ARTICLES

"Unnatural Deaths," Criminal Sanctions, and Medical Quality Improvement in Japan

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INTRODUCTION

A worldwide awakening to the high incidence of preventable harm resulting from medical care,[1] 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.[2] Similar charges are leveled against medical injury compensation systems in the United Kingdom, Australia, and elsewhere.[3] While these criticisms have been strongly countered,[4] they have gained a foothold in the

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1. *See, e.g.*, INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (Linda T. Kohn, Janet M. Corrigan & Molla S. Donaldson eds., 1999) [hereinafter TO ERR IS HUMAN]; PETER DAVIS ET AL., ADVERSE EVENTS IN NEW ZEALAND PUBLIC HOSPITALS: PRINCIPAL FINDINGS FROM A NATIONAL SURVEY (2001), *available at* http://www.moh.govt.nz/publications/adverseevents; WORLD HEALTH ORG., WORLD ALLIANCE FOR PATIENT SAFETY, PROGRESS REPORT 2006-2007 (2008), *available at* http://www.who.int/patientsafety/information_centre/documents/progress_report_2006_2007.pdf; G. Ross Baker et al., *The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada*, 170 CAN. MED. ASS'N J. 1678 (2004); F.D. Dastur, Editorial, *Quality and Safety in Indian Hospitals*, 56 J. ASS'N PHYSICIANS INDIA 85 (2008), *available at* http://www.japi.org/february2008/E-85.htm; T. Schioler et al., *Incidence of Adverse Events in Hospitals: A Retrospective Study of Medical Records*, 163 UGESKR FOR LAEGER 5370 (2001) (Den.); Charles Vincent, G. Neale & M. Woloshynowych, *Adverse Events in British Hospitals: Preliminary Retrospective Record Review*, 322 BRIT. MED. J. 517 (2001); R.M. Wilson et al., *The Quality in Australian Health Care Study*, 163 MED. J. AUSTL. 458 (1995).

2. *See, e.g.*, U.S. DEP'T OF HEALTH & HUMAN SERVS., ADDRESSING THE NEW HEALTH CARE CRISIS: REFORMING THE MEDICAL LITIGATION SYSTEM TO IMPROVE THE QUALITY OF HEALTH CARE (2003), *available at* http://aspe.hhs.gov/daltcp/reports/medliab.pdf; Press Release, The White House, President Discusses Medical Liability Reform (Jan. 5, 2005), *available at* http://www.whitehouse.gov/news/releases/2005/01/20050105-4.html.

3. *See, e.g.*, COMMONWEALTH OF AUSTL., REVIEW OF THE LAW OF NEGLIGENCE FINAL REPORT (2002) (the "Ipp Report"), *available at* http://revofneg.treasury.gov.au/content/Report2/PDF/Law_Neg _Final.pdf; FRANK FUREDI, COURTING MISTRUST: THE HIDDEN GROWTH OF A CULTURE OF LITIGATION IN BRITAIN (1999).

4. *See, e.g.*, TOM BAKER, THE MEDICAL MALPRACTICE MYTH (2005); George J. Annas, *The Patient's Right to Safety – Improving the Quality of Care Through Litigation Against Hospitals*, 354 NEW ENG. J. MED. 2063 (2006); David A. Hyman & Charles Silver, *The Poor State of Health Care Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution?*, 90 CORNELL L. REV. 893 (2005).

public imagination[5] sufficient to place structural reform of medical litigation on the American political agenda.[6]

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,[7] 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[8] and apology for harm done.[9] Drawing in considerable measure on Wagatsuma

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5. *See, e.g.*, WILLIAM HALTON & MICHAEL MCCANN, DISTORTING THE LAW: POLITICS, MEDIA, AND THE LITIGATION CRISIS (2004) (explaining the success of "tort reform" advocates in swaying public opinion); Anthony J. Sebok, *Dispatches from the Tort Wars*, 85 TEX. L. REV. 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)).

6. Barack Obama and Hillary Clinton jointly proposed a bill in 2005 to explore modifications in the existing medical malpractice litigation system. National Medical Error Disclosure and Compensation Act, S. 1784, 109th Cong. (2005) (discussed in Hillary Rodham Clinton & Barack Obama, *Making Patient Safety the Centerpiece of Medical Liability Reform*, 354 NEW ENG. J. MED. 2205 (2006)). Support for reform is found on both sides of the aisle. *See, e.g.*, Fair and Reliable Medical Justice Act, S. 1337, 109th Cong. (2005) (sponsored by Senators Enzi & Baucus). In 2005, Congress enacted the Patient Safety and Quality Improvement Act of 2005 as a step aimed at fostering hospitals' self-critical analysis by standardizing, to an extent, confidentiality protections for error reports. Pub. L. No. 109-41, 119 Stat. 424 (2005) (codified at 42 U.S.C. § 299b-24 (Supp. 2005)).

7. *E.g.*, TO ERR IS HUMAN, *supra* note 1; AUSTL. COMM'N ON SAFETY & QUALITY IN HEALTH CARE, SUBMISSION TO THE NATIONAL HEALTH AND HOSPITALS REFORM COMMISSION: INCLUDING A SAFETY AND QUALITY FRAMEWORK FOR THE FUTURE (2008), *available at* http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/1C0D0866C0742129CA2574FE00009310/$File/NHHRC-Submission.pdf; DEP'T OF HEALTH, AN ORGANISATION WITH A MEMORY (2000) (U.K.), *available at* http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4065083; NAT'L STEERING COMM. ON PATIENT SAFETY, BUILDING A BETTER SYSTEM: A NATIONAL INTEGRATED STRATEGY FOR IMPROVING PATIENT SAFETY IN CANADIAN HEALTH CARE (2002), *available at* http://www.rcpsc.medical.org/publications/ building_a_safer_system_e.pdf.

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 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 AFF. 73 (2003); Kathleen M. Mazor et al., *Communicating with Patients About Medical Errors*, 164 ARCHIVES INTERNAL MED. 1690 (2004).

9. *See, e.g.*, Jonathan R. Cohen, *Advising Clients to Apologize*, 72 S. CAL. L. REV. 1009 (1999); Douglas N. Frenkel & Carol B. Liebman, *Words That Heal*, 140 ANNALS INTERNAL MED.

and Rosett's pioneering 1986 article explaining the importance of apology (in non-medical settings) in Japan,[10] the scholarship in this area portrays honest 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,[11] 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.[12] While its likely effects on lawsuit filings are contested,[13] the disclosure-and-apology philosophy is gaining considerable traction in medical practice.[14]

Compared with the United States, Japan (like most countries) enjoys a comparatively low rate of civil litigation over medical injury.[15] What accounts

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482 (2004); Jennifer K. Robbennolt, *Apologies and Legal Settlement: An Empirical Examination*, 102 MICH. L. REV. 460 (2003).

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 (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 malpractice litigation).

11. *See, e.g.*, Doug Wojcieszak, John Banja & Carole Houk, *The Sorry Works! Coalition: Making the Case for Full Disclosure*, 32 JOINT COMM'N J. ON QUALITY & PATIENT SAFETY 344 (2006), *available at* http://www.jointcommission.org/NR/rdonlyres/5E597FEF-6F86-480D-A1E2-CDD6CB491D3E/0/Sorry_Works.pdf; Sorry Works! Coalition, http://www.sorryworks.net (last visited Dec. 3, 2008) (describing coalition philosophy and activities).

12. *See, e.g.*, Steve S. Kraman & Ginny Hamm, *Risk Management: Extreme Honesty May Be the Best Policy*, 131 ANNALS 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 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). 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." *Id.* at 199. 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. *Id.* at 198-200 & n.35.

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.[16] Are there simply fewer medical injuries in Japan, due to the prevalence in hospitals of the strict quality control for which the nation's manufacturing enterprises are justly famed? When injury claims do arise, are they quickly resolved through non-punitive, harmony-promoting informal dispute resolution processes employing the traditional social lubricant of apology, as the scholarship drawing on the Wagatsuma-Rosett thesis[17] would presume?

Not exactly.

After a twelve-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.[18]) 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.[19]

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.[20] The Supreme Court of Japan

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16. *See, e.g.*, John Haley, *The Myth of the Reluctant Litigant*, 4 J. JAPANESE STUD. 359 (1978); ERIC A. FELDMAN, THE RITUAL OF RIGHTS IN JAPAN: LAW, SOCIETY, AND HEALTH POLICY (2000); FRANK K. UPHAM, LAW AND SOCIAL CHANGE IN POSTWAR JAPAN (1987); J. Mark Ramseyer & Minoru Nakazato, *The Rational Litigant: Settlement Amounts and Verdict Rates in Japan*, 18 J. LEGAL STUD. 263 (1989).

17. *See* sources cited *supra* note 10.

18. Yasushi Tsukamoto, *Criminal Prosecution Arising from Medical Mishaps: A Japanese Perspective*, 24 MED. & L. 673, 677 (2005); *Doctor Acquitted in Girl's Death*, INT'L HERALD TRIB./ASAHI SHIMBUN, Dec. 1, 2005, at 28.

19. The case is the subject of a prize-winning book by a journalist who covered the story. NOBUAKI SUZUKI, AKIKA-CHAN NO SHINZŌ (KENSHŌ): TOKYO JOSHI IDAI BYŌIN JIKEN [AKIKA'S HEART: EXAMINING THE TOKYO WOMEN'S MEDICAL UNIVERSITY HOSPITAL CASE] (2007) (recipient of Kōdansha 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 JIHŌ 156 (Tokyo D. 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

affirmed the CEO's conviction.[21] 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.[22]

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 Cesarean section delivery.[23] The arrest and prosecution sparked a nationwide outcry by medical organizations against heavy-handed intervention by the criminal justice system in the practice of medicine,[24] an outcry that has not abated with the obstetrician's recent acquittal.[25]

Preventable medical injury is widespread in Japan just as it is in other developed nations.[26] 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 has grown in Japan at a pace outstripping the increases in other types of civil actions,[27] although its frequency is still dwarfed

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Tsukamoto, *supra* note 18, at 674-75; and *infra* notes 103-106 and accompanying text.

21. 58(4) KEISHŪ 247 (Sup. Ct., Apr. 13, 2004). The case is further discussed *infra* notes 103-106 and accompanying text.

22. 1880 HANREI JIHŌ 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).

24. *See infra* notes 54-58 and accompanying text.

25. 16 IRYŌ HANREI KAISETSU 20 (Fukushima D. Ct., Aug. 20, 2008); *see also* Yusuke Takatsu, *Doctor Acquitted in Death After Childbirth*, INT'L HERALD TRIB./ASAHI SHIMBUN, Aug. 21, 2008, at 23; *Doctor Acquitted over Cesarean Section Death*, DAILY YOMIURI, Aug. 21, 2008, at 1; *Medical World Circles Wagons*, DAILY YOMIURI, Aug. 21, 2008, at 2.

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%. Of those adverse events, 23% were considered to have been probably preventable. HIDETO SAKAI, IRYŌ JIKO NO ZENKOKUTEKI HASSEI HINDO NI KAN-SURU KENKYŪ [REPORT ON THE NATIONWIDE INCIDENCE OF MEDICAL ACCIDENTS: III] 18 (2006); *see also* Shunya Ikeda, *Iryō jiko hassei hindo chōsa kara erareta wagakuni no kanja anzen no genkyō to kadai* [*Patient Safety Issues Raised by the Study of Medical Accident Incidence*], 14 KANJA ANZEN SUISHIN JĀNARU 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, IRYŌ JIKO TO SHIHŌ 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

by that of medical malpractice litigation in the United States, and medical liability insurance premiums in Japan are still comparatively low.[28] But the character of the Japanese debate over accountability for iatrogenic injury—harm causally related to medical care—is unique. 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.[29] 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.[30] 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.[31]

Responding to an initiative from academic medical societies, Japan's Ministry of Health, Labor, and Welfare embarked in 2005 on an innovative

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944 in 2007. Supreme Court of Japan, Iji kankei soshō jiken no shori jōkyō oyobi heikin shinri kikan [Disposition of Medically Related Litigation and Mean Duration of Proceedings 1998-2007], http://www.courts.go.jp/saikosai/about/iinkai/izikankei/toukei_01.html (last visited Dec. 4, 2008). For pre-1998 figures, see YUTAKA TEJIMA, IJIHŌ NYŪMON [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, at 201, 203; 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 anonymous source, in Tokyo, Japan (July 31, 2008).

29. *See, e.g.*, Robert B Leflar, *Informed Consent and Patients' Rights in Japan*, 33 HOUS. L. REV. 1, 62-63, 94-96 (1996).

30. *See* Leflar & Iwata, *supra* note 15, at 195-98.

31. *See, e.g.*, KOKURITSU DAIGAKU IGAKUBU FUZOKU BYŌINCHŌ KAIGI JŌCHI IINKAI [NAT'L UNIV. HOSP. PRESIDENTS' CONFERENCE], IRYŌ JIKO BŌSHI NO TAME NO ANZEN KANRI TAISEI NO KAKURITSU NI TSUITE – CHŪKAN HŌKOKU [INTERIM REPORT: ESTABLISHING SAFETY MANAGEMENT SYSTEMS FOR THE PREVENTION OF MEDICAL ACCIDENTS] (2000), *available at* http://www.umin.ac.jp/nuh_open /iryoujiko.pdf; *infra* notes 109-110 and accompanying text.

"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 recently 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.[32]

Part I of this Article explains the significance in Japan, hitherto little noticed elsewhere,[33] 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.[34] This duty of police notification of medically

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32. Ministry of Health, Labor & Welfare, Iryō anzen chōsa iinkai setchi hōan (kashō) taikōan [Draft of Proposed Act to Establish the Medical Safety Review Commission (tentative title)], http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/kentou/dl/080613_an.pdf (last visited Dec. 3, 2008) [hereinafter MHLW June 2008 Draft Proposal].

33. I am aware of only five publications focusing on this topic in English-language scholarly journals: Norio Higuchi, *Article 21 of the Medical Practitioners Law*, 51 JAPAN MED. ASS'N J. 258 (2008); Hiroshi Ikegaya et al., *Does Informed Consent Exempt Japanese Doctors from Reporting Therapeutic Deaths?*, 32 J. MED. ETHICS 114 (2006); Leflar & Iwata, *supra* note 15; Tsukamoto, *supra* note 18 (paper presented to the World Congress on Medical Law, Sydney, Australia in August 2004); and Ken-ichi Yoshida et al., *Death During Surgery in Japan*, 360 LANCET 805 (2002) (letter).

34. 58(4) KEISHŪ 247 (Sup. Ct., Apr. 13, 2004).

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 antiregulatory 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 cultural 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

35. James A. Filkins, *"With No Evil Intent": The Criminal Prosecution of Physicians for Medical Negligence*, 22 J. LEGAL MED. 467, 471-72 & 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).

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 unintentional medical acts are seldom widely publicized,[42] 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.[43]

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36. The leading British medical case recognizing criminal liability for involuntary manslaughter under a gross negligence standard is *R. v. Adomako*, [1995] 1 A.C. 171 (H.L. 1994) (appeal taken from Cent. Crim. Ct.).

37. Jon Holbrook, *The Criminalisation of Fatal Medical Mistakes*, 327 BRIT. MED. J. 1118, 1118 (2003).

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 that the number of prosecutions increased subsequent to the 1980s.

39. *See, e.g.*, R. v. Manjanatha, [1995] 131 Sask. R. 316 (upholding sentence of imprisonment). The case is described in ALAN MERRY & ALEXANDER MCCALL SMITH, ERRORS, MEDICINE AND THE LAW 24-25 (2001).

40. *See* P.D.G. Skegg, *Criminal Prosecutions of Negligent Health Professionals: The New Zealand Experience*, 6 MED. L. REV. 220, 225-34 (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 Amendment Act 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, Univ. of Otago, to 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).

41. *See* JOHN BELL, SOPHIE BOYRON & SIMON WHITTAKER, PRINCIPLES OF FRENCH LAW 233 (1998) ("[M]any negligence claims become criminal cases. Thus in 1990, there were 222 civil claims against doctors and 137 criminal prosecutions."); *see also 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 JIHŌ 28 (Yokohama D. Ct., Mar. 28, 1995), *translated in* TIMOTHY STOLTZFUS JOST, READINGS IN COMPARATIVE HEALTH LAW & BIOETHICS 332-40 (Robert B Leflar trans., 2d ed. 2007).

43. *See, e.g.*, TO ERR IS HUMAN, *supra* note 1; ACCOUNTABILITY: PATIENT SAFETY AND POLICY

In Japan, the number of criminal prosecutions of medical personnel is likewise small in comparison with the number of civil actions,[44] but these criminal investigations and trials receive intensive coverage in the media.[45] 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,[46] the pace of medical

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REFORM (Virginia A. Sharpe ed., 2004); BARRY FURROW ET AL., HEALTH LAW (2000); MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM (William M. Sage & Rogan Kersh eds., 2006); MICHAEL L. MILLENSON, DEMANDING MEDICAL EXCELLENCE: DOCTORS AND ACCOUNTABILITY IN THE INFORMATION AGE (1997); ROBERT M. WACHTER & KAVEH G. SHOJANIA, INTERNAL BLEEDING: THE TRUTH BEHIND AMERICA'S TERRIFYING EPIDEMIC OF MEDICAL MISTAKES (2004).

One leading American scholar has addressed the issue of criminal liability for unintentional medical injury as it affects patient safety efforts. *See* George J. Annas, *Medicine, Death, and the Criminal Law*, 333 NEW ENG. J. MED. 527 (1995). Among leading British scholars, Alan Merry and Alexander McCall Smith are two who gave the matter consideration early on. *See* MERRY & MCCALL SMITH, *supra* note 39; Alexander McCall Smith, *Criminal or Merely Human?: The Prosecution of Negligent Doctors*, 12 J. CONTEMP. HEALTH L. & POL'Y 131 (1995).

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 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.

45. 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 JURISUTO 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.

46. Three physicians and two nurses were convicted of professional negligence and fined. 1087 HANREI TAIMUZU 296 (Yokohama D. Ct., Sept. 20, 2001). Both patients survived the mistaken surgeries. *See Heart, Lung Patients Mistakenly Switched*, JAPAN TIMES, Jan. 14, 1999, at 2.

investigations and prosecutions was stepped up significantly.[47] 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,[48] the heart-lung machine blunder at Tokyo Women's Medical University Hospital in 2002,[49] 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 thirteen-hour operation at Jikei Medical University's Aoto Hospital[50]—in each of these highly publicized cases at prominent Tokyo-area hospitals and many others, police arrested medical personnel or filed papers with prosecutors, resulting in criminal charges.[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 whistleblower within the hospital contacted a journalist, the family, or the police.[52]

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47. According to National Police Agency statistics, in 1997 police sent three medical cases to prosecutors; in 2007, they sent ninety-two. Hideo Iida, *Keiji shihō to iryō* [*Criminal Justice and Medicine*], 1339 JURISUTO 60, 61 tbl.1 (2007) (summarizing National Police Agency findings from 1997 to 2005); Nat'l Police Agency, Iryō jiko kankei todokede-tō kensū no suii, rikken sōchisū [Trends in Number of Reported Medical 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 2004, seventy-nine prosecutions were initiated, a rate of 14.8 per year. HIDEO IIDA, KEIJI IRYŌ KAGO II [CRIMINAL MEDICAL MALPRACTICE II] 1 (2006).

48. *See supra* notes 20-22 and accompanying text; *infra* notes 103-106 and accompanying text.

49. *See supra* notes 18-19 and accompanying text.

50. The three physicians were convicted of professional negligence. *Bungling Doctors Held Responsible for Death*, INT'L HERALD TRIB./ASAHI SHIMBUN, June 16, 2006, at 27. This case was featured in a mass market book by a well-known urologist. HIDEKI KOMATSU, JIKEI IDAI AOTO BYŌIN JIKEN: IRYŌ NO KŌZO TO JISSENTEKI RINRI [THE STRUCTURE OF HEALTH CARE AND PRACTICAL ETHICS: THE JIKEI MEDICAL UNIVERSITY AOTO HOSPITAL CASE] (2004).

51. These cases are described in more detail in Leflar & Iwata, *supra* note 15, at 192-96. 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. *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. IIDA & YAMAGUCHI, *supra* note 44, at 435-82 (collecting cases); Haruo Yamaguchi, *Iryō jiko no keiji shobun to purofesshonaru ōtonomii* [*Criminal Sanctions for Medical Accidents and Professional Autonomy*], 695 NIIGATA-KEN ISHIKAIHŌ 2, 2 tbl.1 (2008) (reporting four cases of imprisonment out of 253 criminal sanctions from 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.

52. *See, e.g.*, SUZUKI, *supra* note 19, at 63-69 (recounting letter to patient's family from

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.[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 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

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anonymous whistleblower in Tokyo Women's Medical University Hospital case). One source of inside information for Japanese journalists is an anonymous Internet bulletin board, Channel 2, http://www.2ch.net (last visited Dec. 3, 2008), containing posts on alleged scandals within various Japanese institutions including hospitals.

53. The arguments are offered in various forms in mass market books, for example, HIDEKI KOMATSU, IRYŌ HŌKAI [MEDICINE'S COLLAPSE] (2006); by medical specialty societies, for example, 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 kōi ni kanren shita kanja shibō no todokede ni tsuite: Chūritsuteki senmon kikan no sōsetsu 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), http://jsp.umin.ac.jp/previous/inkai/inkaihokoku/4kyodoseimei.html [hereinafter Joint Declaration]; before government advisory committees, for example, Ministry of Health, Labor & Welfare, Health Policy Bureau, Shinryō kōi ni kanren shita shibō ni kakaru shiin kyūmei-tō no arikata ni kansuru kentōkai [Commission on the Investigation of Causes of Medical Practice-Associated Deaths], Kore made no giron no seiri [Summary of Issues Presented] (Aug. 2007), http://www.mhlw.go.jp/shingi/2007/08/dl/s0824-4a.pdf; and in other online resources and medical blogs put out by organizations, such as the Medical Research Information Center, http://mric.tanaka.md (last visited Dec. 3, 2008) and 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).

death from blood loss during a Cesarean 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 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.[60] The criminal justice system, its proceedings amplified by the media, stepped in to fill that gap.

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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.

56. A nationwide protest petition and resolution was sponsored by two medical associations. Japan Soc'y of Obstetrics & Gynecology and Japan Ass'n of Obstetricians & Gynecologists, Seimei [Proclamation] (Mar. 10, 2006), http://www.jsog.or.jp/news/html/announce_10MAR2006.html.

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 kanren shita shibō ni kakaru shiin kyūmei-tō no arikata ni kansuru kentōkai] (Aug. 10, 2007), http://www.mhlw.go.jp/shingi/2007/08/txt/s0810-2.txt (official meeting transcript).

60. *See* Leflar & Iwata, *supra* note 15; Robert B Leflar, *Medical Error, Deception, Self-Critical Analysis, and Law's Impact: A Comparative Examination*, *in* LAW IN JAPAN: A TURNING POINT 404-32 (Daniel H. Foote ed., 2007).

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."[61] This crime, derived like most of the Criminal Code from the German penal code,[62] 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[63]) at least gross negligence.[64] In Japan, mere negligence is enough.[65]

A second ground for prosecution is concealment or destruction of evidence.[66] This offense has formed the basis for convictions for attempted

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61. KEIHŌ [Criminal Code], art. 211 (Gyōmujō kashitsu chishishō-tō), 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.

62. *See* HIROSHI ODA, JAPANESE LAW 416 (2d ed. 1999).

63. R. v. Adomako, [1995] 1 A.C. 171, 193 (H.L. 1994). *See generally Death Under Anaesthetic: The Case of Dr Adomako*, 36 MED. SCI. & L. 188 (1996) (speeches before British Academy of Forensic Sciences given by *Adomako* defense counsel Lord Williams of Mostyn and prosecutor Ann Curnow); Lord Mackay of Clashfern, *Presidential Address: Involuntary Manslaughter in Relation to Patient Care*, 39 MED. SCI. & L. 277 (1999) (address to the British Academy of Forensic Sciences by the author of the *Adomako* opinion).

64. *See* Leflar & Iwata, *supra* note 15, at 214 n.110, and cases and commentary cited therein.

65. 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, *Kōzōteki kashitsu (2): Iryō kago* [*Structural Negligence (2): Medical Malpractice*], *in* 30 GENDAI SAIBANHŌ TAIKEI 37, 44-45 (Sukeaki 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.

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.)").

66. 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-bunsho sakusei-tō).

cover-ups through alteration of patients' medical records,[67] a practice that plaintiffs' attorneys charge has been widespread in the past.[68]

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,[69] has been applied beyond its original scope of violent deaths, suicides, and the like, to encompass deaths possibly caused by medical management.[70] 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[71] than in other prosecutions, where guilty verdicts are overwhelmingly the norm,[72] and an acquittal may subject prosecutors to public obloquy and professional disgrace.[73] Nevertheless, the code 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

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67. 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.

68. *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).

69. Ishi hō [Medical Practitioners' Law], Law No. 201 of 1948, art. 21.

70. *See infra* notes 98-105 and accompanying text.

71. *See, e.g.*, 16 IRYŌ HANREI 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).

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

73. 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 and presented. Interview with Dean Masahito Inouye, University of Tokyo Faculty of Law, in Tokyo, Japan (July 22, 2008) [hereinafter Interview with Inouye]. Dean Inouye, a criminal law specialist, noted examples of prosecutors who had lost high-profile cases and later attained leadership positions within the procuracy.

of the criminal justice system.[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.[75]

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

Like other professions, medicine in the Anglo-American nations is subject 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.[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.[77]

When things go wrong, hospital peer review committees sometimes limit, suspend, or revoke erring physicians' hospital privileges. Medicare Quality Improvement Organizations,[78] state licensure and discipline boards,[79] and in the

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74. Interview with Inouye, *supra* note 73.

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 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.

76. *See* The Joint Comm'n, Joint Commission Fact Sheets, http://www.jointcommission.org/AboutUs/Fact_Sheets/joint_commission_facts.htm (last visited Dec. 3, 2008); Nat'l Comm. for Quality Assurance, About NCQA, http://www.ncqa.org/tabid/675/default.aspx (last visited Dec. 3, 2008).

77. *See* Am. Bd. of Med. Specialties, What Board Certification Means, http://abms.org/About_Board_Certification/means.aspx (last visited Dec. 3, 2008).

78. *See* Ctrs. for Medicare & Medicaid Servs., Quality Improvement Organizations Overview, http://www.cms.hhs.gov/QualityImprovementOrgs (last visited Oct. 14, 2008) (summary of program). The QIOs' performance is not without critics. *See, e.g.*, John Reichard, *Medicare Quality Improvement Stagnating, Senators Complain*, CQ HEALTHBEAT, Aug. 13, 2007, *available at*

United Kingdom, the General Medical Council,[80] all serve to police the profession as well.[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 U.S. standards,[82] and the sting of liability insurance premiums is far less intense.[83] There has been an exiguity of peer review,[84] although the past few years have seen some improvement on that score.[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.[86] Until

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http://www.commonwealthfund.org/healthpolicyweek/healthpolicyweek_show.htm?doc_id=515505#doc515508 (reporting criticisms by Senator Charles Grassley and a GAO report).

79. For a critical view of the operation of state-level medical disciplinary structures, see Randall R. Bovbjerg, Robert H. Miller & David W. Shapiro, *Paths to Reducing Medical Injury: Professional Liability and Discipline vs. Patient Safety, and the Need for a Third Way*, 29 J. L. MED. & ETHICS 369, 374 (2001).

80. *See* General Medical Council, http://www.gmc-uk.org (last visited Dec. 3, 2008).

81. *See, e.g.*, Susan O. Scheutzow, *State Medical Peer Review: High Cost but No Benefit: Is It Time for a Change?*, 25 AM. J. L. & MED. 7 (1999).

82. *See supra* notes 15 and 27.

83. *See supra* note 28. Individual physicians in Japan are particularly less threatened by the civil liability system than their U.S. counterparts, because most are hospital employees rather than independent contractors, so it is the hospital, not the individual physician, that is the main target of civil malpractice actions. Japan has no system of independent physicians with hospital privileges.

84. *See* JOHN CREIGHTON CAMPBELL & NAOKI IKEGAMI, THE ART OF BALANCE IN HEALTH POLICY: MAINTAINING JAPAN'S LOW-COST, EGALITARIAN SYSTEM 187-90 (1998).

85. Larger hospitals have recently begun instituting internal committees to investigate adverse events. Some of these review committees, contrary to tradition, bring in outside experts to participate. Summaries of four hospital systems' internal adverse event review systems, which include outside experts in their deliberations, are set out in MINISTRY OF HEALTH, LABOR & WELFARE, IRYŌ JIKO CHŌSA NI OITE INGAI NO SENMONKA-TŌ GA KAKAWATTE IRU REI NI TSUITE [EXAMPLES OF INCLUSION OF OUTSIDE-HOSPITAL EXPERTS IN MEDICAL ACCIDENT INVESTIGATIONS] 31-48 (2007), *available at* http://www.mhlw.go.jp/shingi/2007/07/dl/s0726-7d_0019.pdf through /s0726-7d_0022.pdf (report distributed at July 26, 2007 meeting of Shinryō kōi ni kanren shita shibō ni kakaru shiin kyūmei-tō no arikata ni kansuru kentōkai [Commission on the Investigation of Causes of Medical Practice-Associated Deaths]).

86. *See* Naoki Ikegami, *Nihon no iryō seido ni okeru senmon-i no yakuwari* [*The Role of Specialists in the Japanese Health Care System*], 52 SŌGŌ RINSHŌ 3125 (2003); Interview with Dr. Tetsu Yamaguchi, CEO of Toranomon Hospital, in Tokyo, Japan (July 30, 2007) [hereinafter Interview with Yamaguchi]. As of this writing, only the specialties of cardiac and urologic endoscopic surgery have instituted certification programs. *See Docs To Be Vetted on Endoscopic Surgery*, DAILY YOMIURI, June 28, 2004, at 2. *See generally* Naoki Ikegami & John Creighton Campbell, *Japan's Health Care System: Containing Costs and Attempting Reform*, 23 HEALTH AFF.

recently, the health ministry sanctioned practitioners only after a criminal conviction (typically for reimbursement fraud, tax evasion, drug abuse, or morals violations); quality-of-care issues seldom formed the basis for disciplinary measures.[87] 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.[88] Systematic attention to quality control, at least until the public outcry following the Yokohama City Medical University Hospital patient mix-up[89] 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

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26, 35 (2004) ("[L]imited but meaningful progress has been made in the weakest part of the system, professional accountability.").

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 from 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 January 2002 to June 2005, there were 196 sanctions, of which thirty-one arose from professional negligence (8.9 per year). E-mail from Dr. Etsuji Okamoto, Nat'l Inst. of Public Health, to author (July 13, 2006) (on file with author); *see also* Etsuji Okamoto, *An Analysis of Administrative Sanctions and Criminal Prosecutions of Doctors in Japan*, 52 JAPANESE J. PUB. HEALTH 994, 996 tbl.1 (2005) (summarizing types of charges, and numbers and sanctions associated with each); Tsukamoto, *supra* note 33, at 680 ("very rare" for administrative sanctions to be imposed following medical accidents). *See generally* NORIO HIGUCHI, IRYŌ TO HŌ O KANGAERU: KYŪKYŪSHA TO SEIGI [AMBULANCES AND JUSTICE: MEDICINE AND LAW RECONSIDERED] 60-67 (2007) (summarizing system of administrative discipline for physicians).

88. Leflar & Iwata, *supra* note 15, at 191-92. As of August 2008, 2523 of Japan's 8832 hospitals had received this organization's accreditation. Japan Council for Quality Health Care, Nintei byōin kensaku [Accredited Hospitals Listing], http://www.report.jcqhc.or.jp/index.html (last visited Dec. 3, 2008).

89. *See supra* note 46 and accompanying text.

century,[90] organized medicine was caught napping, the health ministry was unprepared, and the tort system's ability to respond had institutional limits.[91] 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.[92] MHLW established a medical safety office in 2000, gradually expanding it in the following years.[93] The health minister issued an "emergency appeal" in 2003 to require continuing medical education.[94]

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90. *See supra* notes 45-52 and accompanying text.

91. For example, there are only 24,300 practicing attorneys in all of Japan, a nation of 127 million. Japan Federation of Bar Associations, http://www.nichibenren.or.jp/en/about/index.html (last visited Dec. 3, 2008). 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, at 202 n.46.

92. KOKURITSU DAIGAKU IGAKUBU FUZOKU BYŌINCHŌ KAIGI JŌCHI IINKAI [NAT'L UNIV. HOSPS. COUNCIL OF JAPAN], IRYŌ JIKO BŌSHI 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 the patient safety budgets of U.S. and U.K. health agencies. Interviews with officials in the Ministry of Health, Labor, and Welfare, Office of Medical Safety, in Tokyo, Japan (July 29, 2003 & Aug. 6, 2004).

94. KŌSEIRŌDŌ-DAIJIN IRYŌ JIKO TAISAKU KINKYŪ APIIRU [EMERGENCY APPEAL FOR MEDICAL

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 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 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 twenty-four 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

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ACCIDENT COUNTER-MEASURES BY THE MINISTER OF HEALTH, LABOR & WELFARE] (2003).

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 MIYABURŌ! [PUT A STOP TO INAPPROPRIATE MEDICAL TREATMENT BY DEMANDING BILLING DISCLOSURE!] (Hisashi Katsumura ed., 2002); KARUTE KAIZAN [FALSIFICATION OF MEDICAL RECORDS] (Hirotoshi Ishikawa ed., 2004); JINTSŪ SOKUSHINZAI: ANATA WA DŌ SURU [WHAT ARE YOU GOING TO DO ABOUT LABOR-INDUCING DRUGS?] (Jintsū sokushinzai ni yoru higai o kangaeru kai eds., 2003).

96. *See* Ministry of Health, Labor & Welfare, Iryō jiko jōhō shūshū-tō jigyō [Medical Accident Information Collection Project], http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/jiko/index.html (last visited Dec. 3, 2008) (outline of current rules). The entity collecting the reports is the Japan Council for Quality Health Care. *See* Nihon iryō kinō hyōka kikō [Japan Council for Quality Health Care], Iryō jiko jōhō shūshū-tō jigyō yōkō [Outline of Medical Accident Information Collection Project], http://www2.jcqhc.or.jp/html/documents/pdf/med-safe/youkou.pdf (last visited Dec. 3, 2008).

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, at 208-10. 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).

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 Society of Legal Medicine (*Nihon hōi gakkai*),[99] 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.[100] 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."[101] 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.[102] The forensic pathologists' 1994 guidelines were not binding authority, and most physicians were probably unaware of them—until the Hirō Hospital case.[103]

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.[104] The Supreme Court of Japan affirmed his conviction for

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99. *See* Japanese Society of Legal Medicine, http://plaza.umin.ac.jp/legalmed/index.en.html (last visited Dec. 3, 2008).

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 REINVENTION OF DEATH 130-46 (2002).

101. *Nihon hōigakkai "ijōshi" gaidorain* [*Japanese Society of Legal Medicine "Unnatural Death" Guidelines*], 48 NIHON HŌIGAKU ZASSHI 357 (1994).

102. *Id.*

103. *See, e.g.*, Toshiharu Furukawa, *Shinryō ni kanren shita "ijōshi" ni tsuite* [*On "Unnatural Deaths" Related to Medical Practice*], 102 NIHON GEKA GAKKAI ZASSHI 554 (2001); Yoshiki Ogawa, *Iryō jiko to ishi no todokede gimu* [*Medical Accidents and Physicians' Duty of Notification*], 3 KEIJIHŌ JĀNARU 40, 42 & n.6 (2006).

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

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-incrimination.[105] 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.[106] 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,[107] 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,[108] 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.[109]

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death but did not notify police, was found not guilty. For a summary of the case, see Tsukamoto, *supra* note 18, at 674-75.

105. 58(4) KEISHŪ 247 (Sup. Ct., Apr. 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.

107. Kōseishō hoken iryō-kyoku kokuritsu byōin-bu risuku maneijimento sutandaado manyuaru sakusei iinkai [Ministry of Health, Labor & Welfare Health Ins. Bureau, Nat'l Hosps. Office, Risk Management Standard Manual Drafting Comm.], Risuku maneijimento manyuaru sakusei shishin [Guide for Drafting Risk Management Manuals] (2000), *available at* http://www1.mhlw.go.jp/topics/sisin/tp1102-1_12.html ("The director of the facility is to notify local police quickly of cases of death or injury resulting from or suspected to have resulted from medical malpractice.").

108. *See* Japan Surgical Society, http://www.jssoc.or.jp (last visited Dec. 3, 2008).

109. Nihon geka gakkai [Japan Surgical Soc'y], *Shinryō kōi ni kanren shita kanja no shibō,*

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. 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.[110] Other organizations issued still different guidelines. Among doctors, hospital administrators, and their legal advisors, confusion has reigned.[111]

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.[112] The following overview of the death inquest system

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shōgai no hōkoku ni tsuite [*Reporting Medical Practice-Associated Deaths and Injuries*], *reprinted in* Hiroyuki Katō, *Iryō jiko jōhō no hōkoku no mondaiten* [*Issues in Reporting Medical Accident Information*], 1249 JURIST 69, 70-71 (2003).

110. NIHON GAKUJUTSU KAIGI [SCI. COUNCIL OF JAPAN], IJŌSHI-TŌ NI TSUITE – NIHON GAKUJUTSU KAIGI NO KENKAI TO TEIGEN [UNNATURAL DEATHS ETC. – OPINION AND RECOMMENDATIONS OF THE SCIENCE COUNCIL OF JAPAN] (2005), *available at* http://www.scj.go.jp/ja/info/kohyo/pdf/kohyo-19-t1030-7.pdf.

111. *See* Yasushi Kodama, *Ishihō 21-jō o meguru konmei* [*The Confusion Surrounding Article 21 of the Medical Practitioners' Law*], 1249 JURIST 72 (2003); Norio Higuchi, *Iryō 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 18, 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. Ikegaya 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 Cesarean section delivery was not proven to have been caused by negligence, it was not an "unnatural" death, so notification of police was not required. 16 IRYŌ HANREI KAISETSU 20 (Fukushima D. Ct., Aug. 20, 2008). 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 19TH 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*

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.[113] They are performed by members 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."[114]

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.[115]

Tsukamoto, *supra* note 18, at 678 ("[T]he 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* Etsuo Okazaki, *Anzen na iryō o kizuku ue de no byōrii no yakuwari* [*The Role of Pathologists in Building Safe Medical Care*], 34 GENDAI IRYŌ 904, 905 fig.1 (2002); *see also* Stephen J. McPhee, *Maximizing the Benefits of Autopsy for Clinicians and Families: What Needs To Be Done*, 120 ARCHIVES PATHOLOGY LABORATORY MED. 743, 744 (1996) (estimating the overall rate in the United States at 10-12%). More recent single-nation data place Japan's autopsy rate even lower, at 3.1%, *see infra* note 114, compared with the rate in England and Wales of 22%, *see* NAT'L CONFIDENTIAL ENQUIRY INTO PATIENT OUTCOME AND DEATH, THE CORONER'S AUTOPSY: DO WE DESERVE BETTER?, 6 (2006), *available at* http://www.ncepod.org.uk/2006Report/introduction.html.

114. In 2005, medicolegal autopsies were performed in 13,570 cases. KEISATSUCHŌ [NAT'L POLICE AGENCY], HEISEI 19-NEN-CHŪ TODŌFUKEN-BETSU SHITAI SHUSŌSŪ [AUTOPSIES HANDLED, BY PREFECTURE] (2007). Hospital autopsies were performed in 19,337 cases. NIHON BYŌRI GAKKAI [JAPANESE SOCIETY OF PATHOLOGY], 48 NIHON BYŌRI BŌKEN SHŪHŌ [ANNUAL OF PATHOLOGICAL AUTOPSY 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

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.[116] Judicial autopsies are conducted at national expense, typically by forensic pathologists.[117] 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 management.[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.[119] If the case is dropped, the autopsy report usually remains permanently inaccessible.[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.[121] These medical examiners' offices, which have authority over about one-tenth of deaths nationwide,[122] are independent of the police and conduct autopsies, at prefectural expense, for public health purposes.[123] These autopsies require neither judicial authorization nor family consent. Practice regarding disclosure of administrative

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Fujimiya, *supra* note 112; and Ken-ichi Yoshida, *Report of Unusual Deaths and the Postmortem Inspection System*, *in* ENCYCLOPEDIA OF FORENSIC AND LEGAL MEDICINE 123 (2005).

116. KEIJI SOHŌ HŌ [Code of Criminal Procedure], arts. 225 & 229.

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., in Tokyo, Japan (July 16, 2008) [hereinafter 2008 Interview with Yoshida].

118. *See* Fujimiya, *supra* note 112, at 147-52; Yoshida, *supra* note 115, at 126-27.

119. *E.g.*, Masahiko Idegawa, *Shiino 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*], ASAHI SHIMBUN, Sept. 16, 2005, at 3 (reporting Hyogo case in which the prosecution delayed family access to autopsy results adverse to the hospital).

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).

121. Nakane, *supra* note 115, at 110-13. The other two medical examiners' offices, in Kanagawa Prefecture (Yokohama area) and Aichi Prefecture (Nagoya area), are scarcely functioning. *Id.* at 111-12 & nn.60-65.

122. STATISTICS AND INFO. DEP'T, MINISTRY OF HEALTH & WELFARE, STATISTICAL ABSTRACTS ON HEALTH AND WELFARE IN JAPAN 2004, at 31 (2005).

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.

autopsy reports to the families and hospitals involved apparently varies.[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 rickety system whose results vary considerably. After a police inspection finds that a death case does not require criminal handling, a police surgeon (*keisatsui*) 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 with the police,[125] too often lacking forensic expertise[126] 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.[127] But for cultural reasons there is considerable resistance among the bereaved to sullying a family corpse.[128] So these "consented autopsies" (*shōdaku kaibō*) 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.[129] Imprecise cause-of-death determinations are said to be especially

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124. *See* HIDEAKI SHIROYAMA ET AL., SHINRYŌ KŌI NI KANREN SHITA SHIBŌ NO CHŌSA BUNSEKI MODERU JIGYŌ NO HŌ-SEIDO TO UNYŌ NI KAN-SURU KENKYŪ [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 Dr. Takashi Nagata, in Tokyo, Japan (Aug. 3, 2007) (same).

125. Fujimiya, *supra* note 112, at 147, 153, 154.

126. *See* Yoshida, *supra* note 115, at 124 (police surgeons have "usually not experienced forensic practice").

127. Shitai kaibō hozon hō [Corpse Autopsy Preservation Law], Law No. 204 of 1949, art. 7.

128. 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, 153-54.

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., in Tokyo, Japan (July 27, 2006); Interview with Yoshinao Katsumata, Dir., Nat'l Research Inst. for Police Sci., in Kashiwa City, Japan (July 27, 2006).

129. Tatsushige Fukunaga, *Shibō shindan/shitai ken-an shisutemu no genjō to mondaiten* [*Death Determinations and the Postmortem Inquest System*], 74 KAGAKU 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.

prevalent in these areas.[130]

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.[131] 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 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

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130. Fukunaga, *supra* note 129.

131. *See, e.g.*, Fujimiya, *supra* note 112, at 156; Toshihiro Suzuki, Iryō jiko-shi kenshō shisutemu o kangaeru [A System for Investigating Accidental Medical Deaths], 1st International Forum on Patient Safety, Tokyo, Japan (Jan. 23, 2006) (on file with author); Ken-ichi Yoshida, Eibei-ken shokoku ni manabu iryō kanren-shi todokede/chōsa no kin-mirai [Notification and Review of Medical Practice-Associated Deaths in Japan: Lessons for the Near Future from Anglo-American Countries], 1st International Forum on Patient Safety, Tokyo, Japan (Jan. 23, 2006) (on file with author).

132. Hisako Takeichi, Ken-ichi Yoshida & Kazuto Inaba, *Shihō kaibō ni okeru izoku e no jōhō kaiji no mondaiten [Problems of Disclosure of Judicial Autopsy Information to the Bereaved]*, 595 HŌGAKU SEMINĀ 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 the 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.

determine the cause of death, it must obtain the family's consent—often no easy task[135]—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 to police of medically related "unnatural deaths" had increased eight-fold from 1998 to 2004 (Figure 1),[139] as many physicians and hospitals, confused by contradictory guidelines about 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.[140] But the death inquest system that these notifications set in motion

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.

139. *Iryō jiko, jiken todokede 200-ken toppa – keisatsuchō matome, sakunen 35% zō* [*Notifications of Medical Accidents, Incidents Top 200, 35% Increase from Last Year – Police Agency Study*], NIHON KEIZAI SHIMBUN, Apr. 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).

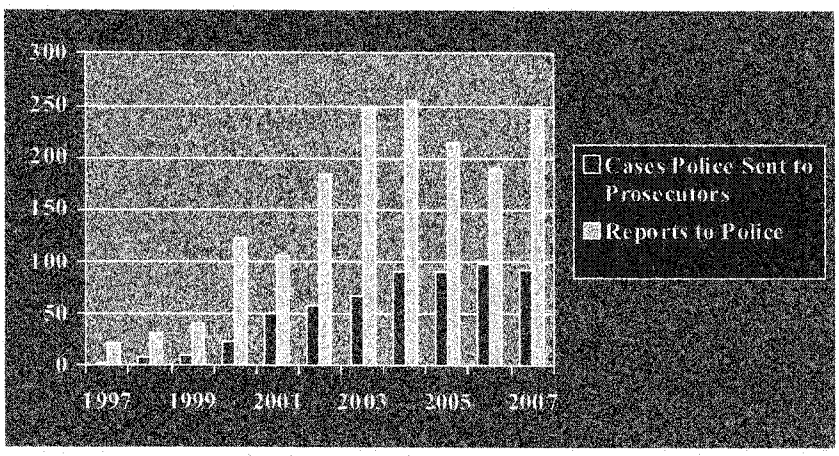

FIGURE 1: Medical Accidents Reported to Police and Cases Police Sent to Prosecutors, Japan, 1997-2007
Source: National Police Agency, Iryō jiko kankei todokede-tō kensū no idō, rikken sōchisū [Trends in Reports of Medically Related Cases and of Cases Sent to Prosecutors] (2008) (on file with author).

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.

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.[141] The proposed new entity would be staffed by impartial experts and would be separate from the police.[142] 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

141. Joint Declaration, *supra* note 53.
142. *Id.*

of the patient and family) review.[143]

The health ministry, its medical safety office understaffed and beset with difficulties in the operation of the accident reporting system,[144] 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.[145]

The health ministry launched the "Model Project for the Investigation and Analysis of Medical Practice-Associated Deaths" in September 2005, initially in four regions, expanded to eight as of this writing.[146] The Model Project (*moderu jigyō*) works in the following manner.[147]

When a patient dies in circumstances possibly related to medical management, the hospital may apply to the region's Model Project office for an investigation. The initiative must come from the hospital, not the patient's family, though the family's consent is necessary.[148] Cases falling within the

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143. Nihon igakkai kamei no omo na 19 gakkai no kyōdō seimei [Joint Declaration of the 19 Chief Societies of the Japanese Association of Medical Sciences] (2004), http://www.mhlw.go.jp/shingi/2007/08/dl/s0810-6b_0005.pdf.

144. *See supra* notes 96-97 and accompanying text.

145. *See Kensatsukan: Kokumin no me tsune ni ishiki* [*Prosecutors: Always Conscious of the Public's Gaze*], YOMIURI SHIMBUN, May 30, 2006, at 7 (interviewing Prosecutor-General Kunihiro Matsuo); Ken-ichi Yoshida, *Iryō kanrenshi: Shinryō kōi ni kanren shita shibō no chōsa bunseki moderu jigyō – Tokyo chiiki heisei 17-nendo no sōkatsu* [*Medical Practice-Associated Deaths: The Model Project on Medical Practice-Associated Death: 2005 Summary for the Tokyo Region*], 24 BYŌRI TO RINSHŌ BESSATSU 535, 536 (2006).

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 Ibaraki, Niigata and Fukuoka prefectures and the Sapporo area in Hokkaido as well. Okayama and Miyagi are the next prefectures targeted for inclusion. *See* Shinryō kōi ni kanren shita shibō no chōsa bunseki moderu jigyō dai-18-kai un'ei iinkai giji shidai [Reference Materials for the 18th Meeting of the Model Project Steering Committee] attachments 3-1 to -3 (July 23, 2008), *available at* http://www.med-model.jp/download/proceedings18.pdf [hereinafter Model Project July 2008 Reference Materials].

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 Dec. 4, 2008). The remainder has been gleaned from interviews with various people familiar with the project's workings. An English-language summary of Model Project procedures is available in SHIROYAMA ET AL., *supra* note 124, at 63-90.

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

scope of Article 21, however that scope is understood, must still be reported to the police. (If, after prompt initial inquiry, the police suspect crime and decide to proceed with an investigation and judicial autopsy, the case is not submitted to the Model Project.) Regional offices, each headed by a physician coordinator, vary somewhat in their approach—the Osaka office always consults 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 proceeds according to a standard approach.

If the Model Project's regional office accepts the case, the office quickly assembles 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" obtains the patient's medical records, interviews hospital staff involved in the patient's care, and encourages the hospital to conduct its own investigation. This evaluation committee includes a member of the autopsy team, an attorney, and outside medical experts nominated by the various specialty societies. The evaluation committee prepares 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, is 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 includes eminent physicians, academics, and attorneys from both plaintiff and defense bars, a summary of the report is made public, with names of patient, medical staff, hospital, and location redacted.

Although as a formal matter, the Model Project has nothing to do with liability claims, the evaluation committee's report is potentially available for use as evidence in both civil[149] and criminal litigation.[150] However, it is envisaged

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Tahara, Director, Ministry of Health, Labor and Welfare, Office of Medical Safety, in Tokyo, Japan (June 23, 2006) [hereinafter Interview with Tahara].

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, at 207-08; and Manabu Wagatsuma, *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

that the formulation of the report may foreclose the need for most civil litigation and discourage the bringing of prosecutions.[151] 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 clarifies the facts, allaying these suspicions. With regard to civil claims, where the facts found indicate the likelihood of a successful claim, it is thought that the evaluation committee's authoritative report may facilitate a rapid settlement.[152] With regard to criminal prosecutions, in most cases taken up by the Model Project, the police initially receive an Article 21 notification and then decline to open an investigation.[153] As of this writing, police have evinced an attitude of restraint, standing back while the Model Project evaluations run 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. The

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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 kaihatsu 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 Shimbun*, 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 tachiba kara* [*Looking Back on One Year of the Model Project for Medically Related Deaths: The Perspective of a Participating Hospital*], 108 NIPPON GEKA 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). In four of the first twenty-three cases submitted to the Model Project, however, the hospitals made no Article 21 notification. Katsushi Tahara, Presentation at the University of Tokyo, Shinryō kōi ni kanren shita chōsa bunseki moderu jigyō ni tsuite [The Model Project for the Investigation and Analysis of Medical Practice-Associated Deaths] (July 8, 2006) (on file with author).

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.

quality of the case reviews, on the whole, is likely 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 insulates 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 is avoided, absent exceptional circumstances.[157] The gain in transparency is dramatic: information gathered in the Model Project review is 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 should assist the formulation of particularized preventive measures against future injury, especially if the recommendations are widely circulated. 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 has not met original expectations. MHLW aimed to conduct 200 autopsies during the first year of the project's operation.[159] In fact, over the first 2¾ years only seventy cases had been undertaken by the project, a rate of just twenty-five cases per year.[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.[161] Some physicians and

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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.

156. *See* Judy Kinkelaar Ring & Barry Slotky, *Independent Review Supports Transparency*, 5 PATIENT SAFETY & QUALITY HEALTHCARE 48, 48 (2008).

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.

159. MODEL PROJECT CENT. OFFICE, SHINRYŌ KŌI NI KANREN SHITA SHIBŌ NO CHŌSA BUNSEKI MODERU JIGYŌ: HEISEI 18 NEN-DO JIGYŌ JISSHI HŌKOKUSHO [REPORT ON THE OPERATION OF THE MODEL PROJECT FOR THE INVESTIGATION AND ANALYSIS OF MEDICAL PRACTICE-ASSOCIATED DEATHS FOR THE YEAR 2006] 26 (2007), *available at* http://www.med-model.jp/download/download_jigyou18.pdf. This number may have been set on the high side by MHLW personnel to justify an adequate budget. Interview with Maemura, *supra* note 153.

160. Model Project July 2008 Reference Materials, *supra* note 146, at attachment 1. Of seventy cases undertaken, only fifty-seven reports have been completed and submitted to families and hospitals as of this writing. *Id.*

161. Tetsu Yamaguchi, Address at the 106th Annual Meeting of the Japan Surgical Society: Ijōshi no todokede to iryō kōi ni kanren shita shibō no chōsa bunseki moderu jigyō [Unnatural

hospitals, concerned that reports produced by Model Project evaluation committees might be used by police as evidence of medical crime,[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.[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.[164] Also, as a practical matter, 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]

Even though the Model Project has undertaken fewer cases than expected, it has 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 are stretched thin: the project is

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Death Notification and the Model Project for the Investigation and Analysis of Medical Practice-Associated Deaths] (Mar. 29, 2006).

162. *See* SHIROYAMA ET AL., *supra* note 124, at 15; Interview with Hatanaka, *supra* note 150. The 2006 arrest of the Ohno Hospital obstetrician, *Medical Blunders*, *supra* note 23, 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; chōshu 1-nen, naze ima – Fukushima kenritsu byōin/teiō sekkai misu-shi* [*Perplexity over Doctor's Arrest in Fukushima C-section Death – Why a Year After Inquiry?*], ASAHI SHIMBUN, Mar. 8, 2006, at 2. However, Fukushima is not one of the Model Project regions, so perhaps police restraint there was less to be expected.

163. Interview with Dr. Yasuyuki Sahara, Chief, Ministry of Health, Labor & Welfare, Office of Medical Safety, in Tokyo, Japan (July 15, 2008) [hereinafter Interview with Sahara].

164. *See* Fujimiya, *supra* note 112 (reluctance to consent to autopsies); Yoshida, *supra* note 145, at 535; Yōko Takeda, Kōseirōdōshō no shinryō ni kanren suru shibō no chōsa bunseki moderu jigyō – chōsei kangoshi (kōdinētā) no shigoto [The Role of the Coordinating Nurse in the MHLW Model Project on Medical Practice-Associated Death], 1st International Forum on Patient Safety, in Tokyo, Japan (Jan. 23, 2006) (on file with author).

During the first two years and nine months of the Model Project, of the 202 cases about which Project offices were initially contacted, 132 were never undertaken by the Project. The most common reason (forty-one cases) was the family's lack of consent. Model Project July 2008 Reference Materials, *supra* note 146, attachment 1. One would surmise that reluctance to allow an autopsy often contributed to the refusal of consent.

165. Interview with Sahara, *supra* note 163.

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 is 10.1 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. Currently, the project is 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, which is standard practice in the Model Project, is logistically difficult in these regions and is likely a cause of delay and unneeded expense even in regions with greater numbers of pathologists. A more efficient evaluation system should be considered, 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

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166. MODEL PROJECT CENT. OFFICE, SHINRYŌ KŌI NI KANREN SHITA SHIBŌ NO CHŌSA BUNSEKI MODERU JIGYŌ: JIGYŌ JISSHI HŌKOKUSHO [REPORT ON THE OPERATION OF THE MODEL PROJECT FOR THE INVESTIGATION AND ANALYSIS OF MEDICAL PRACTICE-ASSOCIATED DEATHS] 81-82 (2008), *available at* http://www.med-model.jp/download/download_jigyou19.pdf. 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. Norihiro Nakajima, Hisako Takeichi & Ken-ichi Yoshida, Moderu jigyō no hyōka – Irai iryō kikan to moderu jigyō kaibō jūjisha no shiten kara [Evaluation of the Model Project from the Perspectives of the Participating Hospitals and Autopsy Physicians] (2007) (unpublished draft report to MHLW) (on file with author). 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 CENT. OFFICE, *supra* note 159, at 10 (noting extension of deadline from three to six months).

168. There are 1928 hospital pathologists working in Japan. Only 119 forensic pathologists have been accredited by the Japan Society of Legal Medicine to perform complete autopsies. Inclusion of graduate students and research assistants who assist with autopsies in university forensic pathology departments pushes the total up to 253. Dai-3-kai shiin kyūmei-tō kentōkai sankō shiryō [The Commission on the Investigation of Causes of Medical Practice-Associated Deaths] 27-28 (2007), http://www.mhlw.go.jp/shingi/2007/06/dl/s0608-4d_0010.pdf. Forensic autopsies are also performed by non-certified personnel trained in the field. Yoshida, *supra* note 115, at 125.

169. Interview with Yoshida, *supra* note 124.

committee, has emphasized that the training of physicians in reviews of clinical practices based on consistent standards is a critical need.[170]

Fourth, the Model Project addresses 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,[171] are correspondingly confined to death inquiries. This restriction also limits the number and scope of evaluations from which quality improvement lessons can be drawn. The system would have to be adapted considerably to handle the much broader range of injury cases.

Fifth, the Model Project lacks explicit statutory authorization. It has been operating solely under health ministry auspices, relying on voluntary cooperation by medical providers and patients. If an evaluation committee requests documentation on a case and the hospital refuses to provide it, the committee lacks legal power to obtain that information.[172] 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 require considerable time commitments from participating experts and the part-time project staff, much of that time volunteered. The Project's annual budget has increased from an initial ¥102 million (US $0.9 million)[173] to ¥127 million (US $1.1 million) in FY 2008 and ¥177 million (US $1.6 million) in FY 2009.[174] But this is a modest budget indeed. It has sufficed so far, due in part to experts' and staffers' enthusiasm for participating in a unique endeavor seen as having national significance, and in part to the unexpectedly small number of cases submitted. But volunteer enthusiasm is unlikely to sustain such an endeavor in the long run. In an era of budget and personnel retrenchment in the public sector and financial constraints in health care,[175] it will take a substantial political commitment to expand the

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170. Interview with Yamaguchi, *supra* note 86.

171. *See* Ring & Slotky, *supra* note 156.

172. Interview with Tahara, *supra* note 148.

173. MINISTRY OF HEALTH, LABOR & WELFARE, HEISEI 17-NENDO YOSAN (AN) NO GAIYŌ (KŌSEIRŌDŌSHŌ ISEIKYOKU) [2005 DRAFT BUDGET FOR MHLW HEALTH POLICY BUREAU], *available at* http://www.mhlw.go.jp/topics/2005/bukyoku/isei/yosan1.html.

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).

175. *See, e.g.*, *Hoken no gensoku hataraku shikumi ni* [*Toward a System that Functions on Insurance Principles*], NIHON KEIZAI SHIMBUN, June 4, 2008, at 27.

enterprise nationwide after the five-year trial period ends in 2010.

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[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 carries 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, *dōshō-imu* ("same bed, different dreams"), but they are gaining 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 serves 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.

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,[177] a blue-ribbon commission under health ministry auspices studied the possibility of expanding the Model Project's

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176. *See supra* notes 61, 65 and accompanying text.

177. Sangiin Kōseirōdō Iinkai [House of Councillors Comm. on Health, Labor & Welfare], Resolution Relating to Proposals for Revision of the Health Insurance Law and the Medical Care Law, at 21 (June 13, 2006), *available at* http://www.mhlw.go.jp/shingi/2007/06/dl/s0608-4d_0009.pdf; Shūgiin Kōseirōdō Iinkai [House of Representatives Comm. on Health, Labor & Welfare], "Anzen de shitsu no takai iryō no kakuho, jūjitsu ni kansuru ken" ni tsuite ketsugi [Resolution Concerning the Provision and Assurance of Safe, High-Quality Health Care], at 21 (June 16, 2006), *available at* http://www.mhlw.go.jp/shingi/2007/06/dl/s0608-4d_0009.pdf.

method of independent expert review of medical accidents nationwide.[178] 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.[179] 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.[180] 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.[181] 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 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

178. The blue-ribbon commission is the Shinryō kōi ni kanren shita shibō ni kakaru shiin kyūmei-tō no arikata ni kansuru kentōkai [Commission on the Investigation of Causes of Medical Practice-Associated Deaths], chaired by Dean Masahide Maeda of Shuto University Tokyo. Its proceedings and reports are available at http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/kentou/index.html (follow "Shiin kyūmei-tō no kentō ni tsuite" hyperlinks near the bottom of the page).

179. Ministry of Health, Labor & Welfare, Shinryō kōi ni kanren shita shibō no shiin kyūmei-tō no arikata ni kansuru kadai to kentō no hōkōsei [Working Plan on Issues Regarding the Investigation of the Causes of Medical Practice-Associated Deaths (First Proposal)] (Mar. 2007), *available at* http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/kentou/dl/2a.pdf; Dai-2-ji shian [Second Proposal] (Oct. 2007), *available at* http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/kentou/dl/2e.pdf; Dai 3-ji shian [Third Proposal] (Apr. 2008), *available at* http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/kentou/dl/2f.pdf.

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*.

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.

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 by 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:

1) deaths suspected to have been intentionally caused (e.g.,

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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, para 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 JIHŌ 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 JIHŌ 72 (Tokyo High Ct., Sept. 30, 2004) (on both contract and tort grounds); *see also* Leflar & Iwata, *supra* note 15, at 212-13 (describing cases).

188. MHLW June 2008 Draft Proposal, *supra* note 32, art. 32, para. 6.

189. *Id.* art. 4, para. 6.

190. KEIHŌ [Criminal Code], art. 211, para. 1; *see also supra* notes 61-65 and accompanying text.

euthanasia);[191]

2) deaths suspected to have resulted from "grave negligence" (*jūdai na kashitsu*),[192] defined as "extreme deviation from standard medical care";[193]

3) deaths involving the suspected concealment, alteration, or forging of medical records with the purpose of covering up the facts;[194] and

4) deaths suspected to have resulted from repeated negligence by a practitioner who has caused similar medical accidents, or engaged in other suspected similar serious misconduct.[195]

Families could still lodge complaints independently with the police, a right that is guaranteed under the Criminal Procedure Code.[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.[197] In an attempt to reassure the medical 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.[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 has been agreed to in principle by the governing Liberal Democratic Party (LDP) and the Japan Medical Association leadership, and it is supported by patients' rights groups.[199]

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191. MHLW June 2008 Draft Proposal, *supra* note 32, art. 25, para. 1.

192. Third Proposal, *supra* note 179, paras. 39, 40(3).

193. *Id.* para. 40(3); MHLW June 2008 Draft Proposal, *supra* note 32, art. 25, para. 2. The regional 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 experience of the caregivers, whether an emergency situation existed, and whether the facility had adequate overall safety systems in place. *Id.*

194. *Id.* art. 25, para. 3.

195. *Id.*

196. KEIJI SOSHŌ HŌ [Code of Criminal Procedure], arts. 230-32 (kokuso no kenri).

197. Ministry of Health, Labor & Welfare, Iryō anzen chōsa iinkai (kashō) no iken boshū ni tsuite [Request for Public Comments on Medical Safety Review Commission Proposal] 11 (2008), *available at* http://www.mhlw.go.jp/seisaku/dl/05a.pdf [hereinafter MHLW Request for Public Comments].

198. *Id.* at 10.

199. *See* Masafumi Tatematsu & Atsuhiko Hayashi, *Iryō jiko chōsa no soshiki-zukuri: Giron*

Nevertheless, the proposal sparked a firestorm of criticism and as of this writing is by no means certain of enactment. The criticisms have come mainly from physicians and some medical groups, as well as from members of the opposition Democratic Party of Japan. The chief criticisms of the proposed legislation are these:

> 1) The definition of "grave negligence" in the legislation 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, who will use the review commissions' reports to

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ōzume, chūmon aitsugu [*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).

200. *See, e.g.*, Masahiro Kami, Iryō kaikaku no genzai [Medical Reform Today], 6th Annual Urology Seminar, in Tokyo, Japan (Aug. 2, 2008) (on file with author). The definition of "grave negligence" is of concern to many medical specialty societies. Nihon Igakkai [Japan Ass'n of Med. Sciences], "Iryō no anzen no kakuho ni muketa iryō jiko ni yoru shibō no gen'in kyūmei saihatsu bōshi no arikata ni kansuru shian – dai-3-ji shian" ni kansuru Nihon Igakkai no kenkai [Opinion of the Japan Association of Medical Sciences on the "Third Proposal Concerning a Medical Safety-Oriented System for Cause-of-Death Investigations and Prevention of Recurrences of Fatal Medical Accidents"], *available at* http://jams.med.or.jp/news/007.html (last visited Dec. 4, 2008) [hereinafter JAMS Opinion].

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.

bolster their cases.[203]

5) The proposal is punitive rather than ameliorative in its methods and perspectives. It does not eradicate criminal law's 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] 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.[206] A key concept in the DPJ plan is internal mediation:[207] hospitals would be required to employ or

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203. Kami, *supra* note 200. The lawyer-bashing tactic draws on U.S. tort reform rhetoric.

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, sōdan shien oyobi funsō no tekisei na kaiketsu no sokushin narabi ni iryō jiko-tō no saihatsu bōshi no tame no Iryō Hō-tō no ichibu o 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 website) (last visited Dec. 4, 2008); Kempou38 no burogu, Minshutō sangiin-iin Suzuki Kan-shi ni kiku: "Iryō jiko-chō" no "Suzuki shian" to Kōrōshō no kashitsu [Interview with DPJ Senator Kan Suzuki: The "Suzuki Proposal" for Medical Accident Review Commission and MHLW's Negligence], http://ameblo.jp/kempou38/entry-10102377584.html (June 2, 2008) (blog interview of Sen. Kan Suzuki, summarizing key aspects of his proposal and criticizing the MHLW proposal).

206. DPJ June 2008 Proposal, *supra* note 205, tit. 1, art. 3, para. 2.

207. The standard Japanese phrase is *naibu ADR* [internal ADR]. A noted proponent of this concept is Professor Yoshitaka Wada. YOSHITAKA WADA & TOSHIMI NAKANISHI, IRYŌ KONFURIKUTO MANEJIMENTO: MEDIEISHON NO RONRI TO GIHŌ [MEDICAL CONFLICT MANAGEMENT: MEDIATION THEORY AND SKILLS] (2006); YOSHITAKA WADA, IRYŌ ADR [MEDICAL ADR] (forthcoming 2009). The use of the American acronym "ADR" in Japanese is an indication that the Wagatsuma-Rosett idea of harmonious extrajudicial dispute settlement, *supra* note 10, has never really penetrated Japanese medicine. The concept of alternative dispute resolution, at least in the medical context, had to be imported from abroad.

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."[208] 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.[209]

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.[210] For prevention of future accidents, reports would go for analysis and dissemination of recommendations to a designated existing entity,[211] probably the Japan Council for Quality Health Care.[212]

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208. DPJ June 2008 Proposal, *supra* note 205, tit. 1, art. 2, para. 3. 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.

209. *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 provided by the hospital and on the assistance of a hospital-employed mediator, would often be buffaloed in this setting. *E.g.*, Interview with Toshihiro Suzuki, in Tokyo, Japan (Aug. 8, 2008) (a high-profile plaintiffs' attorney).

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.

210. DPJ June 2008 Proposal, *supra* note 205, tit. 3, arts. 2-3. For a summary of court decisions on the issue, see *supra* note 187.

211. DPJ June 2008 Proposal, *supra* note 205, tit. 1, art. 3, para. 4.

212. A friendly commentator described the DPJ's proposed accident analysis and recurrence prevention plan as an "expanded image" of the Japan Council for Quality Health Care's existing medical accident information collection system. Sanka iryō no kore kara [Obstetrical Medicine's Future] blog, http://obgy.typepad.jp/blog/2008/06/post-1341-26.html (June 13, 2008) [hereinafter Obstetrical Medicine's Future]. *Cf.* Outline of Medical Accident Information Collection Project, *supra* note 96 (website describing the Council's project).

The health ministry's proposal, by contrast, would lodge the quality improvement

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.[213] Police involvement would presumably be triggered only if patients or families lodged complaints or whistleblowers leaked damaging allegations.[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.[215]

Although much of the medical establishment supports the health ministry's proposal,[216] a groundswell of opposition, fed by influential medical blogs,[217] on the part of individual physicians has 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.[218] 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.[219]

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information dissemination function in the proposed National Medical Accident Review Commission. *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.

213. DPJ June 2008 Proposal, *supra* note 205, tit. 3, art. 4.

214. 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, *supra* note 153.

215. *See* Obstetrical Medicine's Future, *supra* note 212 (quoting Sen. Shinya Adachi, M.D., a key supporter of the DSP proposal).

216. The Japan Medical Association, representing doctors owning private-practice clinics, has endorsed the health ministry proposal, although there is dissent among the ranks. *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, *supra* note 200.

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 iryō no hōkai o kuitomeru kai), http://plaza.umin.ac.jp/~perinate/cgi-bin/wiki/wiki.cgi?page=%A5%EA%A5%F3%A5%AF# p8 (last visited Dec. 4, 2008).

218. *See supra* notes 54-58 and accompanying text.

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

The politics surrounding the rival proposals on medical accident review have been unusual.[220] The opposition DPJ controls the upper house of the Diet, so the ruling Liberal Democratic Party (LDP) cannot ram the health ministry's proposal through without compromise. The health ministry itself, never a heavyweight among Japan's governing agencies, has been further weakened by public wrath over recent episodes of bureaucratic incompetence.[221] Yoichi Masuzoe, the popular LDP Minister of Health, Labor, and Welfare[222] 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.[223] Patients' rights groups, normally critics of the health ministry and the ruling LDP, are backing the health ministry's current proposal;[224] meanwhile, members of the opposition DPJ (a party many of whose leaders come from a progressive background with a history of supporting victims' group causes), are 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 at the time of this writing, as Prime Minister Fukuda's September 2008 resignation and the upcoming general election have left Japanese politics in a state of flux.[226] But 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 recent highly publicized

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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 Shinbun* medical and legal affairs reporter, in Tokyo, Japan (Aug. 13, 2008); Interview with Toshihiro Suzuki, Professor, Meiji 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.

225. *See supra* note 209 (criticisms of internal hospital ADR proposals).

226. *See* Hisako Ueno & Bruce Wallace, *Japan Prime Minister Yasuo Fukuda Resigns*, L.A. TIMES, Sept. 2, 2008, *available at* http://www.latimes.com/news/nationworld/world/la-fg-fukuda2-2008sep02,0,7865629.story.

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 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

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227. *See, e.g.*, Kensaku Fujiwara, Yukiko Takanashi & Atsuko Kobayashi, *Kensatsugawa no ronri hitei: Sanka-i ni muzai* [*Prosecutors' Theory Rejected, Obstetrician Acquitted*], YOMIURI SHIMBUN, Aug. 21, 2008, *available at* http://www.yomiuri.co.jp/iryou/news/iryou_news/20080821-OYT8T00310.htm (quoting health minister Masuzoe's intention to present a bill in the extraordinary Diet session then anticipated during autumn 2008); *Iryō jiko kaimei: shikumi-zukuri kyūmu* [*Urgent Task: Building a Structure for Medical Accident Review*], NIHON KEIZAI SHIMBUN, Aug. 20, 2008, at 1 (calling for medical review system by a "neutral and specialized entity"); Editorial, *Medical Safety Panels Should Be Set Up Soon*, DAILY YOMIURI, Aug. 21, 2008, at 4 (same); *Sankai-i muzai: iryō saisei no kikkake ni* [*Obstetrician Not Guilty: Opportunity for the Rebirth of Medicine*], ASAHI SHIMBUN, Aug. 21, 2008, at 3 (same).

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 the police and prosecutors, enjoy unusually high levels of public trust . . . , especially when viewed in comparison to other countries, including the United States.").

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, will 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] Virginia[232] and Florida[233] have taken limited steps in that direction regarding no-fault compensation for families of infants with neurological damage at childbirth, and Japan is in the final preparatory stages of launching an analogous birth damage compensation system.[234] Neither Japan nor the United

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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).

231. *See, e.g.*, Susan Hershberg Adelman & Li Westerlund, *The Swedish Patient Compensation System: A Viable Alternative to the U.S. Tort System?*, 89 BULL. AM. C. SURGEONS 25 (2004).

232. VA. CODE ANN. §§ 38.2-5000 to -5021 (2007 & Supp. 2008).

233. Fla. Stat. Ch. 766.301 to .316 (2005 & Supp. 2008); *see also* Randall R. Bovbjerg, Frank A. Sloan & Peter J. Rankin, *Administrative Performance of "No-Fault" Compensation for Medical Injury*, 60 L. & CONTEMP. PROBS. 71 (1997) (examining the operation of the Virginia and Florida systems).

234. *See* Editorial, *Compensation for Cerebral Palsy*, JAPAN TIMES, Jan. 10, 2008, at A2, *available at* http://search.japantimes.co.jp/cgi-bin/ed20080110a2.html; Japan Council for Quality Health Care, Sanka iryō hoshō seido [The Japan Obstetric Compensation System] (2008), *available*

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 that are likely commensurable with those measured in Western nations. Awareness of the problem burst on Japan in 1999 and 2000, contemporaneously with the release of *To Err Is Human*[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 or harmonious resolution of disputes through which the conventional wisdom holds that Japan smoothes 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,[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. 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" commenced in 2005 in several prefectures. The project attempts to overcome numerous structural and

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at http://www.sanka-hp.jcqhc.or.jp/outline/index.html (description of the compensation system).

235. TO ERR IS HUMAN, *supra* note 1.

236. *See supra* note 33 and accompanying text.

institutional obstacles, including a splintered, underdeveloped, and secretive death inquest system. Despite a slow start, the project has the potential to bring a new level of transparency to the medical world, to identify and disseminate ways of preventing future harm, and to facilitate the speedy resolution of medical disputes, reserving the intervention of the criminal justice system for only the most hideous cases. The project represents 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 opposition party has countered with a rival proposal, the political scene is in flux, and 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.