling & Logistics electing one co-chair

FDA Adopts SPL for Its New Content of Labeling



Randy Levin

The Food and Drug
Administration has adopted the HL7 Structured Product
Labeling as the electronic format for the newly designed package insert for prescription drug products. As

of June 30, drug manufacturers will begin the task of reformatting package inserts of recently approved drugs. To find out how things are going with the new format, we caught up with Dr. Randy Levin, Director of Health and Regulatory Data Standards, Food and Drug Administration.

Question: Why did FDA decide to use Structured Product Labeling (SPL) for the new electronic product labeling?

Dr. Levin: Actually, FDA began implementing SPL for prescription drug products in June of 2004, with the goal of having everyone using it by fall of 2005. We then announced that beginning October 2005 we would only be accepting content of labeling coded in SPL. Why did we choose SPL for labeling? We found that the HL7 Clinical Document Architecture and Version 3 Reference Information Model supported our goal of improving patient safety through improved access to product information. We are also considering the use of SPL for other products.

Question: How is the implementation of SPL going?

Dr. Levin: It's been going very well. Over the past 8 months, we've received more than 1400 labels in SPL. There are a number of vendors offering software for the creation and management of SPL. And now we are beginning to receive the SPL in the new design.

Question: We understand you are making the labeling in SPL available to the public.

Dr. Levin: Yes, that's right. We are collaborating with the National Library of Medicine in an initiative, called DailyMed, to make the most current version of prescription drug labeling available free of charge on the Internet. Currently, we have made more than 100 labels available on the NLM DailyMed Web site, and we expect to have more than 1000 available by the end of the summer. Most of the approved prescription drug labels should be available by the end of the year.

Question: Can you tell us a little about the new labeling format?

Dr. Levin: We worked for more than a decade on the redesign of the label, or package insert. We held meetings and organized focus groups of physicians to get their input on what information is most important to them. The label is now reorganized with the most important information summarized right at the beginning of the label in a Highlights section. There is a table of contents and a minimum font size. The Highlights data elements describe indications, usage, interactions, and adverse reactions of the drug. And because the data elements are now in SPL, the labeling can be shared electronically across systems, which was not the case in the past.

Question: What is the difference between the old and new formats with regard to SPL?

Dr. Levin: Well, industry is now coding more information about their drug. For example, they are now coding the indications, the limitations of use, the pharmacological classes, food and drug interactions, and common adverse reactions. And all of this information is from the new Highlights section of the labeling.

Question: What terminologies are being used to code the different data elements?

Dr. Levin: We are using terminologies chosen by the U.S. Government as part of the health information technology infrastructure. The source of much of our terminology is the National Cancer Institute NCI Thesaurus. We are using the Veterans Health Administration and Kaiser Permanente Problem List Subset of SNOMED to code medical conditions in the Highlights data elements. For the product pharmacological class, we are using the mechanism of action, physiological effect, and structural class from the Veterans Health Administration National Drug File Reference Terminology. To code the lab test names, we are using Regenstrief Institute's Logical Observation Identifiers Names and Codes (LOINC). These terminologies are also available on the NCI Enterprise Vocabulary Services Web site.

Question: Do many of the labels on the DailyMed Web site have the new Highlights section?

Dr. Levin: No, the requirement to include Highlights applies only to new and recently approved products and will be implemented gradually. So we have just begun to receive labels with the new Highlights section. To facilitate the process, we have been working with the HL 7 Structured Product Labeling Working Group to help implement the new requirement. The working group is developing examples showing how to code the data elements in SPL correctly.

Question: Where can folks go for more information on SPL?

Dr. Levin: They can find more information on our web site at http://www.fda.gov/oc/datacouncil/spl.html. And if anyone has specific questions, they should contact us at SPL@FDA.hhs.gov, and we will provide them with individual assistance.

Tis the Season for Graduation Parties

Update from Headquarters

By Mark McDougall, HL7 Executive Director



Mark McDougall

Many of you were likely invited to recent graduation parties for extended family members or children of

friends and neighbors. The parties may have been for high school or college graduates. At these parties, you may also have seen photos and various forms of achievement displayed. We need your help in gathering old photos of HL7 members (current or from the past) to display at our 20th annual plenary meeting in September.

Send us your old photos

In the spirit of graduation parties we invite you to send us any photos of individuals (including yourself) who have participated in HL7. We would love to see old photos of HL7 members from many years ago. In fact, we would even welcome receiving scanned copies of photographs of your high school graduation, wed-

ding, and pictures of you at work (or play). Depending upon the volume of photos received, we'll package the photos to be displayed in some fashion. We might even create special awards and/or produce a "game show" with prizes. So, please send us your old photos of HL7 members from many years ago.

Recognizing our Benefactors

We are thrilled to have attracted the all time highest number of HL7 benefactors. Their support of HL7 is very much needed and sincerely appreciated. Representatives from our many benefactors are pictured below. A special thank you is extended to the following list of firms that represent our 2006 HL7 benefactors:

Accenture
Centers for Disease Control and
Prevention (CDC)
Duke Clinical Research Institute
(DCRI)
Eclipsys Corporation
Eli Lilly & Company
Epic Systems Corporation

Food and Drug Administration
GE Healthcare Integrated IT
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Kaiser Permanente
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Microsoft Corporation
Misys Healthcare Systems
NHS Connecting for Health
NICTIZ National Healthcare

Novartis

Oracle Corporation

Partners HealthCare System, Inc Pfizer, Inc. Philips Medical Systems QuadraMed Corporation Quest Diagnostics Inc. Science Applications International Corporation Siemens Medical Solutions Health Services Solucient, LLC.

St. Jude Medical U.S. Department of Defense, Military Health System

U.S. Department of Veterans Affairs Wyeth Pharmaceuticals.



Representatives from HL7's 2006 Benefactors shared a proud moment, accepting recognition plaques at the Wednesday morning general session in San Antonio.

Supporters

We are also pleased to recognize the following organizations that have contributed funds at the "supporter" membership category. Their support is also very much appreciated.

Beeler Consulting LLC iNTERFACEWARE Corporation J&J PRD LINK Medical Computing, Inc. NT Medical Systems, Inc. Sentillion, Inc. Silicon Spirit Consulting Group, Inc.

Organizational Member Firms

As listed on pages 23-25, HL7 is very proud to report that the number of HL7 organizational member companies is at an all time high, including 518 companies. We sincerely appreciate their ongoing support of HL7 via their organizational membership dues.

Thanking Our Working Group Meeting Sponsors

Convening a meeting for 500 people is very expensive and we are fortunate to have a number of organizations that generously help HL7 defray some of the costs by sponsoring events or collateral related to our meeting. I would like to recognize the following organizations that sponsored key components of our recent Working Group Meeting in San Antonio, Texas:

IBM —Onsite Meeting Guide
McKesson—Meeting Brochure
Link Medical Computing, Inc.—
Morning Coffee Break
Thomson —Tuesday Continental
Breakfast and Afternoon Break

The additional sponsorship support provided by these organizations contributes heavily to HL7's meeting budget and is much appreciated.

Co-Chairs and Facilitators

The co-chairs of our many Technical Committees and Special Interest Groups, as well as the facilitators, represent the backbone of the HL7 organization. Their role is critical to our ability to manage the volunteers and produce HL7 standards. The HL7 organization is very grateful and appreciative to each of these dedicated volunteers for their tremendous contributions. A sincere thank you is extended to each of these dedicated volunteers listed on pages 26-30.

Boca Raton – Here we come!

I look forward to seeing many of you at the incredibly beautiful Boca Raton Resort in Florida. This property is unlike any hotel at which HL7 has convened meetings. Not only is the beach front property beautiful, but we are also producing an excellent Plenary meeting program plus 21 educational tutorials. Highlights of the Plenary meeting include presentations by:

- Sam Schultz, PhD, HL7's Founding Chairman of the Board
- John Loonsk, MD, Director, Office of Interoperability and Standards, Office of the National Coordinator for Health Information Technology
- Panel presentation on international, national and regional interoperability



Jill Kaufman (IBM) and Dan Russler (McKesson) both accepted sponsor plaques in San Antonio.

For more details on the Plenary Meeting program, please read the cover story and see the detailed schedule on page 2.

Best wishes for a safe and enjoyable summer (or winter, for my good friends down under).

Mark P. Ma Vougall



Years of Standards Development

CCOW Releases Best Practices Guide

By Robert Seliger, Co-Chair, CCOW TC



Robert Seliger

In April, the CCOW Technical Committee released Version 1.0 of the nonnormative document CCOW Standard: Best Practices and Common Mistakes.

The document provides a collection of non-normative recommended best practices and descriptions of common mistakes for application developers to consider when creating CCOW-compliant applications. The content of this document pertains to CCOW Version 1.5, but in general, is applicable to all preceding versions of CCOW as well.

The Health Level Seven Context Management Standard (CMS) defines a means for the automatic coordination and synchronization of disparate healthcare applications that co-reside on the same clinical desktop. Applications that implement the CMS standard enable the user to set the clinical context for the desktop using any of the enabled applications. When the context has been set, all of the enabled applications on the desktop are automatically "tuned" to the same clinical context.

By sharing context, applications are able to work together to follow the user's thoughts and actions as they interact with a set of applications. These applications are said to be "clinically linked." Working together in concert, this cooperative behavior among the applications makes it much easier and safer for users to enter and retrieve the information that they need to deliver care to their patients.

The CMS is extremely prescriptive, but as it is a standard it can only go so far in terms of guiding how applications are actually designed and implemented. Variability among the decisions that application developers make can lead to various amounts of confusion for users of multiple independently-developed CCOW-compliant applications. In order to address this situation, the Best Practices document offers a series of recommendations that, when followed by application developers, will produce a cohesive and uniform set of CCOW-compliant behaviors.

Specifically, the Best Practices document provides recommendations that will enable CCOW-compliant application developers to implement basic CCOW capabilities in the same way. Application developers can do more sophisticated things than are recommended in the document, but they should do so only in addition to, as opposed to instead of, doing the basic things specified in the document.

In other words, application developers are encouraged to do the right things to make their applications behave consistently, in a CCOW sense, with other applications. If an alternative behavior is provided then it is recommended that application users be provided with a means to disable the alternative behavior via a configuration switch so that only the recommended behavior is achieved.

Seventeen best practices are recommended and fourteen common mistakes are described. For each best practice and common mistake, a specific issue is summarized, and then an accompanying recommendation is provided.

For example, consider the best practice regarding changing the context via a scrollable list. The issue and accompanying recommendation presented in the document are as follows:

Applications frequently have lists of patients, observations, encounters, or other objects from which users make selections for further viewing or other actions. Some applications attempt to set the context even when the user is actively scrolling through the list but do not actually tune to the context changes itself. The result is that context is set many times very rapidly by the applications behavior in response to the user's scrolling action. This can create a substantial and unnecessary context change transaction performance load on a system of applications that share a common context.

Recommendation: If an application offers a scrollable list of context sensitive objects, and the user does not expect to change the context until having successfully scrolled to the intended item, then the following practice is recommended. The context should only be set by the application after X seconds have transpired since the user stopped scrolling through the list, where X is configurable on an applicationspecific basis. In addition to, or instead of this timer, the application may also set the context when the user has clearly indicated a selection by clicking on a mouse or performing an equally explicit gesture. Note that an application that implements this behavior must be prepared to

continued from previous page

cancel the selection if the user instructs that the context change be cancelled, and the application must revert back to the current (i.e., unchanged) context.

As an example of a common mistake, consider the display of context-sensitive information when an application is minimized:

Some applications display context-sensitive information even when minimized. For example,

they show the patient name in the label they present in the Microsoft taskbar.

Recommendation: If an application is minimized and the application's icon displays context-sensitive information (e.g., a patient's name), then the application must be sure that this information remains current with the context.

Over time the CCOW Technical Committee is likely to add additional best practices and common mistakes to the document. In the meantime, Version 1.0 of the document should go a long way in providing consistency among applications and minimizing user confusion due to developer's design decisions or implementation mistakes. The document can be downloaded from the HL7 Web site by clicking on the Decision Making Practices link under the Committees header on the www.hl7.org home page.

Congratulations to the following people who passed the HL7 Certification Exam

Certified HL7 V2.4 Chapter 2 Control Specialist

April 19, 2006

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June 13, 2006

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Gopakumar Menon Gaurav Mevawala Seema Pandey

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April 29, 2006

Pushpa Chavan Amitkumar Iain Gowri Kesari Sunil Krishnamurthy Prasad Sharma Patri Manohar Rao Aparna Rambhatla Priyadarshi

<u>|</u>

Join Us in the HL7 Booth at the HIMSS 2007 Exhibit! February 25-March 1, 2007 in New Orleans

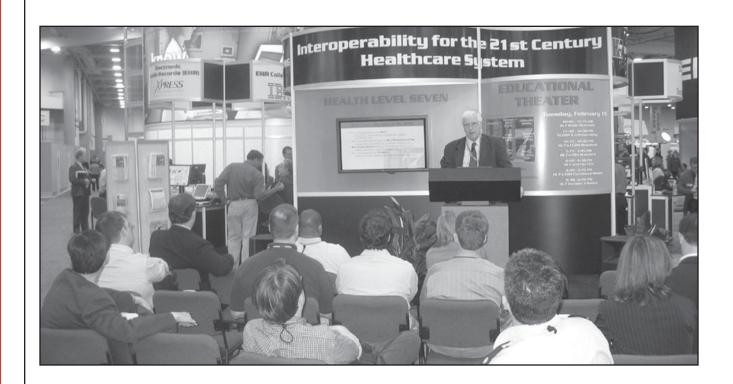
The HL7 exhibit will once again take center stage—join us on the main aisle at the largest healthcare IT conference and exhibition in the US. This year's theme will focus on HL7 standards providing the building blocks to support regional, national and international interoperability.

Come be a part of an exciting opportunity to educate the industry on how HL7 standards provide the foundation on which the healthcare enterprise was built and how they are now the cornerstone for supporting regional, national and international interoperability. HL7 vendors, providers and other members are invited to share how their organization or HL7-enabled products are actively involved in or plan to fill a role in one of the functioning or soon-to-be functioning RHIOs around the nation.

Applications are now being accepted. For details, visit www.HL7.org/HIMSS to see all the ways your organization can partner with HL7 at HIMSS 2007 and tell your HL7 story to HIMSS attendees.



Contact Andrea Ribick at 734-677-7777 x165 or andrea@HL7.org





BE A PART OF



ExL Pharma's 2nd Annual Merging Electronic Health Records and Electronic Data Capture Conference

HL7 is proud to partner with ExL Pharma on its 2nd Annual Merging Electronic Health Records and Electronic Data Capture Conference Taking place September 18-19, 2006 at the Sheraton Four Points in Washington DC.

Featured Presentations include:

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Somesh Nigam, PhD, Senior Director, Enterprise Architecture, Pharma R&D IM, Johnson & Johnson

 Progress Report on the Health Information Technology Standards Panel (HITSP) and other National Healthcare Information Network Initiatives

LeRoy E. Jones, CISSP, Program Manager, HITSP

 Marrying Clinical & Patient Health Data at the Cleveland Clinic Foundation

C. Martin Harris, MD, MBA, Chief Information Officer, Cleveland Clinical Foundation

 Integrating Drug Development and Clinical Research Needs into the National Health Information Infrastructure

William A. Yasnoff, MD, PhD, Managing Partner, NHII Advisors

• Data Integration at the Investigative Site: A Hands-on Perspective of Data Capture at the Site-Level Land

Landen Bain, Healthcare Liaison, CDISC

For more information, to download the conference brochure and to register, please go to: www.exlpharma.com/events/ev_descrip.php?ev_id=40

SPECIAL OFFER:

As a member of HL7, you are eligible for a 20% discount on the registration fee.

To take advantage of this discount, please register online and use the Registration and Discount Code: HL7.

If you have questions or comments, please contact Conference Director, Kristen Hunter at: khunter@exlpharma.com

THE QUEST TO ENABLE THE ELECTRONIC CLINICAL TRIAL: FINDING CLARITY IN A CONFUSING WORLD

December 5-7, 2006 Sheraton Inner Harbor Hotel

300 S. Charles Street Baltimore, MD 21201-2497 Jointly sponsored by DIA, HL7, FDA, AMIA, SAFE, CDISC, and the C-Path Institute

Are you are a producer or supporter of technology and unsure about the types of technology, tools, and initiatives you should be using to optimize and accelerate your drug development process? If so, then plan to attend this three-day conference and get the latest information on:

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- Clinical Data Standards Changing the Drug Development Environment
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- Data Transparency in the Public Interest
- Modeling and Simulation Tools for Enhancing Drug Development
- End-to-End Solutions and Holes in the Continuum Towards an eClinical Trial

To register, go to www.diahome.org or contact Jill McNair at 215-442-6181 or jill.mcnair@diahome.org.

HL7 Appoints a New W3C Advisory Committee Representative

By Kevin Kelly, HL7 Representative to the W3C Advisory Committee

After many years, Paul Biron has stepped down as the HL7 Advisory Committee Representative to the Worldwide Web Consortium (W3C). Kevin Kelly became the new HL7 Advisory Committee Representative in May of this year. Kevin has direct experience in the W3C as a working group member in the XForms Working Group, and as Chair of the Compound Document Formats Working Group for the past two years. He has been involved in HL7

through his employer IBM. Kevin is a Senior Technical Staff Member in IBM's Emerging Software Standards organization focusing on XML and web based standards for the healthcare industry.

The World Wide Web Consortium (W3C) is an international consortium where member organizations, a fulltime staff, and the public work together to develop Web standards. W3C primarily pursues its mission

through the creation of Web standards and guidelines designed to ensure long-



Kevin Kelly

term growth for the Web. Over 400 organizations are members of the Consortium. W3C is jointly run by the MIT Computer Science and Artificial Intelligence Laboratory (MIT CSAIL) in the USA, the European Research Consortium for Informatics and Mathematics (ERCIM) headquartered in France and Keio University in Japan. W3C also has several additional offices worldwide. For more information on the W3C please visit: http://www.w3.org/.

There are many W3C standards and working groups that are relevant to HL7. The W3C is divided into five domains; Architecture, Interaction, Technology and Society, Ubiquitous Web, and Web Accessibility Initiative. Each domain has activities such as XML, Web Services, and Internationalization within the Architecture Domain. And within activities are the working groups such as the XML Core Working Group which produces specifications such as XML, XInclude, and Xlink. There are many W3C working groups that produce XML, Schema, Web markup, Web accessibility and Web internationalization standards. There are even industry focused groups such as the Semantic Web Healthcare and Life Sciences Interest Group.

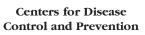
If you have any suggestions about W3C work or HL7 interaction with the W3C, or interest in collaborating with a W3C working group or activity please contact Kevin Kelly at kevin.kelly@us.ibm.com.

HL7 Benefactors















P. E C L I P S Y S





































U.S. Department of Defense Military Health System





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HL7 Names Three New Advisory Committee Members

By Andrea Ribick, HL7 Director of Communications

The HL7 Board of Directors has named three new members to serve on its Advisory Committee: Mitch Hansen, Vice President for Enterprise Systems and Services at Quest Diagnostics; Nicholas Hilger, Senior Vice President, Strategic Development at UnitedHealthcare; and Andrew Updegrove, Co-founder and Partner, Gesmer Updegrove LLP.

"These three gentlemen bring a wealth of diverse and unique experience to our Advisory Committee," said Chuck Meyer, Chair of HL7. "Expanding the Committee to include the diagnostic, health maintenance organization, and legal perspectives represented by Mr. Hansen, and Mr. Hilger, and Mr. Updegrove can only serve to further HL7's objective of becoming ever more responsive to the national and international initiatives now underway and the needs of health IT vendors and users, healthcare providers, and healthcare consumers."

Mitch Hansen leads a diverse group of IT professionals at Quest Diagnostics. His teams are responsible for client connectivity, enterprise application integration, billing operating systems, sales and marketing systems, and web and document services. Mitch has worked in healthcare information systems for over 20 years, beginning in hospital



systems management consulting, before entering the clinical laboratory and diagnostics industry. He was named a 2006 Premier 100 IT Leader by Computerworld magazine, which also selected and honored the EDI project as one of its twelve "Best in Class – 2006" efforts.

"During this time of rapid change in healthcare and information technology, connectivity and interoperability are strategic focus areas for all healthcare service providers and technologists," said Hansen. "It is a privilege to join the HL7 Advisory Committee and contribute to the work of the HL7 organization in establishing and refining standards, to improve our ability to exchange information and in the ultimate interest of better patient care."

As the Senior Vice President, Strategic Development at UnitedHealthcare, **Nicholas Hilger's** responsibilities involve the development of expanded business relationships among health systems, the physician community, national provider constituencies, and healthcare industry companies. Prior to joining UnitedHealthcare, Mr. Hilger



spent over 20 years in hospital system leadership, holding senior positions in health systems including CEO of HealthOne in Colorado, CEO of HealthEast in Minnesota, and CEO of HCA's Chicago Division.

"During my thirty years in the healthcare industry, I've

observed and supported the advancement of information technology as a tool to simplify the healthcare experience for the consumer and provide effective management information for health systems, physicians, and managed care organizations," said Hilger. "HL7 has been, and will continue to be, the all-important standard-bearer for this effort. I am honored to help advise the organization, and hope that my experiences from the provider and managed care sectors will provide strategic value to the HL7 team."

Andrew Updegrove has been structuring and representing technology consortia since 1988 and is the cofounder and partner of the Boston law firm of Gesmer Updegrove LLP. He has worked with over 75 consortia, accredited standards development organizations and open source consortia. He has also been a member of the United States Standards



Strategy Revision Committee, received the President's Award for Journalism from ANSI in 2005, and currently serves on the Boards of Directors of the American National Standards Institute (ANSI) and the Free Standards Group.

"I'm delighted to be joining the Advisory Committee of HL7," said Updegrove. "I've spent the last 18 years working with scores of standard setting organizations, and appreciate how essential standards are to virtually every aspect of our modern, interconnected world. But few areas of IT standardization are as important as those that enable us all to enjoy better health care."

Hansen, Hilger and Updegrove join the following members of the HL7 Advisory Committee: Sam Brandt, MD, Vice President, Chief Medical Informatics Officer, Siemens Medical Solutions Health Services Corporation; Philip Burstein, MD, Vice President Therapeutic Area Management, Biometrics and Data at GlaxoSmithKline; Gary Christopherson; Richard Dixon-Hughes, Managing Director, DH4 Pty Limited, and Deputy Chairman, Standards Australia; Carl Dvorak, Chief Operating Officer, Epic Systems Corporation; Ian R. Ferrier, Founder and Chair of Bogart Delafield Ferrier, LLC.; Mark Frisse, Director of Regional Informatics Programs at the Vanderbilt Center for Better Health, and Professor in the Vanderbilt Department of Biomedical informatics; C. Martin Harris, Chief Information Officer, Chairman, Information Technology Division of the Cleveland Clinical Foundation; Dr. Tim Jones, Clinical and Technical Design Owner, National NHS Care Record, National Programme for IT; Penelope J. Lie, Senior Director in Healthcare Development at Oracle Corporation; Janet Marchibroda, Chief Executive Officer, eHealth Initiative, Executive Director, Foundation for eHealth Initiative; and Don Schoen, Chief Executive Officer and President of MediNotes Corporation.

UPCOMING WORKING GROUP MEETINGS



September 10 – 15, 2006 20th Annual Plenary & Working Group Meeting Boca Raton Resort Boca Raton, FL

January 7 – 12, 2007 January Working Group Meeting Town & Country Resort San Diego, CA



April 29 – May 4, 2007

May Working Group Meeting

Maritim Hotel & Intercontinental Hotel
Cologne, Germany

PLEASE BOOK YOUR ROOM AT THE HL7 MEETING HOTEL

HL7 urges all meeting attendees to secure their hotel reservations at the HL7 Working Group Meeting Host Hotel. In order to secure the required meeting space, HL7 has a contractual obligation to fill our sleeping room block. If you make reservations at a different hotel, HL7 risks falling short on our obligation and will incur additional costs in the form of penalties. Should this occur, HL7 will likely be forced to pass these costs on to our attendees through increased meeting registration fees.

Thank you for your cooperation!

HL7 Names Two New Staff Members

By Andrea Ribick, HL7 Director of Communications

Mary Ann Boyle Meeting Planning Coordinator



Mary Ann Boyle joins HL7 with over seven years of experience at Sigma Financial Corporation, where she performed several roles including director of meeting planning, compliance auditor, office manager and executive assistant to the vice president and president. She has also worked in the retail sector, serving for two years as a store manager at Maidenform. Prior to that, she

worked in the admissions department at Fairbanks Memorial Hospital. Mary Ann earned a Bachelor's degree in Respiratory Therapy from Boise State University in Boise, Idaho. She is married and has three wonderful children.

Terrance Bennett Director of Project Management Office

Terrance Bennett joins HL7 with over 25 years of professional experience—the past 15 in project management. He has been a Project Management Professional (PMP) and is certified with the Project Management Institute (PMI) since 1999. Terrance holds a Master's of Public Administration, from Oakland University as well as a Master's in IT Project Management from George Washington University.



Terrance has worked for companies such as IBM, Accenture, Ford, and Daimler-Chrysler, where he managed portfolios, project management organizations, and projects throughout the United States, in Europe,

First CCHIT Certified Ambulatory EHR Products Announced:

HL7's EHR-S Functional Model Starting Framework for Functionality Certification Requirements

The Certification Commission for Healthcare Information Technology (CCHITSM) recently announced the first list of ambulatory Electronic Health Records (EHR) products to achieve the CCHIT CertifiedSM seal. Products that are CCHIT Certified comply with 100 percent of the tests for functionality and security and included an initial step in interoperability: that of receiving lab results electronically. This certification marks a significant milestone for CCHIT and the healthcare information technology industry as it provides the first ever benchmark for ambulatory EHR products.

An EHR standard is seen as one of the keys to supporting the exchange of information for clinical decisions and treatments, and can help lay the groundwork for nationwide interoperability by providing common language parameters that can be used in developing systems that support electronic

health records. According to CCHIT Chair, Mark Leavitt, MD, PhD, Health Level Seven's EHR-S Functional Model served such a purpose in CCHIT's certification testing process.

"CCHIT's recent launch of Ambulatory EHR certification affirms the work of many volunteers, both within as well as external to our organization," said Leavitt. "In this regard, the HL7 standards development organization has been a particularly important partner for us, supplying the standards for ambulatory EHR functionality as a starting point for CCHIT's efforts in testing EHR product compliance."

The HL7 EHR-S FM provides a reference list of functions that may be present in an Electronic Health Record System (EHR-S). The function list is described from a user perspective with the intent to enable consistent expression of system

functionality. This EHR-S Model, through the creation of Functional Profiles, enables a standardized description and common understanding of functions sought or available in a given setting (e.g. intensive care, cardiology, office practice in one country or primary care in another country).

The EHR-S is now entering the final stages as a draft standard. The document is expected to be submitted as a normative standard in a membership level ballot that will open on July 31, 2006. All HL7 members in good standing may participate in this ballot. This can be accomplished by going to: http://www.hl7.org/ctl.cfm?action=ballots.home. Additional information about the draft standard is available from the dedicated EHR section of the HL7.org Web site at www.HL7.org/EHR.

HL7 EDUCATIONAL SUMMITS

Gain real-world HL7 knowledge TODAY that you can apply TOMORROW

What is an Educational Summit?

The HL7 Educational Summit is a specific schedule of tutorials—newly expanded in 2006 to three days—focused on HL7-specific topics such as Version 2, Version 3 and Clinical Document Architecture. Educational sessions also cover general interest industry topics such as HIPAA Claims Attachments.



November 7-9, 2006 Embassy Suites Hotel Seattle-North/Lynnwood Lynnwood, WA



Why Should I Attend?

This is an invaluable educational opportunity for the healthcare IT community as it strives for greater interoperability among healthcare information systems. Our classes offer a wealth of information designed to benefit a wide range of HL7 users, from beginner to advanced.

Among the benefits of attending the HL7 Educational Summit are:

Efficiency

Concentrated three-day format provides maximum training with minimal time investment

• Learn Today, Apply Tomorrow

A focused curriculum featuring real-world HL7 knowledge that you can apply immediately

• Quality Education

High-quality training in a "small classroom" setting promotes more one-on-one learning

• Superior Instructors

You'll get HL7 training straight from the source: Our instructors are not only HL7 experts — they are the people who help produce the HL7 standards

• Certification Testing

Become HL7 Certified: HL7 is the sole source for HL7 certification testing—now offering testing on V2.5. The first 25 two-day registrants will have their certification fee refunded

• Economical

A more economical alternative for companies who want the benefits of HL7's on-site training but have fewer employees to train



CDA R2 Care Record Summaries in Germany

By Dr Kai U. Heitmann, Director International Affiliates—Board of Directors HL7 USA; Chair, HL7 Germany and Andreas Kassner, German Association of the Healthcare IT Industry (VHitG)



Kai Heitmann

The final and balloted German Sciphox "Arztbrief" (a kind of care record summary) specification based on CDA R2 was recently released. The 150 page implementation guideline was published in March 2006 after the first version in December and an official ballot phase in January/February in Germany. It references the work of the HL7 Structured Document

Committee, IHE, as well as others. It defines a kind of "framework" based on three use cases and several story-boards. A set of about 30 business rules expressed in schematron has also been defined in order to add extra validation opportunities to the created CDA documents.

The largest German vendor's association, VHitG, has initiated and sponsored this development. More than fifteen medium and large sized vendors helped to actively define the "Arztbrief." The official part (ballot) was conducted by Sciphox/HL7 Germany and therefore now has a normative status in Germany. In late May, fifteen vendors demonstrated the CDA R2 document exchange based on this specification at a large German exhibition (equivalent to a small HIMSS). The scenario covered primary care systems, hospital settings, and a rehabilitation setting. Testing began in early May in order to be well

prepared for the interoperability showcase exhibition: a kind of connect-athon like IHE was conducted with all systems involved.

CDA R2 documents are created out of clinical documentation of the respective systems and expressed and exchanged as CDA R2 documents. CDA R2 Level 1 & 2 is used for the documents and Level 3 is also defined and implemented by some vendors for diagnoses and procedures. Receiving the documents not only includes display, but also real integration of the information into the systems.



Live demonstration of the German CDA R2 implementation at the ITeG exhibition in late May.



Preparation days for the ITeG, a large German industry exhibition



HL7 Netherlands Provides Foundation for Future V3 Implementations

By Tom de Jong, HL7 The Netherlands, Co-Chair, Technical Steering Committee



Tom de Jong

As some of you may know, HL7
Version 3 is 'hot' in the Netherlands!
The National
Institute for
Healthcare IT
(NICTIZ) had the vision to base all informa-

tion exchange within the new National Infrastructure for Healthcare (AORTA) on HL7 V3 standards (combined with a SOAP software interface, and an SSL-based secure transport layer).

This strategic choice provided a major push for interest in all kinds of V3 interfaces. In the last few years there have been standardization projects for perinatology, CVA and diabetes care, preventive youth care, trauma registration, primary care and, most notably, the electronic medication record. While all of these projects have been initiated by NICTIZ, it was clear that HL7 Netherlands, as the official affiliate, should have a role in harmonization (both among projects and internationally) and maintenance.

In order to accommodate the myriad of projects, it was essential to provide common guidelines for the most fundamental building blocks from the V3 standard: data types and CMETs (Common Message Element Types). These guidelines would have to build upon the universal specification in the Normative

Edition and add specific implementation rules and clarification from a Dutch perspective.

In late 2005 NICTIZ decided to initiate an effort that took the existing V3 implementation guides (resulting from the above-mentioned projects) and created a single, national guide for the implementation of V3 data types and CMETs. A group of V3 experts was tasked with the creation and the review of a comprehensive and consistent specification, which should henceforth be used as a reference guide in any V3-based project in the Netherlands.

A national ballot was set up to open the document for comments from potential implementers. Balloting V3 standards is a new concept, at least outside the inner circle of people who are active in the international community, so the number of respondents was limited. However, the nature of the ballot comments proved that they had taken their work seriously—so seriously, in fact, that the volunteers within the HL7 Netherlands TSC took quite some time with the ballot reconciliation process.

The final document will be published as a national standard for trial use, with the explicit goal of providing a standardized foundation for the implementation of data types and most common CMETs in any future V3 interfaces. NICTIZ has already included the draft ver-

sion of the document in its full set of specifications for AORTA. The work on this DT-CMET implementation guide proved once again that HL7 V3 provides an excellent framework for electronic interchange in healthcare. But it also confirmed that there are several vague, ambiguous or even inconsistent aspects within the universal standard. These aspects were restricted out or clarified in the Dutch guide, and appropriate ballot comments were posted for the international ballot. Our goal is to ensure that all comments that could be of universal benefit are fed back into the universal V3 standard, with the Dutch guide ultimately limited to providing an implementation profile and guidelines for the specific Dutch context.

In the meantime, the national infrastructure is gearing up to go 'live' in 2007. There have been some inevitable delays, but a sizable group of vendors is now polishing up its software in a 'Proof of Concept' process, to be prepared for a pilot slated to begin immediately following summer. If everything goes as planned, medication data for every Dutch citizen will be transparently available to any authorized healthcare provider, with HL7 Version 3 messages humming along as the standard vehicle for exchange.



Standards and PartnershipThe Perspective from Ireland

By Peter Lennon, Chair, HL7 Ireland



Peter Lennon

Introduction

This article is not just about HL7. It is about the broader health system and the need for progress, nationally and internationally, through standards and partnership which, of course, is the essence of the HL7 approach. For all of us involved with HL7, the success to date and the continuing evolution of the HL7 standard are exciting because such progress represents a key practical component to building a better health service. Rightly, we see technology and standards as means rather than ends. In this article, I would like to reflect on the aforementioned general themes and their relevance to Ireland.

Ireland's Economic Miracle

For almost a decade, Ireland has enjoyed unprecedented economic growth. Generations of mass emigration have been replaced by substantial immigration. A culture of failure has been replaced by an attitude to succeed. Expectations have risen dramatically across society: nowhere more so than in healthcare.

Spending on Healthcare in Ireland

Our economic development has funded a huge increase in spending in the health sector. Government spending now accounts for over 85% of total healthcare expenditure. As a percentage of GNP, it is now the highest in the EU and in per capita terms it is the third highest. As a sector, health accounted for 28.7% of the State's revenue expenditure last year. This year will see an increase of almost 10% over 2005. This means that the State's spending on health now amounts to €3,000 for every citizen or over €9,000 for every taxpayer.

All of this money, together with the cost-free opportunity to learn from

other countries' experiences with ICT (information and communications technology) and associated standards, should have meant that Ireland could develop a healthcare ICT structure that might have served as an international example. However, it hasn't happened for several reasons which are touched on below.

Spending on Healthcare ICT

When it comes to health sector IT development, the amount of government investment is small. In 2006, it will be around €70m. In a recent European study, it was found that Ireland spends less than 0.5% of its health budget on IT, compared to more than 4% in the Netherlands. There are two main reasons for this scenario. First, IT spending has never enjoyed a high profile and has traditionally been a poor relation in healthcare funding allocations. Second and reinforcing the first point, a series of major ICT healthcare failures in 2005 have made it even less of a priority.

The above would suggest that the case for standards would be even further enhanced in Ireland. It has: but, in practice, the principle (to quote from Hamlet) has been honoured more in the breach than the observance. Even stranger, the most successful projects have been standards based while the greatest and most public failures have been otherwise.

A Success Story

The National Healthlink Project (www.healthlink.ie) is a publicly funded electronic communications' initiative which has grown from humble origins to an example-setting national project under a small committed team (led by Marie Lalor, a committee member of HL7 Ireland). The objective of the project is to implement a prototype healthcare communications network with specif-

ic reference to primary care practitioners and acute hospital and agency relationships, and data exchange.

In October 2003, their work led to the launch of Healthlink Online. This is a web-based messaging service which allows the secure transfer of patient information over the Internet. The message types currently available in the HealthlinkOnline system are:

- Laboratory Results
- · Radiology Result
- Death Notifications
- Discharge Notifications
- Discharge Summaries
- A & E Attendance Notification
- Waiting List Updates
- OPD Appointment Updates

Healthlink Online incorporates HL7 messaging, creating a standard messaging engine which allows for the development of a range of services including two-way communication. (At present, the above messages are specified in HL7 (Version 2.4) and formatted in XML (Version 2.0)).

Healthlink's success has been due to its untiring commitment to engaging openly with technical and non-technical stakeholders. It has championed HL7 in Ireland with the result that its success has helped to bring a greater awareness of the benefits of HL7 standards to a wide audience.

The Standards Scene in Ireland

One thing has become absolutely clear in Ireland and, I suspect, it is a universal truth: throwing money at problems not only does not solve them, but generally makes them worse. Health sector spending sometimes seems like a black hole and this can be especially true of health-care ICT projects where grand visions turn out to be overly ambitious. Those of us interested in standards



International HL7 Interoperability Conference IHIC 2006

August 24-25, 2006, Cologne, Germany
By Dr Kai U. Heitmann, Director International Affiliates—

By Dr Kai U. Heitmann, Director International Affiliates— Board of Directors HL7 USA; Chair, HL7 Germany

This year, we will have the 7th event of this kind in a row. The IHIC 2006 conference is formerly known as the International Affiliates Meeting. After successful and well-attended meetings in Dresden (Germany) in 2000, then Reading (United Kingdom), Melbourne (Australia), Daegu (Korea), Acapulco (Mexico) and last year in Taipei (Taiwan), we will now meet late August in Cologne.

Standards in healthcare do not live from their specifications but from their implementations. There is a strong contribution to the HL7 standard development process from people around the globe. A paramount of interest across the world can be utilized to really implement HL7's healthcare information technology standards for global interoperability. Meanwhile, in many countries this interest has already fostered real implementation projects, with profound conceptual and strategic backgrounds, and sometimes even with financial funding. Some countries have chosen the HL7 Version 3 family of standards as a strategy for health-



care communications in their respective countries.

The preliminary program as well as an online registration is available at http://ihic.hl7.de. Experiences from Canada, Great Britain, Germany and the US, as well as from Turkey, The Netherlands, Croatia, Greece, Denmark, Israel, Korea, Taiwan, Japan and Finland are part of the program. In addition, tutorials about the implementation of Version 3, XSLT processing of HL7-XML, and the Clinical Document Architecture (CDA) will be offered during the conference.

On behalf of the Board of Directors of HL7 Germany and HL7 the Netherlands, I invite you to meet in scenic and historic Cologne, Germany, to exchange ideas and share experiences of the latest international developments in HL7.

For more information or to register, please visit: http://ihic.hl7.de

continued from previous page

and partnership in Ireland are certainly not against big projects, it is just that we see the need to have a grounded approach to what we are seeking to achieve. Consequently, there are several groups lobbying on the standards' agenda. For example, HL7 Ireland (www.hl7.ie) was formed in late 2003 to push the standards' vision. Amongst other things, it has held a number of seminars and organized training to promote the cause.

In 2004, the Health Informatics Standards Committee of the National Standards Authority of Ireland (NSAI) (www.nsai.ie) was created to contribute to the development of European and International standards for patient and hospital information systems, specifically through participation in the work of CEN TC 251, ISO TC 215, and HL7; and to advise the statutory NSAI in regard to the need for national standards in the health informatics area.

An even newer and very major player emerging (as a result of a wideranging health reform process) is the Health Information and Quality Authority (HIQA) (www.hiqa.ie). The HIQA is committed to working in partnership with interested parties from all over the wider healthcare community to develop a quality based approach to technology, information and related standards.

Conclusion

While every country's healthcare system is unique, finding new ways of providing services efficiently and effectively will always be critical to the debate over the allocation of resources and funding. In that context, it is imperative to recognize that computerization and electronic communications must be essential components of a modern integrated and quality based patient centered healthcare. The key is ensuring value for money from ICT and the starting point must be standards and partnership....at least, that is the view from Ireland!



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Diagnosticians

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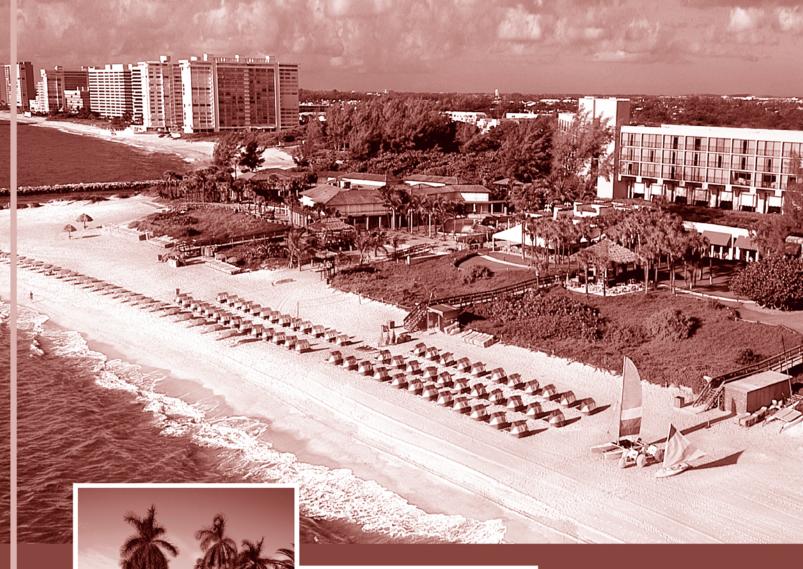
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