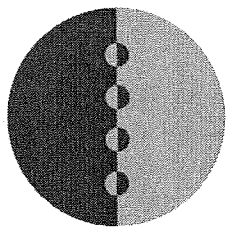


*Today's
Experience
and
Tomorrow's
Expectations*



CDISC®

**PROGRAM
Interchange
North America**

2009

9 - 13 November 2009

Baltimore Marriott Waterfront

Baltimore, MD

USA

THURSDAY, 12 NOVEMBER 2009

07:30 - 16:00

Exhibition Open

CDISC Healthcare Link Demo in the Exhibition Area Today

08:30 - 10:00

Parallel Track 1

Session 5A: Analysis of Clinical Data

Chair: Lynn Difinizio, Biogen Idec

- **ADaM Presentation**
John Roth, Lundbeck
- **Navigating the Roadblocks: Constructing an Analysis Database from SDTM**
Susan Boyer, Ben Vaughn & Jeff Abolafia, Rho
- **Patient Evaluability in the CDISC World**
Nate Freimark, Omnicare Clinical Research

Parallel Track 2

Session 5B: ODM & RFD

Chair: Gary Walker, Quintiles

- **Shortening the CRF Design and Database Set-up Process with a CDISC ODM Metadata-driven Approach**
Claus Lindenau, XClinical
- **Lessons Learned from Implementing RFD for a Multi-Site Clinical Study: Perspectives from both EHR and EDC**
Ilya Sterin, Nextrials, Jason Colquitt, Greenway Medical
- **Adverse Event Report on IHE RFD (Retrieve Form for Data capture) with Japan's Ministry Project SS-MIX. an HL7 Standardized HIS Data Export Promotion**
Michio Kimura, Hamamatsu University, Kiyoteru Takenouchi, Medical Front Corporation

10:00 - 10:30

Break

10:30 - 12:30

Parallel Track 1

Session 6A: ODM

Chair: Dave Handelsman, SAS

- **Standards-Based Approach to Creating One Elegant Multi-System Solution**
Carl Labb, Almac Clinical Technologies, Joseph Dustin, Medidata & Scott Bradley, PHT
- **Technical Aspects of Conversion to ODM**
Michael J. Ward, Eli Lilly & Company
- **Using ODM to Manage Clinical Data Content Standards**
Bruce R. Basson, Eli Lilly & Company
- **Using Incremental ODM Transactions in Systems Integration**
Andrew Smith, Medidata

Parallel Track 2

Session 6B: CDISC in a Data Management System, Define.xml and SDTM

Chair: Steve Kopko, Wyeth

- **CDISC integration in the Oracle Clinical/Remote Data Capture® (OC/RDC) clinical data management system**
Peter Van Reusel, Business & Decision
- **Converting the Define.xml to a Relational Database to Enable Printing and Validation**
Lex Jansen, Octagon Research Solutions
- **Backward Compatibility of SDTMIG**
Tang Li, TechData Service Company
- **Our Experience with Transitioning from SDTM Version 3.1.1 to 3.1.2**
Sarah McLaughlin, Biogen Idec

IHE RFD (Retrieve Form for Data capture)
Connection Test (Adverse Event Report)

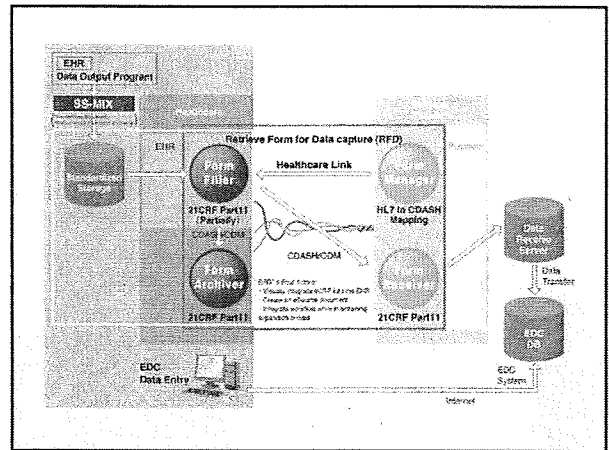
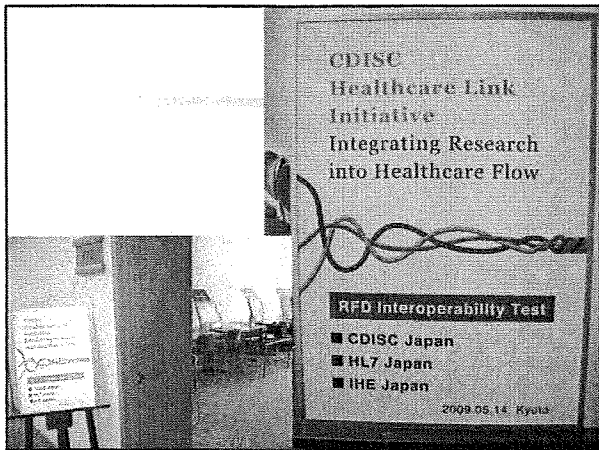
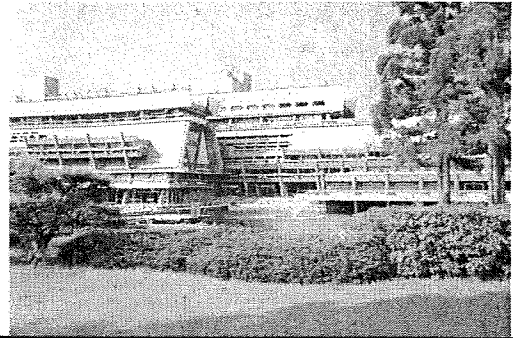
with Ministry Project SS-MIX,
at HL7 Kyoto Working Group Meetings



IHE Japan vice-chair
HL7 Japan chair
Michio Kimura, MD, PhD
Hamamatsu University



HL7 Working Group Meeting
10-15 May, 2009, Kyoto Japan



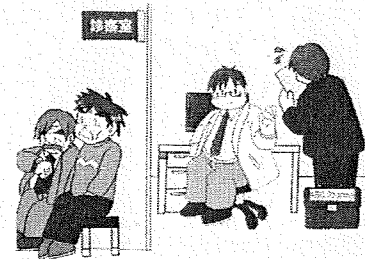
RFD connection demo

- 1. Form Manager by Medical Front prepares report form in CDA and sends to Form Filler
- 2. Form Filler by SBS Information System receives the form and fills it, most of which are pre-populated by CPOE data, archives it at Form Archiver by SBS, and submits to Form Receiver by Medical Front.

Michio Kimura M.D. Ph.D., Hamamatsu University School of Medicine

Post Market Adverse Event Report

- 1. Paper-based
- 2. Manually collected in busy clinics



Michio Kimura M.D. Ph.D., Hamamatsu University School of Medicine

Form Filling

- Manually
- But, most items are in CPOE and EMR



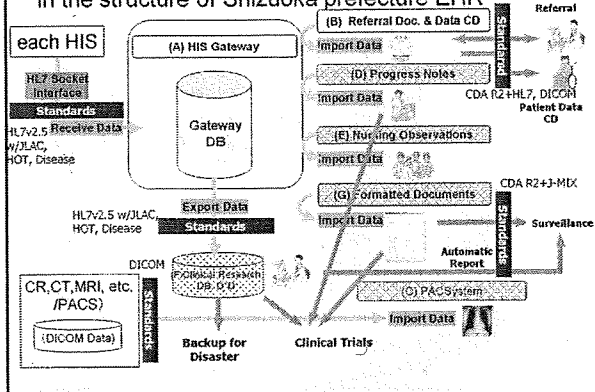
Michio Kimura M.D., Ph.D. Hamamatsu University School of Medicine

CPOE in Japan

- 90%+ in large hospitals (400+ beds)
- Top 2 vendors became able to export patient demographics, prescriptions, lab results, diagnoses, in HL7 v.2 messages
 - by appointment of Ministry of Health Labor Welfare project : SS-MIX
 - Standardized Medical Information Exchange Promotion

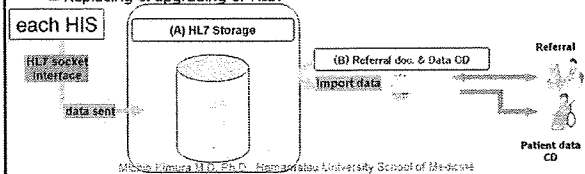
Michio Kimura M.D., Ph.D. Hamamatsu University School of Medicine

SS-MIX standardized repository (A): HIS Gateway in the structure of Shizuoka prefecture EHR



Wide variety of applications on HL7 standardized storage by SS-MIX, a Ministry project

- We have patient demographics, prescriptions & injections, lab results, diagnosis classifications in HL7 v2.5
 - PHR
 - Making documents
 - Data retrieval
 - Interoperability with peripheral systems
 - Replacing & upgrading of HIS.

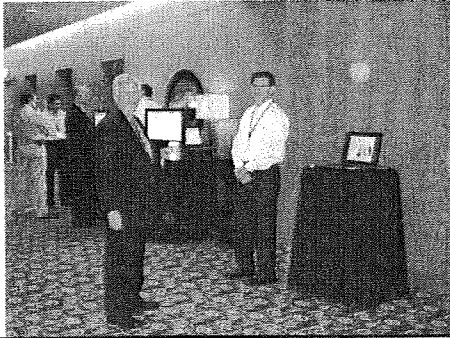


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Demo at CDISC Interchange 2008, Arlington



Demo at HIMSS 2009 Chicago

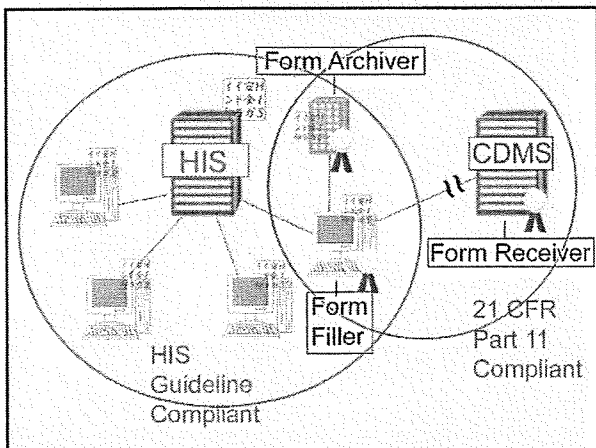
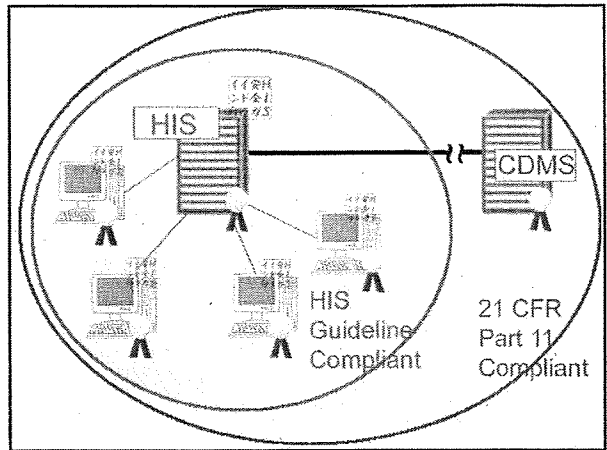
IHE Interoperability Showcase



IHE Japan Connect-a-thon

- Oct 26-30, 2009, Tokyo
- Radiology, Laboratory, Cardiology, IT Infrastructure which will include RFD
- <http://www.ihe-j.org/en/>

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Current Status

- 20 Hospitals mainly in Shizuoka prefecture are ready with SS-MIX standardized repository
- About 50% of all large hospitals in Japan has HL7 v2.5 export feature (EMR: Fujitsu GX series, FX series, NEC HR series, SBS Prime-Karte series, Software Service e-Karte series)
 - They only need to add hardware for the repository, as repository software is provided from Ministry project SS-MIX
- This form filler can be 21 CFR Part 11 compliant

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Current Status(2)

- PMDA (FDA in Japan) launched a 5 year project for "Safety Data Extraction from HIS through IT" with 4 subgroups
 - ▣ e-Claim data, HIS data through SS-MIX, Post market form, Voluntary report submission
 - ▣ SS-MIX team uses high-speed clinical information retrieval system D*D, which is working at 5 Shizuoka hospitals.

Michio Kimura M.D., Ph.D. Hamamatsu University School of Medicine

End of presentation



Correspondence :

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✉ kimura@mi.hama-med.ac.jp

Michio Kimura M.D., Ph.D. Hamamatsu University School of Medicine

6. N. Cheung, S. C. Muttitt, M.Kimura,
M.Lin, E.H.Shorliffe:

AsiaPac Informatics-Update on Informatics Activities
form Pacific Rim Countries,

AMIA 2009 ANNUAL SYMPOSIUM,

San Francisco, CA, USA, Nov. 16, 2009.

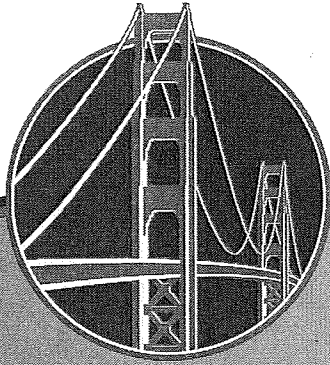
BIOMEDICAL AND HEALTH INFORMATICS

From Foundations to Applications to Policy

November 14-18, 2009

Hilton San Francisco

San Francisco, CA



AMIA 2009

SAN FRANCISCO



AMIA 2009 ANNUAL SYMPOSIUM
ON-SITE PROGRAM

27.75 CATEGORY 1 CME CREDITS AVAILABLE

522 - Demonstrations: Collaborative Technologies
Room: Continental 1/2/3
Theme: Public Health Informatics and Biosurveillance

Session Chair: Gilad Kuperman
A Web Site for Informatics Implementation Lessons and Research Outcomes
B. Dixon, Regenstrief Institute; A. Zafar, Indiana University

The Agency for Healthcare Research and Quality (AHRQ) has made a major investment in health information technology implementation and research, including the creation of a National Resource Center for Health IT (NRC). The primary goal of the NRC is to disseminate lessons learned and research outcomes from AHRQ-funded health IT projects. To effectively achieve its mission, the NRC created a public Web site (<http://healthit.ahrq.gov>). The site features up-to-date information on each AHRQ-funded project, and it synthesizes knowledge across the portfolio. Newer functionality includes the ability to download artifacts (e.g., surveys, decision support rules) created and used during the course of these projects. This web site has the potential to inform future informatics application implementation and research.

Web-based Dictation Portal for Management and Integration of Digital Dictation Files into Anatomic Pathology Workflow
P. Gershkovich, J. H. Sinard, Yale Medical School

Reducing cost of health care is on top of national agendas in the US and throughout the world and healthcare professionals are forced to search for better and less expensive solutions in all areas of clinical care. One of these areas is the Dictation/Transcription process. Existing commercial dictation solutions are expensive and do not easily integrate with current laboratory information systems. Using a rapid application development process, this demonstration uses modern software development tools and methodologies along with Open Source software components allow creation of a highly reliable Web-based integration portal that is scalable by design and works well with off-the-shelf dictation products. In addition, this system is internationalized and can be used elsewhere in the world. The presenters use Google Web Toolkit and server-side J2EE technology to create a solution that links together off-the-shelf, low cost transcription software and our existing Laboratory Information System for Anatomic Pathology. The dictation portal provides file management and routing, error handling, and a dashboard-like status display. Lastly this presentation will demonstrate how this system has saved the department \$150,000 dollars and reduced ongoing cost of maintenance by \$25,000 per year.

LB2 Late Breaking Session
Room: Yosemite C

AsiaPac Informatics—Update on Informatics Activities from Pacific Rim Countries
NT Cheung, Hong Kong Hospital Authority, Hong Kong, Sarah C. Muttitt, MOH Holdings Pte. Ltd., Singapore, Michio Kimura, Hamamatsu University School of Medicine, Japan, Mark Lin, Taiwan, and Edward H. Shortliffe, AMIA

This late breaking session will feature several of the leading authorities on the informatics activities from countries in the Pacific Rim. Panelists from Hong Kong, Singapore, Japan, and Taiwan will discuss current state of Informatics and eHealth in their region.

10:30 AM-1:30 PM POSTERS

Poster Session 1 Preview
Room: Grand Ballroom

The poster preview runs from 10:30 am to 1:30 pm with attendance by authors optional and is designed to allow registrants to browse posters at their leisure. The poster session, with all authors present, will take place from 5:15 pm to 7:00 pm. Numbers represent board assignments.

Theme: 20/20 Global e-Health Informatics Capacity Building

1. Avatars: A Review of Their Use in Patient or Provider Education

K. Hopkins, H. Donovan, University of Pittsburgh; J. Osborn, Carnegie Mellon University

2. Connecting the One Laptop per Child (OLPC) Computer to the Internet: A Model for Developing Countries

K. Kasiviswanathan, University of Maryland; P. Fontelo, National Library of Medicine

Theme: Clinical Decision Support, Outcomes, and Patient Safety

3. Affect of an EHR Based Early Warning System for Potentially Critically Ill Ward Patients on Patient Outcomes

B. Aaronson, D. Stone, G. Fletcher, M. Schaff, D. McMahon, L. Nelson, University of Washington

4. "Smart" Electronic Discharge Summary to Improve Care of Heart Failure and Myocardial Infarction Patients at Discharge

A. Agrawal, I. McFarlane, S. Weiss, K. Rones, Kings County Hospital

Survey to Asia-Pacific Countries/Regions

On Medical Records & EHR

Michio Kimura, MD, PhD
Hamamatsu University
JAMI vice-president

Survey for APAMI 2009 **APAMI2009** Conference at Hiroshima, Nov 22-24

- ✳ President's Panel
 - "What are the Medical Records for?"
- ✳ Sent to Asia-Pacific Delegates of IMIA
- ✳ 12 returns
 - AU, CN, HK, ID, IN, JP, KR, NZ, PH, SG, TH, TW
- ✳ Contents
 - Purpose of Medical Records
 - National ID? National Health ID?
 - EHR Project Status, and Purpose
 - Disclosure and Secondary Use Regulations.

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EHR Project Status

- ✳ Australia: Being partially tested
- ✳ China: Being partially tested
- ✳ Hong Kong: Almost accomplished
- ✳ India: No plan
- ✳ Indonesia: Being partially tested
- ✳ Japan: Being partially tested
- ✳ Korea: Being partially tested
- ✳ NZ: Being partially tested
- ✳ Philippines: No plan
- ✳ Singapore: Being partially tested
- ✳ Thailand: Being partially tested
- ✳ Taiwan: Being partially tested

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National ID? National Healthcare ID?

- ✳ Australia: No, No
- ✳ China: Yes, Social Sec. # is used
- ✳ HK: Yes, National ID is used
- ✳ India: No, No
- ✳ Indonesia: Yes, Yes
- ✳ Japan: No, No
- ✳ Korea: Yes, No
- ✳ NZ: No, Yes
- ✳ Philippines: No, No
- ✳ Singapore: Yes, National ID is used
- ✳ Thailand: Yes, No
- ✳ Taiwan: Yes, National ID is used

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Purpose of EHR, Primary is for continuation of care. What comes after it?

- ✳ Prioritize among:
 - Public Health/Disease Control,
 - Healthcare Cost Cut,
 - Clinical Research
- ✳ Australia: 2:HCC, 3:CR, 4:PH
- ✳ China: 2:PH, 3:HCC, 4:CR
- ✳ HK: 2:HCC, 3:PH
- ✳ Indonesia: 2:HCC, 3:PH, 4:CR
- ✳ Japan: 2:HCC, 3:CR, 4:PH
- ✳ Korea: 2:HCC, 3:PH, 4:CR
- ✳ Singapore: 2:HCC, 3:PH, 4:CR
- ✳ Thailand: 2:PH, 3:CR, 4:HCC
- ✳ Taiwan: 2:HCC, 3:CR, 4:PH

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Purpose of Medical Records, Primary is for Healthcare itself. What comes after it?

- ✳ Prioritize among
 - Clinical Research, Medical Education, Provider Management, Billing/Claiming, Public Health/Disease Control

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Purpose of Medical Records, Primary is for Healthcare itself. What comes after it?

- Australia: Bill, Research, Manage, Edu, PH
- China: Manage, Bill, Research, PH, Edu
- HK: Manage, PH, Bill, Research, Edu
- India: Bill, "Protection against Litigation", Manage, PH, Edu
- Indonesia: Bill, PH, Manage, Edu, Research
- Japan: Bill, Edu, Research, Manage, PH
- Korea: Bill, Edu, Research, Manage, PH, "Legal Document"
- NZ: Manage, Bill, "Health Policy", PH, Edu, Research
- PH: Bill, Research, PH, Manage, Edu
- Singapore: Bill, PH, Manage, Research, Edu
- Thailand: Bill, Manage, Edu, Research, PH
- Taiwan: Bill, Manage, Research, Edu, PH

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Disclosure (patient name identified) to;

#: O: Unconditional, C: Conditional, X: Not done/prohibited

	The patient	Referred physician	Insurance payer	PH Dept.	Health Policy Dept.
CH	O	O	O	C(Act)	X
HK	O	O	X	O	O
IN	O	O	X	C(Act)	O
JP	O	O	O	C(Act)	C(Act)
KR	O	X	O	O	X
PR	O	O	O	C(de-ID)	C(de-ID)
SG	O	C(Pt's consent)	C(Pt's consent)	C(Act)	C(Act)
TH	X	O	X	O	O

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Secondary Use (patient name enough anonymized, without consent) by ;

#: O: Unconditional, C: Conditional, X: Not done/prohibited

	PH Dept.	Health Policy Dept.	Non-profit	For-Profit	Any regulation for secondary use?
CH	C(Act)	O	O	O	No
HK	O	O	C(Univ. only)	X	No
IN	X	X	C(IRB)	C(IRB)	No
JP	O	X	C(IRB)	X	Yes
KR	C(Act)	X	X	X	Yes
PR	O	X	X	X	No
SG	C(Act)	C(Act)	C(IRB)	C(IRB)	No
TH	X	X	O	IX	No

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Health IT Acceptance by Citizens (not patients): Survey at Japan and US

(Definitely Yes-Probably Yes-Neutral-Probably No-Definitely No)

#: "Only you can view your medical record through internet"

☑ Japan 35%-19%-21%-12%-12%

☑ US 51%-6%-7%-5%-30%

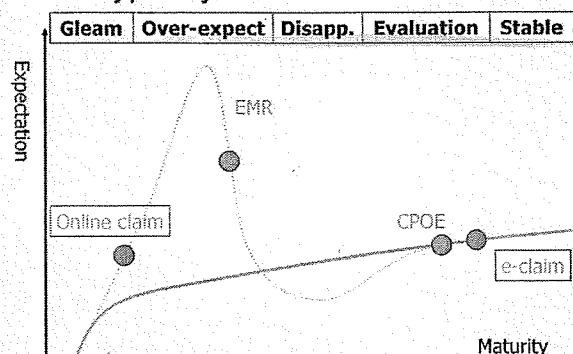
#: "Do you prefer to have your EHR (lifelong health record)?"

☑ Japan 33%-41%-14%-7%-5%

☑ US 18%-25%-15%-17%-25%

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IT Hype Cycle



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End of Presentation

APAMI2009

#: APAMI, JCMI, IMIA WG4

☑ Conference Center at Hiroshima Peace Memorial Park

☑ Nov 21-25



Michio Kimura M.D.

7. M. Kimura:

What are the Medical Records for? ,

A-01, Proceedings APAMI2009,

Hiroshima, Japan, Nov. 22-24, 2009.

The 6th Conference

APAMI2009

A CoMHI meeting

Proceedings



November 22-24, 2009
International Conference Center
at Peace Memorial Park
Hiroshima, Japan

Timetable of APAMI 2009 in a CoMHI meeting

	Room A	Poster	Room C	Room D	Room E	Room F
22 Nov (Sun)	08:55-09:00		APAMI 2009 Welcome greetings			
	09:00-10:30		Poster Set up	APAMI 2009 Handed Round Session of APAMI-GRID		
	10:40-12:10		Poster Exhibition	APAMI 2009 President's Panel		
	13:30-15:30	CoMHI Joint Session Nursing Informatics		CoMHI Joint Session Interoperable eHealth Standards		
	15:40-17:40					
23 Nov (Mon)	09:00-10:30		CoMHI Joint Session Clinical Decision Support System			
	10:40-12:10		Poster Exhibition	IMIA/APAMI/JAMI Presidents' Special Lec.		
	13:30-15:30					
	15:40-17:40					
24 Nov (Tue)	08:30-				APAMI 2009 Oral Session1 O-01 ~ 03 Nursing Informatics	
	09:00-10:30		CoMHI Joint Session IMIA WG4 (SIHIS) Workshop Reports		Oral Session2 O-04 ~ 10 System Security and Patient Safety	
	10:40-12:10		Poster Exhibition	APAMI 2009 Oral Session3 O-11 ~ 16 Database and analysis		
	13:30-15:30			CoMHI Joint Session Fostering human resources	APAMI 2009 Oral Session4 O-17 ~ 21 Telemedicine	APAMI 2009 Oral Session5 O-22 ~ 27 e-Health and Disease
	15:40-17:40		Poster Removal	APAMI 2009 Closing greetings	CoMHI Joint Session Patient Safety and Medical Informatics	APAMI 2009 Oral Session6 O-28 ~ 32 EHR and Standardization

Table of APAMI09 Presentations

<Special Contributions>

1. APAMI President Panel

A-01 The President's Panel; What are the Medical Records for?

Organized by Prof. Micho Kimura (President of APAMI2009, Japan)

Peter Croll (Australia), BaoLuo Li (China), CP Wong (Hong Kong), SB Gogia (India), YunSik Kwak (Korea), Stephen Chu (New Zealand), Alvin Marcelo (Philippines), ChowYuen Ho (Singapore), Wansa Paoin (Thailand), YuChuan Li

2. APAMI- EFMI-AMIA Handed Round Session "GRID"

A-02 Grid and Cloud Computing for International Biomedical and Health Research

Organized by Prof. Yu-Chuan (Jack) Li (Taipei Medical University, Taiwan)

Simon Lin (APAMI), Yannik Legre (EFMI), George Mihalas (EFMI), Ted Shortliffe (AMIA), Don Detmer (AMIA), Alvin Margolis (IMIA-LAC4)

3. Nursing Informatics (CoMHI Joint Session 1)

W-01 Current situation and future perspective of nursing informatics among Asian countries

Organized by Prof. Hyeoun-Ae Park (Seoul National University, Korea)

Kimikazu Kashiwagi (Japan), Polun Chang (Taiwan), Yumiko Uto (Japan), Kengo Miyo (Japan), Satoko Tsuru (Japan), Johanna Feng (Taiwan)

4. Standardization (CoMHI Joint Session 2)

W-02 Interoperable eHealth Standards

Organized by Prof. Yun Sik Kwak (Kyungpook National University, Korea)

Masaaki Hirai (Japan), and by APAMI WG 1, Standards

5. Clinical Decision Support System (CoMHI Joint Session 3)

W-03 Clinical Contents Model: Definition, Methods, and Practical Use

Organized by Prof. Yoon Kim (Seoul National University, Korea)

Stanley M. Huff (USA), SunJu Ahn (Korea), KyungHee Cho (Korea), YoungTaeg Koh (Korea)

What are the Medical Records for?

Michio Kimura

Hamamatsu University, APAMI 2009 President

Panelists: Peter Croll (*Australia*), BaoLuo Li (*China*), CP Wong (*Hong Kong*), SB Gogia (*India*), YunSik Kwak (*Korea*), Stephen Chu (*New Zealand*), Alvin Marcelo (*Philippines*), ChowYuen Ho (*Singapore*), Wansa Paoin (*Thailand*), YuChuan Li (*Taiwan*)
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1. Background

As medical records become electronic, use of valuable information for many kinds of purposes are expected. It is a good opportunity to look into the purpose of medical records in many countries'/regions' circumstances.

This panel comprises two parts; an episode of Hiroshima day, and questionnaire reports from each participant.

2. Prologue: Medical Records at Dr. Ban's Clinic, 9km from the Epicenter of A-Bomb

Dr. Ban's clinic was located at Ban village, 9 kilometers northwest of Hiroshima city center.

Immediately after 6 Aug 1945, Hiroshima Day, his clinic became extremely crowded by injured people. Most patients just after the bomb were suffering from physical injuries like heat burn, wounds, etc. A few days later, signs and symptoms of the visiting patients changed from physical injuries to severe diarrhea, hair loss, mal nutrition, which were called A-Bomb syndrome.

Dr. Ban was so scientific minded that he always asked patients "Where were you at the blast?", and he noted the answer in the medical records. Looking at the medical records, he found that some patients who were not in Hiroshima at the blast, were showing the same A-Bomb syndrome. He had a hypothesis that A-Bomb syndrome could be infectious. Actually, it was by inner radiation by radioactive foods and water.

He wanted to propagate this hypothesis and liked to warn people coming for help from outside Hiroshima to take mask, water and food with them.

But it was prohibited by Japanese police, not to make bad influence to the morale of Japanese people, though they already noticed that the blast was atomic bomb.

On August 15, Japan surrendered and US occupation came to Hiroshima very soon for investigation.

This time, Dr. Ban hoped to propagate the hypothesis, but it was again prohibited and his medical records and death certificates he issued were confiscated by US occupation, probably for the fear of these facts known to Soviet Union.

There is a question: "What is the medical records for?"

3. Questionnaire to APAMI Panelists

A questionnaire was sent to each panelist and their answers are to be presented at the panel. It includes;

In what language, records are written?

The primary purpose of medical record is definitely for care of the patient. What comes second among ; Clinical research? Medical education? Healthcare institute management? Billing/claiming/reimbursement? Public health/disease control?

Does your country/region have lifetime unique ID for residents? Does your country/region have lifetime unique healthcare ID for patients? Is there any regulation for linkage to other ID?

One of the main aspect of EHR(Electronic Health Record) is for one lifetime record for one patient. In your country/region, it is; accomplished? Almost accomplished? Being partially tested? or No plan?

"Better healthcare with past history" will be the primary purpose of EHR. What are other purposes of the EHR; Healthcare cost cut? Clinical research? Public health/disease control?

About disclosure (patient name identified and without patient's consent); To the very patient, To the physician who referred the patient, To the insurance payer, To Ministry's public health department, To Ministry's health policy department, disclosure is; unconditional? on certain conditions? or prohibited/not done? (And also same questions for secondary use of medical records with disidentification).

4. Remarks from the President

There are many situations, many circumstances of healthcare delivery in each country/region. The president hopes that this panel and whole APAMI 2009 could be a good start for mutual understanding and future collaborations.

