“Unnatural Deaths,”
Criminal Sanctions, and Medical Quality Improvement in Japan
(updated version)

Robert B Leflar*

Introduction
I. The Significance of Criminal Law in Japan’s Regulation
   of Medical Practice
   A. Criminal Prosecution for Unintentional Medical Acts
   B. Legal Grounds for Criminal Prosecutions
   C. The Social Structure of Responsibility for Medical Harm:
      Japanese Medicine’s Accountability Vacuum
II. The Information Gap, “Unnatural Deaths,” and the
    Examination of Corpses
    A. The Information Gap on Patient Safety
    B. “Unnatural Deaths” and Police Investigations
    C. Japan’s Problematic Death Inquest System
III. The “Model Project” and the Proposed National Peer Review System
    A. Inception and Operation of the Model Project
    B. The Model Project: A Tentative Evaluation
    C. The Proposed National Peer Review System and Its Critics
    D. Significance for Health Policy in Western Nations
Conclusion

* Arkansas Bar Foundation Professor of Law, University of Arkansas School of Law,
  Fayetteville; Adjunct Professor, University of Arkansas for Medical Sciences, Colleges of
  Medicine and Public Health, Little Rock. The author can be contacted at rbleflar@uark.edu.
This is a slightly revised and updated version of an article by the same title that first
article was prepared with the support of the Japan Foundation and its Center for Global
Partnership and of the Japan Society for the Promotion of Science. The article could not
have been completed without the generous assistance of Norio Higuchi of the University of
Tokyo Faculty of Law and his colleagues at that university’s International Center for
Comparative Law & Politics, and at the university’s “soft law” COE grant research group.
Thanks are also due to Eric Feldman, Robert Field, Naoki Ikegami, Futoshi Iwata, Tim Jost,
Yoshinao Katsumata, Yasushi Kodama, Kazue Nakajima, Mark Ramseyer, Bill Sage,
Yasushi Tsukamoto, Ken-ichi Yoshida, and many other informants and critiquers, as well as
to Adam Oliver and the members of the U-J-U Network he initiated, many of whom
commented on an earlier version of the article.
Both Western and Japanese names are given family names last, for consistency’s sake.
Currency conversions were conducted at a rate of approximately US $1 = ¥110.
INTRODUCTION

A worldwide awakening to the high incidence of preventable harm resulting from medical care, combined with pressure on hospitals and physicians from liability litigation, has turned international attention to the need for better structures to resolve medical disputes in a way that promotes medical safety and honesty toward patients. The civil justice system in the United States, in particular, is criticized as inefficient, arbitrary, and sometimes punitive. It is charged with undermining sound medical care by encouraging wasteful expenditures through defensive medicine; by driving information about medical mistakes underground where it escapes analysis, undercutting quality improvement efforts; and by forcing physicians in liability-prone specialties such as obstetrics out of practice. Similar charges are leveled against medical injury compensation systems in the United Kingdom, Australia, and elsewhere. While these criticisms have been strongly countered, they have gained a foothold in the public imagination sufficient to place structural reform of medical litigation on the American political agenda.


One enlightened response to mounting concerns over medical error and liability has been a partial shift in focus, in the United States and other Western nations, from the blameworthiness of individual physicians to the correction of system-related deficiencies in the quality of care, and from confrontational litigation between patients and health care providers to a more integrative approach emphasizing disclosure to patients and families of the underlying facts, and apology for harm done. Drawing in considerable measure on Wagatsuma and Rosett’s pioneering 1986 article explaining the importance of apology (in non-medical settings) in Japan, this scholarship portrays honest

1465 (2007) (reviewing HALTON & McCANN, supra; BAKER, supra note 4; and HERBERT M. KRITZER, RISKS, REPUTATIONS, AND REWARDS: CONTINGENCY FEE LEGAL PRACTICE IN THE UNITED STATES (2004)).


8 See e.g., Thomas H. Gallagher, David Studdert, & Wendy Levinson, Disclosing Harmful Medical Errors to Patients, 356 NEW ENG. J. MED. 2713 (2007); Thomas H. Gallagher & Wendy Levinson, Disclosing Harmful Medical Errors to Patients: A Time for Professional Action, 165 ARCHIVES OF INTERNAL MED. 1819 (2005); Thomas H. Gallagher et al., Disclosing Unanticipated Outcomes to Patients: The Art and Practice, 3 J. PATIENT SAFETY, 158 (2007); Rae M. Lamb et al., Hospital Disclosure Practices: Results of a National Survey, 22 HEALTH AFFAIRS 73 (2003); Kathleen M. Mazor et al., Communicating with Patients about Medical Errors, 164 ARCHIVES OF INTERNAL MED. 1690 (2004).


10 Hiroshi Wagatsuma & Arthur Rosett, The Implications of Apology: Law and Culture in Japan and the United States, 20 LAW & SOC’Y REV. 461 (1986); see also Cohen, supra note 9 (both drawing on Wagatsuma & Rosett); Robbennolt, supra note 9 (same); John O. Haley, Comment, The Implications of Apology, 20 LAW & SOC’Y REV. 499, 504-05 (1986) (noting evidence of the impact of apology on preventing U.S. medical practice litigation).
disclosure as more than an ethical and professional duty, and sincere apology as more than a way of fulfilling the emotional needs of patients, families, and medical personnel. These scholars, and the “Sorry Works!” movement that their writing has spurred, also assert that contrary to long-standing assumptions of liability insurers and hospital defense lawyers, disclosure and apology have in fact the practical benefit of diffusing some of the dissatisfaction that leads to compensation claims, thereby potentially shrinking liability burdens. While its likely effects on lawsuit filings are contested, the disclosure-and-apology philosophy is gaining considerable traction in medical practice.

Compared with the United States, Japan (like most countries) enjoys a comparatively low rate of civil litigation over medical injury. What accounts for this relative paucity of medical lawsuits? The stereotype of a nation populated by long-suffering victims with a cultural aversion to the assertion of rights has long been punctured.  

---


12 See, e.g., Steve S. Kraman & Ginny Hamm, Risk Management: Extreme Honesty May Be the Best Policy, 131 ANNALS OF INTERNAL MED. 963 (1999) (Lexington, Ky. Veterans Administration Hospital study); R.M. Stewart et al., Transparent and Open Discussion of Errors Does Not Increase Malpractice Risk in Trauma Patients, 243 ANNALS OF SURGERY 645 (2006); see also Clinton & Obama, supra note 6, at 2207 (describing the University of Michigan Health System program and its results).

13 See David M. Studdert et al., Disclosure of Medical Injury to Patients: An Improbable Risk Management Strategy, 26 HEALTH AFF. 215 (2007) (suggesting that the likely effect of more widespread candor will be that more claims are brought by alerted patients than will be foregone by mollified ones).

14 See e.g., Gallagher, Studdert & Levinson, supra note 8.

15 See Robert B Leflar & Futoshi Iwata, Medical Error as Reportable Event, as Tort, as Crime: A Transpacific Comparison, 12 WIDENER L. REV. 189 (2005), reprinted in 11 ZEITSCHRIFT FUR JAPANISCHES RECHT/JOURNAL OF JAPANESE LAW 39 (2006) [hereinafter cited as “ZJR/JJL”]. We employed claims data to suggest that “an American in 1997 was as much as 40 to 50 times as likely (as an upper-bound estimate) to have filed a medical malpractice claim than was a Japanese.” 12 WIDENER L. REV at 199, 11 ZJR/JJL at 49. We also noted, however, that the large quantity of claims paid by Japanese hospitals and liability insurers but not reflected in publicly available claims statistics has the effect of inflating that ratio considerably. 12 WIDENER L. REV at 198-200 & n. 35, 11 ZJR/JJL at 49-50 & n. 35.

formal dispute resolution processes employing the traditional social lubricant of apology, as the scholarship drawing on the Wagatsuma-Rosett thesis would presume? Not exactly.

After a 12-year-old girl died during heart surgery at Tokyo Women’s Medical University Hospital in 2001 due to improper functioning of a heart-lung machine, police arrested two physicians, one for professional negligence causing death and the other for falsification of the patient’s medical records. (The first was acquitted, the second convicted.) More than a dozen families whose children had died or suffered serious injury at that hospital, renowned for its pediatric cardiac surgery program, formed a “victims’ alliance” seeking compensation, reform of hospital safety practices, and apology for errors committed and facts concealed. After lengthy negotiations, most of the families received out-of-court settlements accompanied by expressions of regret from the hospital, but no public acknowledgement of, or apologies for, negligence or chart doctoring.

The CEO of Tokyo’s well-known Hirō Hospital was arrested, along with two nurses, after a patient’s death from an accidental injection of toxic disinfectant in 1999. The nurses were convicted of professional negligence causing death, and the hospital CEO of falsifying the death certificate and failing to report the case to police in a timely fashion. The Supreme Court of Japan affirmed the CEO’s conviction. The favorable ruling on the family’s civil claim that the hospital’s explanation to them about the patient’s death was inadequate was upheld in the Tokyo High Court.

Police marched an obstetrician in handcuffs out of Ohno Hospital in Fukushima Prefecture in 2006 upon belatedly learning of the 2004 death of one of his patients following a difficult Cæsarean section delivery. The arrest and prosecution sparked a nationwide outcry by medical organizations against heavy-handed intervention by the

---

17 See sources cited supra note 10.
19 The case is the subject of a prize-winning book by a journalist who covered the story. NOBUAKI SUZUKI, AKIKA-CHAN NO SHINZÔ (KENSHÔ): TOKYO JOSHI IDAI BYÔIN JIKEN [AKIKA’S HEART: EXAMINING THE TOKYO WOMEN’S MEDICAL UNIVERSITY HOSPITAL CASE] (2007) (recipient of Kôdansha nonfiction award). The book recounts that the hospital’s internal structure and safety practices were indeed improved in the aftermath of the highly publicized deaths and injuries.
20 1771 HANREI JIHÔ 156 (Tokyo Dist. Ct., Aug. 30, 2001). The attending physician was also convicted of failing to notify police of the patient’s death. For a summary of the case, see Tsukamoto, supra note 18, at 674-675, and infra notes 103-106 and accompanying text.
21 58(4) KEISHC 247 (Sup. Ct., April 13, 2004). The case is further discussed infra notes 103-106 and accompanying text.
22 1880 HANREI JIHÔ 72 (Tokyo High Ct., Sept. 30, 2004).
23 Obstetrician Held over Malpractice, INT’L HERALD TRIB. / ASAHI SHIMBUN, Feb. 20, 2006, at 22; Editorial, Medical Blunders, INT’L HERALD TRIB. / ASAHI SHIMBUN, May 15, 2006, at 31 (commenting on Ohno Hospital case and others).
criminal justice system in the practice of medicine, an outcry that did not abated with the obstetrician’s acquittal.

Preventable medical injury is widespread in Japan just as it is in other developed nations. The problem of fixing accountability for medical harm in a way that promotes patient safety is front and center in Japan as well. Civil litigation over medical injury grew during the last quarter of the 20th century at a pace outstripping the increases in other types of civil actions, although its frequency is still dwarfed by that of medical malpractice litigation in the United States, and medical liability insurance premiums in Japan are still comparatively low. But the character of the Japanese debate over accountability for iatrogenic injury—harm causally related to medical care—is unique.

24 See infra notes 54-58 and accompanying text.
26 A health ministry-sponsored review of 4389 randomly selected patient records at eighteen top hospitals that volunteered to participate found an adverse event rate of 6.0%. Of those adverse events, 23% were considered to have been probably preventable. HIDETÔ SAKAI, IRYÔ JIKÔ NO ZENKOKUTÈKI HASSÉI HINDÔ NI KAN-SURU KENKYÛ [REPORT ON THE NATION-WIDE INCIDENCE OF MEDICAL ACCIDENTS: III] 18 (2006); see also Shunya Ikeda, Iryô jiko hassei hindô chôsa kara erareta wagakuni no kanja anzen no genkyô to kadai [Patient Safety Issues Raised by the Study of Medical Accident Incidence], 14 KANJA ANZEN SUSHIN JÔNARU 56 (2006) (summarizing key study results). This 6% adverse event rate is not incommensurate with reports from other advanced nations, although differences in methodology make direct comparisons suspect. Cross-national data are summarized in CHARLES VINCENT, PATIENT SAFETY 42 (2006), in a chart of studies from seven countries showing adverse event rates ranging from 3-5% at the low end (United States) to almost 17% at the high end (Australia).
27 See TATSUO KUROYANAGI, IRYÔ JIKÔ TO SHIHÔ HANDAN [MEDICAL ACCIDENTS AND JUDICIAL DECISIONS] 3 tbl. 1 (2002) (showing a 129% increase in medical malpractice case filings from 1990 to 2001 as compared to a 46% increase over the same period for civil cases generally). According to the Supreme Court Administrative Office, the number of medical malpractice cases filed in court grew from 234 in 1976 to 1110 in 2004, though filings have diminished since then to 877 in 2008. Supreme Court of Japan, Ijikentei soshin jiken no shori jikô no shi [Disposition of Medical Related Litigation and Mean Duration of Proceedings 1999-2008], [http://www.courts.go.jp/saikosai/about/iinkai/tzikkenkei/toukei_01.html (last visited April 15, 2010). For pre-1999 figures, see YUTAKA TEJIMA, IBISHÔ NYÔMON [A PRIMER OF MEDICAL LAW] 137 (2005).
28 The premium paid by a physician member of the Japan Medical Association liability insurance program in 2003 was ¥70,000 (US $640). General hospitals insured by Yasuda Fire & Marine Co. paid ¥16,130 (US $150) per bed in 2000. See Leflar & Iwata, supra note 15, 12 WIDENER L. REV at 201, 203, 11 JZR/JJL at 51, 53; Kazue Nakajima et al., Medical Malpractice and Legal Resolution Systems in Japan, 285 JAMA 1632, 1633 tbl.1 (2001). A well-informed source close to the liability insurance industry who requested anonymity reported that, as of 2008, Yasuda’s successor company, Sonpo Japan, charges hospitals about ¥30,000 (US $280) per bed. This is a significant percentage increase since 2000, but still far less than premiums paid by U.S. hospitals. Interview with an anonymous source, in Tokyo, Japan (July 31, 2008).
Civil liability trends, though widely remarked upon, are not central. Rather, the debate hinges around the less frequent but intensely publicized use of the criminal law as a regulator of medical practice. Police investigate and prosecutors sometimes charge doctors for professional negligence and concealment of adverse events, particularly in spotlighted cases of grave harm where doctors and hospitals offered patients and families neither honest explanations nor timely, sincere apologies.

Japanese society has been opening up to principles of transparency in many areas, even in the realm of medicine with its customary secrecy. But a succession of cover-ups at prestigious hospitals, exposed by repeated prosecutions accompanied by front-page reportage, has contradicted crystallizing public expectations of candor and has fueled public skepticism about the medical profession’s once-unquestioned benevolence and competence, even at its top ranks. The profession itself, while alarmed at and resentful of what it views as excessive police intrusion into medicine’s domain, has recognized the need for greater openness.

Responding to an initiative from academic medical societies, Japan’s Ministry of Health, Labor and Welfare embarked in 2005 on an innovative “Model Project,” whereby independent experts in specified prefectures investigate possibly iatrogenic hospital deaths, report to the family, the hospital, and the public about the facts, and offer suggestions for preventing similar accidents in the future. The Model Project was conceived in the hopes that cases taken up by the project would rarely be the target of criminal prosecution and that the project would improve transparency within medicine, facilitate extrajudicial resolution of private damage claims, and spur systemwide quality improvement efforts. Beset by start-up difficulties and undermined by physicians’ continuing unease about external peer review and potential police involvement, the Model Project has not met initial expectations for case uptake. Nevertheless, the health ministry has proposed legislation to build on the Model Project’s process by creating a new structure that in essence would constitute a national system of peer review, thereby reforming the nation’s procedures for handling the problem of medical error.

Part I of this Article explains the significance in Japan, hitherto little noticed elsewhere, of criminal law in regulating medical practice. The Article offers reasons of Japanese law and social structure for the role played by criminal law in medicine. Prominent among those reasons has been Japanese medicine’s accountability vacuum: the weakness of other institutional mechanisms for medical quality control, such as peer review, hospital accreditation, specialty certification, licensure and discipline, death inquests, and civil liability litigation.

Part II recounts and analyzes the initial attempts of Japan’s health ministry and medical establishment to address rising public concerns over medical error, against a background of inadequate information about the problem’s nature and dimensions (Section II.A) and a problematic legal and institutional structure for remedying the informational deficit. In Section II.B, the Article explores the controversy over the legal requirement that police be notified of “unnatural deaths”—a requirement interpreted by the Supreme Court to apply not only to deaths from violent crime, natural disaster, and suicide, but also to deaths from potentially iatrogenic causes. This duty of police notification of medically related deaths, against the background that “professional negligence causing death or injury” is an offense under the Criminal Code, has the theoretical (and sometimes practical) effect of turning hospitals into crime scenes, and doctors and nurses into death inquiry suspects. This phenomenon has called forth a powerful protest from medical circles, a reaction bearing a resemblance to the medical “tort reform” movement in the United States. The controversy over police investigation of “unnatural deaths” in Japanese hospitals also compels an examination (Section II.C) of Japan’s obscure and peculiar system for death inquiries, a system that has hindered systematic quality-improvement-oriented analysis of fatalities related to medical treatment.

Part III of the Article tells the story of the launching of the health ministry-funded Model Project, which is designed to strengthen the death inquest system and bring greater transparency to Japanese medicine. Section III.A explains the project’s workings, and Section III.B evaluates its strengths and weaknesses. Section III.C then examines proposed legislation sponsored by the health ministry building on the Model Project to create a national peer review system, criticisms of that proposal from an insurgent anti-regulatory movement within Japanese medicine, and an opposition party alternative. Finally, Section III.D considers whether recent Japanese developments might offer clues to the redesign of medical injury dispute resolution systems in the United States and other Western nations. The Article concludes that although institutional, legal, and cul-
tural differences render one nation’s initiatives problematic for others to follow, the Japanese proposals for impartial expert reviews of medical accidents could serve as a guidepost for design of new structures for compensation and prevention of medical injury.

I. THE SIGNIFICANCE OF CRIMINAL LAW IN JAPAN’S REGULATION OF MEDICAL PRACTICE

A. Criminal Prosecution for Unintentional Medical Acts

Criminal prosecutions for severe misjudgment in the conduct of medical care are not unknown in the Western world, although they are extremely rare in comparison with the number of civil malpractice actions. In the United States, one writer estimated the number of prosecutions for medical acts during 1981-2001 at just two to three dozen.\(^{35}\) Across the Atlantic, the number of recent prosecutions of British physicians for gross negligence manslaughter\(^ {36}\) has been variously enumerated as twenty-three cases (1990-2003)\(^ {37}\) and thirty-eight cases (1990-2005).\(^ {38}\) Prosecutions of doctors sometimes occur in Canada,\(^ {39}\) New Zealand,\(^ {40}\) and France\(^ {41}\) as well. However, prosecutions for un-

35 James A. Filkins, “With No Evil Intent”: The Criminal Prosecution of Physicians for Medical Negligence, 22 J. LEGAL MED. 467, 471-472 & nn. 51 & 53 (2001) (describing nine appellate cases, and estimating from “15 or so” to “perhaps two dozen” more non-appellate cases during the twenty-year period of his research).
38 R. E. Ferner & Sarah E. McDowell, Doctors Charged with Manslaughter in the Course of Medical Practice, 1795-2005: A Literature Review, 99 J. ROYAL SOC’Y MED. 309, 311 tbl.2 (2006). This review found the number of prosecutions to have increased subsequent to the 1980s.
40 See P.D.G. Skegg, Criminal Prosecutions of Negligent Health Professionals: The New Zealand Experience, 6 MED. L. REV. 220, 225-234 (1998) (describing eight prosecutions for negligence of medical providers from 1982 to 1998, and commenting that compared to other Commonwealth jurisdictions, the number of such prosecutions was “remarkably large”). Professor Skegg reports, however, that since the Crimes Act Amendment 1997 raised the criterion for criminal liability from mere negligence to “a major departure from the standard of care expected of a reasonable person to whom [the] duty applies,” id. at 244, only one health care practitioner (a midwife) has been prosecuted, and she was found not guilty. E-mail from Professor Peter Skegg, University of Otago, to the author (July 24, 2008) (on file with author); see also Kay Sinclair & Blair Mayston, Cheers as Midwife Acquitted, OTAGO DAILY TIMES, Mar. 22, 2006, at 1 (reporting on verdict).
intentional medical acts are seldom widely publicized, and they are sufficiently uncommon that they do not constitute a source of significant apprehension for physicians in the Western nations. Nor does the application of criminal law much concern American scholarship on medical injury and patient safety: most leading works in the area do not treat the subject at all.

In Japan, the number of criminal prosecutions of medical personnel is likewise small in comparison with the number of civil actions, but these criminal investigations and

---

41 See John Bell, Sophie Boyron & Simon Whittaker, Principles of French Law 233 (1998) (“Many negligence claims become criminal cases. Thus in 1990, there were 222 civil claims against doctors and 137 criminal prosecutions.”); id. at 217 & n.56, 218-19 & nn. 61 & 64, 226 & n.84 (examples of cases).

42 Extensive publicity has been given on both sides of the Atlantic to prosecutions of physicians for intentional killings of patients. The best-known examples are the prosecutions of Dr. Jack Kevorkian in the United States, see People v. Kevorkian, 527 N.W.2d 714 (Mich. 1994), and of Dr. Harold Shipman in the United Kingdom, see R. v. Sec’y of State for Health, (2001) 1 W.L.R. 292 (Q.B.). Similarly, in one highly publicized case a Japanese physician was convicted of euthanizing a dying patient. Japan v. Tokunaga, 1530 HANREI JIHO 28 (Yokohama D. Ct., March 28, 1995), translated in Timothy Soltzfuus Jost, Readings in Comparative Health Law & Bioethics 332-340 (Robert B Leflar trans., 2d ed. 2007).


Criminal liability for medical mistakes was addressed by a scattering of other U.S. legal writers about a decade ago. See, e.g., Filkins, supra note 35; Paul R. Van Grunsven, Medical Malpractice or Criminal Mistake? An Analysis of Past and Current Criminal Prosecutions for Clinical Mistakes and Fatal Errors, 2 DePaul J. Health Care L. 1 (1997); Kara M. McCarthy, Note, Doing Time for Clinical Crime: The Prosecution of Incompetent Physicians as an Additional Mechanism to Assure Quality Health Care, 28 SETON HALL L. REV. 569 (1997). For a recent critique of British medical jurisprudence related to the crime of gross negligence manslaughter, see Oliver Quick, Medical Killing: Need for a Specific Offence?, in Criminal Liability for Non-Aggressive Death 155 (C.M.V. Clarkson & Sally Cunningham eds., 2008) (favoring application of subjective recklessness standard for medical criminal prosecutions).

44 See Hideo Iida & Issei Yamaguchi, Keiji Iryō Kago [Criminal Medical Malpractice] 1-2 (2001) (finding 137 prosecutions of medical cases in the postwar period, which is “extremely small” in comparison with the number of civil malpractice cases). The pace of
trials receive intensive coverage in the media. After an infamous mix-up in 1999 at Yokohama City Medical University Hospital, in which a heart patient had part of his lung tissue removed and a lung patient with a similar name underwent a heart valve procedure, the pace of medical investigations and prosecutions stepped up significantly. The image of squads of police deploying into hospitals to seize evidence of medical crime has become a part of public consciousness. The fatal injection at Hirō Hospital in 1999, the heart-lung machine blunder at Tokyo Women’s Medical University Hospital in 2002, and a botched laparoscopic prostatectomy the same year by neophyte surgeons reading from the equipment manual and consulting the manufacturer’s representative by phone during a 13-hour operation at Jikei Medical University’s Aoto Hospital in each of these highly publicized cases at prominent Tokyo-area hospitals and in many others, police arrested medical personnel or filed papers with prosecutors, resulting in medical prosecutions accelerated after this book appeared, in keeping with intensified public and prosecutorial concern with the problem of medical error. See infra note 47.

The yearly number of articles about medical error in the Nikkei Telecon 21 database of leading newspapers jumped from 383 in 1998 to 1258 in 1999, the year of the Yokohama Medical University Hospital patient mix-up case and the Hirō Hospital case, and to 3047 in 2000. The number remained in the 2700-3100 range from 2001 to 2004, though it dipped to 2239 in 2005. Yasushi Kodama, *Iryō anzen: How safe is safe enough?* 1339 JURIST 67, 73 fig.2 (2007). This count does not separate articles about criminal cases from other medical error topics, but it makes it clear that the early criminal prosecutions provided the initial spur to the increased level of coverage. The number of media reports spiked again in the summer of 2008 in connection with the prosecution of the Ohno Hospital obstetrician. See supra note 25 and accompanying text.

According to National Police Agency statistics, in 1997 police sent 3 medical cases to prosecutors; in 2007, they sent ninety-two. Hideo Iida, *Keiji shihō to iryo [Criminal Justice and Medicine]*, 1339 JURIST 60, 61 tbl.1 (2007) (summarizing National Police Agency findings from 1 997 to 2005); Nat’l Police Agency, *Iryo jiko kankei todokede-tō kensū no idō, riken söchī [Trends in Reports of Medically Related Accidents and of Cases Sent to Prosecutors]* (May 21, 2008) (presenting 2006-2007 statistics) (on file with author). Putting the matter in historical perspective, the number of criminal prosecutions for medical acts during the fifty-three postwar years 1946-1998 was 137, or 2.6 per year. For the five years and three months from January 1999 through March of 2004, seventy-nine prosecutions were initiated, a rate of 14.8 per year. HIDEO IIDA, KEIJI IRYŌ KAGO [CRIMINAL MEDICAL MALPRACTICE II] 1 (2006).

The three physicians were convicted of professional negligence. *Bungling Doctors Held Responsible for Death, INT’L HERALD TRIBUNE/ASAHI SHIMBUN*, June 16, 2006, at 27. This case was featured in a mass-market book by a well-known urologist. HIDEKI KOMATSU, *JIKEI DAIDAI OTO BYÖIN JIKEN: IRYŌ NO KÖZŌ TO JISSENTEKI RINRI [THE STRUCTURE OF HEALTH CARE AND PRACTICAL ETHICS: THE JIKEI MEDICAL UNIVERSITY AOTO HOSPITAL CASE]* (2004).
criminal charges.\textsuperscript{51} In many of these cases, including the last three noted above, medical personnel altered patient records, deceived family members, or otherwise attempted to obscure the truth. Often the facts were revealed only after a whistle-blower within the hospital contacted a journalist, the family, or the police.\textsuperscript{52}

Strong arguments of philosophy and policy are advanced in Japan against the use of criminal law to discipline physicians and nurses for unintentional professional acts.\textsuperscript{53} To summarize those arguments: 1) Since the acts are unintentional, the prospect of punishment offers little in the way of effective deterrence. 2) The severity of punishment (both as formal penalty and as besmirching of reputation) tends to be out of proportion to the evil punished, in a field where grave consequences may ensue from single acts of simple carelessness. 3) Police are inexpert investigators, with little understanding of the subtleties of medicine. 4) Criminal investigations often take considerable time, interfere with

\textsuperscript{51} These cases are described in more detail in Leflar & Iwata, note 15 \textit{supra}, 12 \textsc{Widener L. Rev} at 192-196, 11 \textsc{ZJR/JJL} at 43-46. Most medical prosecutions have resulted in convictions, although the conviction rate of medical defendants is less than the 99%-plus rate at which criminal defendants in general are found guilty. \textit{See J. Mark Ramseyer & Minoru Nakazato, Japanese Law: An Economic Approach} 178 (1999) (overall conviction rate in 1994 of 99.9%). Medical defendants who are convicted typically receive a fine or probation or both, rather than imprisonment. \textsc{Iida \& Yamaguchi, supra} note 44, at 435-82 (collecting cases); Haruo Yamaguchi, \textit{Iryō jiko no keiji shobun to purufueshonaru ōtonomi [Criminal Sanctions for Medical Accidents and Professional Autonomy]}, 695 \textsc{Nigata-Ken Ishikaihō} 2, 2 tbl.1 (2008) (reporting four cases of imprisonment out of 253 criminal sanctions 1950-2007). The conviction itself, however, is usually enough to force a career change, through either loss of medical license or personal shame, so effectively the punishment is quite significant.

\textsuperscript{52} \textit{See, e.g., Suzuki, supra} note 19, at 63-69 (recounting letter to patient’s family from anonymous whistle blower in Tokyo Women’s Medical University Hospital case). One source of inside information for Japanese journalists is an anonymous Internet bulletin board, Channel 2, \texttt{http://www.2ch.net} (last visited Dec. 3, 2008), containing posts on alleged scandals within various Japanese institutions including hospitals.

\textsuperscript{53} The arguments are offered in various forms in mass-market books, for example, \textsc{Hideki Komatsu, Iryō hōkai [Medicine’s Collapse]} (2006); by medical specialty societies, for example, \textsc{Japanese Soc’y of Internal Med., Japan Surgical Soc’y, Japanese Soc’y of Pathology \& Japanese Soc’y of Legal Med.}, 4 gakkai kyōdō seimei – Shinryō kō ni kanren shita kanja shibō no todokede ni tsuite: Chūritsuteki sembon kikan no sosetsu ni mukete Chūritsuteki sembon kikan no sosetsu ni mukete [Joint Declaration of Four Societies Regarding Notification to Police of Medical Practice-Associated Patients’ Deaths: Toward the Establishment of an Impartial Expert Institution] (2004), \texttt{http://jsp.umin.ac.jp/previous/inkai/inkaihokoku/4kyodoseime.html} [hereinafter Joint Declaration]; before government advisory committees, for example, \textit{Ministry of Health, Labor \& Welfare, Health Policy Bureau, Shinryō kō ni kanren shita shibō ni kaku no shi ni, toshihō to hōkai o kuitomeru kai [Commission on the Investigation of Causes of Medical Practice-Associated Deaths], Kore made no giron no seiri [Summary of Issues Presented] (Aug. 2007), \texttt{http://www.mhlw.go.jp/shingi/2007/08/dl/s-0824-4a.pdf}; and in other online resources and medical blogs put out by organizations, such as the Medical Research Information Center, \texttt{http://mric.tanaka.md} (last visited Dec. 3, 2008) and \textsc{Shūsanki iryō no hōkai o kuitomeru kai [Association to Prevent the Collapse of Perinatal Medicine], http://plaza.umin.ac.jp/~perinate/cgi-bin/wiki/wiki/cgi} (last visited Dec. 3, 2008).
hospitals’ own case review process, and disrupt patient care. 5) Fear of criminal liability deters physicians from undertaking risky but highly beneficial procedures, to patients’ detriment, and drives doctors away from socially important but liability-prone fields such as obstetrics and emergency medicine. 6) The goal of improving patient safety is poorly served by criminal law’s focus on individual blame, turning attention away from the systemic deficiencies at the root of much preventable harm. (Substituting “civil” for “criminal” and “plaintiffs’ lawyers” for “police,” the reader will recognize the arguments set out in this paragraph as roughly analogous to those advanced by many proponents of medical “tort reform” in the United States.)

The stridency of these criticisms reached a particularly high pitch after the humiliating arrest and handcuffing, broadcast on national news, of an obstetrician in February 2006 at Ohno Hospital in rural Fukushima Prefecture after a patient’s death from blood loss during a Cæsarean section delivery.54 The physician was later acquitted,55 but his arrest, detention, and prosecution sparked protests by physicians’ groups across the nation.56 Employing the slogan “Medicine’s collapse” (iryō hōkai),57 this movement called editorial and political attention to the increasing shortage of physicians willing to attend childbirths outside metropolitan areas and to accounts of hospital emergency rooms turning away ambulances for fear of liability exposure. Targeted as one chief cause of those problems has been criminal law’s intrusion into the practice of medicine.58

In the face of these arguments, what accounts for the emphasis Japan has placed on criminal law in the regulation of medical error? Part of the explanation relates to the structure of the criminal law itself. The language of two provisions of the Criminal Code and one provision of the Medical Practitioners’ Law is construed broadly enough to encompass acts that sometimes occur in the course of medical practice. Police and prosecutors have simply considered it their professional duty to enforce the law, particularly while under the gaze of journalists and a public that is newly sensitized to the fact of widespread medical injury, and counts on the criminal justice system to expose the facts and vindicate the public interest.59 A second line of explanation has to do with the social

54 See sources cited supra note 23.
55 16 IRYŌ HANREI KAISETSU 20 (Fukushima D. Ct., Aug. 20, 2008); see also news accounts listed supra note 25.
57 The phrase was apparently coined by Dr. Hideki Komatsu in his 2006 book. See KOMATSU, supra note 53.
58 An excellent collection of materials representing this perspective can be found at Medical Research Information Center, http://mric.tanaka.md (last visited Dec. 3, 2008).
59 This viewpoint was well expressed by Hiroyuki Ohta, Director of the Criminal Planning Division of the National Police Agency, at a meeting of the health ministry’s Commission on the Investigation of Causes of Medical Practice-Associated Deaths [Shinryō kōi ni
structure of responsibility for injury in the course of medical care. This perspective concerns the need for public accountability of the medical profession for its errors—a need that historically has not been sufficiently met by professional self-regulation, administrative oversight, the death inquest system, or civil litigation. The criminal justice system, its proceedings amplified by the media, stepped in to fill that gap.

B. Legal Grounds for Criminal Prosecutions

Prosecutors’ standard charge against medical personnel under the Criminal Code of Japan is “professional negligence causing death or injury.” This crime, derived like most of the Criminal Code from the German penal code, has no specific equivalent in Anglo-American jurisprudence. The rare convictions for unintentional medical acts in recent years in the United States, the United Kingdom and Canada almost all involve charges of a higher level of mens rea: intent, recklessness, or (in England and Wales) at least gross negligence. In Japan, mere negligence is enough.

<table>
<thead>
<tr>
<th>Note</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>61</td>
<td>KEIHÔ [Criminal Code], art. 211 (Gyômujô kashitsu-chi shishô-tô), providing a prison sentence of up to five years and a fine of up to ¥100,000 (US $900). This crime is most commonly charged in connection with traffic offenses, but other professionals such as architects of buildings that collapsed and pilots of airplanes that crashed have also felt its bite. Articles 209 and 210 of the Criminal Code also sanction negligence causing injury and negligence causing death respectively, but they are seldom if ever employed in medical prosecutions.</td>
</tr>
<tr>
<td>62</td>
<td>See HIROSHI ODA, JAPANESE LAW 416 (2d ed. 1999).</td>
</tr>
<tr>
<td>64</td>
<td>See Leflar &amp; Iwata, supra note 15, 12 WIDENER L. REV at 214 n. 110, 11 ZJR/JJL at 64-65 n.110, and cases and commentary cited therein.</td>
</tr>
<tr>
<td>65</td>
<td>Controversy exists among academics about whether the definition of “negligence” is the same in criminal as in civil law, or whether it targets a more limited set of acts and omissions. See, e.g., Manabu Yamazaki, Közôteki kashitsu (2): Iryô kago [Structural Negligence (2): Medical Malpractice], in 30 GENDAI SAIBANHÔ TAIKEI 37, 44-45 (Motoaki Tatsuoka ed., 1999) (setting out differing views, and favoring an identical definition in both fields). The courts have not resolved the issue. In practice, exercising their discretion, prosecutors choose to indict and prosecute only a small fraction of physicians who might be sued for civil malpractice. But however defined, it is “negligence” (kashitsu) that article 211 of the Criminal Code sanctions and “negligence” that must be proven, not something more.</td>
</tr>
</tbody>
</table>
A second ground for prosecution is concealment or destruction of evidence. This offense has formed the basis for convictions for attempted cover-ups through alteration of patients’ medical records, a practice that plaintiffs’ attorneys charge has been widespread in the past.

The third basis for recent prosecutions of physicians is failure to notify the police in timely fashion of “unnatural deaths.” This notification requirement, found in Article 21 of the Medical Practitioners’ Law, has been applied beyond its original scope of violent deaths, suicides, and the like, to encompass deaths possibly caused by medical management. As such, it has become the target of intense controversy and criticism, as discussed below.

Police and prosecutors do not relish working up medical crime investigations. They often feel out of their depth. Cases tend to be complicated, the evidence difficult to muster and master, and the ascertainment of the standard of care and of causal relationships problematic. Expert assistance and the commitment of substantial resources are necessary. Acquittals occur more frequently in medical cases than in other prosecutions, where guilty verdicts are overwhelmingly the norm, and an acquittal may subject prosecutors to public obloquy and professional disgrace. Nevertheless, the code Japan shares the perspective that ordinary negligence can form the basis for prosecutions of physicians with other civil law nations such as France. See BELL, BOYRON & WHITTAKER, supra note 41, at 227 (“Ordinary fault” (faute ordinaire) is the typical basis of liability for délits); id. at 206 (“délits” defined as “less serious offenses [than murder or rape] requiring a mental element and carrying some form of moral disapproval (such as theft, fraud, assault, etc.)”).

Keihō [Criminal Code], art. 104 (Shōko inmetsu-tō). A related crime, for which the CEO of Hirō Hospital was convicted, see supra note 48, is the creation of, with the purpose to use, false official documents. Keihō [Criminal Code], art. 156 (Kyogi kō-bunshō sakusei-tō).

One of the physicians in the Tokyo Women’s Medical University Hospital case was convicted on this ground. See supra notes 18-19 and accompanying text.

See, e.g., HIROTOSHI ISHIKAWA, KARUTE KAIZAN WA NAZE OKIRU [WHY MEDICAL RECORDS ARE FALSIFIED] (2006); Doctor Removed Healthy Breasts, JAPAN TIMES, June 2, 2000, at 2 (reporting tampering with patient records to conceal normal results of pathological tests of breast tissue).

Ishiho [Medical Practitioners’ Law], Law No. 201 of 1948, art. 21.

See infra notes 98-105 and accompanying text.

See, e.g., 16 IROYOHANREI KAISETSU 20 (Fukushima D. Ct., Aug. 20, 2008) (Ohno Hospital case); Judgment of Tokyo High Ct., Nov. 20, 2008 reported in Atsuko Kinoshita & Makoto Inagaki, Medical Mishaps Hard to Rule on Criminally, DAILY YOMIURI, Nov. 22, 2008, available at http://www.yomiuri.co.jp/dy/national/20081122TDY03103.htm (acquittal of Kyorin University Hospital physician); see also Doctor Acquitted in Girl’s Death, INT’L HERALD TRIB. / ASAHI SHIMBUN, Dec. 1, 2005, at 28 (acquittal of one of two physicians charged in Tokyo Women’s Medical University Hospital case).

See RAMESEYER & NAKAZATO, supra note 51 (reporting an overall conviction rate above 99%).

DAVID T. JOHNSON, THE JAPANESE WAY OF JUSTICE: PROSECUTING CRIMES IN JAPAN 46, 107, 238 (2002). On the other hand, even an unsuccessful prosecution in a difficult case does not necessarily impede a prosecutor’s career path if the case has been well researched
provisions described above make it clear that the statutory duty of law enforcement officials to protect the public extends into the hospital. That duty accords with public expectations of the criminal justice system.\textsuperscript{74} When an injured patient, family member, or whistleblower brings forward a charge of death or injury from professional negligence, or when an Article 21 unnatural death notification arrives, the police will look into the matter, and if the evidence is sufficient, they will set into motion the machinery of the criminal process.\textsuperscript{75}

C. The Social Structure of Responsibility for Medical Harm: Japanese Medicine’s Accountability Vacuum

Like other professions, medicine is subject in the Anglo-American nations to discipline from a variety of sources, external and internal. Tort law—specifically, medical malpractice law—casts the longest shadow in the United States, for better or worse, and it plays an important role in the United Kingdom, Canada, and Australia as well. Perhaps more important for the routine organization of U.S. risk management activities, quasi-public accrediting organizations, such as the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance, set detailed standards and carry out periodic on-site assessment activities to exert pressure for quality improvement.\textsuperscript{76} Medical specialty boards carry out stringent initial screening and require periodic recertification to ensure that practitioners acquire and preserve the necessary skills and keep up with the field.\textsuperscript{77}

When things go wrong, hospital peer review committees sometimes limit, suspend, or revoke erring physicians’ hospital privileges. Medicare Quality Improvement Organ-

---

\textsuperscript{74} Interview with Inouye, supra note 73.

\textsuperscript{75} The recent intensification, described in Part III, of the controversy over criminal law’s regulatory oversight of Japanese medicine has not deterred police from investigating some cases of alleged medical error. See, e.g., Shittō misu yōgi shorui sōken [Papers Sent to Prosecutors on Suspicion of Surgical Error], ASAHI SHIMBUN (Yamagata ed.), Feb. 26, 2008, at 35 (describing police action subsequent to hospital’s internal peer review and hospital’s payment of ¥20 million [US $180,000] to family). The number of medical personnel actually prosecuted, however, is reported to have decreased from a high of twelve in 2005 to three in 2006 and none at all in 2007. Kinoshita & Inagaki, supra note 71.


zations,\textsuperscript{78} state licensure and discipline boards,\textsuperscript{79} and in the United Kingdom, the General Medical Council,\textsuperscript{80} all serve to police the profession as well.\textsuperscript{81}

In Japan, by contrast, the analogous structures have historically been weak or dysfunctional. Tort litigation, while more common than in the past, is still infrequent at least by United States standards,\textsuperscript{82} and the sting of liability insurance premiums is far less intense.\textsuperscript{83} There has been an exiguity of peer review,\textsuperscript{84} although the past few years have seen some improvement on that score.\textsuperscript{85} Medical specialty societies have been remiss in assuring quality in most fields of specialty: physicians can proclaim and advertise expertise in medical specialties and practice in them without certification, and even for specialty society members, recertification requirements are lax, where they exist at all.\textsuperscript{86} Until recently, the health ministry had sanctioned practitioners only after a crim-
nal conviction (typically for reimbursement fraud, tax evasion, drug abuse, or morals violations); quality-of-care issues seldom formed the basis for disciplinary measures. Japan’s hospital accreditation authority, the Japan Council for Quality Health Care (Nihon iryō kinō hyōka kikō), operates on a far smaller scale and with a lower profile than JCAHO, its U.S. analogue. A central reason is that unlike in the United States, Japanese hospitals need not be accredited to obtain payment for services rendered, and most have not undergone the accreditation process. Systematic attention to quality control, at least until the public outcry following the Yokohama City Medical University Hospital patient mix-up and other notorious cases noted above, had simply never been a significant aspect of the formal structure of Japanese health care.

When the realization that medical error is remarkably common and often concealed burst upon the Japanese public’s consciousness at the turn of the century, organized medicine was caught napping, the health ministry was unprepared, and the tort system’s

87 Interview with officials in the Ministry of Health, Labor, and Welfare, Office of Medical Safety, in Tokyo, Japan (Aug. 6, 2004). The Ministry of Health, Labor, and Welfare issues administrative sanctions to physicians, dentists, and pharmacists on advice of the Medical Ethics Council (Idō shingikai). In 2002, in response to the furor over highly publicized medical error cases, the Medical Ethics Council adopted a policy whereby serious malpractice could form the basis for an administrative sanction even in the absence of a criminal conviction. Since then, the Council has issued a few more license suspensions and orders for health care personnel to undergo re-training. This latter sanction has been strengthened in accordance with 2006 amendments to the Iryō Hō [Medical Services Law], Law No. 84 of 2006. Etsuji Okamoto has gathered statistics indicating that Medical Ethics Council/MHLW sanctions numbered 392 during the thirteen-year period 1989 to 2001, of which only eighteen arose from a patient’s death or injury from professional negligence, a rate of 1.4 such sanctions per year nationwide. During the subsequent period from 2002 to June 2005, there were 196 sanctions, of which thirty-one arose from professional negligence (8.9 per year).


89 See supra note 46 and accompanying text.

90 See supra notes 45-52 and accompanying text.
ability to respond had institutional limits. For want of other adequate mechanisms of public accountability, police and prosecutors stepped into the breach, employing the statutory weapons at their disposal, in keeping with public expectations of the criminal justice system as protector of society. Whatever the drawbacks of reliance on the criminal law as a regulator of medical practice, and they are many, prosecutions in the high-profile cases in the first years of this century did serve as a wake-up call to the health ministry and the medical profession. The Japanese criminal justice system, its workings spotlighted by the media, has been filling an accountability vacuum.

II. THE INFORMATION GAP, “UNNATURAL DEATHS,” AND THE EXAMINATION OF CORPSES

A. The Information Gap on Patient Safety

Reacting to the medical prosecutions and accompanying publicity, leaders of the medical world and officials of the Ministry of Health, Labor and Welfare (MHLW) began devising measures to address perceived deficiencies in the nation’s health care safety framework. The National University Hospital Council of Japan called on its member hospitals in 2000 to set up safety systems on an urgent basis. MHLW established a medical safety office in 2000, gradually expanding it in the following years. The health minister issued an “emergency appeal” in 2003 to require continuing medical education.

Both the health ministry and the leaders of the medical profession quickly realized that one of the critical problems the nation faced was a giant information gap. No one

---

91 For example, there are only 28,812 practicing attorneys in all Japan, a nation of 127 million. Japan Federation of Bar Associations website, http://www.nichibenren.or.jp/en/about/index.html (last visited April 16, 2010). Few of these attorneys handle medical malpractice cases, on behalf of either plaintiffs or defendants, although their number is increasing. See Leflar & Iwata, supra note 15, 12 WIDENER L. REV at 202 n. 46, 11 ZJR/JJL at 52 n. 46.

92 KOKURITSU DAIGAKU IGAKUBU FUZOKU BYOINCHÔ KAIGI JÔCHI INKAI [NATIONAL UNIVERSITY HOSPITAL COUNCIL OF JAPAN], IRYÔ JIKÔ NO TAME NO ANZEN KANRI TAISEI NO KAKURITSU NI [ESTABLISHING SAFETY MANAGEMENT SYSTEMS FOR THE PREVENTION OF MEDICAL ACCIDENTS] (2001).

93 The staffing and funding of this office have been thin. Personnel increased from three to eight as of 2004. The ministry-wide budget relating to medical safety, including that for general policy, drug safety, the operation of various advisory committees and research groups, and the training of risk managers at national hospitals rose from ¥459 million (US$4.2 million) in 2001 to ¥930 million (US$8.5 million) in 2002 and ¥1.44 billion (US$13.1 million) in 2003—rapid year-on-year increases, to be sure, but still quite modest sums in comparison with patient safety budgets of U.S. and U.K. health agencies. Interviews with Ministry of Health, Labor, and Welfare, Office of Medical Safety, in Tokyo, Japan (July 29, 2003 & Aug. 6, 2004).

knew the magnitude of the medical safety problems that existed, no one had any clear idea of their nature, and no reporting systems were in place to find out. Moreover, with repeated hospital cover-ups on the front pages and in the nightly news, the public had little faith in the willingness or capacity of the profession itself to engage voluntarily in the honest investigation of medical accidents and self-critical analysis of facts found that are essential for safety improvement programs.\(^{95}\)

To counter this information gap, the health ministry issued rules requiring hospitals to create internal accident tracking systems and to report, initially, near misses and, later, accidents involving harm to an independent quasi-public entity for enumeration and analysis.\(^{96}\) While these efforts were getting underway, with mixed success at best,\(^{97}\) the prosecution and conviction of the CEO of Tokyo’s Hirō Hospital turned attention to a separate reporting requirement, originally instituted for entirely different purposes: the requirement that a physician notify police within 24 hours after examining a corpse and determining that the death was “unnatural.”

**B. “Unnatural Deaths” and Police Investigations**

The “unnatural death” notification requirement, found in Article 21 of the Medical Practitioners’ Law,\(^ {98}\) for many years had been understood to apply to deaths from non-medical criminal activity, sudden accidents, suicides, epidemic infections, and the like, much like the public safety and public health-oriented notification requirements standard in the United States, the United Kingdom, and other countries. But in 1994, the Japanese

\(^{95}\) An outpouring of books and other mass market publications pointed accusing fingers at the medical establishment. See, e.g., RESEPUTO KAIJI DE FUSEI IRYŌ O MIYABURÔ! [PUT A STOP TO INAPPROPRIATE MEDICAL TREATMENT BY DEMANDING BILLING DISCLOSURE!] (Hisashi Katsumura ed., 2002); KARUTE KAIZAN [FALSIFICATION OF MEDICAL RECORDS] (Hiroshi Ishikawa ed., 2004); JINTSŪ SOKUSHINZAI: ANATA WA DO SURI? [WHAT ARE YOU GOING TO DO ABOUT LABOR-INDUCING DRUGS?] (Jintsū sokushinzai ni yoru higai o kangaeru kai, eds., 2003).


\(^{97}\) A brief critical evaluation of the MHLW’s early efforts at setting up a reporting system can be found in Leflar & Iwata, supra note 15, 12 WIDENER L. REV at 208-210, 11 ZJR/JJL at 58-60. One of the chief problems was that the limited contents of the reports often permitted only aggregation of the data, not the kind of close analysis of individual cases that can result in useful suggestions for prevention of future accidents.

\(^{98}\) Ishi hō [Medical Practitioners’ Law], Law No. 201 of 1948, art. 21. Violations are punishable by a criminal fine of up to ¥500,000 (US$4,500). Id. art. 33-2(1).
Society of Legal Medicine (Nihon hōi gakkai), an association of forensic medicine specialists chiefly based in medical university faculties whose daily work involves collaboration with police on crime investigations, promulgated a set of guidelines aimed at broadening the interpretation of the definition of notifiable “unnatural deaths” to include those possibly caused by medical management. The 1994 guidelines applied the police notification requirement to “unexpected deaths related to the course of medical treatment and deaths suspected of being so related.” The guidelines stated that unexpected deaths during or soon after procedures such as injections, anesthesia, surgery, medical tests, or childbirth; deaths possibly related to medical treatment; and sudden deaths during or soon after medical treatment whose cause is unclear should all be subject to the notification requirement. The forensic pathologists’ 1994 guidelines had no binding authority, and most physicians were probably unaware of them—until the Hirō Hospital case.

That case arose from a patient’s death in 1999 at a well-known Tokyo hospital after a nurse injected her with what the nurse thought was a heparin solution. In fact, the syringe contained a toxic disinfectant and had been left on the cart by another nurse. Following a decision reached the next day by a hospital committee, the hospital CEO ordered the death certificate to be falsified and sent no notification to the police for eleven days. He was prosecuted and convicted for both deliberate acts. The Supreme Court of Japan affirmed his conviction for violating the Article 21 requirement of notification within twenty-four hours, rejecting his contention that the requirement to notify police on pain of a criminal fine violated the constitutional privilege against self-

---

100 The perceived need for such an interpretation was sparked in part by the controversy over heart transplantations from patients judged to be brain dead. The story of the national debate over whether the first such heart transplant in Japan was medically justified or whether it implicated “unnatural deaths”—a criminal abuse of an ambitious transplant surgeon’s position in his quest for worldwide glory—is ably recounted in Feldman, supra note 16, at 82-109, 131-40; and Margaret Lock, Twice Dead: Organ Transplants and the Re-invention of Death 130-146 (2002).
102 Id.
104 1771 Hanrei jihō 156 (Tokyo D. Ct., Aug. 30, 2001). The two nurses were convicted of professional negligence, and received suspended sentences. The attending physician was convicted of violating Article 21, and received a fine and license suspension. None of these defendants appealed their convictions. A Tokyo metropolitan hospital bureau official, who was advised of the death but did not notify police, was found not guilty. For a summary of the case, see Tsukamoto, supra note 18, at 674-75.
incrimination. In upholding the conviction, the Court recognized that the Article 21 “unnatural death” notification requirement could properly be applied to at least some iatrogenic deaths.

The Hirō Hospital CEO’s conviction sent earthquake shocks through Japanese medicine. A great many patients die in hospitals. Which of these deaths should be considered “unnatural” and therefore notifiable to police? Would a reluctance to contact police, if an iatrogenic death later somehow comes to light, intensify the public’s criticism of the medical profession for concealing its mistakes? On the other hand, would a practice of routine notification to police of every case of possible malpractice, as a health ministry guidance manual seemed to recommend, have the effect of inviting police investigators into hospitals for fishing expeditions, disrupting patient care and subjecting doctors and nurses to the threat of prosecution for professional negligence?

The Japan Surgical Society, one of the two largest and most influential medical specialty organizations, took the view that some kind of reporting to outside authority was advisable. The surgeons’ group issued a somewhat muddled position paper (before the Supreme Court decision in the Hirō Hospital case) contesting the idea that Article 21 requires notification of deaths possibly connected to medical management. The Surgical Society’s position paper advanced the idea that deaths caused by foreseeable complications related to surgery performed with appropriate informed consent should not be considered “unnatural,” but nevertheless called on its members as an ethical matter voluntarily to send “reports” (as distinguished from notifications) to police or to some other independent entity, when there is clear malpractice or strong suspicion of serious malpractice, resulting either in death or in serious injury. After the Supreme Court’s decision in the Hirō Hospital case, the prestigious Science Council of Japan followed with a report acknowledging, like the Japan Surgical Society position paper, the importance of promoting the transparency in health care that the public is coming to expect, but calling for communicating accident information to police on a more limited basis.

---

105 58(4) KEISHŌ 247 (Sup. Ct., April 13, 2004). The hospital CEO did not appeal his conviction for falsifying the death certificate. A good summary of the case and its implications is to be found in Ogawa, supra note 103.

106 See, e.g., Tsukamoto, supra note 18.


109 Nihon geka gakkai [Japan Surgical Society], Shinryō kōi ni kanren shita kanja no shibō, shōgai no hōkoku ni tsuite [Reporting Medical Practice-Associated Deaths and Injuries], reprinted in Hiroyuki Katō, Iryō jikō jōhō no hōkoku no mondai [Issues in Reporting Medical Accident Information], 1249 JURIST 69, 70-71 (2003).
Deaths clearly the result of medical negligence should be notifiable, stated the Science Council, but those where negligence is less clear should first be reviewed by experts before determining whether police should be notified. Other organizations issued different guidelines. Among doctors, hospital administrators, and their legal advisors, confusion reigned.

C. Japan’s Problematic Death Inquest System

Adding to the confusion is Japan’s splintered, underdeveloped system for death inquests, a structure hindering systematic quality-improvement-oriented analysis of fatalities related to medical treatment. As leading forensic pathologist Tatsuya Fujimiya observed, the Japanese death inquest system “does not investigate . . . non-criminal death in any depth” and fails to focus on prevention of future accidents. The following overview of the death inquest system examines the problems of that system from a patient safety standpoint—problems that the health ministry’s “Model Project” and proposed legislative reform, addressed in Part III of this Article, are designed to ameliorate.

Autopsies are conducted in a considerably smaller proportion of all deaths in Japan than in the United States or other Western nations. They are performed by members


111 See Yasushi Kodama, Ishihô 21-jô o meguru konmei [The Confusion Surrounding Article 21 of the Medical Practitioners’ Law], 1249 JURIST 72 (2003); Norio Higuchi, Iryô ni okeru kihan to sofuto rō [Norms and Soft Law in Medicine], 1 SOFT LAW J. 39, 51-53 (2005) (hypothetical case illustrating potential for confusion); Tsukamoto, supra note 33, at 677. According to one survey, many physicians are under the erroneous impression that a medically related death need not be reported to police as long as the patient gave informed consent to the procedure involved, or if the reasons for the death were explained to the family. Ikenaga et al., supra note 33.

One count on which the Ohno Hospital obstetrician was recently acquitted was an alleged Article 21 violation. The district court found that since the patient’s death during Cæsarian section delivery was not proven to have been caused by negligence, it was not an “unnatural” death, so notification of police was not required. Judgment of Fukushima Dist. Ct., Aug. 20, 2008, supra note 25. Whether other courts will accept the apparent link between negligence and “unnaturalness” remains to be seen.

112 Tatsuya Fujimiya, Legal Medicine and the Death Inquiry System in Japan: Their Development and a Comparative Study, in MEDICINE AND THE LAW: PROCEEDINGS OF THE 119TH INTERNATIONAL SYMPOSIUM ON THE COMPARATIVE HISTORY OF MEDICINE, EAST AND WEST 129, 152, 156 (Yasuo Otsuka & Shizu Sakai, eds., 1998) (article from a 1994 symposium); see also Tsukamoto, supra note 33, at 678 (“the medical examiner system in Japan is far from satisfactory”).

113 A 1998 World Health Organization survey placed Japan’s autopsy rate lowest among twenty-two developed nations, at 4% compared to 12% in the United States, 20% in Canada, 24% in the United Kingdom, and 37% in Sweden. See Setsuo Okazaki, Anzen na iryô o kizuku ue de no byôrii no yakuwarai [The Role of Pathologists in Building Safe Medical
of two rival specialties, clinical pathology (byōrigaku) and forensic pathology (hōigaku). Clinical pathologists, typically hospital employees, conduct hospital autopsies in cases where there is no question of “unnatural death”—the majority of cases. Forensic pathologists, who are usually based in university medical faculties or local medical examiners’ offices, perform medicolegal autopsies when a death might be classed as “unnatural.”

Medicolegal autopsies, the kind performed by forensic pathologists, fall into two classes: judicial autopsies (shihō kaibō) for cases determined to be criminal or for which criminal investigation is required, and non-judicial autopsies for what are considered “public health” purposes. The non-judicial autopsies are split again, depending on where they take place: administrative autopsies (gyōsei kaibō) in a few urban areas with medical examiner systems set up under the post-World War II American occupation, and “consented autopsies” (shōdaku kaibō) in the rest of Japan.

When a death is criminal, or suspected as such by the initial police inspection, the case is handled in uniform fashion throughout Japan. The police or prosecutor may apply to the district court for a judicial autopsy. Judicial autopsies are conducted at national expense, typically by forensic pathologists. Consent of the next of kin is not required. The focus is on evidence of crime, so seldom does the judicial autopsy result in a precise determination of non-criminal causes of death possibly related to medical care.

---

114 In 2005, medicolegal autopsies were performed in 13,570 cases. KEISATSUCHÔ [NAT’L POLICE AGENCY]. HEISEI 19-SEN-CHÔ TÔDÔFUKEN-BETSU SHHAI SHUSÔSU [AUTOPSIES HANDLED, BY PREFECTURE] (2007). Hospital autopsies were performed in 19,337 cases. NIHON BYÔRI GAKKAI [JAPANESE SOCIETY OF PATHOLOGY]. 48 NIHON BYÔRI BÔKEN SHHÔ [ANNUAL OF PATHOLOGICAL AUTOPSIES CASES IN JAPAN] 1007 (2006). Together, these autopsies constitute 3.1% of the 1,083,796 total deaths in Japan for that year. MINISTRY OF HEALTH, LABOR & WELFARE, VITAL STATISTICS OF JAPAN 139 (2006) (data on file with author).

115 The best explanation of this convoluted system is found in Ken-ichi Nakane, Wagakuni no kenshi seido [Japan’s Death Inquest System], 2007 REFUARENSU 96. The brief description presented here generally follows the structure of Nakane’s analysis, although not all the critical comments should be attributed to him. For English-language descriptions of the system, see Fujimiya, supra note 112; Ken-ichi Yoshida, Report of Unusual Deaths and the Postmortem Inspection System, in ENCYCLOPEDIA OF FORENSIC AND LEGAL MEDICINE 123 (2005).


117 Police pay roughly ¥250,000-300,000 (US $2300-2800) for a judicial autopsy. Interview with Professor Ken-ichi Yoshida, Univ. of Tokyo Faculty of Med., Tokyo, Japan (July 16, 2008) [hereinafter 2008 Interview with Yoshida].

management.\textsuperscript{118} Even if the autopsy report were to contain such information, neither the family nor the hospital is typically allowed access during the police investigation, which may take months or years.\textsuperscript{119} If the case is dropped, the autopsy report usually remains permanently inaccessible.\textsuperscript{120}

In contrast to the unified system for criminal death investigations, inquiries into deaths of unknown cause for which criminal investigation is not required differ considerably from one jurisdiction to another. Among the five urban prefectures with medical examiners’ offices, three (Tokyo, Osaka, and Hyogo) carry out significant numbers of administrative autopsies.\textsuperscript{121} These medical examiners’ offices, which have authority over about one-tenth of deaths nationwide,\textsuperscript{122} are independent of the police and conduct autopsies, at prefectural expense, for public health purposes.\textsuperscript{123} These autopsies require neither judicial authorization nor family consent. Practice regarding disclosure of administrative autopsy reports to the families and hospitals involved apparently varies.\textsuperscript{124}

All other areas of Japan lack well-functioning medical examiners’ offices, and in these regions death inquests outside the criminal sphere are carried out under a ramshackle system whose results vary considerably. After a police inspection finds that a death case does not require criminal handling, a police surgeon (\textit{keisatsu}) typically enters “natural death” on the death certificate, and that is the end of the matter. The police surgeon is usually a general practitioner on contract to the police,\textsuperscript{125} too often

\begin{itemize}
\item \textsuperscript{118} See Fujimiya, supra note 112, at 147-152; Yoshida, supra note 115, at 126-127.
\item \textsuperscript{119} \textit{E.g.}, Masahiko Idegawa, \textit{Shin shiraberu (3): Keiji shihō no genkai – kaibō kiroku kaiji made 3-nen [Death Investigations (3): The Limits of Criminal Justice – 3 Years until Disclosure of Autopsy Record]}, \textit{ASAHI SHIMBUN}, Sept. 16, 2005, at 3 (reporting Hyogo case in which the prosecution delayed family access to autopsy results adverse to the hospital).
\item \textsuperscript{120} See Fujimiya, supra note 112, at 153; Ikegaya et al., supra note 33, at 116; Ryōko Hatanaka, Wagakuni ni okeru iryō jiko chōsa taisei no genzai [The Current Structure of Medical Accident Investigations in Japan], Medical Accident Information Center Symposium, Nagoya, Japan (May 27, 2006).
\item \textsuperscript{121} Nakane, supra note 115, at 110-113. The other two medical examiners’ offices, in Kanagawa Prefecture (Yokohama area) and Aichi Prefecture (Nagoya area), are scarcely functioning. \textit{Id.} at 111-12 & nn. 60-65.
\item \textsuperscript{122} \textit{STATISTICS AND INFO. DEP’T, MINISTRY OF HEALTH & WELFARE, STATISTICAL ABSTRACTS ON HEALTH AND WELFARE IN JAPAN} 2004, at 31 (2005).
\item \textsuperscript{123} Administrative autopsies are carried out under authority of the Shitai kaibō hozon hō [Corpse Autopsy Preservation Law], Law No. 204 of 1949, art. 8.
\item \textsuperscript{124} See HIDEAKI SHIROYAMA ET AL., SHINRYO KŌI NI KANREN SHITA SHIBŌ NO CHŌSA BUNSEKI MODERU JIGYŌ NO HÔ-SEIDO TO UNYÔ NI KAN-SURU KENKYÛ [THE OPERATION AND LEGAL STRUCTURE OF THE MODEL PROJECT FOR THE INVESTIGATION AND ANALYSIS OF MEDICAL PRACTICE-ASSOCIATED DEATHS] 5-8 (2006) (reporting disclosure of autopsy results in Osaka and Hyogo; no information on Tokyo); Interview with Professor Ken-ichi Yoshida, Univ. of Tokyo Faculty of Med., in Tokyo, Japan (July 17, 2007) (reporting nondisclosure of autopsy results in some cases in Tokyo) [hereinafter 2007 Interview with Yoshida]; Interview with Takashi Nagata, in Tokyo, Japan (Aug. 3, 2007) (same).
\item \textsuperscript{125} Fujimiya, supra note 112, at 147, 153, 154.
\end{itemize}
lacking forensic expertise and without much interest in exploring possible non-criminal death causes. In these regions without medical examiners’ offices, non-judicial medicolegal autopsies may be conducted only with the family’s consent. But for cultural reasons there is considerable resistance among the bereaved to sullying a family corpse. So these “consented autopsies” are often difficult to arrange.

One result of this splintered death inquest system is that the performance of non-judicial medicolegal autopsies for public health purposes is a relatively rare event in most of Japan—the areas lacking well-functioning medical examiner systems. Precise cause-of-death determinations are said to be especially prevalent in these areas. Among the various problems that have been identified with regard to Japan’s death inquest system, the most important is its heavy emphasis on the investigation of crime, rather than on the determination of non-criminal causes of death in a fashion that might aid in future prevention. To be sure, since professional negligence is a crime, police investigation and judicial autopsy are possible in cases of suspected malpractice. But the decision about the need for judicial autopsy, in most of the country, is made by law enforcement personnel (such as a detective or police surgeon) rather than by a qualified pathologist. If a judicial autopsy is carried out, it is performed by a forensic pathologist who may lack sufficient expertise in examining non-criminal death causes. Often, neither the family nor the hospital can obtain the autopsy results in timely fashion, if at

See Yoshida, supra note 115, at 124 (police surgeons have “usually not experienced forensic practice”).
Shitai kaibō hozon hō [Corpse Autopsy Preservation Law], Law No. 204 of 1949, art. 7.
Prominent among these reasons is the desire to bring the body from the hospital for Buddhist funeral services. See, e.g., LOCK, supra note 100, at 306-09 (anthropologist’s exploration of public resistance in Japan to dissections); Fujimiya, supra note 112, at 148, 153-154.
Among East Asian societies, Japan is not the most resistant to the performance of autopsies. The autopsy rate in the Republic of Korea is considerably lower. Interview with Masashi Fukayama, Univ. of Tokyo Faculty of Med., Tokyo, Japan (July 27, 2006); Interview with Yoshinao Katsumata, Dir., Nat’l Research Inst. for Police Sci., in Kashiwa City, Japan (July 27, 2006).
Tatsushige Fukunaga, Shibō shindan/shitai ken-an shisutemu no genjō to mondaiten [Death Determinations and the Postmortem Inquest System], 74 KAGAKU [SCIENCE] 1298 (2004). In the three regions with functioning medical examiner systems, autopsies were conducted in 2003 in 24%-66% of deaths classed as “unnatural.” In regions without well-functioning medical examiner systems, autopsies were conducted in far fewer deaths deemed “unnatural”—e.g., Kyoto (1% or less), Fukuoka (< 1%), western Tokyo (4%). Id. 1299-1301.
Fukunaga, supra note 129.
all.132 In most of Japan, if a family seeks a non-judicial inquiry into a death from a suspected iatrogenic cause, the autopsy may well be carried out at the same hospital where the death occurred, raising concerns about impartiality.133 And in some regions that lack a medical examiner system, the family must often foot the bill.134 If the medical facility itself seeks to carry out a hospital autopsy to determine the cause of death, it must obtain the family’s consent—often no easy task135—and bear the expense itself.136

In sum, Japan’s death inquest system has provided little assistance in elucidating iatrogenic harm and ascertaining possible preventive measures. Neither medical circles nor families bereaved could confidently rely on the system’s effectiveness in support of medical safety.

The year 2004 was a particularly stormy one for Japanese medicine and health policy administration. As the year dawned, the patient safety enterprise was a ship scarcely out of port. The dimensions of the medical error problem were uncertain, its causes not well specified, and approaches to ameliorating its effects scattershot and unfocused. The number of civil malpractice filings was mounting,137 but peer review of physicians for patient-endangering practices was ill-developed and administrative discipline virtually nonexistent. In April 2004, the Supreme Court affirmed the conviction of the CEO of Hirō Hospital for failing to notify police of the “unnatural death” there.138 Notifications

132 Hisako Takeichi, Ken-ichi Yoshida & Kazuto Inaba, Shihō kaibō ni okeru izoku e no jōhō kaigi no mondaiten [Problems of Disclosure of Judicial Autopsy Information to the Bereaved], 595 HÔGAKU SEMINÂ 76-80 (2004); Yoshida, supra note 115, at 127; supra notes 119-120 and accompanying text.

133 In Aichi prefecture (Nagoya), for example, consented autopsies are performed at a different hospital than the one where the death occurred. See SHIROYAMA ET AL., supra note 124, at 5. This practice of switching autopsy sites, which prevails in Osaka prefecture as well, is designed in part to mitigate possible family concerns that the autopsy report might be part of an internal cover-up. See, e.g., SUZUKI, supra note 19, at 57 (suspecting hospital deception in Tokyo Women’s Medical University Hospital case, the family refused consent to hospital autopsy).

Legitimate family concerns about colleague-protective autopsy reports are by no means confined to Japan. See Kevin E. Bove & Clare Iery, The Role of Autopsy in Medical Malpractice Cases, II: Controversy Related to Autopsy Performance and Reporting, 126 ARCHIVES PATHOLOGY LABORATORY MED. 1032, 1035 (2002) (noting U.S. cases generating suspicion of concealment “intended to provide protection to a colleague”).

134 See Fujimiya, supra note 112, at 149, 153; Fukunaga, supra note 129, at 1300, 1302 (describing family payment responsibility in Yokohama and surrounding Kanagawa prefecture, and implying that in other prefectures the situation is similar); Nakane, supra note 115, at 111.

135 See Fujimiya, supra note 112, at 148. Often, after the long, complicated process involving police officers and a police surgeon’s examination, the family simply desires to take the remains away for mourning rituals, rather than subject the corpse to autopsy. See Yoshida et al., supra note 33, at 805.

136 2008 Interview with Yoshida, supra note 117.

137 See sources cited supra note 27.

138 See notes 103-106 and accompanying text.
to police of medically related “unnatural deaths” had increased eight-fold from 1998 to 2004 (Figure 1), as many physicians and hospitals, confused by contradictory guidelines over Article 21’s proper scope and no doubt seeking to avoid the fate of the Hirō Hospital chief, chose to err on the side of caution and send notifications whenever circumstances raised the possibility of professional negligence.

![Figure 1: Medical Accidents Reported to Police and Cases Police Sent to Prosecutors, Japan, 1997-2007](image)


But the death inquest system that these notifications set in motion offered little basis for confidence that iatrogenic harm would be discovered, much less prevented. In the midst of these inauspicious circumstances, the “Model Project” was conceived and fashioned.

139 Iryō jiko, jiken todokede 200-ken toppa – keisatsucho matome, sakunen 35% zō [Notifications of Medical Accidents, Incidents Top 200, 35% Increase from Last Year – Police Agency Study], NIHON KEIZAI SHIMBUN, April 30, 2004, at 30 (increase from thirty-one in 1998, before the notorious Yokohama switched-patient-surgery and Hirō Hospital cases, to 255 in 2004). This enumeration included reports of injuries as well as deaths. The number of formal police investigations opened and cases sent to prosecutors on the basis of these notifications jumped from nine in 1998 to ninety-one in 2004, remaining roughly at that level since then. NAT’L POLICE AGENCY, supra note 47.

140 Hatanaka, supra note 120. Despite this eight-fold increase, it is likely that only a small proportion of medical practice-associated deaths were reported to police. See SAKAI, supra note 26 (estimating that adverse events occur in 6% of all hospitalizations).
III. THE “MODEL PROJECT” AND THE PROPOSED NATIONAL PEER REVIEW SYSTEM

A. Inception and Operation of the Model Project

Japan’s medical leaders deplored intensified police involvement in the monitoring of medical practice, but also felt keenly the weakening of public trust in medicine and understood the need for clearer accountability in the handling of medical accidents. Four medical specialty societies, representing internists, surgeons, clinical pathologists, and forensic pathologists, issued a joint declaration in April 2004 calling for the creation of a new system to conduct reviews of possibly iatrogenic deaths, inform the parties of the facts found, and offer preventive solutions. The proposed new entity would be staffed by impartial experts, and would be separate from the police. The idea appealed to other medical groups, allowing them to paper over (at least temporarily) their differences in support of the concept of what came to be called “third party” (dai-san-sha, i.e., independent both of the hospital at which the accident occurred and of the patient and family) review.

The health ministry, its medical safety office understaffed and beset with difficulties in the operation of the accident reporting system, saw the proposal as an opportunity to move safety efforts forward and agreed to fund the effort on a five-year trial basis, perhaps to serve as a model for a nationwide peer review system. The Ministry of Justice and the National Police Agency adopted a stance of implicit acquiescence, giving up none of their jurisdiction to enforce the laws relating to medical crime and making no definitive public commitment to change any practices, but content to allow the experiment to proceed without hindrance.

The health ministry launched the “Model Project for the Investigation and Analysis of Medical Practice-Associated Deaths” in 2005, initially in four regions, expanded to ten as of this writing. (At the close of the five-year trial period in March 2010, the

141 Joint Declaration, supra note 53.
142 Id.
144 See supra notes 96-97 and accompanying text.
146 In Japanese, the Model Project is styled “Shinryō kōi ni kanren shita shibō no chōsa bunseki moderu jigyō.” The Project was launched in Tokyo, Osaka, Aichi (Nagoya) and Hyogo (Kobe) prefectures, and has been expanded to include Miyagi, Ibaraki, Niigata, Okayama, and Fukuoka prefectures and the Sapporo area in Hokkaido as well. See http://www.medsafe.jp/model.html (last visited April 18, 2010); Shinryō kōi ni kanren shita shibō no chōsa bunseki moderu jigyō dai-18-kai un’ei inkai gijō shidai [Reference
project’s information-gathering and -analysis functions were transferred to a separate entity, Nihon iryō anzen chōsa kikō (Japan Medical Safety Research Council), affiliated with the Japan Council on Quality Health Care.)

The Model Project (moderu jigyō) has worked in the following manner. When a patient died in circumstances possibly related to medical management, the hospital could apply to the region’s Model Project office for an investigation. The initiative had to come from the hospital, not the patient’s family, though the family’s consent would be necessary. Cases falling within the scope of Article 21, however that scope is understood, would still have to be reported to the police. (If, after prompt initial inquiry, the police suspected crime and decide to proceed with an investigation and judicial autopsy, the case was not submitted to the Model Project.) Regional offices, each headed by a physician coordinator, vary somewhat in their approach—the Osaka office always consulted the police before accepting a case, for example, while the Tokyo office sometimes has not when no Article 21 notification was thought necessary—but in general an investigation would proceed according to a standard approach.

If the Model Project’s regional office accepted the case, the office quickly assembled a team of three physicians not connected with the hospital—a clinical pathologist, a forensic pathologist, and a specialist in the field of the patient’s treatment—to conduct a thorough autopsy to determine the cause of death. A separate “evaluation committee” would obtain the patient’s medical records, interview hospital staff involved in the patient’s care, and encourage the hospital to conduct its own investigation. This evaluation committee would include a member of the autopsy team, an attorney, and outside medical experts nominated by the various specialty societies. The evaluation committee would prepare a report setting out the facts of the case, a medical (not legal) evaluation of the course of care, and conclusions on how the accident could have been prevented. This report, together with the autopsy report and other relevant material, would be shared with both the family and the hospital, originally by a target date of three months after the case’s submission. After review by the Model Project’s Tokyo-based steering committee, which included eminent physicians, academics, and attorneys from both

---

147 The basis for much of the outline of the Model Project’s methods in the following two paragraphs is set out in the website for the Model Project, http://www.med-model.jp (last visited April 18, 2010). The remainder has been gleaned from interviews with various people familiar with the project’s workings. English-language summaries of Model Project procedures are available in SHIROYAMA ET AL., supra note 124, at 63-90, and Norihiro Nakajima et al., Interim Evaluation of the Model Project for the Investigation and Analysis of Medical Practice-Associated Deaths in Japan, 2009 J. MED. SAFETY 34.

148 The usual explanation for this apparent anomaly is that the hospital management is more likely to be aware of the existence of the Model Project than the family. Interview with Katsushi Tahara, Director, Ministry of Health, Labor and Welfare, Office of Medical Safety, in Tokyo, Japan (June 23, 2006) [hereinafter Interview with Tahara].
plaintiff and defense bars, a summary of the report would be made public, with names of patient, medical staff, hospital, and location redacted.

Although as a formal matter, the Model Project had nothing to do with liability claims, the evaluation committee’s reports are potentially available for use as evidence in both civil and criminal litigation. However, it is envisaged that the formulation of the report may foreclose the need for most civil litigation and discourage the bringing of prosecutions. Suspicions on the part of the bereaved about what befell the patient are the reason for many lawsuits and complaints to police. The evaluation committee report clarified the facts, allaying these suspicions. With regard to civil claims, where the facts found indicated the likelihood of a successful claim, it is thought that the evaluation committee’s authoritative report could facilitate a rapid settlement. With regard to criminal prosecutions, in most cases taken up by the Model Project, the police initially received an Article 21 notification and then declined to open an investigation.

---

149 For discussions of a 2003 Tokyo High Court decision allowing disclosure of part of a hospital’s internal report concerning a patient’s death to the patient’s family, see Leflar & Iwata, supra note 15, 12 WIDENER L. REV at 207-208, 11 ZJR/JJL at 57-58; Manabu Wagtsuma, Iryō jiko keika hōkokusho no teishutsu gimu [The Duty to Submit Reports on the Course of Medical Accidents], 183 JURIST 42 (2006).

150 Interview with Tahara, supra note 148. Japanese law, in which judges are the fact-finders, has few of the restrictions on admissibility of relevant evidence found in common-law systems relying on juries for fact determinations. According to a memorandum of understanding between MHLW and the Ministry of Justice, if the police demand information obtained by a Model Project evaluation committee, the project managers are “not absolved from the duty [to comply with the police demand]” (“gimu o manugareru koto de wa nai”). This phrase is sufficiently ambiguous to admit of two interpretations: one by alarmed representatives of medical groups that police demands cannot be refused, and another, by Model Project representatives seeking to reassure physicians, that police demands should not be refused but are not legally compulsory. During at least the early period of the Project’s operation, apparently the police did not make any such demands for information. Interview with Ryōko Hatanaka, Shakai gijutsu kenkyū kōkai sentā [Research Institute of Science and Technology for Society] in Tokyo, Japan (June 15, 2006) [hereinafter Interview with Hatanaka].

151 See, e.g., Hikaru Tanaka, Iryō jiko funsō shori seido no dōnyū kentō; Kōrōshō “saiban yori jinsoku” ni kitai [Study of Introducing Dispute Resolution System for Medical Accidents; MHLW Expectation: “Quicker than Lawsuits”], ASahi SHIMBUN, June 29, 2005, at 3.

152 Id.

153 Interview with Akira Maemura, Reporter, Nikkei Shim bun, in Tokyo, Japan (Aug. 13, 2008) [hereinafter Interview with Maemura]; see also Mitsuru Sawa & Seisaku Uchigasaki, Iryō kanrenshi moderu jigyō: Kono 1-nen o furikaette – Iryō kanrenshi ni kansuru moderu jigyō ni jian o todokedeta byōin no tachiha kara [Looking Back on One Year of the Model Project for Medically Related Deaths: The Perspective of a Participating Hospital], 108 NIPPON GAKKAI ZASSHI 89 (2007) (reporting an example of a case at Itabashi Hospital in Tokyo where the hospital initially notified police, who after initial inquiries determined the case to be non-criminal and referred it back to the Model Project); Model Project July 2008 Reference Materials, supra note 146, at attachment 1 (of 202 hospital death cases in which the Model Project was contacted, only twenty-three were declined by the Project on grounds that a judicial or administrative autopsy was called for by the police or medical examiner).
Police have evinced an attitude of restraint, standing back while the Model Project evaluations ran their course.154

B. The Model Project: A Tentative Evaluation

As a concept, there is much to be said in favor of the Model Project’s approach. The quality of the case reviews, on the whole, has likely been superior to those typically undertaken in the past: three experts from different fields participate in each autopsy, and are joined by other specialists on the evaluation committee.155 The fact that the reviews are conducted by outside experts, typically of high reputation, brings objective, up-to-date knowledge to bear on the review process.156 This also has insulated the process from widespread public suspicion of internal self-protection generated by the string of hospital cover-ups exposed over the last several years. Heavy police involvement has been avoided, absent exceptional circumstances.157 The gain in transparency is dramatic: information gathered in the Model Project review has been made available in detailed form both to the family and to the hospital, although the summary released to the public is less comprehensive.158 The evaluation committee’s specific recommendations for quality improvement have assisted to some extent the formulation of particularized preventive measures against future injury. The trustworthiness of the evaluation committee reports may prove to facilitate speedy extrajudicial redress for deserving families.

However, the Model Project got off to a somewhat rocky start, and case uptake did not meet original expectations. MHLW aimed at 200 autopsies during the first year of

---

154 See SHIROYAMA ET AL., supra note 124, at 11 (example of police restraint in Aichi Medical University Hospital case). Those managing the Model Project have counted on criminal justice officials to recognize that if evidence gathered through Model Project investigations becomes fodder for prosecutions of medical personnel, the Model Project would immediately be viewed by the medical world as merely a tool of the police, dooming the project to utter failure.

155 Putting members of the rival specialties of clinical pathology and forensic pathology on the job together should also have the long-term effect of diminishing the tribal antagonism between the two groups.


157 See supra notes 153-154 and accompanying text.

158 For summaries of cases completed through July 2008, see Model Project July 2008 Reference Materials, supra note 146 at attachment 2.
the project’s operation.\textsuperscript{159} In fact, over the project’s five years only 105 cases were undertaken, a rate of just twenty-one cases per year.\textsuperscript{160} The reasons for the low case uptake are complex. Cooperation from hospitals in the participating regions is uneven. In part, this is because the Model Project’s existence was at first little known to physicians and hospital administrators and its purposes were poorly understood.\textsuperscript{161} Some physicians and hospitals, concerned that reports produced by Model Project evaluation committees might be used by police as evidence of medical crime,\textsuperscript{162} may have withheld cases from the project for that reason. As noted above, applications to submit cases to the Model Project for review must come from hospitals, not from aggrieved families (though family consent is necessary). While this stricture may have been understandable as an initial means of encouraging hospital participation, it has tended to rule out cases in which hospitals judge that their interests would be adversely affected by outside review. Then as the project progressed with relatively few cases submitted, hospital administrators may have found no compelling trend to invoke the project’s process, no herd to follow.\textsuperscript{163}

A second set of reasons for the Model Project’s slow start relates to family concerns. As explained above, there exists a widespread cultural resistance to consenting to autopsies, which are at the core of the Model Project’s method.\textsuperscript{164} Also, as a practical matter,

\begin{footnotesize}
\begin{enumerate}
\item[160] http://www.med-model.jp/kekka.html (last visited April 18, 2010). Of 105 cases undertaken, only eighty-two reports have been completed and submitted to families and hospitals as of this writing. Id.
\item[161] Nakajima et al., supra note 147; Tetsu Yamaguchi, Address at the 106th Annual Meeting of the Japan Surgical Society: Ijōshi no todokede to iryo kōi ni kanren shita shibō no chōsa bunseki moderu jigyō [Unnatural Death Notification and the Model Project for the Investigation and Analysis of Medical Practice-Associated Deaths] (Mar. 29, 2006).
\item[162] See SHIROYAMA ET AL., supra note 124, at 15; Nakajima et al., supra note 147; Interview with Hatanaka, supra note 150. The 2006 arrest of the Ohno Hospital obstetrician, Medical Blunders, supra note 150, lent some cogency to this concern, since the Fukushima police acted on the basis of the hospital’s own internal self-critical investigation. Sanka-i taihō ni konwaku; chōshū 1-nen, naze ima – Fukushima kenritsu byōin/teiō sekai misu-shi [Perplexity over Doctor’s Arrest in Fukushima C-section Death – Why a Year after Inquiry?], ASAHI SHIMBUN, March 8, 2006, at 2. However, Fukushima is not one of the Model Project regions, so perhaps police restraint there was less to be expected.
\item[163] Interview with Dr. Yasuyuki Sahara, Chief, Ministry of Health, Labor & Welfare, Office of Medical Safety, Tokyo, Japan (July 15, 2008) [hereinafter Interview with Sahara].
\item[164] See Fujimiya, supra note 112 (reluctance to consent to autopsies); Yoshida, supra note 145, at 535; Yōko Takeda, Köseirōdōshō no shinryō ni kanren suru shibō no chōsa bunseki moderu jigyō – chōsei kangoshi (kōdīnētā) no shigoto [The Role of the Coordinating Nurse
family members’ first concern is with mourning the deceased. Often, only after the first stage of grieving do they turn attention to the possibility that substandard medical care might have occurred; but after cremation, autopsy is no longer possible.165

The Model Project undertook fewer cases than expected. Yet it encountered various difficulties in implementation, and limitations have become evident that must be addressed before its methods and design can be expanded to a nationwide scale. First, personnel were stretched thin: the project has been staffed on a part-time basis by physicians and nurses, almost all of whom have other full-time jobs. Delays in completing reports have been the rule: the mean time from submission of a case to explanation of the final report to family and hospital over the project’s first four years was 10.4 months,166 compared to the originally contemplated deadline of three months.167

Second, the Model Project has been hampered by the weaknesses in Japan’s death inquest system. The project was essentially confined to regions where sufficient pathology expertise is available. The number of clinical (hospital) pathologists is not large, and the count of forensic pathologists is even smaller.168 In many prefectures there may be only one or two forensic pathologists, based at the local university.169 The three-specialist autopsy, standard practice in the Model Project, has been logistically difficult

---

165 Interview with Sahara, supra note 163.
166 MODEL PROJECT CENTRAL OFFICE, SHINRYŌ KŌI NI KANREN SHIHTA SHIBÔ NO CHÔSA BUNSEKI MODERU JIGYÔ: JIGYÔ JISSHI HÔKOKUSHÔ [REPORT ON THE OPERATION OF THE MODEL PROJECT FOR THE INVESTIGATION AND ANALYSIS OF MEDICAL PRACTICE-ASSOCIATED DEATHS] 32 (2009), available at http://www.med-model.jp/download/download_jigyous20.pdf (shiryô 5) (last visited April 18, 2010). None of the completed final reports met the initial three-month deadline. Id. One survey found the delays to have been a significant source of frustration to the families involved. Nakajima et al., supra note 147. However, a leader of the Model Project’s steering committee suggested that what is most important is taking the time to get the reports right, and that the delays may have the positive effect of interposing a cooling-off period between families and hospitals. Interview with Yamaguchi, supra note 86.
167 MODEL PROJECT CENTRAL OFFICE, supra note 159, at 10 (noting extension of deadline from three to six months).
169 Interview with Yoshida, supra note 124.
in these regions and a cause of delay and unneeded expense even in regions with greater numbers of pathologists. Future reviews might well consider a more efficient evaluation system involving a less intensive commitment of professional resources, utilization of advanced imaging technology, and coordination with hospitals’ internal investigation committees in instances where those committees have demonstrated effectiveness.

Third, variations in standards applied to Model Project case reviews have engendered significant criticisms. Dr. Tetsu Yamaguchi, CEO of Tokyo’s well-known Toranomon Hospital and a leader of the Model Project’s steering committee, has emphasized that training of physicians in reviews of clinical practices based on consistent standards is a critical need.\footnote{Interview with Yamaguchi, supra note 86.}

Fourth, the Model Project addressed only death cases. Its chief impetus was the medical world’s strong distaste for police involvement in the review of medical practices, and it is usually an Article 21 “unnatural death” notification that triggers police involvement. The exclusion of cases of serious injury may have served the useful initial purpose of keeping the number of case reviews within manageable limits while the enterprise was gearing up. But limiting the project’s scope also means that the benefits accruing from systematic impartial external peer review, such as objective evaluation, transparency, and building of public trust,\footnote{See Ring & Slotky, supra note 156.} were correspondingly confined to death inquiries. This restriction also limited the number and scope of evaluations from which quality improvement lessons could be drawn. The system would have to be adapted considerably to handle the much broader range of injury cases.

Fifth, the Model Project lacked explicit statutory authorization. It operated solely under health ministry auspices, relying on voluntary cooperation by medical providers and patients. If an evaluation committee requested documentation on a case and the hospital refused to provide it, the committee lacked legal power to obtain that information.\footnote{Interview with Tahara, supra note 148.} This problem requires a legislative remedy, if independent reviews are to be instituted nationwide.

Sixth is the question of long-term funding. The intensive case reviews conducted in the Model Project required considerable time commitments from participating experts and the part-time project staff, much of that time volunteered. The Project’s annual budget increased from an initial ¥102 million (US $0.9 million)\footnote{MINISTRY OF HEALTH, LABOR, & WELFARE, HEISEI 17-NENDO YOSAN (AN) NO GAIYÔ (KÔSEI RÔDÔ SHÔ SEIKYÔKU) [2005 DRAFT BUDGET FOR MHLW HEALTH POLICY BUREAU], available at http://www.mhlw.go.jp/topics/2005/bukyoku/isei/yosan1.html.} to ¥127 million (US $1.1 million) in FY 2008 and ¥177 million (US $1.6 million) in FY 2009.\footnote{E-mail from Dr. Yasuyuki Sahara, Chief, Ministry of Health, Labor & Welfare, Office of Medical Safety, to author (Aug. 25, 2008) (on file with author).} But this is a modest budget indeed. It sufficed in part because of experts’ and staffers’ enthusiasm for participating in a unique endeavor seen as having national significance, and in

\footnote{170 Interview with Yamaguchi, supra note 86.} \footnote{171 See Ring & Slotky, supra note 156.} \footnote{172 Interview with Tahara, supra note 148.} \footnote{173 MINISTRY OF HEALTH, LABOR, & WELFARE, HEISEI 17-NENDO YOSAN (AN) NO GAIYÔ (KÔSEI RÔDÔ SHÔ SEIKYÔKU) [2005 DRAFT BUDGET FOR MHLW HEALTH POLICY BUREAU], available at http://www.mhlw.go.jp/topics/2005/bukyoku/isei/yosan1.html.} \footnote{174 E-mail from Dr. Yasuyuki Sahara, Chief, Ministry of Health, Labor & Welfare, Office of Medical Safety, to author (Aug. 25, 2008) (on file with author).}
part to the unexpectedly small number of cases submitted. But volunteer enthusiasm cannot sustain such an endeavor in the long run. In an era of budget and personnel re-trenchment in the public sector and financial constraints in health care, it will take a substantial political commitment to expand the enterprise nationwide now that the five-year trial period has ended.\textsuperscript{175}

Finally, and most significantly, lurking in the background of the medical safety debate is the specter of criminal prosecution. The boundary between cases subject to prosecution for the crime of professional negligence causing death or injury\textsuperscript{176} and cases merely subject to civil liability or administrative sanction needs clearer delineation. As with any definition of a crime, the line between acts that are punishable and acts that are not inevitably will be indistinct in some cases, subject to interpretation and most importantly to prosecutorial discretion. But for any system of peer review to work, health care personnel need reliable assurance that ordinary human errors will not invite police interrogation.

Still, the Model Project has carried within it the seeds of significant advances. In the midst of a society still largely structured on a vertical, hierarchical basis where collaboration among different disciplines is difficult, the project has collected under one roof physicians from varied and sometimes rival fields of medicine, nurses, plaintiffs’ and hospital lawyers, academics, and health bureaucrats. These may be strange bedfellows with different motives and goals, or as the Japanese saying puts it more picturesquely, \textit{dōshō-imu} (“same bed, different dreams”), but they have gained experience working together in a common enterprise and creating a model for interdisciplinary cooperation. The need for a system of impartial review of medical accidents is clearly recognized, and the Model Project has served as a road test for the creation of such a system. Through the Model Project experience, recognition of the importance of reforming the nation’s fragmented death inquest system is beginning to grow. Experience may prove that the expert reports generated by the project’s reviews will lead to smoother resolution of medical injury claims, setting a guidepost for alternative dispute resolution systems—a guidepost from which other nations seeking better ways of handling medical injury disputes, including the United States, may find useful direction.

\textsuperscript{175} At the end of the five-year trial period on March 31, 2010, most oversight and information-gathering and -analysis functions of the Model Project were transferred to a new entity, Nihon iryō anzen chōsa kikō [Japan Medical Safety Research Council], affiliated with the Japan Council on Quality Health Care (JCQHC, Nihon iryō kinkō hyōka kikō). See \url{http://www.medsafe.jp} (last visited April 18, 2010). The future scale of case review activities is unclear at this writing.

\textsuperscript{176} See supra notes 61, 65 and accompanying text.
C. The Proposed National Peer Review System and Its Critics

Pursuant to resolutions passed in 2006 by the Committees on Health, Labor and Welfare of the Japanese Diet, the blue-ribbon commission under health ministry auspices studied expanding the Model Project’s method of independent expert review of medical accidents nationwide. Their study included a series of public hearings, public comments on three successive proposals, and informal negotiations with stakeholders from the health care sector, the ruling Liberal Democratic Party, and patients’ groups. In June 2008, the commission proposed new legislation building on the basic structure of the Model Project, but modifying it to address most of the Project’s weaknesses noted above. The proposed legislation aims to create what would amount to a national system of peer reviews, external to the hospitals involved, of fatal medical accidents.

The proposal would establish “regional medical accident review commissions” to conduct the medical-practice-associated death inquiries that are currently the responsibility of the police under the infamous Article 21. The purpose of the commissions’ reviews would not be to determine liability, but rather to use the information found in cause-of-death investigations to develop recommendations for improving medical safety. Physicians would be obligated to report to hospital management cases of inpatient deaths suspected either to have resulted from medical error or to have been caused by an unforeseen result of medical treatment, and hospital management in turn, after checking

---


180 See supra notes 98-111 and accompanying text.

181 MHLW June 2008 Draft Proposal, supra note 32, arts. 1 & 12, para. 1. The health ministry proposal’s nickname, “jiko-chō,” is taken from the name of the medical accident review commissions, iryō jiko chōsakai.
the facts, would have a duty to notify the regional commissions of these cases.182 Physicians’ and hospitals’ existing obligation under Article 21 to notify the police of such cases would be extinguished.183 Bereaved families could also invoke regional commission review, without hospital consent, and regardless of whether the hospital management had notified the case to the commission.184 The regional commissions, composed chiefly of medical experts but also including non-medical members, would be tasked with reviewing the cases (in cooperation with but independently of hospitals’ internal review processes)185 compiling reports on the cases, and suggesting prevention measures. The regional commissions would have the power not only to question health care personnel involved in the incidents and to conduct autopsies, but (unlike Model Project evaluation committees) could also compel the production of documents and reports from the hospital.186

Hospital management would have an explicit legal duty to explain honestly to the family the circumstances and causes of the patient’s death.187 In cases involving system errors (in addition to mistakes of individual caregivers), prefectural governments would be given new authority to impose “improvement orders” on hospitals.188 A National Medical Accident Review Commission would gather reports compiled by the regional commissions, analyze them, and formulate and disseminate nationwide recommendations for the prevention of similar accidents in the future.189

The criminal justice system would still have a role to play under the health ministry’s proposal, albeit a diminished one, since the Criminal Code provision sanctioning “professional negligence causing death or injury” would remain.190 The regional commissions would be required to report cases to police in the following four situations:

---

182 Id. art. 32, paras. 2(1), 2(4), 3.
183 Id. art. 33. Article 21 itself would remain on the books, so notification to police of deaths from violent crimes, suicide, contagious infection and the like would still be required.
184 Id. art. 15. This would expand families’ rights compared with the Model Project structure. Cf. supra note 148 and accompanying text.
185 Third Proposal, supra note 179, para. 32. An exception would be made for a category of large high-level hospitals deemed to have adequate internal review processes, tokutei kinō byōin. These hospitals would be authorized to conduct their own case reviews in lieu of regional commission review, as long as the review team included members external to the hospital. Id. paras. 33-35.
186 MHLW June 2008 Draft Proposal, supra note 32, art. 17.
187 Id. art. 32(1). Some Japanese courts have already determined that such a duty exists as a matter of contract law, as an implied term of the patient-provider agreement. See e.g., 1907 HANREI JIHÔ 112, 124-25 (Kyoto D. Ct., July 12, 2005); 1194 HANREI TAIMUZU 243 (Tokyo D. Ct., Jan. 30, 2004), aff’d in relevant part, 1880 HANREI JIHÔ 72 (Tokyo High Ct., Sept. 30, 2004) (on both contract and tort grounds); see also Leflar & Iwata, supra note 15, 12 WIDENER L. REV at 212-213, 11 ZJR/JJL at 62-63 (describing cases).
188 MHLW June 2008 Draft Proposal, supra note 32, art. 32, para. 6.
189 Id. art. 4, para. 6.
190 KEIHÔ [Criminal Code], art. 211, para. 1; see supra notes 61-65 and accompanying text.
1) deaths suspected to have been intentionally caused (e.g., euthanasia);\textsuperscript{191}
2) deaths suspected to have resulted from “grave negligence” (jūdai na kashitsu),\textsuperscript{192}
declared as “extreme deviation from standard medical care”;\textsuperscript{193}
3) deaths involving the suspected concealment, alteration, or forging of medical
records with the purpose of covering up the facts;\textsuperscript{194} and
4) deaths suspected to have resulted from repeated negligence by a practitioner who
has caused similar medical accidents, or other suspected similar serious misconduct.\textsuperscript{195}

Families could still lodge complaints independently with the police, a right that is
guaranteed under the Criminal Procedure Code.\textsuperscript{196} The National Police Agency has informally agreed, however, to “recommend” to complainants that cases first be presented
to the regional commissions for expert evaluation.\textsuperscript{197} In an attempt to reassure the medi-
cal profession, the police agency has also informally agreed to respect the commissions’
evaluations and to carry out its law enforcement responsibilities using the commissions’
conclusions as its primary basis.\textsuperscript{198}

The health ministry proposal was hammered out through negotiations among various
stakeholders within and outside government, including medical groups, top Diet
members with health policy interests, the National Police Agency, and the ministries of
justice and finance. The proposal was agreed to in principle by the then-governing
Liberal Democratic Party (LDP) and the Japan Medical Association leadership, and was
supported by patients’ rights groups.\textsuperscript{199} Nevertheless, the proposal sparked a firestorm
of criticism and as of this writing has not been enacted. The criticisms have come

\textsuperscript{191} MHLW June 2008 Draft Proposal, \textit{supra} note 32, art. 25, para. 1.
\textsuperscript{192} Third Proposal, \textit{supra} note 179, paras. 39, 40(3).
\textsuperscript{193} \textit{Id.} para. 40(3); MHLW June 2008 Draft Proposal, \textit{supra} note 32, art. 25, para. 2. The re-
gional commissions would make case-by-case determinations taking into account factors
such as the size of the health care facility, the geographical environment, the level of experi-
cence of the caregivers, whether an emergency situation existed, and whether the facility had
adequate overall safety systems in place. \textit{Id.}
\textsuperscript{194} \textit{Id.} art. 25, para. 3.
\textsuperscript{195} \textit{Id.}
\textsuperscript{196} \textit{Keiji Soshō Hō [Criminal Procedure Code],} arts. 230-232 (kokuso no kenri).
\textsuperscript{197} Ministry of Health, Labor & Welfare, \textit{Iryo anzen chōsa iinkai (kashō) no iken bōshū ni
tsuite [Request for Public Comments on Medical Safety Review Commission Proposal]} 11
(2008), \textit{available at} \url{http://www.mhlw.go.jp/seisaku/dl/05a.pdf} [hereinafter MHLW Request
for Public Comments].
\textsuperscript{198} \textit{Id.} at 10.
\textsuperscript{199} \textit{See Masafumi Tatematsu & Atsuhiyo Hayashi, Iryo jiko chōsa no soshiki-zukuri: Giron
ōsume, chūmin aitsu-gō [Building a Structure for Medical Accident Review: Debate Enters
the Endgame; Demands Pile Up], ASahi Shimbun, May 22, 2008, at 33 (noting positions of
various groups); Iryōban jikochō: Kinkyū kōkai shimpō [Emergency Public Symposium on
the Medical Accident Review Commission Proposal], in Tokyo, Japan (Aug. 4, 2008)
(statements of patients’ group leaders) (on file with author).
mainly from physicians and some medical groups, as well as from members of the Democratic Party of Japan. The chief criticisms of the proposed legislation are these:

1) The definition of “grave negligence” is insufficiently precise. Practitioners would not know what acts would be considered illegal. This uncertainty would tend to retard innovative non-standard practices.200

2) The regional review commissions constitute an unnecessary expansion of government. Patients and doctors should work out problems among themselves, without creation of a new bureaucratic apparatus.201

3) Reports compiled by the review commissions, and even documents and interview notes obtained during their investigations, could be available for use against hospitals and health care personnel in criminal, civil, and administrative discipline proceedings.202

4) The main beneficiaries of the review commissions’ reports will be plaintiffs’ attorneys, using the review commissions’ reports to bolster their cases.203

5) The proposal is punitive rather than ameliorative in its methods and perspectives. It does not eradicate criminal law intervention into medical practice. It would accelerate, not retard, “iryō hōkai,” medicine’s collapse.204

Taking account of these criticisms, Senator Kan Suzuki of the Democratic Party of Japan (DPJ) put forward a counterproposal, the “Patients’ Support Act,” in June 2008.205


201 See e.g., Kami, supra note 200.

202 Statement of Hirotoshi Nishizawa, President, Zen Nihon Byōinkyokai [All Japan Hosp. Ass’n], (May 12, 2008) (on file with author). According to the health ministry’s explanation, however, interview notes and other groundwork on which final commission reports are based would not be released to investigatory authorities absent a court order. MHLW Request for Public Comments, supra note 197, at 11.


204 A common theme of the medical blogs is a criticism of what is said to be the health ministry proposal’s punitive nature. See infra note 217.

205 Iryō ni kakaru jōhō no teikyō, sódan shien oyobi funsō no tekisei na kaiketsu no sokushin narabi ni iryō jiko-tō no saiatsu bōshi no tame no Iryō Hō-tō no ichibu no kaisei suru hōritsu (kashō) an kosshi shian (tsūshō: Kanja shien hōan) [Outline of Proposed Act to Amend the Medical Services Law to Provide Information Relating to Medical Care, Counseling/Support and Proper Resolution of Disputes, and Prevent Recurrence of Medical Accidents (tentative title); Short title: Patients’ Support Act] (June 2008) (on file with author) [hereinafter DPJ June 2008 Proposal]; see also The Democratic Party of Japan, Jūten seisaku 50 [50 Key Policies], http://www.dpj.or.jp/special/jyuten50/01.html#04 (summary on DPJ web-
The DPJ proposal has points in common with that of the health ministry, but differs in important respects.

The focus of the DPJ proposal is not so much on elucidating the causes of medical accidents and preventing them, as it is on facilitating the resolution of disputes between hospitals and patients and families. The DPJ proposal would lodge the responsibility for reviewing medical accidents (serious injuries as well as deaths) not in regional commissions established by government, as in the health ministry’s plan, but rather in the hospitals themselves. A key concept in the DPJ plan is internal mediation: hospitals would be required to employ or contract for mediators to “promote understanding of medical care by patients and families and dialogue with health care providers, and to assist in resolution of disputes.” If within-hospital mediation fails and a family rejects the hospital’s explanations or proposed resolution of the dispute, the family would have the recourse of seeking either an external expert review of the case or external mediation through a prefectural Medical Safety Support Center.

---

206 DPJ June 2008 Proposal, supra note 205, tit. 1, art. 2, para. 2. The contrast between the DPJ’s emphasis on internal hospital ADR as the key resolution point for medical injuries and the health ministry’s emphasis on external, government-sponsored expert review calls to mind the debate in the United States over what some call the privatization of justice—the trend to outsource conflicts once the bailiwick of the state-erected judicial system to private-sector dispute resolution mechanisms. However, if private ADR fails, under the DPJ proposal the family could still invoke public processes, in contrast to private arbitration foreclosing access to U.S. courts by the losing party.

207 Id. tit. 1, art. 3, para. 3. The meaning of the condition for seeking external review or mediation, viz. that the family “cannot accept” (nattoku dekinai) the hospital’s response, depends on an interpretation in context of the ambiguous concept nattoku (acceptance, satisfaction). “Nattoku” can include a range of acceptance behaviors from satisfied agreement to a grudging, resigned willingness to go along with what is proposed because nothing better is worth trying to obtain in the circumstances. The use of the negative, nattoku dekinai, in the DSP plan sets the trigger for external review outside the latter, “grudging willingness” end of the range. This means that in effect families would invoke the external review or mediation mechanisms only if they find the hospital’s framing of the dispute and proposed resolution of it intolerable. Critics charge that families, dependent on information and interpretations
The DPJ proposal, like the health ministry’s, would place on hospitals and doctors an explicit statutory duty of honest explanation of any adverse events to patients and families.\textsuperscript{210} Reports would go for analysis and dissemination of accident-preventive recommendations to a designated existing entity,\textsuperscript{211} probably the Japan Council for Quality Health Care.\textsuperscript{212}

A key selling point of the DPJ proposal, to the medical profession at least, is that it would abolish Article 21 outright. No longer would physicians or hospitals have the obligation to report medical practice-associated “unnatural deaths” to the police.\textsuperscript{213} Police involvement would presumably be triggered only if patients or families lodged complaints or whistle-blowers leaked damaging allegations.\textsuperscript{214} The DPJ proposal, however, like the health ministry’s proposal, would not change the Criminal Code’s underlying sanction against professional negligence causing injury or death.\textsuperscript{215}

Although much of the medical establishment supports the health ministry’s proposal,\textsuperscript{216} a groundswell of opposition, fed by influential medical blogs,\textsuperscript{217} on the part of

\begin{itemize}
\item provided by the hospital and on the assistance of a hospital-employed mediator, would often be buffed in this setting. \textit{E.g.}, Interview with Toshihiro Suzuki, in Tokyo, Japan (Aug. 8, 2008) (a high-profile plaintiffs’ attorney).
\item Nothing in the DPJ plan would foreclose families from seeking assistance from private attorneys or filing complaints with police. In this respect the DPJ and health ministry proposals do not differ.
\item DPJ June 2008 Proposal, \textit{supra} note 205, tit. 3, arts. 2-3. For a summary of court decisions on the issue, \textit{see supra} note 187.
\item DPJ June 2008 Proposal, \textit{supra} note 205, tit. 1, art. 3, para. 4.
\item The health ministry’s proposal, by contrast, would lodge the quality improvement information dissemination function in the proposed National Medical Accident Review Commission. \textit{See supra} note 189 and accompanying text. This decision likely reflects dissatisfaction with the Japan Council for Quality Health Care’s past performance on this score.
\item DPJ June 2008 Proposal, \textit{supra} note 205, tit. 3, art. 4.
\item Police and prosecutors are likely to oppose this feature of the DPJ proposal, since it would eliminate a key source of information about truly unacceptable hospital practices. Interview with Maemura, \textit{supra} note 153.
\item \textit{See Obstetrical Medicine’s Future, supra} note 212 (quoting Senator Shinya Adachi, M.D., a key supporter of the DSP proposal).
\item The Japan Medical Association, representing doctors owning private-practice clinics, has endorsed the health ministry proposal, although there is dissent among the ranks. \textit{See Tatematsu & Hayashi, supra} note 199. The Japanese Association of Medical Sciences, an umbrella organization of 105 medical specialty societies, polled its members in spring 2008; of fifty-two responses, thirty-five member societies favored the health ministry plan, seven favored it with conditions, five were opposed, and five gave other responses. JAMS Opinion, \textit{supra} note 200.
\end{itemize}
individual physicians touched off an avalanche of protests to Diet members, forcing them to pay attention to an issue that most had ignored in the past. The blogs and protests are manifestations of an insurgent antiregulatory movement within the medical profession, sparked by the 2006 arrest of the Ohno Hospital obstetrician. This movement aims at halting the asserted “collapse” of Japanese medicine by removing or minimizing criminal law’s intrusion into medical practice and reducing the health ministry’s oversight role, as well as by providing greater support to doctors practicing obstetrics and emergency medicine.

The politics surrounding the rival proposals on medical accident review have been unusual. When the proposals were formulated in 2007-2008, the opposition DPJ controlled the upper house of the Diet, so the ruling Liberal Democratic Party (LDP) could not ram the health ministry’s proposal through without compromise. The health ministry itself, never a heavyweight among Japan’s governing agencies, had been further weakened by public wrath over episodes of bureaucratic incompetence. Yoichi Masuzoe, the popular LDP Minister of Health, Labor, and Welfare whose selection as Minister was based partly on his televised criticisms of bureaucratic overreaching and underperforming, actually linked informally with DPJ critics and put the brakes on his own ministry’s first two proposals in 2007, in effect blocking their submission to the Diet. Patients’ rights groups, normally critics of the health ministry and the ruling LDP, backed the health ministry’s proposal.

217 See e.g., Medical Research Information Center Merumaga, http://mric.tanaka.md (last visited Dec. 4, 2008); Lohas Medical Blog, http://lohasmedical.jp/blog/ (last visited Dec. 4, 2008). A list of approximately eighty other blogs, e-mail magazines, and the like can be found on the website of the Association to Prevent the Collapse of Perinatal Medicine (Shūsanki iryo no hōkai o kuitomeru kaikō bunka) http://plaza.umin.ac.jp/~perinate/cgibin/wiki/cgi?pagename=A5%EA%A5%F3%A5%AF#p8 (last visited Dec. 4, 2008).

218 See supra notes 54-58 and accompanying text.

219 Interview with Kami, Professor, Univ. of Tokyo Inst. of Med. Sci., in Tokyo, Japan (Aug. 4, 2008) [hereinafter Interview with Kami].

220 See id.; Interview with Masahide Maeda, Dean, Shuto Univ. Tokyo, in Tokyo, Japan (Aug. 7, 2008) (Chair of the blue-ribbon study commission described in supra note 178 and accompanying text) [hereinafter Interview with Maeda]; Interview with Akira Maemura, Nikkei Shimbun medical and legal affairs reporter, in Tokyo, Japan (Aug. 13, 2008); Interview with Toshihiro Suzuki, Professor, Meijii Univ. Law Sch., in Tokyo, Japan (Aug. 8, 2008).

221 Chief among these episodes is the mismanagement of the nation’s pension records by the branch of the ministry responsible for social security. See Mari Yamaguchi, Social Security Scandal Shakes Japan, WASH. POST, Sept. 2, 2007, available at http://www.washingtonpost.com/wp-dyn/content/article/2007/09/02/AR2007090200146_2.html.

222 Masuzoe, a former University of Tokyo professor, samurai drama actor, and popular TV talk show figure, led the Liberal Democratic Party ticket nationally in votes received during the last Upper House election. He belongs to none of the LDP factions.

223 Interview with Kami, supra note 219; Interview with Maeda, supra note 220.

224 Tatematsu & Hayashi, supra note 199.
with a history of supporting victims’ group causes), were advancing a proposal seen by many as threatening injured patients’ rights with medical provider domination.\(^{225}\)

How this complex political configuration will be resolved is unclear. The DPJ swept into power in August 2009 elections.\(^{226}\) But Prime Minister Hatoyama’s cabinet, as of the time of this writing, had taken no action on either the health ministry’s or the DPJ’s own proposal.

Still, there appears to be sufficient room for adjustment of opposing positions that some revised proposal, incorporating aspects of the two rival plans, should be feasible. Both schemes agree on this: the importance of ascertaining, to the extent possible, the causes of potentially iatrogenic harm and honestly informing patients and families of the course of events. The two proposals differ only with regard to the structure of ascertainment. And the highly publicized acquittal of the Ohno Hospital obstetrician has lent considerable impetus to efforts to enact a national medical accident review system centered on professional analysis rather than criminal investigation.\(^{227}\)

D. Significance for Health Policy in Western Nations

What messages might the recent Japanese experience offer to health policy and medical jurisprudence specialists in the United States and other Western nations? Differences in institutional and legal structures and in cultural assumptions counsel caution in drawing lessons from another nation’s journey. Still, the following points may be worthy of consideration.

1) Those concerned about the onerous impact of tort law on medical practice might take comfort from the scarcity of police investigators in the hospital corridors of Western countries, and from the absence of physicians and nurses in police detention cells.

2) When the public distrusts the integrity of hospital case review processes and doubts the candor of providers’ explanations of adverse events, pressure will mount for external review of those events. Likewise, to the extent providers (and their insurers) are not...

\(^{225}\) See supra note 209 (criticisms of internal hospital ADR proposals).


forthcoming about compensation, apology for injury, and recurrence prevention measures, external review may be sought. When judicial processes are easily accessible, are perceived as trustworthy and fair, and function swiftly and efficiently, they fulfill this external review function admirably. But neither American courts litigating medical malpractice, nor Japanese courts litigating medical crime, have met these ideals.²²⁸ Wariness about courts’ proper functioning has led both American and Japanese societies to consider alternative means of adverse event examination and dispute resolution.

The Japanese experiment with impartial expert review, external to the hospital involved, is a response to highly publicized error episodes shaking much of the public’s faith in medicine’s integrity, when Japanese medicine’s self-policing mechanisms were seen to have failed. Conditions in other nations’ health care systems differ, and the torque of reform drives ameliorative efforts in divergent directions—more centralized in Japan, for example, and more pluralistic in the United States.²²⁹ Still, the concept of case review by expert panels staffed chiefly by independent medical specialists along with representation from other pertinent disciplines (such as law, engineering, systems management, and others), without foreclosing recourse to the courts, is attractive in the context of any modern medicolegal system.

3) Ultimately, this author hopes that compensation for harm suffered by patients whose condition is worsened by medical treatment, and the cost of needed medical care for those patients, might be provided on an “avoidable harm” or “preventable harm” basis rather than on a fault basis, at least for some designated categories of medical accidents.²³⁰ Sweden currently operates such a system.²³¹ Virginia²³² and Florida²³³ have

²²⁸ Indeed, public dissatisfaction with the judiciary in general is higher in the United States than in Japan. See John O. Haley, Litigation in Japan: A New Look at Old Problems, 10 WILLAMETTE J. INT’L L. & DISP. RESOL. 121, 139 (2002) (“Public opinion polls . . . routinely show that [Japanese] judges, along with police and prosecutors, enjoy unusually high levels of public trust . . ., especially when viewed in comparison to other countries, including the United States.”).

²²⁹ For instance, both the Japanese health ministry’s proposal for a few regional medical accident review commissions reporting to a single national commission and its system for reporting adverse events to the Japan Council for Quality Health Care, are far more centralized in nature than the system of Patient Safety Organizations (PSOs) to be set up under the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. §§ 299b-21 to 299b-26 (Supp. 2005). Under the Department of Health and Human Services’ final rule implementing the 2005 law, PSOs numbering in the hundreds or thousands will apply for certification to receive adverse event and near-miss information developed by health care providers, analyze it, and disseminate accident-prevention suggestions, without necessarily undertaking any evaluation of the care provided. See Patient Safety and Quality Improvement, 42 C.F.R. §§ 3.10 to 3.552 (2008).

²³⁰ For excellent overviews of proposals to overhaul the medical tort system along these lines, see Randall R. Bovbjerg & Laurence R. Tancredi, Liability Reform Should Make Patients Safer: “Avoidable Classes of Events” Are a Key Improvement, 33 J. L. MED. & ETHICS 478 (2005); Michelle M. Mello et al., “Health Courts” and Accountability for Patient Safety, 84 MILBANK Q. 459 (2006).
taken limited steps in that direction regarding no-fault compensation for families of infants with neurological damage at childbirth, and Japan has launched an analogous birth damage compensation system.\textsuperscript{234} Neither Japan nor the United States is yet at the happy stage of expanding this concept to cover a broader range of medical injuries. But review of adverse events by impartial experts is at the core of all such endeavors. The method of impartial expert review of medical practice-associated deaths, which Japan’s Model Project has adopted, is one guidepost along the road to this type of systemic reform.

CONCLUSION

The Japanese health care system inflicts preventable injury on its patients at rates generally commensurable with those measured in Western nations. Awareness of the problem burst on the nation in 1999 and 2000, contemporaneously with the release of \textit{To Err Is Human}\textsuperscript{235} by the Institute of Medicine in the United States, as reports on a series of health care calamities at famous hospitals graced the front pages of Japanese newspapers. Most of these disasters were not accompanied by the apologies to victims and harmonious resolution of disputes through which the conventional wisdom holds that Japan smooths its social frictions. Instead, they were exposed despite cover-ups and attempts to deceive patients and families.

The story of medical error demonstrates once more that the trajectories of national responses to common crises are often strongly affected by each society’s legal and institutional structure. In contrast to most Western nations, in Japan the criminal law has played a significant role in the regulation of harmful medical practice, much to the consternation of the medical profession.

Criminal law’s prominence in Japanese regulation of medical error, seldom remarked on outside Japan,\textsuperscript{236} is in part attributable to the structure of the law itself. Professional negligence causing death or injury is a crime, as is the failure to notify police of “unnatural deaths,” now interpreted to encompass deaths from medical mismanagement.

\begin{itemize}
\item \textsuperscript{233} Fla. Stat. Ch. 766.301 to .316 (2005 & Supp. 2008); see also Randall R. Bovbjerg, Frank A. Sloan & Peter J. Rankin, \textit{Administrative Performance of “No-Fault” Compensation for Medical Injury}, 60 L. CONTEMP. PROBS. 71 (1997) (examining the operation of the Virginia and Florida systems).
\item \textsuperscript{235} \textit{To ERR IS HUMAN, supra} note 1.
\item \textsuperscript{236} See supra note 33 and accompanying text.
\end{itemize}
In part, however, the role played in Japanese medicine by criminal law has been a matter of *faute de mieux*: police and prosecutors initiated criminal investigations and prosecutions because no other social mechanisms were adequate to police the medical world. The Japanese criminal justice system filled an accountability vacuum.

Reacting to the loss of public trust in medicine brought about by repeated revelations of error and deception, and dismayed by the prospect of police intrusion into medical matters, leaders of the Japanese medical profession presented a plan for impartial expert review of medical practice-associated deaths, with reports provided to the family, the hospital, and the public. Funded by the health ministry, this five-year “Model Project” was carried out from 2005 to 2010 in ten prefectures. The project attempted to overcome numerous structural and institutional obstacles, including a splintered, underdeveloped, and secretive death inquest system. Despite a smaller-than-anticipated case uptake, the project has had some success in bringing a new level of transparency to the medical world, in identifying and disseminating ways of preventing future harm, and perhaps in facilitating the speedy resolution of medical disputes, reserving the intervention of the criminal justice system for only the most reprehensible cases. The project has represented an attempt at wedging ajar a portal historically closed in Japan, illuminating some of the medical profession’s weaknesses long kept in shadow, and encouraging the kind of quality improvement in medicine for which other sectors of Japan’s economy have long been famed.

Building on the Model Project’s methods, Japan’s health ministry has proposed what amounts to a national system of peer reviews, external to the hospitals involved, of potentially iatrogenic hospital deaths. The Democratic Party of Japan has countered with a rival proposal. At this writing neither proposal has become law. But the highly publicized arrest, detention, and prosecution of an obstetrician for a patient’s death during childbirth in rural Fukushima prefecture, and his acquittal in August 2008, seem to have crystallized Japanese public opinion around the view that the criminal justice system is too heavy-handed a tool for proper regulation of medical quality. A systemic reform based on the concept of impartial non-criminal external review of medical accidents, if enacted, could serve as one guidepost for other nations seeking to design improved structures for compensation and prevention of medical injury.
ZUSAMMENFASSUNG


Die vorliegende Abhandlung verdeutlicht zunächst (Teil I), dass die prominente Rolle des Strafrechts für die Verhaltenssteuerung in der medizinischen Praxis in Japan auf ein Verantwortungsvakuum zurückzuführen sein dürfte, welches durch die Schwäche anderer institutioneller Mechanismen bedingt und mangels Alternative vom Strafrecht gefüllt wird.

Anschließend (Teil II) geht der Autor auf die anfänglichen Bemühungen des japanischen Gesundheitsministeriums ein, vor dem Hintergrund erhöhter Medienaufmerksamkeit dem beträchtlichen Informationsdefizit zu begegnen, welches bisher bezüglich der Art und dem Ausmaß des Problems besteht. Dieses führt der Autor auch darauf zurück, dass es in Japan häufig die Polizei ist, welche die Todesursache in Fällen möglicher Behandlungsfehler untersucht. Hintergrund ist die sehr kontrovers diskutierte strafbewehrte Pflicht zur Anzeige „unnatürlicher Todesfälle“, die von der japanischen Rechtsprechung auch auf Fälle möglicher medizinischer Fehler erstreckt wird.


(d. Red.)