

sidering the challenges each situation may face, which should be coherent with private sector development and government leading policy, has been proven to be important.

Acknowledgment

This work was partially supported by Japan Ministry of Health, Labour and Welfare Grant-in-Aid for Scientific Research [H21-iryō-shitei-012] "Research on Formatted Documents Creation and Sharing Based on Standardized Storage of Clinical Information".

The authors of this paper represent the organizations involved in the two projects. In addition to them, we would like to express gratitude for all the people who supported the projects in the past. The special thanks from the project founder go to Dr. Hiroyuki Doi, Ex-Director of Shizuoka Prefecture Health & Welfare Bureau, who invented and promoted Shizuoka style EMR.

References

- Agarwal G, Crooks VA. The nature of informational continuity of care in general practice. *Br J Gen Pract* 2008; 58 (556): e17–24.
- Olola CH, Rowan B, Narus S, Hales J, Poynton M, Nebeker J, Evans RS. Enhancing continuity of care through an emergency medical card at Intermountain Healthcare: using Continuity of Care Record (CCR) standard. *AMIA Annu Symp Proc* 2007; 11: 1063.
- Dolin RH, Giannone G, Schadow G. Enabling joint commission medication reconciliation objectives with the HL7/ASTM Continuity of Care Document standard. *AMIA Annu Symp Proc* 2007; 11: 186–190.
- Campbell SL. HL7 (Health Level 7) – the future becomes a reality. *Health Inform* 1990; 7 (5): 24–26.
- Wang Y, Best DE, Hoffman JG, Horii SC, Lehr JL, Lodwick GS, Morse RR, Murphy LL, Nelson OL, Perry J. ACR-NEMA digital imaging and communications standards: minimum requirements. *Radiology* 1988; 166 (2): 529–532.
- Spilker C. The ACR-NEMA Digital Imaging and communications Standard: a nontechnical description. *J Digit Imaging* 1989; 2 (3): 127–131.
- Kimura M, Ohyama N, Inamura K, Ando Y, Shigemura N, Shima Y, Saito T. IS&C (Image Save & Carry) standard: standardized exchange media for medical information. *Proc MEDINFO-95* 1995; 8 (Pt 1): 207–211.
- Kimura M. Role of standardization. *Comput Meth Prog Bio* 1994; 43 (1): 19–20.
- Rishel W. Standards seen as a key to managing healthcare costs. *Comput Healthc* 1992; 13 (11): 23–24.
- Kimura M, Tani S, Sakusabe T. Towards Japanese EHR; Shizuoka Style EMR Project, Deployment Stage, Proceedings of CJKMI2005, China-Japan-Korea Conference on Medical Informatics, Shenzhen, China, Nov. 10, 2005. pp 4–5.
- Kimura M, Hirai M. HL7 Japan CDA Referral Document Deploys Nationwide. M2 Keynote, International HL7 Interoperability Conference IHIC 2006. Cologne, Germany, August 25, 2006.
- <http://sciencelinks.jp/j-east/article/200122/000020012201A0334640.php> or (in Japanese) Tsuchiya F. The future view and problems of standardization of drug code. *Gekkan Yakui* 1998; 40 (11): 85–88.
- Kimura M, Kanno T, Tani S, Satomura T. Standardizations of clinical laboratory examinations in Japan. *Int J Med Inform* 1998; 48: 239–246. Or (in Japanese) Japanese Society of Laboratory Medicine. Laboratory test code, the 10th revision. *Rinsho Byouri Shuppan* 1998 or <http://www.jslm.org/>
- The Ministry of Health, Labour and Welfare standard EMR Promotion Committee final report, 2005. (See also: Shin-Iryo, 2005 July, pp 75–78.) (in Japanese)
- Kimura M, Ohe K, Yoshihara H, Ando Y, Kawamata F, Tsuchiya F, Furukawa H, Horiguchi S, Sakusabe T, Tani S, Akiyama M. MERIT-9: a patient information exchange guideline using MML, HL7 and DICOM. *Int J Med Inform* 1998; 51: 59–68.
- Schadow G, Russler DC, Mead CN, McDonald CJ. Integrating medical information and knowledge in the HL7 RIM. *Proc AMIA Symp* 2000. pp 764–768.
- Lee CJ, Hornik RC. Physician trust moderates the Internet use and physician visit relationship. *J Health Commun* 2009; 14 (1): 70–76.
- http://wiki.ihe.net/index.php?title=Portable_Data_for_Imaging
- <http://www.hci-bc.com/ss-mix/eng/index.html>
- Kimura M. General Purpose Portable Data: MERIT-9 Referral document conforming both HL7 CDA R2 and IHE PDI (Portable Data for Image) in Shizuoka Prefecture EHR project. The 6th HL7 International Affiliates Meeting & The 4th Asia-Pacific HL7 Conference on Healthcare Information Standards, Taipei, Taiwan, July 21, 2005.
- Kimura M, Takenouchi K. 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. *Proc. of CDISC Interchange North America 2009*, Baltimore, MD, November 12, 2009.
- Kimura M, et al. High-Speed Clinical Data Retrieval System with Event Time Sequence Feature. *Methods Inf Med* 2008; 47: 560–568.
- Furuta T, et al. CYP2C19 genotype is associated with symptomatic recurrence of GERD during maintenance therapy with low-dose lansoprazole. *Eur J Clin Pharmacol* 2009; 65 (7): 693–698.
- Kimura M. Genome Data into cloned Whole Clinical Database? Quick and Safe Tool for Genomic Study. *Proc of 2009 Summit on Translational Bioinformatics, American Medical Informatics Association*, March, 2009.
- Kimura M. Study for Japanese version EHR realization, the opinion poll about the medical informatics among citizens, the 2008 FY Ministry of Health, Labour and Welfare grant-in-aid scientific research report, 2009 (in Japanese).
- Morin RL. Outside images on CD: a management nightmare. *J Am Coll Radiol* 2005; 2 (11): 958.
- ISO/IEC 18033-3: 2005 Information technology – Security techniques – 37 Encryption algorithms – Part 3: Block ciphers
- http://wiki.ihe.net/index.php?title=Cross-Enterprise_Document_Sharing
- Kimura M. Image Sharing, EHRs and IHE®: Specific IHE Profiles and Experiences from Around the World. *RSNA2009 (Radiology Society of North America) session II42*, December 3, 2009, Chicago, IL.
- Giokas D. Canada's Interoperable EHR. Infoway chooses the more challenging path, the greater benefits. *J AHIMA* 2008; 79 (5): 56–57.
- Becker MY. Information governance in NHS's NPfIT: a case for policy specification. *Int J Med Inform* 2007; 76 (5–6): 432–437.
- Jian WS, Hsu CY, Hao TH, Wen HC, Hsu MH, Lee YL, Li YC, Chang P. Building a portable data and information interoperability infrastructure framework for a standard Taiwan Electronic Medical Record Template. *Comput Methods Prog Bio* 2007; 88 (2): 102–111.
- Kim Y. National Healthcare Information Network Development in Korea. *Proc of APAMI 2006, Asia-Pacific Conference on Medical Informatics*, 2006.
- Ammenwerth E, Schnell-Inderst P, Machan C, Siebert U. The Effect of Electronic Prescribing on Medication Errors and Adverse Drug Events: A Systematic Review. *J Am Med Assoc* 2008; 15 (5): 585–600.
- Kawazoe Y, Ohe K. An ontology-based mediator of clinical information for decision support systems: a prototype of a clinical alert system for prescription. *Methods Inf Med* 2008; 47 (6): 549–559.

14. M. Kimura, A. Endo:

MIHARI Project-

PMDA's Pharmacovigilance

project with information

out of Japan's HIS

CDISC interchange Japan,

Tokyo, July 21, 2010.

CDISC JAPAN INTERCHANGE SESSION DETAILS

TUESDAY, 20 JULY 2010

(Interchange Conference, Cosmos hall, 3rd Floor)

(Japanese-English simultaneous interpretation is available)

09:00 - 17:00 Registration

09:30 - 17:30 Exhibition Open (6th Floor)

**09:30 - 10:30 Session 1:
Welcome & Keynote**

Chair: Yoshio Tsukada / J3C Chair

- **Welcome to the 2010 CDISC Japan Interchange**

Yoshio Tsukada / J3C Chair

- **State of the CDISC Union**

Rebecca Kush / CDISC President & CEO

- **Keynote Speech**

Key Factors for Development of Clinical Research in Japan – Potential of Introduction of National ID System (* Under Discussion) -

Shinichi Nozaki / Counselor Office of Health and Welfare for Director-General for Policy Planning and Evaluation, MHLW

- **Keynote Speech**

Recent trend of Clinical Trials and Clinical Researches – Interim review of “new 5 yearly clinical trial activation plan” -

Yuta Nakaya / Office of Clinical Trial Promotion, Research and Development Division, Health Policy Bureau, MHLW

10:30 - 11:00 Coffee break

**11:00 - 12:30 Session 2:
CDISC Regional Update**

Chair: Hiroshi Azuma / J3C Vice Chair

- **CDISC Europe**

Pierre-Yves Lastic / E3C Chair

- **CDISC Korea**

Sukil Kim / K3C Chair

- **CDISC Japan**

Kiyoteru Takenouchi / J3C Past Chair

12:30 - 13:30 Lunch break

**13:30 - 15:00 Session 3:
CDISC Standards Update**

Chair: Kiyoteru Takenouchi / J3C Past Chair

- **CDISC Standards: Current & Future**

Rebecca Kush / CDISC President & CEO

- **CDISC SHARE: The CDISC metadata repository**

Gary Walker / Quintiles

- **Integrating Business Processes between Healthcare and Research**

Landen Bain / CDISC

15:00 - 15:30 Coffee break

**15:30 - 17:00 Session 4:
Integration of Standards and Processes**

Chair: Motohide Nishi / J3C

- **Disease-specific Data Standards: Case Studies in TB, Cardiology and Neurology**
Bron Kistler / CDISC Director
- **Define.XML –It's Not just for Submissions Any More**
Joel Hoffman / Phase Forward
- **Introduction about our activities on diffusion and implementation of CDISC standards in Translational Research Informatics Center**
Kotone Matsuyama / TRI Center

18:00 - 20:00 Evening Reception

WEDNESDAY, 21 JULY 2010

(Interchange Conference, Cosmos hall, 3rd Floor)

(Japanese-English simultaneous interpretation is available)

09:00 - 17:00 Exhibition Open

**09:00 - 10:45 Session 5:
Safety Data and CDISC**

Chair: Yutaka Sugihara / J3C

- **Using CDASH data collection forms for automated SAE reporting**
Andrew Newbigging / Medidata Solutions Worldwide
- **Doing more with SDTM – Safety Signal Detection on Clinical Trial Data**
Robbert P. van Manen / Phase Forward
- **E2B Under the Umbrella of HL7 and BRIDG: Looking to the future of data integrations between Pharmacovigilance (E2B) and Clinical Trial Management**
Joerge Dillert / Phase Forward Europe
- **MIHARI Project – PMDA's Pharmacovigilance project with information out of Japan's HIS**
Michio Kimura / Hamamatsu University School of Medicine, Ayumi Endo / Pharmaceuticals and Medical Devices Agency

10:45 - 11:15 Coffee break

**11:15 - 12:45 Session 6:
CDISC - Current Practice & Future in Japan**

Chair: Toshiaki Ogawa / J3C

- **Neotor Project: A real academic clinical trial using CDISC ODM-based EDC**
Takahiro Kiuchi / UMIN Center
- **Remoted-SDV using electronic regional medical network system**
Akimasa Yamatani / National Hospital Organization Kanazawa Medical Center
- **Industry Effort for Implementation of CDISC in Japan**
Yoshiko Terui / JPMA

12:45 - 13:45 Lunch break

13:45 - 15:15**Session 7:****CDISC More in Japan***Chair: Hisao Iizuka / J3C*

- **Activities on CJUG CDASH**
Kazuki Furuno / CJUG CDASH Team, Mochida
- **CJUG Activities on SDTM implementation team**
Yoshiteru Chiba / CJUG SDTM team, UMIN Center
- **Activities on CJUG ADaM**
Hiroki Takagi / CJUG ADaM Team, Sanofi-Aventis

15:15 - 15:45

Coffee break

15:45 - 16:45**Session 8:****Vendor Applications and Tools***Chair: Kenji Nagaya / J3C*

- **Cloud based Clinical Trial Management Systems (CTMS)**
Chris Merriam-Leith / Transgenic Software
- **Simplifying trial data extraction with CDISC ODM as web service interface**
Herve Ouambo Fotso / Phase Forward Europe

16:45 - 17:00**Closing Address***Hiroshi Azuma / J3C Vice Chair*

MIHARI Project – PMDA's Pharmacovigilance project with information out of Japan's HIS

Michio Kimura
Hamamatsu University School of Medicine,
Ayumi Endo
Pharmaceuticals and Medical Devices
Agency

Healthcare in Japan

- ⌘ Healthcare cost: 8% of GDP
 - ⌘ Rated among top by WHO
 - ⌘ 9,000 hospitals and 90,000 Clinics
 - ⊠ Average outpatient session: 3 to 5 minutes
 - ⌘ All residents are covered by some insurance
 - ⌘ Free access: patient can go to any provider
 - ⌘ Fee for service basis
 - ⊠ Regardless of type of the insurance, service rates are fixed by MHLW, which is very low
 - ⊠ DPC (Japanese DRG-PPS) has installed in large hospitals since 2006.
 - ⌘ CPOE: 60% in hospitals (90% in 400+beds)
 - ⌘ EMR: 30% in hospitals, 10% in clinics.
- Michio Kimura M.D. Ph.D. Hamamatsu University School of Medicine

MIHARI Project *Medical Information from Healthcare providers for Assessment of Risk, Initiative*

検討会: 電子診療情報等の安全対策への活用に関する検討会
A study group for application of electronic healthcare
information to pharmacovigilance

座長: 関原成允 国際医療福祉大学 大学院長
Chair: Prof. Shigekoto Kaihara, Dean, International University
of Health and Welfare

設置: H21年7月、5年計画
Five year project from July 2009

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

Motivations

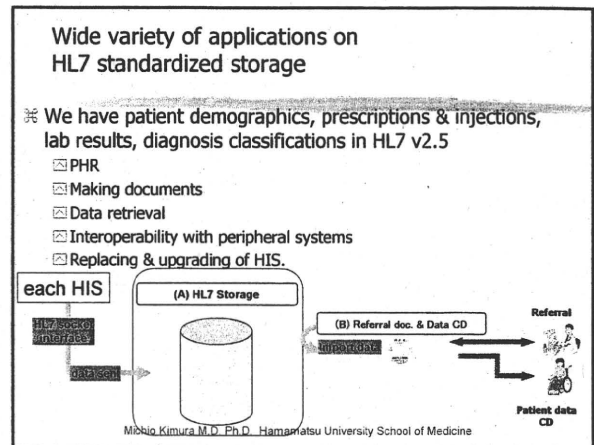
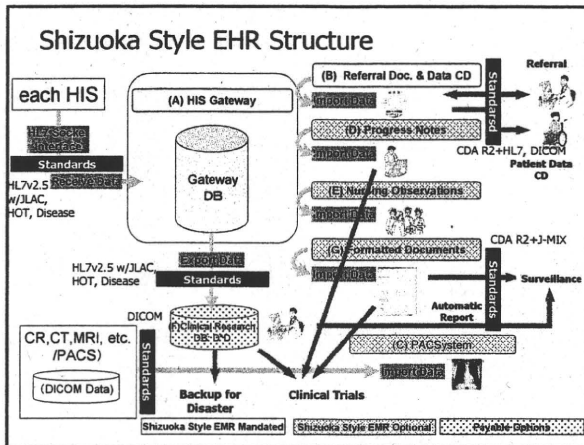
- ⌘ MHLW sentenced "responsible" for exclusion of HCV contaminated coagulants is a slow process, and "ordered" to improve information collection process
 - ⌘ MHLW's advisory concluded in making better use of electronic healthcare information (reimbursement claims and HIS)
 - ⌘ PMDA's project according to this.
- Michio Kimura M.D. Ph.D. Hamamatsu University School of Medicine

4 WGs for each information source

- ⌘ Reimbursement claims and DPC(DRG)
 - ⌘ Hospital information system
 - ⌘ Spontaneous adverse events reported to PMDA
 - ⌘ Post market surveillance collected by pharma co.
- Michio Kimura M.D. Ph.D. Hamamatsu University School of Medicine

National project SS-MIX: HL7 standardized clinical information storage

to be used as a basis of HIS WG



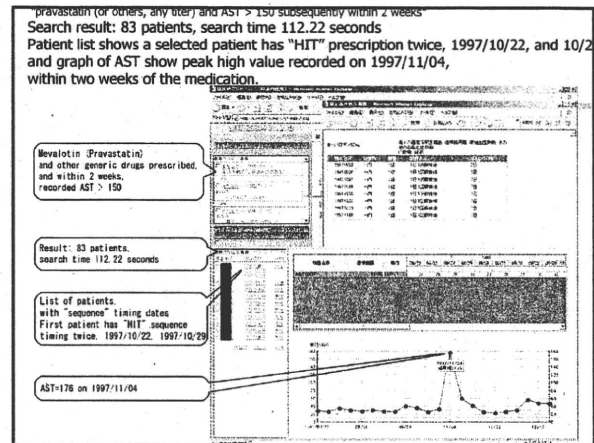
Hamamatsu University's Clinical Database: D*D

☞ 73,709,298 records of 10 years of Lab. results, Prescriptions, Diagnoses,,

☞ "Pravastatin (any titer, with generics) prescribed and recorded AST > 150 within two weeks" resulted in "83 Patients", took 112.22 seconds

☞ Even in Note PC!

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



Search examples in Hamamatsu University Hospital

☞ In 2007, number of patients with HbA1c=6.6-8.0, then examined again in 2-3 months

- ☑ -5.8: 55 cases, 5.9-6.5: 289 cases, 6.6-8.0: 657 cases, 8.1+: 192 cases

☞ "Gemzar"(gemcitabine, a cytosine-antimetabolites) injected patient: 181 cases

- ☑ "After the injection" interstitial pneumonia (ICD-10 J84.x) diagnosed case: 7 cases

☞ Stroke onset, and within 3 years recurrence?

- ☑ Classification "Stroke" is not reliable, as it can be used for reimbursement reasons of CT scan.

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

Side effects noted with lab results in package insert 3 year case search before and after first medication

Trasozole™ (Ibuprofen)(Ccr<30ml/min) ○ ○ x ○ 8 x 4 x 7 445	Valixa™ (Valganciclovir) (PT<2) ○ ○ x ○ 1 1 x 1 22	BezatoSR™ (Bezafibrate)(Cr>2m) ○ ○ x ○ 2 3 x 5 214
Alkeran™ (melphalan)(WBC<2000) ○ ○ x ○ 35 7 x 14 38	activacin™ (Alteplase)(Pt<50000) ○ ○ x ○ 3 0 x 5 0	Lipidil™ (Fenofibrate)(Cr>2.5mg/d) ○ ○ x ○ 1 x x 3 77
Alkeran™ (melphalan)(Pt<50000) ○ ○ x ○ 27 1 x 14 35	Imuran™ (Azathioprine)(WBC<200) ○ ○ x ○ 5 10 x 18 128	Benet™ (Sodium Risedronate)(Cr<30ml) ○ ○ x ○ 5 8 x 9 438
Fludara™ (Fludarabine)(Ccr<30ml/min) ○ ○ x ○ 2 1 x 2 100	Selara™ (Eplerenone)(Ccr<50ml) ○ ○ x ○ 2 2 x 3 39	Clexane™ (Enoxaparin)(Ccr<30ml) ○ ○ x ○ 1 1 x 0 58

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

Odds ratio against control

- All newly introduced drugs(2007-2009) medicated patients were checked of 5 lab results before/after first medication
- 4th grade medical student's research report

	Control	AST	BUN	CK	Albumin	WBC
Abilify(R) Aripiprazole	Akineton(R) BiperidenHCl	1.388	1.378	0.751	3.182	0.262
Meymax(R) MoxifloxacinHCl	Tarivid(R) Ofloxacin	1.108	0.394			1.56
Calceol(R) Calcitonin	Notran(R) DiclofenacNa	2.015		0.741	3.523	0.794
Orvasol(R) Clozapine	Selavent(R) Salmeterol				8.25	1.34
Gabapen(R) Gabapentin	Akineton(R) BiperidenHCl		0.005		1.174	5.895
Comtar(R) Entacapone	Akineton(R) BiperidenHCl			2.19		0.895
Crestol(R) RosuvastatinCa	Mevalotin(R) Pravastatin	0.501	2.217	4.052	11.57	0.872
ReQuip(R) RopiniroleHCl	Akineton(R) BiperidenHCl					12.33

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

Pilot study by PMDA for 5 Shizuoka hospitals (total 3500 beds), which have D*D clinical search

- For events which can be evaluated by lab results, disease classifications, DPC classifications, non-intervening search can be done
- Year 1: 2009
- 8 known adverse events

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

Theme 1

- Neuroleptic Malignant Syndrome by Olanzapine
- ICD10: G210
- CPK>1000

Michio Kimura M.D.

<p>検索テーマ①: オランザピンによる悪性症候群</p> <p>対象者検索条件(新規処方症例)</p> <p>主条件</p> <p>A) 対象期間: 2007年7月1日~2010年1月31日</p> <p>B) 対象薬: オランザピン¹⁾の処方あり</p> <p>C) 投与時年齢: 20歳以上</p> <p>除外条件</p> <p>D) 対象期間: 2007年4月1日~2007年6月30日</p> <p>E) 対象薬: オランザピンの処方あり</p> <p>投与時年齢設定なし</p> <p>対象者 条件式: (A) and B) and C) not (D) and E)</p> <p>ケース検索条件(副作用発症例)</p> <p>a) 病名: オランザピンの全処方から2か月以内に悪性症候群(ICD10: G210) 確定診断あり</p> <p>主条件</p> <p>b) 臨床検査値: オランザピンの全処方から2か月以内にCPK1000 IU/L以上</p> <p>除外条件</p> <p>c) 臨床検査値: オランザピンの初回投与3週間前CPK1000 IU/L以上</p> <p>d) 処方: オランザピンの全処方から2か月以内にダントロンナトリウム(注射薬)²⁾の処方あり</p> <p>ケース 条件式: [a) or (b) not c) or d)] and 対象者</p>

Post Market Adverse Event Report

- Paper-based
- Manually collected in busy clinics



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

Form Filling

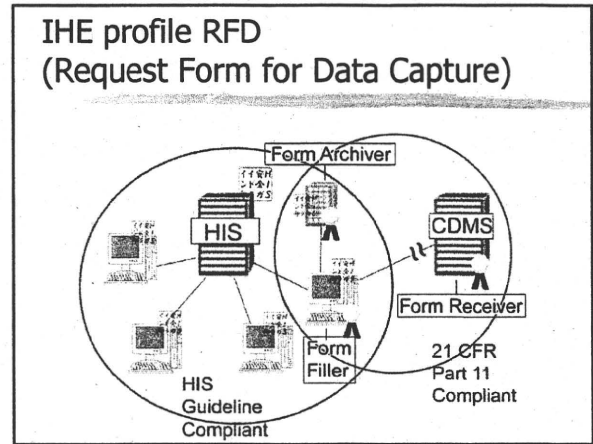
- Manually
- But, most items are in CPOE and EMR



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

Item	Unit	Reference	10/10	10/11	10/12	10/13	10/14	10/15	10/16	10/17	10/18	10/19	10/20	10/21	10/22	10/23	10/24	10/25	10/26	10/27	10/28	10/29	10/30	10/31
AST	U/L	0-40	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60	63	66	69	72	75
ALT	U/L	0-40	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60	63	66	69	72	75	78
ALP	U/L	40-100	45	50	55	60	65	70	75	80	85	90	95	100	105	110	115	120	125	130	135	140	145	150
LDH	U/L	100-250	110	120	130	140	150	160	170	180	190	200	210	220	230	240	250	260	270	280	290	300	310	320
T-Bil	mg/dL	0.1-1.2	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3
Cr	mg/dL	0.6-1.2	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8
Ca	mg/dL	8.8-10.0	9.0	9.1	9.2	9.3	9.4	9.5	9.6	9.7	9.8	9.9	10.0	10.1	10.2	10.3	10.4	10.5	10.6	10.7	10.8	10.9	11.0	11.1
CRP	mg/L	0-0.5	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2
TP	g/dL	7.0-8.5	7.5	7.6	7.7	7.8	7.9	8.0	8.1	8.2	8.3	8.4	8.5	8.6	8.7	8.8	8.9	9.0	9.1	9.2	9.3	9.4	9.5	9.6
Fe	mcg/dL	50-150	55	60	65	70	75	80	85	90	95	100	105	110	115	120	125	130	135	140	145	150	155	160
Cl	ml/min	10-120	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
BUN	mg/dL	7-20	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
HGB	g/dL	12-16	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
WBC	/mm ³	4,000-10,000	4,500	5,000	5,500	6,000	6,500	7,000	7,500	8,000	8,500	9,000	9,500	10,000	10,500	11,000	11,500	12,000	12,500	13,000	13,500	14,000	14,500	
HT	cm	150-180	155	160	165	170	175	180	185	190	195	200	205	210	215	220	225	230	235	240	245	250	255	260

診療科目	医師	診療内容	検査	処方	備考
内科	山田 太郎	高血圧、糖尿病	血圧測定、血糖測定	降圧剤、降糖剤	経過観察
外科	田中 次郎	胃切除術	術前検査	麻酔薬	術後経過良好



CPOE(Computerized Physician's Order Entry) 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
- 594 hospitals (March 2010)
- MHLW standard designation ...March 2010
- HL7 v2.5, HL7 CDA R2, DICOM and IHE PDI, Codes (ICD10 disease code, drug code, lab exam code)

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

MHLW notification

10 May 2010
Director Health Policy Bureau
Director Health Insurance Bureau

Notification concerning IT standards to be adopted

1. MHLW Standards
 Followings are to be designated as MHLW standards:
 - Standard Master for Pharmaceutical Products (SHOT reference number)
 - ICD10 Standard (Japanese Code Master for Electronic Medical Records)
 - Patient Referral Document & Clinical Data Document
 - Standard for internal documents for hospitals
 - The PDF/Portable Data for Hospital Integration Profile, and its Application Guideline
 - ISO TS 11075-4001/2007 Health Informatics - Medical equipment format - Part 10001
 - Encoding rules
 - Digital Signature and Certificates in Medicine (DCDM)
 - The JAHG Protocol for Clinical Laboratory Data Communication

2. Evaluation
 All the medical information systems are built or installed in health care facilities, are highly reliable from view points of information availability to support systems according to MHLW standards. It is also useful for system healthcare cooperation systems and medical safety, and it is needed to keep standardizations and interoperability for medical information systems.
 In order to the implementations of MHLW standards are required for reference and indices and work-related projects of medical information systems by MHLW.

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

5 Healthcare IT Roadmaps

- 「どこでもMy病院」
"My clinic, everywhere", PHR project
- 「シームレスな地域連携医療」
"Seamless regional healthcare"
- 「レセプト情報の活用による医療の効率化」
"Efficient healthcare by reimbursement data"

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

Cabinet's office unveiled (June 2010) 5 healthcare IT roadmaps

- 「どこでもMy病院」
"My clinic, everywhere", PHR project
- 「シームレスな地域連携医療」
"Seamless regional healthcare"
- 「レセプト情報の活用による医療の効率化」
"Efficient healthcare by reimbursement data"

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

Cabinet's office unveiled (June 2010) 5 healthcare IT roadmaps (cont.)

⌘「医療情報データベースの活用による医薬品
等安全対策」

☒ "Pharmacovigilance by HIS data"

⌘「高齢者在宅医療介護見守り支援」

☒ "Home care for elderly by IT"

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

End of presentation



Maracana Stadium, Rio de Janeiro

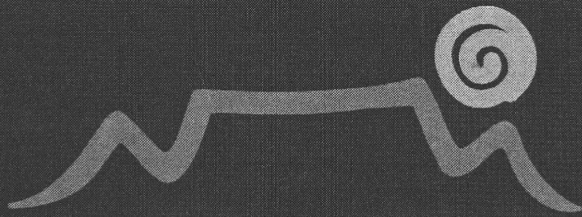
Michio Kimura M.D. Ph.D. Hamamatsu University School of Medicine

15. M. Kimura, , YC Li, YS Kwak :

Survey for Asia-Pacific

Countries/Regions; What are the Medical,
Records for?

MEDINFO 2010, 13th World Congress on Medical
and Health Informatics,
Cape Town, South Africa, September 13,
2010.



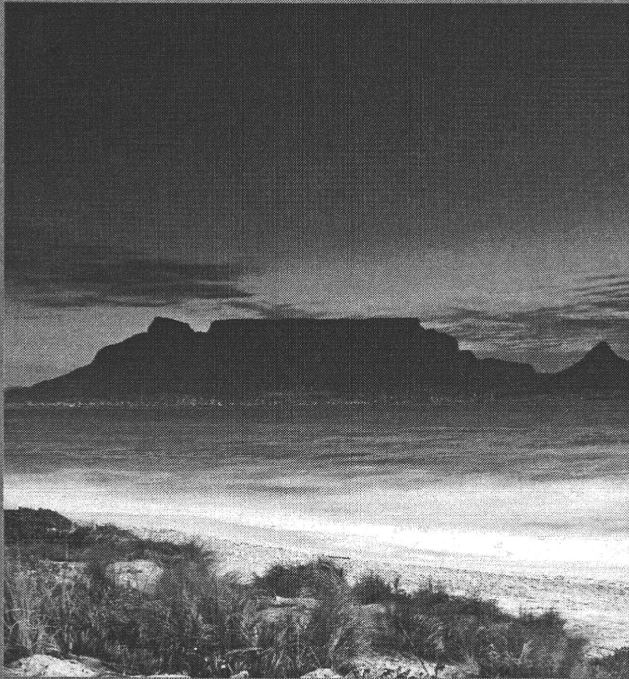
MEDINFO

2010

CAPE TOWN
SOUTH AFRICA

13th World Congress on Medical
and Health Informatics

12th to 15th September 2010



CAPE TOWN
International
Convention Centre



International
Medical
Informatics
Association



CONFERENCE PROGRAMME



PROGRAMME OVERVIEW - MONDAY 13 SEPTEMBER 2010

TIME:	VENUE:	ACTIVITY:
08h30 – 10h00	Audi 1	Student Paper Awards
Session 1		Plenary 2 Dr Marion Ball Prof Reinhold Haux
10h00 -10h30	Exhibition Hall 4	Break
Session 2		Parallel Session
10h30 – 12h15		Papers
	1.4.1 & 1.4.2	Public Health Informatics I
	1.4.3 & 1.4.4	Translational Bioinformatics
	1.6.1 & 1.6.2	Interoperability Issues
	1.6.3 & 1.6.4	Specialised Registries
	2.4.1 & 2.4.2	Adoption Determinants
	2.4.4 & 2.4.5	Implementation
	2.6.1 & 2.6.2	Intelligent Analysis of Monitoring Data
	2.6.4 & 2.6.5	Emerging Technologies
	Audi 1	Surveillance
	Roof Terrace	Mining Clinical Narratives
12h15 – 13h30	Exhibition Hall 4	Lunch Poster Session & Poster Tours 1
13h30 – 15h00		Parallel Session
Session 3		Papers
	1.4.1 & 1.4.2	System Usability
	1.4.3 & 1.4.4	Coding and Terminologies
	1.6.1 & 1.6.2	Citizen-Centric eHealth
		Panels
	1.6.3 & 1.6.4	979 HON code Certification: 13 years of services for improving the quality of health online information
	2.4.1 & 2.4.2	963 Accelerating the Translation of Knowledge into Clinical Decision Support: Four National Demonstration Projects
	2.4.4 & 2.4.5	875 Information Models for Supporting Semantic Interoperability and System Development: Collaborative Efforts from the Domain
	2.6.1 & 2.6.2	757 Automatic data analysis in Biomedicine: Applications and Challenges
	Roof Terrace	518 Social Media – New Tools for Personal Health and Wellbeing
	Audi 1	441 Survey for Asia-Pacific Countries/Regions; “What are the Medical Records for?”
15h00 – 15h30	Exhibition Hall 4	Break
15h30 – 17h15		Parallel Session
Session 4		Papers
	Audi 1	Nursing Informatics
	1.4.1 & 1.4.2	Telemedicine

Correct at date of print - 20 August 2010

13

MEDINFO 2010 |
CAPE TOWN INTERNATIONAL
CONVENTION CENTRE

TIME:	VENUE:	ACTIVITY:
	Audi 1	441: Survey for Asia-Pacific Countries/Regions; What are the Medical Records for? (M Kimura, YC Li, YS Kwak)
15h00 15h30	Exhibition Hall 4	Break
15h30 17h15		Parallel Session
Session 4		Papers
	Audi 1	<p>Nursing Informatics Chair: Heimar Marin</p> <p>120: Clinical users prospective on telemonitoring of patients with long term conditions: understood through concepts of Giddens s structuration theory & consequence of Modernity (U Sharma, M Clarke)</p> <p>176: Analysis on data captured by barcode medication administration system with PDA for reducing medical error at point of care in Japanese Red Cross Kochi Hospital. (M Akiyama, A Koshio, N Kaihotsu)</p> <p>993: Foundations for a Nursing Services Reference Model (L Heslop, K Toh, E Hovenga)</p> <p>653: Ambulatory orthopaedic surgery patients knowledge with Internet-based education (K Heikkinen, S Salanterä, H Leino-Kilpi)</p>
	1.4.1 & 1.4.2	<p>Telemedicine Chair: Maurice Mars</p> <p>859: Leapfrogging Paper-Based Records Using Handheld Technology: Experience from Western Kenya (M Were, J Kariuki, V Chepng'eno, M Wandabwa, S Ndege, P Braitstein, J Wachira, S Kimaiyo, B Mamlin)</p> <p>59: Cell phone Short Messaging Services (SMS) in Health care pertaining to HIV/AIDS in South Africa. (KC Mukund Bahadur, P J. Murray)</p> <p>203: Deploying Portable Ultrasonography with Remote Assistance for Isolated Physicians in Africa: Lessons from a Pilot Study in Mali (CO Bagayoko, M Niang, ST Traoré, G Bediang, JM Naef, A Geissbuhler)</p> <p>774: Exploring Feasibility of Home Telemanagement in African Americans with Congestive Heart Failure (J Finkelstein, E Cha, C Dennison)</p> <p>224: A Configurable Home Care Platform for Monitoring Patients with Reminder Messaging and Compliancy Tracking Services (D Capozzi, G Lanzola)</p>
	1.4.3 & 1.4.4	<p>Communication and Workflow Issues Chair: Nicola (Nikki) Shaw</p> <p>212: Why is it so difficult to measure the effects of interruptions in healthcare? (F Magrabi, SYW Li, AG Dunn, E Coiera)</p> <p>397: Impact of a Critical Care Clinical Information System on Interruption Rates During Intensive Care Nurse and Physician Documentation Tasks (M Ballermann, N Shaw, K Arbeau, D Mayes, N Gibney)</p> <p>749: Peri-operative Communication Patterns and Media Usage Implications for Systems Design (ES Karlsen, P Toussaint)</p> <p>806: Do CPOE Actually Disrupt Physicians-Nurses Communications? (S Pelayo, F Anceaux, J Rogalski, MC Beuscart-Zephir)</p> <p>839: The Avoidable Misfortune of a Computerised Patient Chart (I Sørby, G Seland, Ø Nytrø)</p>



APAMI Panel:

What are the Medical Records for?

Michio Kimura, Jack Li, CP Wong

continued and revised from the panel at Hiroshima, Nov 2009



APAMI2009

Survey on Medical Records and EHR to Asia-Pacific delegates

Peter Croll(AU), BaoLuo Li(CN), CP Wong(HK), SB Gogia(ID), Anis Fuad(IN), Michio Kimura(JP), YunSik Kwak(KR), Stephen Chu(NZ), Alvin Marcelo(PH), ChowYuen Ho(SG), Wansa Paoin (TH), YuChuan Li(TW)

APAMI2009

Questionnaire sent to APAMI delegates (12 valid answers)

- ☒ Purpose of medical records is primary for healthcare itself, what are 2nd? 3rd?
- ☒ Do your country/region has national ID? national health ID?
- ☒ What is the status of your country/region's EHR(lifelong health record) project status?
 - ☒ Purpose of EHR is primary for continuity of care, what are 2nd? 3rd?

APAMI2009 Ichio Kimura M.D. Ph.D. Hamamatsu University School of Medicine

Questionnaire sent to APAMI delegates (12 valid answers)(cont'd)

- ☒ What language is used for; medical records? nursing records?
- ☒ Disclosure of medical record contents to patient, referred physician, insurance payer, public health dept., health policy dept. are unconditional/conditional/prohibited?
- ☒ Secondary use of medical record (dis-identified) by public health dept., health policy dept., non-profit research, for-profit research, are unconditional/conditional/prohibited? Any general regulations?

APAMI2009 Ichio Kimura M.D. Ph.D. Hamamatsu University School of Medicine

Follow-up questionnaires on ID (1)

- ☒ Does your country/region have unique ID for residents?
 - ☒ If YES, the ID is used/linkable to following purposes?
 - ☒ Healthcare claim person number
 - ☒ Healthcare record patient number at each provider
 - ☒ Healthcare record patient number among providers (unique EHR patient number)
 - ☒ Pension record number
 - ☒ Taxpayer's number
 - ☒ Driver's license number
 - ☒ Passport number
 - ☒ Employee number

APAMI2009 Hamamatsu University School of Medicine

Follow-up questionnaires on ID (2)

- ☒ Does your country/region have unique healthcare ID for patients?
 - ☒ If YES, the ID is used/linkable to following purposes?
 - ☒ Healthcare claim person number
 - ☒ Healthcare record patient number at each provider
 - ☒ Healthcare record patient number among providers (unique EHR patient number)
 - ☒ Pension record number
 - ☒ Taxpayer's number
 - ☒ Driver's license number
 - ☒ Passport number
 - ☒ Employee number

APAMI2009 Hamamatsu University School of Medicine

Follow-up questionnaires on Privacy regulations

☞ Is there any regulation/legislation concerning secondary use of private data? (Person's ID enough anonymised, and without person's consent)

- No
- General privacy regulations only
- General privacy regulation, which puts emphasis on healthcare
- Privacy regulation, specially for healthcare

APAMI2009 Ichio Kimura M.D. Ph.D. Hamamatsu University School of Medicine

Languages used

	Medical records	Regulations on description	Nursing records	Medical school education	Nursing school education
Australia	English	Must be English	English	English	English
China	Chinese		Chinese	Chinese	Chinese
HK	English		English	English	English
India	English		English	English	English
Indonesia	Indonesia	Must be Indonesia	Indonesia	Indonesia	Indonesia
Japan	Japanese	Must be Japanese	Japanese	Japanese	Japanese
Korea	Korean & English	Must be Korean	Korean & English	Korean & English	Korean & English
NZ	English		English	English	English
Philippines	English		English	English	English
Singapore	English		English	English	English
Thailand	Thai & English		Thai & English	Thai & English	Thai & English
Taiwan	English		Chinese	Chinese	Chinese

APAMI2009 Ichio Kimura M.D. Ph.D. Hamamatsu University School of Medicine

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

APAMI2009 Ichio Kimura M.D. Ph.D. Hamamatsu University School of Medicine

Does your country/region have unique ID for residents?

☞ If YES, the ID is used/linkable to following purposes?

YES or NO	AU	CN	HK	IN	ID	JP	KR	NZ	PH	SG	TH	TW
Healthcare Claim Number	-	N	U	-	N	N	L	-		U	U	U
Hospital Patient Number	-	N	L	-	L	N	L	-		U	L	L
Unique EHR Number	-	N	U	-	N	N	L	-		U	N	N
Pension Record Number	-	L	U	-	N	N	L	-		U	N	U
Taxpayer's Number	-	U	L	-	N	N	L	-		U	L	U
Driver's License Number	-	L	U	-	L	N	L	-		U	L	U
Passport Number	-	N	L	-	L	N	L	-		U	L	L
Employee Number	-	L	L	-	N	N	L	-		U	N	L

APAMI2009 Ichio Kimura M.D. Ph.D. Hamamatsu University School of Medicine

unique healthcare ID for patients?

☞ If YES, the ID is used/linkable to following purposes?

YES, NO or Citizen D	AU	CN	HK	IN	ID	JP	KR	NZ	PH	SG	TH	TW
Healthcare Claim Number	-	-	U	N	-	U	-	U		N	U	U
Hospital Patient Number	-	-	L	L	-	L	-	N		N	L	L
Unique EHR Number	-	-	U	N	-	N	-	N		N	N	N
Pension Record Number	-	-	U	N	-	N	-	N		N	N	U
Taxpayer's Number	-	-	L	N	-	N	-	N		N	L	U
Driver's License Number	-	-	U	N	-	N	-	N		N	L	U
Passport Number	-	-	L	N	-	N	-	N		N	L	L
Employee Number	-	-	L	L	-	L	-	N		L	N	L

APAMI2009 Ichio Kimura M.D. Ph.D. Hamamatsu University School of Medicine

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

APAMI2009 Ichio Kimura M.D. Ph.D. Hamamatsu University School of Medicine

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**

APAMI2009 Ichio Kimura M.D. Ph.D. Hamamatsu University School of Medicine

Disclosure (patient name identified, without patient's consent) to;

☞ **O: Unconditional, C: Conditional, X: Not done/prohibited**

	The patient	Referred Dr	Insurance	Public Health	Health Policy
AU	C(Summary)	X	X	C(Infections)	C(Claim query)
CN	O	O	O	C(If Name required)	X
HK	O	O	O	X	O
ID	O	O	X	C(Notifiable Disease)	O
IN	O	O	O	O	O
JP	C(Approval)	O	C(Claim query)	C(Notifiable Disease)	X
KR	O	X	O	O	X
NZ	C(Approval)	X	C(Claim data)	C(Disease Control)	X
PH	O	O	O	C(per protocol)	C(per protocol)
SG	O	X	X	C(Infection Act)	C(Stats. Act)
TH	X	O	X	O	O
TW	X	X	X	X	X

APAMI2009 Ichio Kimura M.D. Ph.D. Hamamatsu University School of Medicine

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

☞ **O: Unconditional, C: Conditional, X: Not done/prohibited**

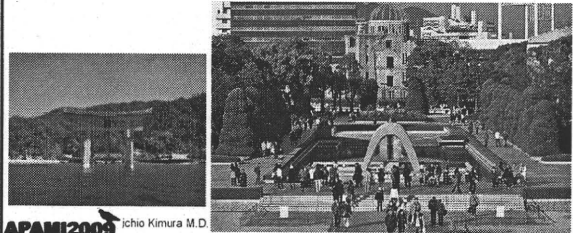
	Public Health	Health Policy	non-profit	for-profit	Any reg.?
AU	O	O	O	O	O
CN	C	O	O	O	X
HK	O	O	C(Universities)	O	X
ID	O	O	C(Approval)	C(Approval)	X
IN	C(Certain Disease)	C(Certain Disease)	C(Approval)	C(agency member)	X
JP	X	X	C(IRB)	X	O
KR	C(Outbreak)	X	X	X	O
NZ	C(No other purpose)	C(No other purpose)	C(No other purpose)	X	O
PH	O	X	X	X	X
SG	C(Stats Act)	C(Stats Act)	C(IRB)	C(IRB)	X
TH	X	X	O	X	X
TW	O	O	O	O	X

APAMI2009 Ichio Kimura M.D. Ph.D. Hamamatsu University School of Medicine

End of Presentation

☞ **Memory of APAMI 2009 in Hiroshima**

- ☑ **Peace Memorial Park and Museum (next to the venue)**
- ☑ **Miyajima Shrine on the Sea (50 minutes boat or train ride)**



APAMI2009 Ichio Kimura M.D.

