

## **Institutional adaptation in risk regulation in the health sector in England and Japan: Proactive response or staged retreat?**

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### **Abstract**

This paper compares the two contrasting health delivery systems of England (nationally run) and Japan (predominantly privately run), and contrasts different patterns of institutional adaptation in risk-based safety regulation in the hospital sector. By looking at similar initial reactions from both governments after the major malpractice incidents in the late 1990s, the paper argues that institutional arrangements can be disrupted under pressure from the general public, opening up a pathway for a new type of risk regulation, with a greater emphasis on patient rights. However, as public saliency in the printed media decreased, the different trajectories of England and Japan became visible. Accordingly, institutional configurations began to play an important role in deciding policy choices, as did interaction between government and the public perceptions as presented by the media. As a result, ‘staged retreat’ can be observed in the system where political accountability was not firmly established, while ‘selective adaptation’ became more frequent in the system where elected officials still play a role in agenda setting. The article sheds light on the dynamic conservatism of the health systems, by drawing on both theoretical argument and empirical data (newspaper archive and semi-structured interviews).

### **Introduction**

Clinical errors, alarming events and risks to patient safety, often signal defects in the health system, putting individual doctors, hospitals or the medical professions in the dock. In some cases, government can also be held responsible for the lack of resources allocated to the sector or the absence of an appropriate risk management system. Such highly-charged events and their impact on central government’s responses have been studied (Alink et al. 2001; Lodge and Hood 2002), but similar cases in the hospital setting have not been given much attention, particularly in relation to the policy responsiveness of government. This paper examines the extent to which central government was responsive to public criticism surrounding malpractice incidents at a hospital site.

The term “medical malpractice system” can be defined as ‘a collection of organisations and processes for dealing with the relationships between patients, doctors, and society when something goes amiss in the

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medical treatment transaction. This includes, therefore, ways in which patients lodge complaints, ways in which complaints are reviewed and addressed, protection for doctors, mechanisms for disciplining doctors, use of the court system, assistance for doctors who have physical or psychological problems, compensation for injured patients, and mechanisms for prevention’ (Rosenthal 1987: 5). Normally victims follow the procedures established in each country, making complaints to a responsible agency or filing a lawsuit. Doctors may appeal if the verdict seems unfair. In the two countries, these risk prevention and disciplinary systems varied greatly when the biggest incident of this kind, both in terms of media saliency and impact on paradigm shift, came to light in the mid/late-1990s. Due to the nature of medical injuries and malpractice, the conventional procedures within the system may not always be fit to dissolve public disquiet. Government needed to respond to ‘crises’ by reviewing and upgrading the system as well as installing new preventive measures. A convergence of policy directions could be observed under heightened public attention and in response to a popular trend of public loss of trust in the medical professions and public hospitals.

However, as public saliency in the printed media decreased, the different trajectories of England and Japan became visible. Accordingly, institutional configurations began to play an important role in deciding policy choices, as did interaction between government and the public perceptions as presented by the media. Consequently, what Hood et al. (2001) termed ‘staged retreat’ was observed in terms of transparency of the new risk regime in the system where political accountability was not firmly established, while ‘selective adaptation’ became more frequent in the system where elected officials still play a role in agenda setting. The ‘staged retreat’ hypothesis is considered to be in between ‘the hypothesis of neutral compliance and the autopoietic dynamic-conservatism hypothesis’ (Hood et al 2001: 150). ‘Retreat’ signifies a move away from an initially preferred goal, restoring the original order. On the other hand, ‘selective adaptation’ is defined as a strategy for institutions to adopt for survival, and therefore implies that the preferred goal may keep changing.

The paper primarily analyses the gap between predictions drawn from institutional designs and actual government responses immediately after the incidents. It underlines the fact that heightened pressure could bring major changes to the risk regulatory regime, couched in similar terms such as patient safety, learning from mistakes, and third-party involvement. Yet a long process of rearranging institutional setups reveals variations in the speed of implementation and the level of openness of the regimes. The paper first outlines different institutional arrangements, then briefly describes the background to each case, which emerged as the most controversial medical event of the decade in its respective country. The aim is to highlight the standing of the medical professions vis-à-vis government and the general public. The paper then describes the main actors’ reactions and policy developments, examining whether different institutional arrangements or issue saliency had any impact on the course of those changes.

### **Government-doctor relationship and professional autonomy**

In Britain, the state regulation of medicine dates back to the Medical Act of 1858, when the forerunner of

the General Medical Council was created with responsibility for the licensing of doctors and supervising education and disciplinary matters. The GMC administers the registration of medical practitioners and the Medical Register, and supervises undergraduate medical education in Britain through formal inspection and recommendations. Its authority is granted through an Act of Parliament. Formally, it is a sub-committee of the Privy Council, is not a public authority or standing committee under the DH, and is funded by doctors on the register. The GMC has been granted a high degree of autonomy. Specialists in England are certified by diplomas issued by the Royal College of Physicians and the Royal College of Surgeons, although they are not compulsory for doctors to claim their specialist status or to obtain a consultant post in the NHS. However, due to this activity, separation between specialists (consultants) and generalists (GPs) has emerged over time. The semi-autonomous characteristic of the GMC has led to criticism over the concentration of doctors among its members, and the resulting favourable treatment when “disciplining” their fellow doctors (Waring 2005; Walshe and Shortell 2004; Salter 2000).

After World War II, the Japan Medical Association (JMA) was reconstituted as a voluntary professional organisation in 1947, under the auspices of the United States Set out by the American Occupation in Japan, medical schools were standardised into six-year university level programmes, with mandatory national licensing examinations. The Ministry of Health and Welfare (MHW until 2001, then MHLW after the merger with the Ministry of Labour) administers the examination, according to the Medical Care Law of 1946 (Art.10). The licence is not subject to review and renewal, and therefore, once acquired, is lifelong. When it comes to human resources, professors at teaching hospitals wield power over their medical staff, and over where their students obtain their posts. With authorities in each clinical department, the close-knit, family-like network was nurtured. Consequently, specialties were divided further into subspecialties according to an autonomous unit of a clinical department, and this became called *Ikyoku-sei* (medical personnel management system based on clinical department) (Campbell and Ikegami 1999).

Disciplinary measures are taken by the Medical Ethics Council (Idō Shingikai, MEC)<sup>2</sup> if clinical errors are reported. The MEC has the power to revoke the licence, or put restrictions in place in cases where there are questions about a doctor's fitness to practice. The MEC is responsible to the Ministry, and thirty members including the Presidents of the JMA and the Japan Dentist Association are appointed by the Minister every two years. Half of MEC members are physicians and surgeons. Yet in the past, the MEC normally waited for judicial verdicts for such cases before deciding to sanction doctors and demand closures of their clinics or hospitals. Therefore, the whole process takes a few decades before the issue is settled.

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<sup>2</sup> The MEC was founded in 1948. The members consist of two Presidents (one for the Japan Medical Association and one for the Japan Dental Association) and eight scholars (term 2 years). When banning medical practices, the Minister is obliged to consult the MEC. Although it can decide on administrative measures, unless there is a serious charge against them, the MEC cannot proceed to action.

Although the importance of the self-regulated GMC in Britain and the courts in Japan and their implications for healthcare professional regulations is worth noting, the medical professions generally have a significant amount of discretion over management as well as clinical decisions in both countries (Glennister 1994; Hill and Hupe 2002; Eckstein 1960). The significant difference lies in the way that the government’s regulation of the medical professions shapes the scope for government intervention as well as the perceptions of the general public towards the role of the state in health care. Garpenby defined three different types of professional autonomy: clinical, collective and individual. “While clinical autonomy is the main concern of scientific bodies, it is individual autonomy that occupies the interest of trade union bodies. Occasionally they overlap in concern for various issues, and there is no clear-cut borderline between them (...) Collective autonomy can be described as the freedom for the medical profession as a collective to regulate and control certain aspects of the health care system – for example clinical standards, ethical standards and professional conduct”

Drawn upon the concepts of ‘autonomy’ (Garpenby 1989: 11), it becomes clear that the degree and nature of professional autonomy vary greatly. The enshrined tradition of clinical autonomy in England confers advantages not only on the medical professions themselves, but also on central decision makers, acquitting them from involvement in difficult decisions or, on the other hand, taking policy initiatives without “appearing to be infringing medical autonomy” (Klein 2001: 66). With a strong tradition of ministerial accountability and party competition in England, the government is held accountable for their policy output. In Japan, the JMA, in perpetual conflict with the MHW over payment, allied itself with the long-term governing party LDP. The tripartite fee-schedule bargaining and doctors’ informal but robust networks created solid institutions of its own, leaving no clear line of accountability for the electorate, as the policy-making process was closed to the general public. Protection of professional autonomy in Japan, however, was a double-edged sword, as closed and rigid subsystem<sup>3</sup> policy-making without sensors to the external environment could blur and undermine central government’s sensitivity to public criticism. Given the quick turnover of ministers<sup>4</sup>, the influence of each minister over health policy has inevitably been limited, but blame has also been shifted easily to someone more in charge, particularly the medical professions or individual hospital managers (who are also doctors)<sup>5</sup>.

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3 A subsystem is ‘a part of the whole political system that interacts more intensely with its participants than with other parts of the political system’ (Jones 1994: 164).

4 In between 1970 to 2006, there have been 39 ministers, in contrast to 15 each for the UK. The average of more than 1 minister per annum is noteworthy.

5 The exception was a drug-induced HIV case by contaminated needles, of which over many years the MHW and some senior doctors had been aware but negligent, instigated a minister’s apology. In 1996, the then non-LDP Welfare Minister Naoto Kan officially apologised to the public, ‘creating’ the word ‘accountability’ in Japanese politics for the first time (Van Wolferen 2001).

In summary, although both countries possess a government arena for deciding disciplinary measures when the system goes wrong, the government in England is more exposed to political pressure for policy change than its counterpart in Japan, but also has a wider scope for taking new initiatives without fearing direct electoral consequences (Moran and Wood 1993; Kondō 2005; Ham 2004; Tuohy 1999). The next section presents predictions based on institutional arrangements described above. These predictions will be compared with those based on issue saliency in the following section.

### **Predictions based on institutional arrangements**

With regard to predictions based on institutional designs, central government in England is constantly faced with a struggle between its strong ministerial responsibility and the medical profession's autonomy. The responsible self-regulatory body in the malpractice system is the General Medical Council (GMC). Thus, it would be the medical professions who would succumb to strong pressure, but also since the NHS is politically sensitive, the Secretary of State is expected to respond. In between political accountability and self-regulation, the government, rather than the self-regulatory body, which is not publicly accountable, may face political pressure or have an obligation to tackle the problem.

In contrast to the English case, individual doctors in Japan normally had to face court cases on their own, risking losing their licence to practise indefinitely. Malpractice-hit hospitals teeter on the verge of losing their reputation once such scandals are broadcast. The government's consultative body, the Medical Ethics Council (*Ido Shingikai* or MEC), normally waits for the court ruling before making its own judgment, and the whole process can take a couple of decades before the final settlement. Nevertheless, given the high saliency of the issue, and at the time of public apprehension and mistrust, central government (the MHW), as the only credible public authority, might respond and come up with some new schemes to take control of the matter.

In England, since events must create high pressure on both the political and medical systems, the relevant Hospital Trust, the Department of Health and the General Medical Council, as well as politicians, would share responsibility and react accordingly. The opposition parties in parliament might criticise the government's reaction. Policy responses could be overarching, driven by both the political and medical sides. High responsiveness of central government is expected.

On the other hand, the predominance of private clinicians and the supremacy of judicial verdicts are the customary procedures in Japan, and therefore individuals are blamed when things go wrong. Central government (and its disciplinary committee, the MEC) played a role in sanctioning them, but never took the initiative to tackle the patient safety issue nationally. Preventive measures were up to each clinic and hospital. Under heightened pressure, however, these institutional weaknesses (e.g. lengthy legal procedure or absence of a risk management system) may be revealed and criticised. The institutional arrangements translate into low responsiveness of central government.

The next section shows the chronology of each episode, followed by its issue saliency.

### Predictions based on issue saliency and public criticism of central government

In highly charged cases such as medical incidents, it is not only the institutional arrangements, but issue saliency, and the increasing criticism of central government and medical professions, that may also have a large impact on government responses. Figures 1 and 2 below demonstrate how often newspaper media referred to each incident. Search terms include the names of hospitals where the incident occurred (Bristol Royal Infirmary in England, and Yokohama City University Hospital (YCUH, Yokohama Shiritsu Daigaku Byōin) in Japan). The two cases would be expected to appear in the newspapers in a rather abrupt manner at the point at which the event occurred, yet the English case was the exception here, in that the scandal went unnoticed initially, but later heightened attention was sustained over a fairly lengthy period. For all similarly shocking incidents, these profiles demonstrate different patterns of public attention concerning the issue in the two countries. Figures 1 and 2 provide comparative data of public exposure of the accidents through newspaper circulation, and are followed by another figure, which indicates the level of exposure, to show the average exposure of the events in relative terms.

The Japanese case gained a greater amount of attention, As the type of policy suggests, there is a high likelihood that the incidents could provoke prompt reactions from the medical professions at least, if not central government as well. Formal government procedures can be disrupted and affected by intensified media coverage, not just by internal pressure coming from institutional setups of health systems, but also by growing concerns of the general public.

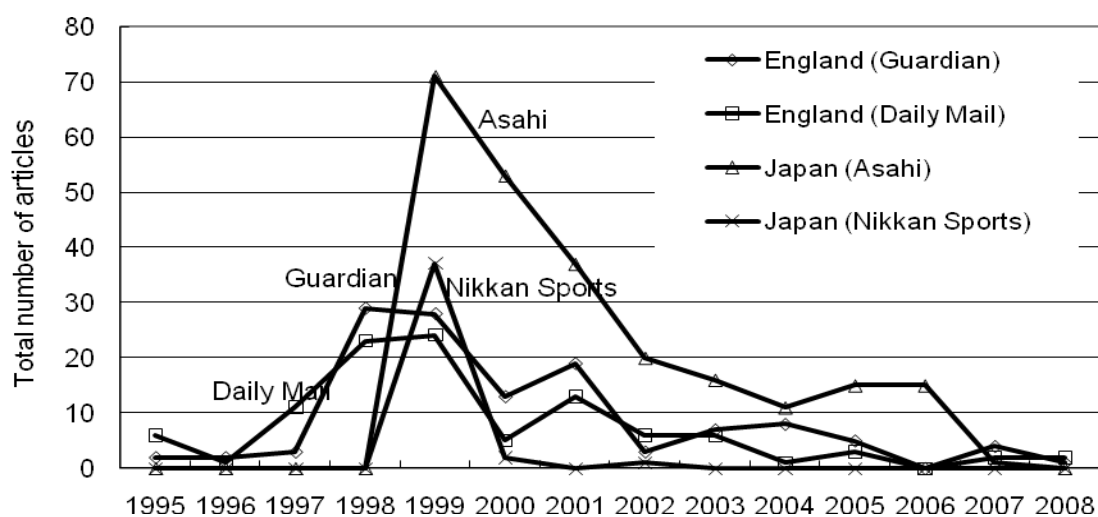
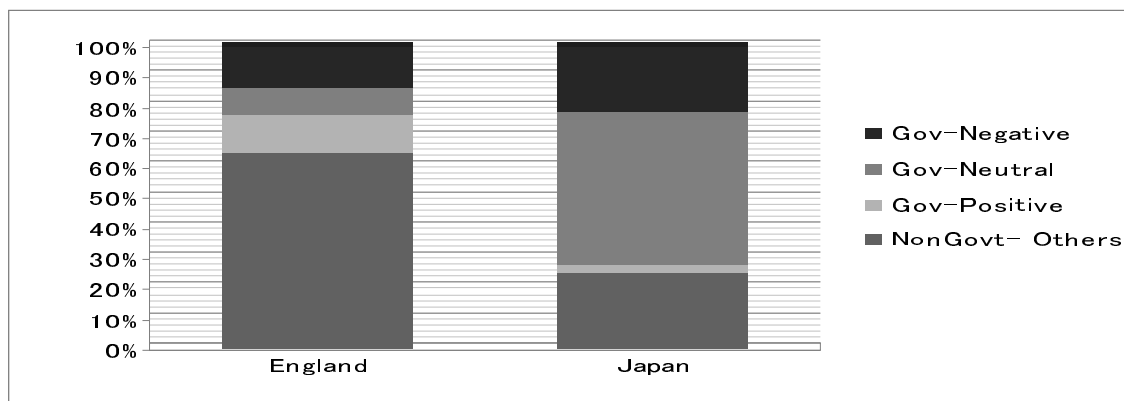


Figure 1: Issue saliency

(Sources: The Guardian/Asahi Shimbun/Daily Mail/Nikkan Sports)

By looking at the breakdown of article types (positive, neutral and negative treatment of government and non-government bodies (including NHS executives, hospital doctors, etc.)), the very frequent mention of the government in the Japanese newspapers (government referred to in 75% of articles relating to the case) is conspicuous, given the lack of political accountability in the country’s health system, compared to 35% in England. Furthermore, criticism of government also accounted for 21% of the total articles in Japan, compared to 14% in England. Even the ratio of criticism of central government (21%) is very rare in Japan. Considering the sheer amount of media coverage as well as the period of high saliency, this case is remarkable.



**Figure 2: Proportion of reports critical of government**

Therefore, the predictions based on the negative reports can be summarised in the next page.

In England, issue saliency was not high, although public attention remained relatively high for a longer period. The level of public criticism of central government was, surprisingly, not high (14%), as criticism was mostly targeted at the medical professions as a whole. Therefore, central government did not receive as much criticism as it should have done, as institutional designs might suggest. Both issue saliency and the level of public criticism were not high and therefore the responsiveness of central government is predicted to be low. In contrast to this, the saliency in Japan was also high and acute. Although the level of criticism of central government was not as high (21%) as the case of local hospital reorganisation (33%), the proportion of articles mentioning central government in total was unprecedented, and higher than the English case. The responsiveness of government is expected to be fairly high, with wide-ranging responses. Some structural changes in the hospital sector are predicted.

The next section will introduce each episode and explore how government actually responded to the scandals. For this case study, each episode also accompanies shifting issue saliency, focusing on the first few months until it reached the peak.

## **England: Children’s Heart Surgery at Bristol Royal Infirmary**

In disciplinary matters, a great degree of autonomy was traditionally granted to the medical professions. The effectiveness of the General Medical Council was critically questioned over this incident, as it was discovered that doctors were not sanctioned, but the whistle-blower had been cast aside instead. At the initial revelation, the issue did not receive much attention, but the saliency gradually increased as the Labour Party entered government. One prediction based on institutional designs is that central the government responds to such a case with the utmost urgency, as it is politically liable. The other prediction based on public saliency shows the opposite. This episode examines the responsiveness of central government to public criticism expressed in the media.

### **Background: whispering limited to the self-regulatory body**

The Bristol Royal Infirmary (BRI) case came to be widely known by the public in 1995. However, as early as 1990, anaesthetist Dr Stephen Bolsin had already noted a high death rate in babies at the BRI, and raised his concerns with other colleagues. Yet operations continued until Joshua Loveday died in 1995, which first brought the issue to the media’s attention.

In April 1995, the Bristol Royal infirmary, part of Bristol Healthcare trust, admitted that it had stopped a pioneering technique for open heart surgery for infants after nine out of thirteen babies operated on died over an 18-month period prior to 1993. It was revealed after four anaesthetists refused to participate in further operations because of the high likelihood that the babies were too young to survive surgery. The deaths happened between January 1992 and October 1993. The technique, called ‘switch’, was first used in Britain in 1977, and at the BRI in 1992, as a last-chance procedure used on 'blue' babies, born with their pulmonary and aortic arteries the wrong way around. It was reported that the mortality rate at the BRI was 66 per cent – six times higher than the national average of 11 per cent. In July 1993, six cardiac anaesthetists asked for a formal review of the switch technique programme among fears of further deaths. However, this never took place. The DH, being informed of the situation, had funded the United Bristol Healthcare Trust £2m for paediatric cardiac surgery in 1992. Dr Peter Doyle, senior medical officer at the DH, demanded that the cardiac surgery department in Bristol should prepare a report.

The review of 2,500 open-heart adult cardiac operations between January 1993 and November 1995 found that the quality of heart surgery in Bristol was in line with the national average, but singled out Dr Wisheart for "further investigation". Before the inquiry’s final report was due in March 1997, he decided to step down. Hence, public disclosure of this case of the ‘BRI tragedy’ had already taken place in 1995 (Department of Health 2001; Aylin et al. 2001; Kewell 2006).

The following section will trace the episode, examining why and how the government responded to external pressures, if the pressures were not exerted upon them.

## Episode and Analysis

### Phase 1: Mounting criticism of the medical professions (1997-2001)

As the report was submitted in March 1997, the then Health Secretary, Stephen Dorrell, under the Conservative government announced an inquiry into cardiac surgery at the hospital, after an independent expert review indicated that Dr Wisheart's open-heart surgery patients were four times more likely to die than those treated by his colleagues. The inquiry report, *Independent Review of Adult Cardiac Surgery* concluded that “the performance of one consultant surgeon appeared to be significantly poorer than the other surgeons” (BMJ 1997; 314: 919, 29 March 1997) *The Independent* detailed the events, revealing that fact that those surgeons including Dr. Wisheart were either awarded the NHS incentive bonus even after the news came out in 1995, or left the country.

The Labour government came to power in May 1997. Criticism continued to be concentrated on the lukewarm handling of the GMC and its culture of secrecy. As the Professional Proceedings Committee of the GMC began in October 1997, the former Health Secretary and also the Bristol MP William Wildegrave expressed his concern that the GMC should only fulfil its function as the doctors’ own watchdog (The Independent, 10 October 1997). The same line was adopted by the new Secretary of State for Health, Frank Dobson, when he found out that the GMC did not immediately strike the other surgeon, Dr Dhasmara, off the medical register (E-2). The GMC was heavily criticised not only by politicians, but also by protesters, including parents of the children who died or suffered brain damage after the surgery. Dobson promised a public inquiry, finally setting it up on 18 June 1998.

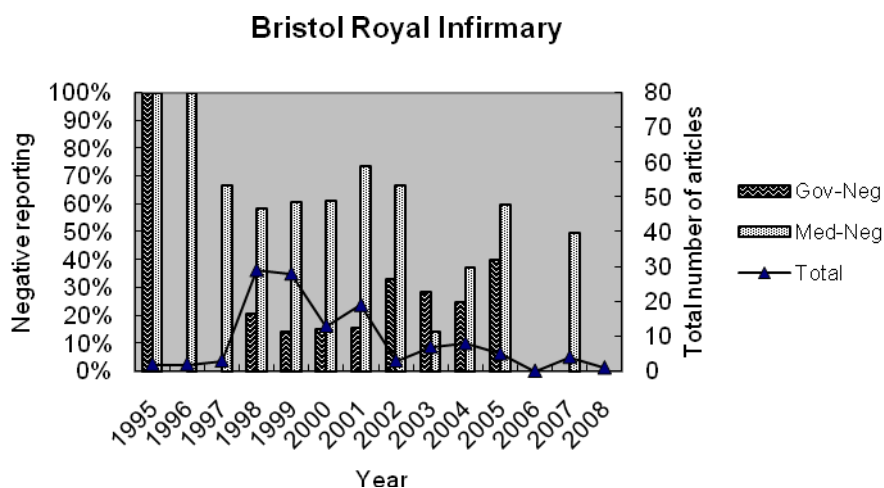


Figure 3: Number of reports critical of government and medical professions  
 (The Guardian, 1995-2006/Phase 1: 1997- mid-2001; Phase 2: mid-2001 - 2006)

In his statement to the House of Commons, Dobson declared that the government would identify any professional, management and organisational failures. “The Government are not going to wait for the

outcome of the inquiry before taking action to put in place new machinery for setting and maintaining clinical standards” (*Hansard*, 18 June 1998, Column 529-30). Dobson went on, and emphasised the government’s future plan, which were to be laid out in the White Paper “the New NHS” published in December that year. A range of measures included establishment of a national institute for clinical excellence, a commission for health improvement and a clear duty of clinical governance on NHS trusts, compulsory participation of doctors in national external audits and publication of treatment success rates at local hospitals.

The subsequent disciplinary hearing was reported as the most important medical inquiry of the decade. It revealed that by the time of the operation in August 1994, eight of Mr Wisheart's 14 infant patients had already died during or after similar surgery. Nonetheless, during the hearings, Mr Wisheart, together with his fellow surgeon, Dr Dhasmana, and Dr. Roylance, former chief executive of the Bristol United Healthcare NHS Trust, all denied charges of serious professional misconduct. The charges relate to two types of complex surgery to correct congenital heart defects performed on babies at BRI between 1988 and 1995.

Several criticisms were raised in response to the verdict of the GMC inquiry. A former government advisor on health, Professor Rudolf Klein, commented that the Bristol case shows ‘that the GMC cannot put institutions on trial’ (*The Independent*, 30 May 1998). The health editor of the paper claimed that ‘(t)he case, which began last October, is the longest in the GMC's history and has already had widespread repercussions. It has exposed a central weakness in the NHS - the absence of clear standards against which doctors' performances can be measured. To patients it seems extraordinary that there are no measures for judging whether a doctor is good at the job. Medical organisations have previously argued that clinical practice is too complex, and patients too varied, for measures to be meaningful. That view is now history.’ (*The Independent*, 31 May 1998)

The focus was gradually shifted from individual doctors’ malpractice to general structural problems in the NHS. The media attention culminated in June 1998. On 3 June, in the House of Commons debates, the Labour MP for neighbouring Wansdyke, Dan Norris, pointed out the failure of the minister’s intervention in the Bristol Trust matters (*Hansard*, 3 Jun 1998, Column 365). In reply, Tony Blair promised that an independent commission for health improvement and a quality control system would be put in place in every hospital across the country. The government responded promptly. Secretary of State Dobson declared that from October 1998, new league tables would be introduced in the whole hospital sector which would carry an annual chart of the numbers of deaths at hospitals treating patients for serious diseases, including cancer and heart problems. This move received a welcome from the NHS managers and the Royal College of Nursing, but they also voiced cautions.

With immediate effect, from October 1998, all hospitals in England and Wales began publishing annual statistics showing the death rates of patients, highlighting unusual mortality statistics at the BRI. In addition, the inquiry was set up by the Health Secretary under Section 84 of the National Health Service Act 1977,

and Professor Ian Kennedy, Professor of Health Law, Ethics and Policy at University College London, was appointed as a chairman. The scope for the inquiry was extended by request from both Labour and Liberal Democrat MPs to include cases of adult cardiothoracic surgery.

Up until the opening of the inquiry in 1999, there was some progress on the disciplinary actions by the GMC. Dr John Roylance, former chief executive of the Bristol Royal Infirmary, announced his decision to take his case to the Privy Council. Although he was found guilty of serious professional misconduct by the GMC for failing to halt operations, he claimed that from his position as a chief executive, it was impossible to intervene into consultants' professional decisions (The Independent, 18 July 1998). In the meantime, the government stepped up its intervention, and decided that a controversial heart surgeon would have his pension drastically reduced (The Independent, 9 August 1998). Then, the public inquiry was officially announced by Secretary of State Dobson on 12 August 1998. A preliminary hearing began in Bristol in the autumn, and full public hearings started in Bristol and London from early 1999.

In response, the Senate of Surgery of Great Britain and Ireland<sup>6</sup> announced that all consultant surgeons should be subject to regular checks throughout their careers to ensure their skills are up to standard. The Senate argued that the protection of patients was paramount and that the "public must be reassured we provide a safe and appropriate service" (The Independent, 23 October 1998). In the following year, the GMC decided that doctors must agree to continuous monitoring of their skills to preserve public confidence and to see off government threats to intervene in their regulation.

The public inquiry was opened on 16 March 1999. Parents of the victims were the first witnesses to give evidence, and one after another, families' personal accounts in the media painted the BRI as “a chronically malfunctioning hospital” (The Independent, 17 March 1999). It was revealed that the heart ward was known as the ‘killing fields’ and ‘departure lounge’ (18 March/19 October 1999), and accused of ‘gambling on heart’ (19 March 1999). From June through the summer of 1999, doctors and chief executives (and a doctor struck off after the incident), testified at the inquiry hearings. During the hearings, ‘workload’ pressure on the surgeons became apparent, and this concern was highlighted. Dobson reacted to this by proposing to increase the number of consultants (The Independent, 3 August 1999)

There came a warning about the way all the blame was placed at the door of the medical professions and concerns about the effects of too much attention on individual doctors' performances. Nigel Heaton, chief executive of a London teaching hospital, stressed that surgeons could refuse to operate on high-risk patients if success rates for individual doctors would be overemphasised (The Independent, 7 September 1999). However, the direction towards stricter monitoring was not changed by government (Bevan and Cornwell 2006). Behind this, there were a series of medical scandals (e.g. Rodney Ledward and Harold Shipman) that

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<sup>6</sup> It represents the 10,000 most senior surgeons in Great Britain and Ireland.

led to the criminal court. These cases further reinforced mistrust in the profession and justifying the cause of such a third-party watchdog.

In October, the government announced the launch of a new watchdog, the Commission for Health Improvement. Prime Minister Tony Blair professed his strong intentions of risking upsetting doctors in order to raise standards. Blair commented that “(n)o government can eliminate human error, or remove risk. But we can put in place the right systems, spread the best practice and scrutinise performance in far better ways than we have done in the past” (The Independent, October 29 1999). The commission was to be given a comprehensive remit and the Secretary of State for Health was also given the necessary powers to act swiftly on its recommendations. “He can remove a hospital management if it does not respond to recommendations, sack the boards of health authorities or trusts, and pass the names of individual doctors to disciplinary bodies” (The Independent, October 29 1999).

The Select Committee on Health (chaired by David Hinchcliffe) published its sixth report entitled ‘A culture of blame?’ In it, they state: “(w)e consider that there should be a culture of organisational responsibility, as well as individual responsibility, within the NHS in dealing with adverse incidents and poor outcomes. We recommend that the Department of Health reviews and reports on the implementation of clinical governance.” (House of Commons, Select Committee on Health, 6<sup>th</sup> Report, 1999) In November 1999, towards the end of the public inquiry, MPs in the Select Committee for Health quickly drew up a proposal, that relatives of people who die unexpectedly in hospital should have a legal right to demand an inquiry by independent experts (The Independent, 21 November 1999).

In combatting a failing NHS trust, the new Secretary of State, Alan Milburn promised that clinical indicators of death rates following surgery would be published, and patient forums would be restructured after the abolishment of the Community Health Councils. Nonetheless, this centralist approach met with opposition from several MPs<sup>8</sup>, as such changes would weaken the local monitoring process and undermine the bottom-up system. In July 2001, however, on the recommendation of the report, *An Organisation with Memory*, the National Patient Safety Agency (NPSA) was established. Its main task is to ‘co-ordinate the reporting of patient safety incidents and to learn from these incidents in order to improve patient safety in the NHS’<sup>9</sup>

## **Phase 2: Promoting organisational learning and no-blame culture (mid-2001 to 2004)**

The tone of all these debates started to change, as the National Health Service Reform and Health Care Professions Bill was presented to Parliament on 8 November 2001, and reached the second reading later in

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<sup>7</sup> <http://www.publications.parliament.uk/pa/cm199899/cmselect/cmhealth/549/54902.htm>

<sup>8</sup> They include Ms Gisela Stuart MP, Dr. Howard Stoate MP and Ms. Julie Morgan MP.

<sup>9</sup> <http://www.npsa.nhs.uk/npsa/about>.

the same month. It did not become an issue for adversarial politics between government and the Opposition, but rather an intra-party row between the frontbench and backbench of the Labour Party. It was the third piece of legislation that the Blair government introduced, following the Health Act (1999) and the Health and Social Care Act (2001). The bill proposed some new developments in the area of regulation of risks.

Firstly, it promised to set up a council for the regulation of health care professionals to ensure that individual regulatory bodies, such as the GMC and nursing regulator the UKCC, "act in the interests of patients". It would have the power to appeal against decisions by professional regulators which it felt were not in the public interest; secondly, it decided to transfer "fitness to practice" (professional conduct) cases from the privy council to the high court, and extend existing powers to bring the pharmacy profession under the auspices of the law governing the regulation of health care professions (The Guardian, 14 November 2001).

The DH's response to the Kennedy report 'Learning from Bristol' was published in January 2002 (Department of Health 2002). It showed its commitment to its plan to make the NHS safer, more open and accountable. Therefore, with the introduction of new agencies such as NPSA and the Commission for Healthcare Improvement, two approaches to risk in the hospital sector emerged and were enshrined in those organisations. With the notion of clinical governance, all doctors were required to participate in audits and were potentially subject to monitoring regimes (Klein 2001: 210-1), while the activities of the NPSA embodied the promotion of a no-blame culture in medicine.

Another development, as part of the government response to the report, was discussions as to whether the patient death rate of every heart surgeon in the country should be made public within two years. Health secretary Milburn announced that it would be 'a first step to giving the public hard information about the performance of every doctor – and the right to go elsewhere if they choose' (The Guardian, 18 January 2002). It was advocated as "a milestone in the development of a more open, responsive and patient-centred NHS", although surgeons expressed concern over negative long-term effects, as surgeons would avoid high-risk but necessary operations.

However, despite all 'responses', the government did not respond positively on every point proposed by reports from the public inquiry and the experts. From the 198 recommendations in the report, the government showed its reluctance to act, or disagreed on a few important issues. The first point of dissent was as to whether to establish a no-fault compensation scheme, with a sliding scale of payments for victims of medical accidents, in order to 'end blame culture and persuade doctors to admit their mistakes'. The government disagreed and proposed instead a dual system, leaving recourse to the courts as a possibility. Secondly, the government was not in agreement over the possible separation of management and medical practice, when doctors chose to take on chief executive posts. The report recommended that they should not be allowed to practise, as their skills and knowledge in the field could work negatively against patient

safety, while the government defended the profession’s right to choose. The third point was the authority of the agency. Although the report suggested that NICE should be the sole organisation to set yardsticks and provide guidelines for doctors on treatment, the government rejected the view, claiming that the royal colleges, medicines control agency and others, as experts, should also play a major part in the standard setting process. The government therefore adopted a more profession-friendly stance than it claimed throughout the process.

As the issue saliency had decreased by then in early 2003, another policy question was put to the government. The review group, based on the recommendations of the Kennedy inquiry, was composed of consultants in paediatric and congenital cardiac services, and several parents from the Children’s Heart Federation. The group submitted a proposal to government. Its main recommendation suggested that in order to maintain surgeons’ expertise and skills in children’s complex heart operations, the unit should deal with at least 300 cases annually, and therefore the government should centralise its unit into 7 or 8 hospitals, from the current number of 14. However, the health minister, Jacqui Smith, said that the government was “not persuaded of the review group’s proposals” (9 January 2003). As one consultant commented, politicians were ‘saying there is no need for change. But underlying it, I think, is the Kidderminster effect<sup>10</sup>. If government accepted this view, they would have to close down local services, which could put MPs jobs at risk. The proposal was postponed.

Overall, the government exhibited an extensive sensitivity and responsiveness to public criticism, as institutional designs predicted. Yet, particularly in the second phase, once the issue was brought into parliament, other political considerations derailed the primary focus in the inquiry, and the government did not even take up any of the experts’ recommendations.

### **Phase 3: More scandals and prevalence of accountability logics (2004 to 2008)**

The fifth report of the Shipman Inquiry, published in December 2004, reignited the debate about professional misconduct and the limits of self-regulation. Inquiries into other criminal cases (e.g. Ayling/Neale, Kerr and Haslam) led to continued high media interest in patient safety.

Concerning the hospital sector, local risk management and learning from mistakes continued to be strongly emphasized by government, and the National Reporting and Learning System was rolled out by NPSA to complement those mechanisms. While NPSA has no statutory powers to make the reporting of incidents or near-misses mandatory, reporting activities of every Trust were reflected in their performance measure, rendering it quasi-obligatory. A report from the National Audit Office in 2005 acknowledged that progress

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<sup>10</sup> This refers to the shocking electoral result in 2001 of an independent candidate Dr Richard Taylor (Wyre Forest) who won a seat of a former junior minister John Lock (Labour) by campaigning against the downgrading of Kidderminster Hospital.

was made in alleviating the blame culture. However, the slow pace of the progress and effectiveness of the NPSA was also questioned (The Guardian, 3 November 2005). Inadequacy of the system was criticised by the media and the opposition party. Edward Leigh (Chairman of the Commons Public Accounts Committee, Conservative Party) was quoted as saying ‘although the National Patient Safety Agency was set up to ensure that valuable lessons learned from patient safety incidents could be analysed and shared both locally and nationally there is limited evidence of an effective activity’ (Daily Mail, 3 November 2005).

In 2006 and onwards, major developments were observed in the regulatory framework. Sir Graeme Catto, the President of the GMC, has described new proposals for doctors to be required to renew their registration every five years as “the biggest change to medical regulation in one hundred and fifty years” (Department of Health, 2008). As detailed above, until now the medical profession has possessed almost unique control over professional status. The new system, drawing on the report ‘Good doctors: safer care’ (Chief Medical Officer 2006) (and before it, the consultative document ‘Supporting doctors, protecting patients’ (Department of Health 1999) and Merrison’s 1975 proposals (Gornall 2006)), will amongst other things involve patients being “asked for views on their doctor” (Department of Health 2008). The system will create an “ongoing duty of accountability of the individual practitioner to the regulator” (Kaye 2006: 109). In terms of openness of clinical competency data, health ministers continued to be the protector of patient rights, and ‘want to give more data to patients to help them choose the right hospital on medical grounds instead of them relying on local gossip or promotional material from trusts about quality of meals and availability of car parking’ (The Guardian, 28 August 2007). Even the professional associations such as the Society for Cardiothoracic Surgery supported the idea. Amid discussions around patient safety with a stronger emphasis on professional competency, patient rights and revalidation, organisational learning became secondary and the effectiveness of the incident reporting system began to be questioned (Godlee 2007; Sari et al. 2007; Vincent 2007). The logic of learning has, however, become embedded in the NPSA and other bodies and therefore institutionalised.

### **Responsiveness in England**

The issue received little public attention in 1995, when the news came out for the first time. However, the English health system in which the institutional vulnerability puts the political dimension at risk of public criticism prompted a quick response from government, and this case exceptionally saw little criticism of central government. More proactive responses were given against professional autonomy, and the government published individual doctors’ death rates. Government determination to put the case into the public domain was shown in its decisions to have the public inquiry and give it a great amount of discretion. The initiatives led to the extension of an increased remit of the CHI to inspect and publish reports regularly so that failing bodies could be detected and redressed at an earlier stage. This incident in particular called into question patient safety management of the NHS. Therefore, unprecedented attention was paid to the

malpractice case in the macropolitics domain<sup>11</sup>, in which government took the lead but did not have to take the blame. As a result, institutional change was brought about to the way in which the professional autonomy had previously been protected. With high sensitivity to health care delivery, the government succeeded in strengthening its grip over autonomous professionals, while displaying its competency to respond and rise to the challenge of patient safety. However, central government’s strong initiatives created the two approaches to patient safety, i.e. promoting accountability of doctors and enhancing a learning mechanism of the NHS organisations. These two conflicting views are now represented by regulatory bodies such as the revamped GMC and to a degree the NHS Litigation Authority and NPSA. These recent developments, in conjunction with incessant pressure from the media and active involvement of senior elected officials in patient safety initiatives<sup>12</sup>, did not support ‘staged retreat’ by any means, and yet seemed to promote selective adaptation, rather than coherent regulation (Dodds and Kodate, work in progress).

### **Japan: surgeries performed on wrong patients at Yokohama City University Hospital**

The Japanese health system had long been governed on an ad-hoc basis concerning government intervention. Although the disciplinary mechanism was installed at ministry level, the decision normally followed court rulings. In contrast to the close relationship between the policy experts in the governing LDP party and the JMA, ministers were detached from such issues, which constituted the weakness of the Japanese health system. There was no channel for the general public which could effectively influence government policy. The outbreak of several medical incidents shook the entire political circle and medical professions. Institutionally, the responsiveness of central government is expected to be weak, although a shift in public saliency and interest could bring about a great change, as institutional vulnerabilities might be exposed effectively.

#### **Background: case-by-case treatment of malpractice cases**

Legal cases related to medical malpractice have captured occasional public attention since the 1980s. Taking a complaint to court became the norm, as the Japanese health system had never established a malpractice system in the public domain. The term ‘medical incident’ (iryō kago) in Japan is clearly distinguished from ‘medical accident’ (iryō jiko) which refers to both unpredictable and inevitable cases and human error committed on the hospital site. The underlying difference between the two concepts is that criminal laws are applied to the former (medical incident), as involuntary manslaughter, but not to the latter (medical accident). To complicate the situation, ‘medical mistakes’ (Iryō misu) is often used in the media without distinguishing the two concepts, simply criticising the medical profession. This represents a swing from one

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<sup>11</sup> Macropolitics, in contrast, is “produced when the community at large and the leaders of the government as a whole are brought into the discussion and determination of policy” (Jones 1994: 164).

<sup>12</sup> For example, the Prime Minister, Gordon Brown gave a speech at the ‘Patient Safety Congress’ in London (May 2008).

extreme to the other, where doctors are perceived as god-like figures but then risk becoming ‘criminals’ without any systematic support. The thin line between ‘accident’ and ‘incident’ generally drawn in courts, based on whether the mistake was made during purely clinical (and therefore professional) practice (e.g. failure in detecting the early signs of a cancer) or simply human error (injection of the wrong type of medicine) (Komatsu 2004: 20). Article 21 of the Medical Practitioner Law postulates that upon discovery of an unnatural death, medical staff are obliged to report it to the police. However, since such an act could be extremely harmful to professional lives of individual doctors as well as the hospital, there is little incentive to report properly. Only a few cases had actually been reported each year, even though voices of concern and apprehension had been raised from nurses in the past (Yoshida 2004: 20).

As a result, sporadic events were dealt with case by case, mostly in court, and the government’s council, the MEC, endorsed the judgement. Structural problems had not been paid a fair amount of public attention until the end of 1990s, when a series of serious medical malpractice cases captured the headlines, first at Yokohama City University Hospital (YCUH) on 11 January 1999, followed by another at Tokyo Metropolitan Hiroo Hospital one month later<sup>13</sup>. In the former case, a patient who needed a heart operation was mistaken for another patient who required a lung operation. They both underwent the wrong operation, and died within the year. This case inevitably sparked huge public concern and media reports, which led to the uncovering of systemic failures and ‘hidden’ medical errors.

## **Episode and Analysis**

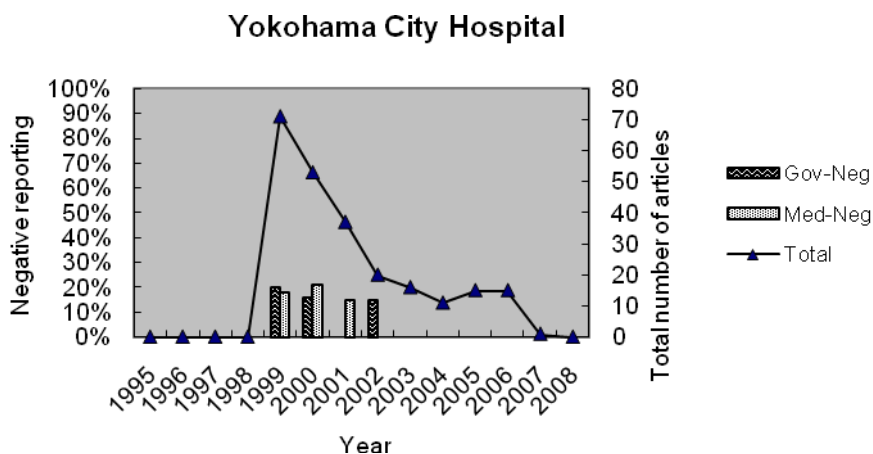
### **Phase 1: Shock waves and government proposals (1999-2000)**

When the Yokohama case became public in January 1999, the number of articles soared. The shock among the general public was immense, as the mistake (i.e. failure to identify the right patient for the right surgery) appeared considerably primitive, and not at all a clinical matter. The initial announcement and public briefing was held at the hospital on 13 January. The manager, Dr Tomihisa Koshino, made a public apology for the accident of conducting surgeries on the wrong patients. However, he announced that there would only be an internal inquiry and the results would not be open to public. He told the press that the decision to have only an internal inquiry was because the victims’ families would not give them consent to do otherwise. He also admitted that the accident was reported to the city’s mayoral office, which managed the university hospital, in the afternoon of the same day, and to the prefectural branch of the police the following day, but not to the MHW. The media criticised the slow response by the hospital manager and the responsible Yokohama City University, as well as its hesitation to make information public. However, the reports’ focus was initially

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<sup>13</sup> A nurse injected a patient with steriliser solution instead of a physiological salt solution mixed with heparin. The patient died within 2 hours. It was later found out that the hospital managers and Tokyo Metropolitan government staff initially sought to cover up the accident. It was revealed that the Health Bureau of the Metropolitan Government demanded that the hospital should not report to the police until the reason for the incident was found out within the hospital. As a result, the incident was reported to the police eleven days later.

concentrated on the question: “how could the nurses mistake their patients’ identities?” Less than two weeks late, another mistake related to blood transfusion was discovered at the same hospital (Nikkei Shimbun, 24 January 1999) only worsened the situations.



**Figure 4: Number of reports critical of government and medical professions**  
 (Asahi Shimbun, 1995-2006/ Phase 1: 1999 - 2000; Phase 2: 2000 - 2004; Phase 3: 2004 - 2008)

The first reaction came from the Japan Nursing Association. President Takako Mito issued a circular in protest against the media reports, claiming that the incident was not due to a particular individual nurse’s lack of attention, or through the fault of the nursing team at the YCUH, but owing to the hospital system in general. The central government had already stepped in by 2 February, by announcing that the MHW was planning to set up a working group of experts and professionals to establish government guidelines for preventive measures. The MHW also alerted every prefectural government on the issue and demanded that safety measures be put in place. In parallel, the President of the JMA made a public announcement that all the medical professions should take safety measures seriously. The issue also started to be discussed in the Diet. In the Diet’s Select Committee, on Health and Welfare, and Justice on 10 February, an officer from the MHW, together with representatives of the Ministry of Education and the police, explained the situation and possible future procedures. The then opposition<sup>14</sup> New Clean Party (Kōmei) Member of Parliament Yutaka Fukushima demanded an explanation for the incident in the Budget Select Committee, one week later on 18 February. The Minister of Health and Welfare, Sōhei Miyashita, replied by suggesting a tighter in-hospital management and monitoring. On the previous day, the working group (for the establishment of in-hospital management for the prevention of patient misrecognition), chaired by Dr Haruhiko Kikuchi<sup>15</sup>, was officially set up within the Ministry.

<sup>14</sup> Eight months later, in October 1999, the New Clean Party would officially join the government with the LDP.

<sup>15</sup> President of the National Cardiovascular Center (Kokuristu Junkankibyō Sentā).

Another opposition party member, the Social Democratic Party Diet Member Kiyoko Kusakabe (House of Councillors) raised the issue of insufficient staff numbers, especially nurses, as the main cause of this incident, and questioned the responsibility of government. The minister denied the accusation, showing the data and pointing out that there had been an ongoing improvement, not deterioration (11 March 1999). From March to May, public attention on this accident rose again, as concern became widespread and articles began focusing on further cases allegedly concealed by the profession. The media was generally critical of the medical profession and hospital staff, but also pointed out more structural factors such as the lack of a learning culture within the organisation (Yomiuri, 25 February, 22 March; Mainichi, 17/22 March; Asahi 22 March 1999). The evidence that the staff at the YCUH had never been aware of similar malpractice cases committed in the past (i.e. Kumamoto prefecture in April 1993) was demonstrated as an example of the systemic failure. One article (Yomiuri, 25 February 1999), drawing a contrast with the UK, where the public authority exists and government is engaged in building such a system, stated that a ‘safety system must be constructed’. These were indirect criticisms of central government, or its long-term absence from the domain.

However, most criticism was targeted at the professions. The group of lawyers who run the consultation centre for medical malpractice criticised conventional preventive measures at hospitals as being ‘thirty years behind’ compared to other fields (Yoshirō Shibara, Deputy Director of Medical Errors Information Center, Yomiuri, 23 March 1999). Lawyers were often quoted as a mouthpiece for patients/victims, accusing the medical profession of its secretive nature (Yomiuri, 25 February 1999; Mainichi, 11 April 1999). This was due to the lack of a publically accountable system for dealing with malpractice. Having to deal with such cases, the lawyers became powerful agents who could mobilise the voices of patients and raise their concerns over defects in the health system.

On 22 March, the internal investigation committee of the YCUH submitted its interim report. The committee consisted of six members, a deputy mayor as chairman and doctors, a lawyer and an expert on medical affairs. The report presented detailed accounts of every stage in the two surgical procedures where mistakes and negligence had occurred. As a proposal for a preventive measure, the report strongly recommended the establishment of an obligatory reporting system and the introduction of a risk management system, similar to the one in the aviation industry. The strengthening of the management team of the hospital and the curriculum of the medical school were also put forward as a ‘proposal’, but the committee was divided over the decision as to whether this should be a rather more nuanced ‘recommendation’. A member of the committee expressed his concern that the proposal would be watered down and may not have any effect at the stage of implementation (Mainichi, 23 March 1999).

The working group in the government submitted the blueprint of the guideline to the MHW on 16 April.

On 12 May, a report<sup>16</sup> was completed by the working group and circulated to hospitals, clinics, prefectures and concerned organisations.

In June, the City of Yokohama decided to penalise the 31 staff members involved in the incident, and to suspend two unnamed professors who carried out the two operations for two months. The city authorities emphasised the fact that the penalty was more severe than any previous similar case. It was revealed, however, that the decision was delayed by protests by the dean of the city university, the former manager and the former faculty head, who were all on the list. They protested on the grounds that they had already stepped down from the posts, and therefore sanctions were redundant (J-5).

The responsiveness of central government resulted from a considerably high level of ‘pressure’, emerging from public concerns over and criticism of insufficient effort made by central government. The proportion of criticism of government (20%) was comparatively high, given the considerable amount of coverage, and the role, if not the responsibility, of central government was exposed and questioned.

After three months had passed, the focus was shifted to how the ministry was dealing with the accident. The YCUH had been a government-authorised, special-functioning hospital<sup>17</sup>, and therefore granted special fee schedule and tax cuts. The MHW decided to ‘advise’ that Yokohama city should submit the plea to the ministry to have that status withdrawn, since the accreditation system had originally no punishment mechanism for the ministry to interfere or remove the title. This was a highly exceptional decision. The government was accused of having created this loophole in its design of the accreditation system.

Media reports also highlighted the fact that the number of medical accident cases (taken to the Supreme Court) were on the increase, with the number doubling in a decade (369 cases in 1989, 629 cases in 1999, 2703 unresolved cases as of 1999). Along with the accident in Yokohama, cases such as Wakayama Prefectural University Hospital<sup>18</sup> and Tokyo Metropolitan Hiroo Hospital were given as proof that the Yokohama case is just the tip of the iceberg. A group of lawyers working on the matter began raising concerns, pointing out structural defects within the system, rather than individual doctors’ incompetence or tort, where there is no reporting obligation of such cases to the ministry (Nikkei Shimbun, 28 June 1999). A voluntary group, Investigation Committee of Medical Accidents (Iryōjiko chōsakai), founded under the

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16 [http://www1.mhlw.go.jp/houdou/1105/h0512-2\\_10.html](http://www1.mhlw.go.jp/houdou/1105/h0512-2_10.html)

17 Hospitals with 500 beds, ICU and more than 10 specialties are allowed to apply for this status, which is to be certified by the MHW. They also have to increase their ratio of referring patients by up to 30%. As of July 1999, 82 hospitals were accredited, including the YCUH.

18 In October 1994, a girl died after being injected with milk. The following year, the hospital was accredited by the ministry as a special-functioning hospital. In 1997, after the media discovered and revealed the ‘accident’ which was concealed from her family, and never existed in the hospital record, the hospital promised an internal inquiry. The inquiry was eventually suspended, and the doctor who ordered a nurse to change the record was never found.

auspice of doctors and lawyers, organised a symposium in Osaka. There, it was reported that out of 250 court cases in the previous four years, 195 (78%) fell into the category of ‘medical incidents’, not inevitable or unpredictable cases (Asahi Shimbun, 15 May 1999).

Six months after the accident, on 1 July, Mayor of Yokohama, Hidenobu Takahide, submitted the plea to the Minister of Health and Welfare Sōhei Miyashita, to withdraw its own status, and the minister accepted the request. By August, public attention on the particular Yokohama case died down, but the demand for the policy responsiveness of government continued to rise. In September, a final report came out from the university hospital internal inquiry. The report spelled out in great detail new safety procedures as well as reforms of the management team. For the first time as a university-affiliated hospital, a new hospital manager would be appointed separately from the dean. These reforms were to be checked by an external inspection committee. The report was submitted to the MHW as well as the Ministry of Education.

The MHW launched its very first three-year pilot study, gathering data on medical accidents, including medical incidents and near misses by collaborating with hospitals across the country. In October, the external inspection committee was set up for rebuilding public trust in that hospital. Committee members were selected, as a new inquiry was launched. This was the measure to ensure that the recommended schemes were carried out so that the hospital would be given back its Special-functioning Hospital status. The ministry also decided to amend the regulation itself, empowering its authority to disqualify its accredited status. In November, the Medical Research Council (now part of the Social Security Council, under the MHLW) ruled that there would be an amendment to the ministerial ordinance, enacted in April 2000. Under the new regulation, the Special-functioning Hospital is required to have a guideline for accident prevention and an internal committee for risk management.

In February of the following year, after the external inquiry was completed with the publication of its report, the City of Yokohama resubmitted an application for the accreditation. The report praised conscientious efforts of the staff and the management for the reform, while it recommended that the hierarchical network at the university hospital (*Ikkyoku-sei*) should be abolished. The medical institutions, which were long thought to be untouchable, were linked to the malpractice cases, and openly criticised.

## **Phase 2: Establishment of ministerial risk management team (2000 - 2004)**

As the issue at YCUH appeared to have been resolved, a further series of scandals appeared in the media. The case of the Tokyo Metropolitan Hiroo Hospital was finally brought to the public prosecutor’s office under suspicions of involuntary manslaughter after more than a year since the accident happened. A dossier of the hospital manager (physician) was also sent to the public prosecutor’s office, in violation of “Physicians Law”. This case attracted a fair amount of media coverage, as the Tokyo Metropolitan government’s original intention of cover-up was revealed (Mainichi, 15 October 1999). The Tokyo government commanded that the accident should be brushed under the carpet. Soon after this, another

malpractice case occurred at the Kyoto University Hospital, where a 17-year old girl died after ethanol, instead of distilled water, was injected by mistake into her artificial respirator. What was worse, the University Hospital already had a medical accident prevention committee installed ten years previously.

On 16 March, at the Medical Research Council of the MHW, a talk was held with regard to the reapplication of the YCUH for the Special-functioning status. Against expectations, the reapplication was turned down, based on the fact that the deputy director of the hospital commented that ‘the operations were not necessarily in vain’ (Yomiuri, 17 March 2000). He resigned after this revelation. Despite all this, Mayor Hidenobu Takahide once again announced that the city would make every effort to regain the accreditation. The public prosecution commenced on 22 March.

Under these circumstances, the ministry stepped up its intervention. The Medical Research Council summoned the medical staff from Kyoto University Hospital for questioning. Since Kyoto University Hospital is one of the leading teaching hospitals in the country, and under the jurisdiction of the Ministry of Education, this was quite exceptional. The ministry’s survey revealed that only one third of the 82 Special-functioning hospitals had an internal committee for accident prevention and even fewer a quarter, had a manual (Asahi Shimbun, 28 March 2000). A medical accident consultant and lawyer, Akira Morita, expressed his doubt as to ‘whether accreditation for the Special-functioning hospital and everyday risk management at each hospital are two separate matters’ (Yomiuri, 7 May 2000). For national hospitals (now considered to be all independent administrative bodies), the MHW is in charge of management, and can therefore intervene much more directly. The ministry drew up its own manual on risk management and attempted to encourage hospitals to embrace its recommendations. The Minister of Health, and an influential Welfare politician and expert, Yūya Niwa, convened public (national, prefectural and quasi-public), and private clinics, and teaching hospitals, in order to circulate the guidance in March. His successor Yuji Tsushima followed the same procedure and convened hospital directors in September.

In December, the YCUH’s resubmission of application was finally accepted. Simultaneously, the MHW announced its new accreditation framework. The decision included the expansion of the remit of the Medical Research Council to summon hospital managers to their inquiry. Sanctions were clarified into four categories according to the level of seriousness of accidents: (1) withdrawal of accreditation, (2) supervision needed, (3) observation as interim measures, and (4) no guidance needed. The results were also made public on the ministry’s webpage. In October 2002, the MHLW amended the Ministerial Ordinance to oblige all health providers to ensure safety measures by reporting medical errors. In addition, a new accreditation system (Specific-function hospital or “Highly-advanced care hospital”) has given the MHLW a mechanism to compel health providers to follow the ministerial instructions and guidelines (since April 2002).

The responsiveness of central government throughout the process was unprecedented in Japan, where judgement over these cases had previously been delegated to courts. There has been a long spell of

government reluctance to set up a publicly-funded malpractice system. With neither electoral competition over hospital matters, nor a government forum for real discussions, the issue had been neglected. However, at the outbreak of the YCUH and other incidents, the systemic failure was brought to public attention, criticising central government as well as individual doctors, nurses and the whole medical profession. A series of accidents kept the issue in focus, and under macropolitics, responses of government became more extensive and were gradually integrated into the whole accreditation scheme. Elected senior officials' involvement was also unprecedented. The lack of political channels (e.g. ministerial accountability) between patients and government finally began to be made public due to disrupted institutional arrangements by the accidents.

### **Phase 3: Pilot scheme, staged retreat and slow change (2004 - 2008)**

As previously noted, unlike the UK case, adverse incidents in Japan normally ended up in a criminal court. In April 2004, the then Manager of Tokyo Metropolitan Hiroo Hospital was sentenced guilty by the Supreme Court of Japan for the violation of the Medical Act Article 21 (doctor's duty to report unusual deaths to the police). This prompted vehement reactions from professional societies. Medical professions feared that this case could set the precedence, and their surgical mistakes could be subject to scrutiny by the police as a possible criminal act of manslaughter. On 2 April 2004, the Japanese Societies of Medicine, Surgery, Pathology and Legal Medicine put forward their joint letter to request for a new third-party organisation for death investigation on therapeutic deaths, which is to be established outside the authority of the police (Yoshida 2004: 523). Immediate response from the MHLW was that they got a budget for a pilot scheme for such investigation organisations in several districts across the country (Asahi, 7 October 2004).

Concerning the collection of data regarding incidents and near-misses, the government decided to make the reporting of large hospitals (totalling 255 hospitals) mandatory in October 2004. Government delegated this task of gathering data to the third-party accreditation body, the Japan Council for Quality Health Care (JCQHC). It started to provide patients with information on health care organisations, and took over some of the ministerial functions, such as campaigning for safety measures. In April 2005, the Council announced the very first statistics on medical errors of large hospitals (276 hospitals as of March 2005). The number of errors totalled 533 in 6 months, of which 83 cases resulted in death. However, the credibility of a purely clinical evaluation by the Council was questioned when the former JMA president, Eitaka Tsuboi, was appointed as the President of the Council in 2004. Some concerns were raised that close-knit, collusive policy-making still remained powerful. Sceptical voices pointed out that the Council, under the guise of a third-party assessment body, conducted only internal checkups on their friends.

Following the first publication of adverse incidents in large hospitals, the Council for Regulatory Reform within the Cabinet Office called for mandatory publication of death rates in hospitals. Yet the MHLW was opposed to this, claiming that crude death rates can be misleading unless the data is modified to rightly reflect the critical status of patients and their disease profiles (Asahi, 30 October 2005). There is also

criticism voiced by prominent surgeons and physicians as to the lack of a third-party institution devoted to recording and analysing the causes of medical accidents and the division of jurisdictions among different ministries (university hospitals under the MEXT, municipal hospitals under the MIAC and the remainder under the MHLW) (Asahi 26 December 2005; J-5). Although a search for a new structure of risk regulation within the hospital sector had been launched, it still points to the structural vulnerabilities within the Japanese health institutions, which lack the central authority and competence of the MHLW, and political accountability. These characteristics allowed for a long process of negotiation and change, and ultimately ‘staged retreat’ in terms of speed of change and transparency of data to the public.

Furthermore, another adverse incident became a criminal case in March 2006, two years after the incident occurred. A gynaecologist at Oono Fukushima Prefectural Hospital was arrested, although the prefecture admitted their mistake earlier and reconciliation with the victim and her family had been under way. ‘Unnatural deaths’, to which the government assigned no clear definition, became a focal point of discussions and criticisms, and the public made a protest against the arrest (Asahi, 8 March/12 April/15 May 2006). The lack of gynaecologists in Japan and worsening working environment for doctors prompted public apprehension and outcry, this time in favour of the professions. Finally, the MHLW announced in May 2007 that there would be the third-party body on medical accidents, based on the American style (Alternative Dispute Resolution), consisting of lawyers and doctors, which could be a radical departure from the conventional approach (Yomiuri, 18 May 2007; Asahi 12 May 2007).

### **Responsiveness in Japan**

As institutional arrangements suggested, at the beginning it seemed that public attention was paid to the hospital director’s responsibility, rather than ministerial or government responsibility. However, overall media reporting discussed the issue more from a structural point of view, not focusing on individual cases or nurses’ responsibility. As a result of widespread mistrust in the health providers, welfare ministers had to openly make official appeals to reassure the general public about the state of affairs surrounding hospitals. This policy outcome was remarkable in that it indicated that a health system without high sensitivity to public opinion could force central government to respond to public concerns and pressure. The conventional closed policymaking with the limited number of actors was disrupted and had to be reconsidered. The former institutional arrangement was disproportionately weighted towards the medical professions at the expense of patients and victims who had to go through lengthy legal processes against a powerful profession. After the incidents, the government embarked on tightening control over health providers. The MHW adopted a more proactive role through changes in the accreditation system, and introduction of a reeducation system for physicians who are suspended from practice. The government also strengthened the power of the Medical Ethics Council, and sought to enhance information gathering capability of the ministry. Therefore, depending on the pressure level, the institutional arrangements can be disturbed, and this could create an incentive for central government to be more responsive. However, as developments in the third stage demonstrated, the government was reactive, rather than responsive, and did

not take an interventionist stance, leaving major decisions to professional societies and the conventional decision-making structure. Staged retreat was observed in the professions’ slow pace of implementation and cautious approach in favour of the medical professions.

**Conclusion: knee-jerk reactions or institutionally-guided responsiveness?**

Judging from the nature of the issues, it was predicted that political institutions would be disrupted under heightened pressure. The results showed that the responsiveness of the central government in question was high in both cases, but in different ways. In Japan, the institutional vulnerabilities of the health care system were exposed by the media, and central government was required to intervene. In England, although the saliency was rather low, the responses of central government were extensive and stimulated the redesign of the conventional institutions. In both England and Japan, professional autonomy was scrutinized. This demonstrated how reforms in the hospital sector could evolve. Although both cases demonstrated high responsiveness, the trigger for the responses was different in England than for Japan. For Japan, it was the media and public criticism that stepped up pressure on central government, while for England, it was government who captured the window of opportunity and pushed the issue out into the open.

In terms of the saliency, the Bristol Royal Infirmary case surprisingly did not gain much attention. Instead, it remained in the media for a long time (11 years) and criticisms were conspicuously focused mainly on the medical professions until saliency of the issue gradually phased out. However, this rather low saliency did not stop central government from being responsive. It could be explained by the sensitivity of central government in England, which has always been politically vulnerable within the English health system.

On the other hand, the Japanese case was prominent for a shorter period. The effects of acute public attention could be observed from the prompt responses from both central governments. The great impact on responsiveness in Japan could be explained by the ratio of articles referring to government (75%). This high level of public saliency and successive government responsiveness was unprecedented in health care policymaking in Japan, and these incidences later led to the emergence of stronger commitments by government and even the ruling party LDP, on the issue of staff shortage. New policy initiatives were adopted, with the aim of building up risk management teams in each hospital and informing patients of accredited hospitals, through strengthening data collection and assessment functions of the JCQHC. Despite all these changes, the pace of local implementation and remit of the JCQHC were rather limited. In particular, it was the medical profession who proposed and actively promoted the establishment of a third-party dispute resolution mechanism so that they could be exempt from the constant fear of prosecution while practising. In the public discourse, the medical professions became victims, if not as much as harmed patients. Doctors regained solid ground for shaping a policy in risk regulation in the sector.

Therefore, in England, despite only moderate coverage in the media, the Bristol case became widely discussed, primarily due to the subsequent public inquiry, and strongly associated with policy innovations

that followed in a systemic fashion (larger remit for independent watchdogs and target-setting for health care for children). Even with low visibility, the British government stepped in, and effectively intervened in the professional self-governing body. This shows that the English health system has developed a strong mechanism for detecting and reacting to crisis, with strong political accountability at the centre. Yet, it was peculiar that government in England also showed irresponsiveness by disagreeing and ignoring some recommendations from the public inquiry and the commissioned working group, once the discussions reached Parliament.

In England, it is the institutional vulnerability of the NHS, transferred to the political class, that brought about politicians’ great sensitivity and instigated prompt reactions. What is also important is that the government in England was given a strong mandate, and therefore legitimacy and leverage to intervene on behalf of the electorate against the medical professions. In contrast, in Japan, an institutionally established quick turnover of ministerial posts and the lack of political accountability with regard to hospital issues signify that a stronger administrative role has to be taken by the non-elected officials. This makes it all the more remarkable when the ministers made special written appeals to the general public at the time of the incidents.

When the issue saliency was rather high, the governments in the two countries were all under pressure to discuss the matter more openly in the public domain. Therefore, there was a knee-jerk element in the government’s immediate reaction, as they wished to assuage the general public and restore trust in hospital services. Yet in the process of building up a new system of risk management, the interactions between government, the media and the medical professions became more intricate, as the original institutional arrangements either facilitated or hindered further drastic changes. One key factor might be whether the pressure was kept up by other incidents or patient safety champions among the general public, and in particular by other professions (e.g. lawyers) supporting the popular cause of protecting patient rights.

Lastly, just to reiterate the point, these cases proved the argument that when the pressure is on, government seeks to respond to popular calls for building a more transparent system and securing safety for patients, irrespective of the institutional constraints. In this domain of risk management, central government is becoming increasingly more sensitive and responsive to public spheres. Accordingly, although policy direction may appear to be converging, there needs to be careful analyses of institutional arrangements and different ‘risk regimes’ (Hood et al. 2001) for long-term policy development as well as of the constant tensions between government and medical professional autonomy.

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