

## Forwards by key participants



Fumimaro Takaku, President of the Japan Association of Medical Sciences,  
Chair of Patient Safety Committee of Japan Government,  
President of Jichi Medical University, Former Dean of Medical School in the University of Tokyo



Tomomitsu Hotta Dean & Prof. Tokai University, Medical School, Japan

The incidence and cost of malpractice claims has escalated exponentially over the past 10 years in Japan. It has been reported that the number of death caused by malpractice in health care may be consistent with that by traffic accidents. The claims include staggering financial and emotional costs to patients, to their families, and to physicians and health care institutions. Once adverse events occur, most interests are served when the incidents are evaluated to determine if any legal liability might exist. Appropriate guidelines are to provide quality care for all of patients and their families. This includes not only the technical aspects of care but also humaneness which will always be our highest priorities. This International Forum will be focused on the safe management of health care and I would to chair the panel discussion “safe drug management for cancer patients”.



Ryoji Sakai Chair, Union of Risk Management for Preventive Medicine (URMPM)

Risk management in medicine covers many health topics in a community including clinical management. Japanese Governmental activities for patient safety have just began since 2002. Thus, the earliest purpose of this International Forum is to introduce the advanced systems of patient safety in North America and Europe to Japan. By now, let us discuss and identify better international strategy for patient safety, with many active scientists and governmental executives from those countries and a couple of international organizations. The URMPM hopes to continue this kind of Forum in other countries in the future.

Prof. Sakai was mainly educated in the University of Tokyo, Faculty of Medicine, and engaged in educational and research jobs in the University of Tokyo, Harvard University, Swiss Federal Institute of Technology, University of Science Malaysia, Sanren University (China), etc.

Ken-ichi Youshida

Prof. The University of Tokyo, Graduate School of Medicine, Forensic Medicine, Japan

The famous litigation on the mistaken injection of disinfectant raised controversies on report of medical practice associated deaths to the police according to the Medical Act article 21. After the controversy, the pilot study on investigation and analysis of deaths associated with medical practices has commenced since September 2005, with a financial support from the Ministry of Health, Welfare, and Labor. In this study, a forensic pathologist, a pathologist, and a clinical specialist co-operatively perform autopsy, and qualified specialist review the medical practice on the basis of autopsy, audit, and medical record. Then, the Regional Committee reviews the report of the qualified specialist. The final report is disclosed to the concerned parties. To establish this model project enterprise, the procedures for autopsy, investigation, and review must be established. Specialists (doctors, nurses) to coordinate the investigative process must also be educated. Additionally, management and resolution for error/liability of doctors, accident prevention, emotional care, and compensation are required. During these processes, patients, families, doctors, nurses, pathologists, lawyers, and administrators should understand mutually. Information disclosure and privacy has to be negotiated. As the transparency ensures fairness of investigation and human right, medical experts must be responsible for accountability. To overcome these issues, we must be aware of various aspects and viewpoints associated with issues associated with medical practices, and discuss on the required revolution in the system in near future. These are the themes addressed in this special symposium.

In Anglo-Saxon countries, law defines the report of deaths associated with medical practices to an administrative organization, where legally qualified administrators disclose the cause of death by autopsy, and investigation. The information is disclosed to the concerned parties. Additionally, more systematic approaches have been undertaken to prevent accidents. To this end, we must discuss whether we should encourage report by crime immunity, and also how we should deal with doctor's errors. Moreover, as indemnity is not almighty, we must also consider on emotional care, and administrative disposition for technical and ethical issues of practitioners. As results of intensive social discussions, the laws and systems have undergone revolution in these countries.

Dr. K Yoshida will overview these issues by comparison of the systems of the foreign countries and Japan. Dr. T Noguchi reviews the revolution on the medical laws and systems in California. Dr. J Ibrahim introduces the review & liaison system of deaths associated with medical practices, to prevent similar accidents. Dr. Y Takeda will introduce the "model project enterprise" as an attending coordinator (nurse).

Medical practices require informed consent, and the information is also requested after unexpected deaths and accidents. Dr R Lefler has pointed out the uniqueness of the perception of informed consent in Japan. Consistently, Mr. Kawai's study showed that the unique perception misleads the doctor's understanding on report of death investigation in Japan. Dr. H Takeichi points out the undesirable effects of the privacy protection law, while the most serious problem on the legal autopsy of medical practice associated deaths is that the investigative information cannot be disclosed properly to the concerned parties. Doctor E Katayama shows the perspectives on the system failure and legal liability in Japanese litigations. Dr. T Suzuki, a leading lawyer advocating patient's right, has proposed renovation of law and system on death investigation associated with medical practices. Dr Inaba was a judge, and a government lawyer for medical malpractice. He has then investigated the alternative dispute resolution (ADR) system on medical disputes in USA, and advocated the ADR practices in Japan. Finally, Dr. K Tahara (the Ministry of Health, Welfare, Labor) will present the direction of the pilot study from the administrative point of view.

The lecturers will get together to discuss the required near future system for medical practice associated deaths in Japan at the end of this symposium.



Allen Vaida      Executive Director of Institute of Safety Medical Practice, PA, USA

Allen J. Vaida is the Executive Director for the Institute for Safe Medication Practices (ISMP) in Huntingdon Valley, PA. He previously served as Vice President of Clinical Operations (Chief Operating Officer) at Mercy Suburban Hospital in Norristown, PA. Prior to his appointment as Vice President in 1995, Vaida held the positions of Director of Pharmacy and then Assistant Vice President and Director of Pharmacy at Suburban General Hospital in Norristown, PA. Dr. Vaida has served on various committees and as a board member for several healthcare organizations including as a Trustee for ISMP from its incorporation in 1994 through his employment as Executive Director in 2000. Vaida served on the United States Pharmacopeia's Safe Medication Use Expert Committee from 2000 through 2005 and is Clinical Assistant Professor at the University of the Sciences in Philadelphia, Assistant Adjunct Professor at Temple University School of Pharmacy, Adjunct Associate for the Centers for Health Policy and Primary Care and Outcomes Research at Stanford University and Stanford University School of Medicine, and adjunct faculty for the Executive Patient Safety Fellowship offered through Virginia Commonwealth University, Richmond, VA. He currently serves on the Advisory Board of the Maryland Patient Safety Center. He has given professional presentations on hospital and pharmacy systems and management, error prevention strategies, healthcare outcomes, integrated systems and interdisciplinary collaboration. Vaida has published numerous articles in the pharmacy literature and served as a script and production consultant for the videos, *Reducing Medication Errors through Failure Mode and Effects Analysis* and *Pharmaceutical Care in OncologyTherapy: Caring Enough to Understand*. He has made numerous presentations on medication error reduction strategies and the importance of nonpunitive reporting programs. Dr. Vaida is a past president of the Pennsylvania Society of Health-System Pharmacists and a recipient of the Pharmacist of the Year Award in Pennsylvania and the Jonathan Roberts Award from the Delaware Valley Society of Health-System Pharmacists. He was elected as a Fellow of the American Society of Health-System Pharmacists in 1995. Vaida received a Bachelor of Science in Biology from the University of Scranton, a Bachelor of Science in Pharmacy from the Philadelphia College of Pharmacy and Science and a Doctor of Pharmacy degree from the University of Minnesota.



Thomas Noguchi

Emeritus Prof. University of South California, Forensic Medicine, USA

Prof. Noguchi's 15 years as the chief medical examiner for Los Angeles County earned him the sardonic nickname of "Coroner to the Stars." Noguchi graduated from Nippon Medical School in 1951; he was appointed a deputy coroner for Los Angeles County in 1961 and became the county's chief medical examiner in 1967. As such he performed or oversaw autopsies on celebrities including Marilyn Monroe, Natalie Wood, and Robert F. Kennedy. Noguchi became a celebrity in his own right, and his high profile made him a somewhat controversial figure. He stepped down as chief coroner in 1982 but continued to work with the county, finally retiring in 1999. His 1983 memoir *Coroner* was a best-seller.

Noguchi was widely considered to be the model for Jack Klugman's character in the TV series *Quincy...* Noguchi was president of the National Association of Medical Examiners from 1982-83.

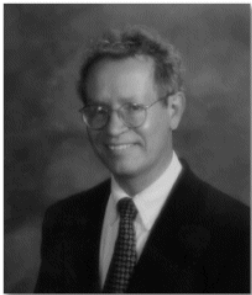


Joseph E Ibrahim

A foundation professor and director of Aged Care Medicine at Peninsula Health, Australia.

Prof. Ibrahim also a founding member of the Clinical Liaison Service (2002), at the State Coroner's Office and the Victorian Institute of Forensic Medicine established to assist the State Coroner's investigations into health care related deaths.

Professor Ibrahim has travelled extensively and the highlights include providing consulting advice on developing hospital accreditation systems in Lebanon, training in clinical risk management in Dubai, Malaysia and Indonesia. Recent research projects include developing performance indicators for Effective Discharge, Stroke Care Outcomes and investigating the under-reporting of hospital deaths to the Coroners Office.



Robert Leflar

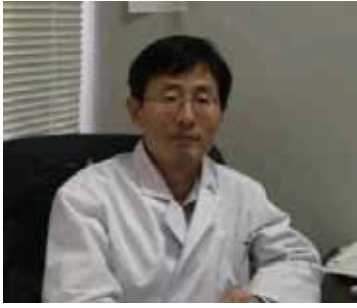
Prof. University of Arkansas, School of Law, Arkansas, USA

Prof. Leflar's specialties are health law, products liability, torts, contracts, and international comparative law. During 2000-2002, as the recipient of an Abe Fellowship, he has been conducting a research project on comparative health law, based partly at Harvard and Tokyo Universities. He has previously had two fellowships abroad: Fulbright Scholar (Japan 1988-89); and Japan Foundation Fellow (Japan 1992). Prior to law teaching, Leflar clerked for Judge George Edwards (U.S. Court of Appeals, 6th Circuit) and was staff attorney for Public Citizen Health Research Group in Washington. He is active in various public interest organizations such as the Arkansas Chapter of the Sierra Club, and is a devoted baseball fan.



Kimiro Meguro

Prof. The University of Tokyo, Institute of Industrial Science, Tokyo, Japan



Taro Shirakawa

Prof. The University of Kyoto, Health Promotion & Human Behavior, Japan



Alexander A. Zukiwski

Vice President Associate Therapeutic Area Head Oncology  
Johnson & Johnson Pharmaceutical Research & Development, L.L.C., USA

His educational background was based on Canadian medicine and pharmacology, such as University of Alberta and University of Calgary. And he worked oncology in McGill University, University of Texas, etc. He serves the present role since 2003 after Director of Clinical Oncology in Hoffmann-La Roche, and Vice President of Clinical Affairs-Oncology in Ortho Biotech Products, L.P, New Jersey in the US.



Hiroshi Takeda

Prof. Osaka University, Department of Medical Informatics, Osaka, Japan

Born in 1947 at Kyoto Prefecture, Japan and graduated from Osaka University Medical School in 1971. Fellow in the Dept. of Clinical Pharmacology (Prof.L.I.Goldberg) at the University of Chicago. Senior Specialist for Scientific Affairs, the Ministry of Education, Science and Culture of Japan (1983-1985). Director in the Dept. of Medical Information Science (1998-). He is also the director of center for clinical quality management in Osaka University hospital and is the first president of the Clinical Safety Management Association of Japanese National University Hospitals. He is currently the Vice-President (2004-2007) for special affairs of the International Association of Medical Informatics. He has been the director of board members of the non-profit-organization (NPO), Organization for Community Health Care Information network Systems (OCHIS) and the chairman of the exhibition committee of the 27<sup>th</sup> general assembly (2007) of the Japan Medical Congress



Martin A. Makary    Assistant Professor of Surgery and Health Policy & Management  
Associate Residency Director    Department of Surgery and  
Co-Director Johns Hopkins Quality and Safety Research

Group Johns Hopkins University, USA

He was educated at Health Policy & Management in Harvard School of Public Health, Medical School of Thomas Jefferson University, Biology in Bucknell University, University of Pittsburgh, and The American University. He got many awards, such as White House Fellow National Finalist through his professional jobs in Brigham & Women's Hospital, Department of Medicine and Massachusetts General Hospital, Department of Surgery in Boston, USA.

#### Jostacio M. Lapitan

Dr Jostacio M. Lapitan, who holds a Doctor of Medicine degree from the University of the Philippines, is currently a Technical Officer of the World Health Organization (WHO) Centre for Health Development based in Kobe, Japan. Before this posting, Dr Lapitan has served as a Public Health Officer of the WHO Country Office for Timor-Leste, a Consultant to the WHO Western Pacific Regional Office and a Medical Coordinator for Medecins Sans Frontieres-Belgium.



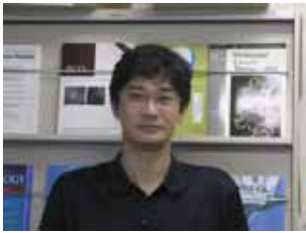
Eiji Katayama    Adjunct Prof. Institute of Frontier Science, The University of Tokyo,  
Japan

'I will speak about the legal responsibility from the viewpoint of the failure of a hospital as an organization for securing the patient's life. There have been not many cases discussing about it in the Japanese courts' judgments. I will take some cases and analyze them. Hopefully, this will give a new legal aspect of the issue of medical security.'



Ryuya Horiuchi

Professor, Department of Clinical Pharmacology, Gunma University Graduate School of Medicine  
Director of Department of Pharmacy, Gunma University Hospital), Japan



Yuichi Ando

Assistant Professor      Department of Clinical Oncology, Saitama Medical School, Japan.

His academic originality was Nagoya University School of Medicine, Japan, and worked in National Cancer Institute (Bethesda, MD, USA) from 1999 to 2002. Followings are his message.

“Individualization of drug dosage is crucial to cancer chemotherapy to reduce unnecessary toxicity and to improve its therapeutic efficacy because the therapeutic index is often narrow. This presentation focuses on pharmacokinetic and pharmacogenetic strategies for optimizing drug dosage in cancer chemotherapy”



Shirley V. Chaves

URMPM International Secretary



URMPM & JSRMPM secretaries (part-time)

Makino, Higashino & Kitamura

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This page is maintained by [Ms. Shirley V.V. Chaves](#). To contact me with suggestion, comments and question, please email to [Shirley](#).  
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