Contemporary Japan, 2018
https://doi.org/10.1080/18692729.2018.1501794

Regulating risks in healthcare in Japan: Between new politics and the tradition of liberal practice in medicine

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Abstract

Liberal practice in the medical professions has long been the tradition and de-facto position of the Japanese government. However, accountability and transparency in healthcare governance have recently drawn scrutiny, primarily due to several adverse events in hospitals. While New Public Management and risk-based approaches have not penetrated the design of regulatory management and compliance strategies, there has been increased institutional capacity and a search for a new mechanism of regulating risks in healthcare. This paper attempts to identify the directions of policy developments in Japan. It questions whether the conventional model of professional self-regulation in medicine is eroding, as in many English-speaking countries. The article demonstrates that while we may identify some common trends such as greater transparency and the creation of arm's length bodies, policy decisions prove deeply embedded in governance arrangements, and professional self-regulation in healthcare remains resilient, particularly in Japan.

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Keywords: regulatory state; accountability; risk; medical professions; patient safety; Japan; healthcare; comparative health policy

Introduction

It has been more than two decades since Beck (1992) argued that new patterns of risk and uncertainty will shake the stability of our traditional institutions. Still today, states and societies are grappling with the uncertainty of safety regulation in many high-risk industries, ranging from nuclear energy, the oil and gas industry and aviation to healthcare (Callon et al., 2009).

Almost at the same time, as privatization was being promoted, an increasing need for regulation also has arisen. It has been argued that the role of government gradually shifted from that of taxing and welfare redistribution to that of regulation, which is aimed at improving the efficiency of the economy, promoting competition and protecting consumers and citizens (Majone, 1997, Ayres & Braithwaite, 1995; Moran, 2002, Power, 2007; Christensen & Lægreid, 2007; Levi-Faur, 2014, Walravens, 2017). With a move away from the conventional 'command and control' type of governance, a more flexible, transparent, participatory yet responsive type of governance now seems to be the desired form. For example, many countries have adopted risk-based approaches in the design of regulatory management and compliance strategies to varying degrees (OECD, 2010; Rothstein et al., 2013). In parallel, New Public Management is one of the methods adopted in many Western countries to reform and relax traditional controls of central bureaucracy, by creating separate units and bodies that have direct operational responsibilities for audit, evaluation and oversight (Hood & Scott, 1996; Hood et al., 2001; Hood & Lodge, 2006; Callon et al., 2009).

Accordingly, the relationships between the state and professionals have changed over time. In high-risk industries in particular, transferring lessons from one industry to another has been encouraged and promoted, with lesson-learning taking place nationally and internationally. As a result, the self-regulation model for many professions has been called into question (Braithwaite et al., 2007; Black, 2008; Rees, 2008), and learning models have been promoted as an alternative mode of ensuring safety and quality (Healy & Braithwaite, 2006).

In the realm of healthcare organizations and medical professions, regulation has undergone significant reform in many post-industrial economies over recent years. As the high cost of harm to patients, healthcare systems and societies is recognized, patient safety in many countries has been placed firmly on policy agenda (Kohn et al., 1999; Slawomirski et al., 2017). In the UK, following a series of malpractice scandals, powers of setting standards, monitoring performances, and handling disciplinary matters have been transferred from the General Medical Council to other agencies such as the Council for Healthcare Regulatory Excellence, which was established in 2003 and is now renamed the Professional Standards Authority for Health and Social Care (Currie et al., 2009; Waring et al., 2010; Dixon-Woods et al., 2011). In Australia, ethical and professional responsibility was codified in law in 2010, under which registered health practitioners must inform the Australian Health Practitioner Regulation Agency if they find any 'notifiable conduct' (Bourgeault & Grignon, 2013; Bismark et al., 2014). This includes a risk of substantial harm in the practitioner's practice. This paradigm shift from the self-regulation model to the state-backed, third-party bodies' monitoring and interventions was instigated by high-profile cases (Benish & Levi-Faur, 2012). In some cases, the system and procedure for license, registration, and monitoring fitness to practice have been reviewed, while a variety of performance measurements including mandatory reporting of adverse events and publication of safety records have been introduced

(Kovacs et al., 2014; Archer et al., 2016; European Commission, 2014; Mølleret al., 2016). There seems to be an overall trend towards responsive regulation across many countries.

While research tends to focus on the relationship between the state and medical professions or healthcare organizations, the changing relationships between the state, arm's length bodies (ALBs) and patients / citizens have been little explored.[1] If the role of regulation has become greater for democratic governments, the protection of citizens from medical harm should be more openly debated, and associated with democratic processes. This article addresses this issue, using the case of Japan.

Figure 1 outlines a generic model of healthcare governance for patient safety regulation. Three components in the activities of risk regulation (Hood et al., 2001, p.21) are standard-setting (rules and norms), information gathering (feedback) and behavior modification (correction).

[1] Arm's-length bodies (ALBs), often called 'quangos', are quasi-autonomous, non-departmental public bodies. While their day-to-day operations and decision-making are independent of the government, they receive government funding.

https://doi.org/10.1080/18692729.2018.1501794

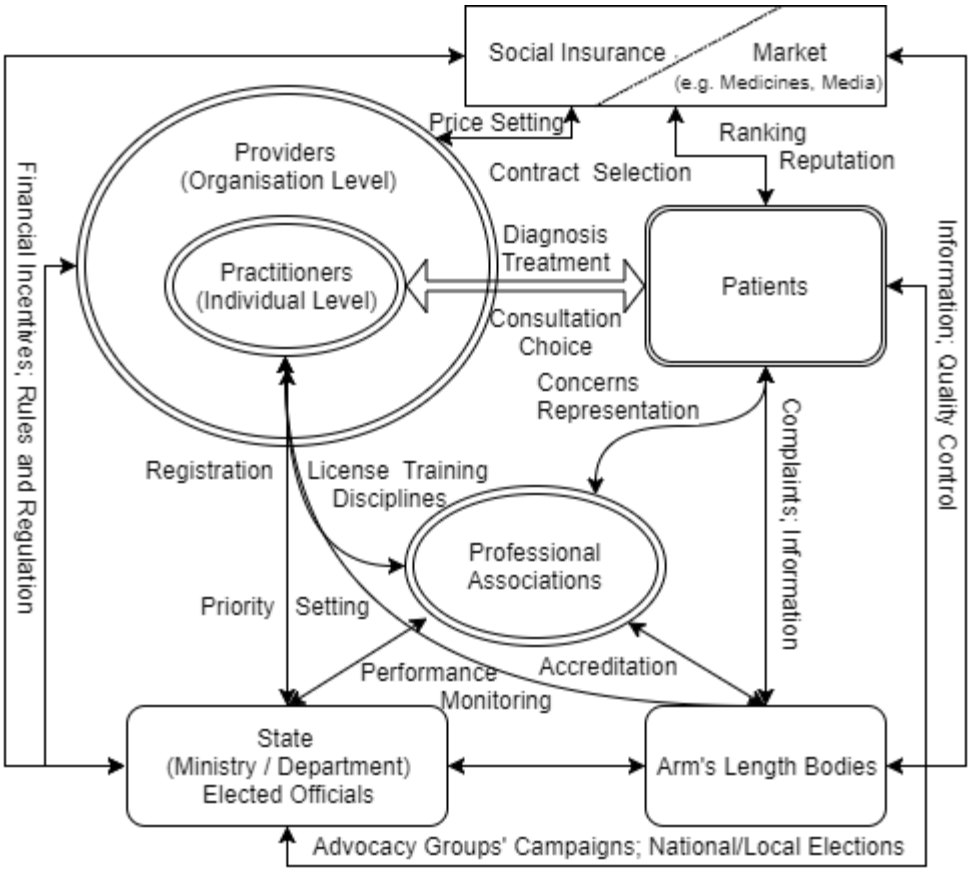

Figure 1. Generic model of healthcare governance for patient safety regulation (author).

Apart from the main transactional / relational exchanges between practitioners and patients, the functions in Figure 1 can be classified into these three categories. Inspection, accreditation, reporting and certification are closely associated with information gathering, while financial incentives, rewards, sanctions, license revocation, and media reports feed into the function of behavior modification. Registration, licensing, and professional training and education are closely linked with standard-setting. This is where professional groups have played decisive roles. Price setting could be seen as a standard-setting activity, which reflects rules agreed upon among key stakeholders. When the price is renegotiated and adjusted, the act could also work as a tool for behavior modification. The figure, however simplified, is a useful guide for thinking about the

complexity of the healthcare system, with a particular focus on how the key stakeholders are interconnected through various regulatory functions. It could be used as a conceptual lens to highlight strong characteristics of a country's system and/or to capture its changes over time.

Background and research questions

The Japanese healthcare system has long been under strain, due to a rapidly ageing population, increasing demands and costs, and the lack of integration of a non-Japanese workforce in the health sector. Similarly, the regulation of risks to patients has come under severe scrutiny since the late 1990s because of several scandals and an increase in the number of litigations. As a result, there have been several reform attempts over the last twenty years (Hirose, 2016). The collection of incident data by a third-party organization (Hirose et al., 2003), and a no-fault compensation scheme for cerebral palsy (Hasegawa et al., 2016) are two examples of such reforms. However, the liberal model of medical practice (i.e. emphasis on a direct and private doctor-patient relationship over governmental intervention) (Immergut, 1992) remained almost the norm, with some adjustments around accountability and transparency. The recent report, published by KPMG International, highlights the weaknesses of the Japanese healthcare system in transparency and governance (KPMG International, 2017, p.11). The report looks at 32 countries' healthcare systems, giving scores for transparency in six respects: quality of healthcare, patient experience, finance, governance, personal healthcare data and communication of healthcare data. Japan ranks 26th, performing only marginally better than average in two respects (quality of healthcare and finance).

The aim of this paper is to understand the extent and direction(s) of changes made to the regulation of risks to patient safety in Japan. There are two research questions: (i) what the key drivers are for regulatory change in Japan, and (ii) to what extent policy changes in Japan can be seen as a

departure from the conventional model of healthcare regulation, in comparison with other countries' recent reforms.

Although the literature tends to examine changes in healthcare regulations from one particular perspective such as public administration (e.g. to achieve cost-containment, to infuse private sector practices) and medical sociology (e.g. dominance of medical professions), the reform process of regulating healthcare is iterative, path-dependent (i.e. embedded in a wider socio-political context) and dynamic. This article therefore investigates interactions between high-profile adverse events, a political system and policy developments. In Japan, while the adverse events called attention to systemic issues, including negligence and risks to patients, the actual policy change has taken a long time, and the compromised reform plan was implemented after public attention over these issues dwindled and policy stability was restored. As a result, the policy outcome led to an increased level of discretion and responsibilities of medical institutions for patient safety, while the central government seeks to regain effective control. As the market competition intensifies with scarce resources (doctors and nurses) and global spending limits enforced by the finance ministry, the state has remained reluctant overall to directly intervene and curb practitioners' autonomy, and elected officials still play a minor role in setting agendas for such regulatory reforms.

Data and research methods

This article primarily uses two sets of data: the print media, including the major newspapers *Asahi Shimbun, Kōhoku Shimpō, Mainichi Shimbun, Nihon Keizai (Nikkei) Shimbun, Sankei Shimbun,* and *Yomiuri Shimbun*, and policy documents, including the annual reports of the relevant ALB, i.e. the Japan Council for Quality Health Care (JCQHC). For the print media, the period covered primarily runs from January 1st 1997 to December 31st 2016. By using those data, the article

addresses how the policy developments and outcome in Japan were affected by a broader political context, the level of media attention and the model of healthcare provision.

While much has been written about the transformation of the self-regulation of medical doctors in the UK and many other Anglo-Saxon countries, it is little known whether other countries are equally moving away from self-regulation. For example, if we look at three European countries (France, Germany and the Netherlands) with healthcare systems built on the Bismarckian social insurance model, the liberal practice of medicine and self-regulation seem more persistent and resilient here than in the UK and other English-speaking countries (Busse et al., 2009; Bourgeault & Grignon, 2013; Hassenteufel & Palier, 2007; Kroneman et al,. 2016). The three countries' healthcare systems differ from the public provision model (e.g. the UK and Nordic countries), and private (both for-profit and not-for-profit) providers play a large role (Chevreul et al. 2015; Kroneman et al. 2016), as in Japan. This characteristic adds complexity to effective regulation. The above-mentioned KPMG report on transparency put the four Nordic countries, plus the UK, Australia and New Zealand ahead of the Netherlands (8th), France (15th), and Germany (16th) in the overall ranking. Yet these countries outperform Japan.

This case study therefore attempts to identify the key drivers for regulatory change in Japanese healthcare in the past two decades, while trying to discover any trajectories that are similar to other countries' reforms. The study helps underscore possible structural factors within broader political institutions, in addition to the role of major incidents that instigate reforms to risk regulation across different countries. As risk regulation in both the public and private sector has become one of the central functions of government, this is a critical question to address and examine.

In order to set the scene, the next section will describe trends in recent reforms, particularly in the Continental European countries, to compare them with Japan.

Patient safety regulation in European countries

Surveying healthcare regulation reforms across Europe, there are certain commonalities and differences. The similarities include a stronger push towards collecting and publishing quality-related data, and increased patient representation (European Commission, 2014; KPMG International, 2017). Professional registration, licensing and revalidation (a process that qualified professionals must go through in order to renew their registration with their professional bodies) have also come under scrutiny, and the governments now play a role in monitoring these with varying degrees of involvement (Kovacs et al., 2014). While the principle of self-regulation appears to remain the norm, there have been some notable changes. In the Netherlands, doctors may be struck off the medical register for failing to comply with revalidation requirements (Smith et al., 2012, p.43). On the other hand, the functions of ALBs and how each government established them differ greatly. Arm's-length bodies, ranging from executive agencies to non-departmental public bodies, are typically created and employed in the UK and English-speaking countries. They began to be applied in other countries (Simonet, 2014) as a way of splitting the government's commissioning role and its delivery of services (Pollitt and Bouckaert, 2011). France is in the process of restructuring healthcare governance while creating such agencies and strengthening the capacity of the central government (Bergeron and Castel, 2015; Hassenteufel, 2014). While Germany has a unique federal structure, the principle of subsidiarity (which signifies that social issues should be handled at the most immediate / local level that is consistent with their resolution) remains strong. For example, corporatist arrangements such as the sickness funds and regional associations of Statutory Health Insurance physicians are key players. As an additional player, the

Institute for Quality and Efficiency in Healthcare was established as an agency in 2004. In the same year, the quasi-public corporations were unified and formed into the Federal Joint Committee. However, the Committee, consisting of federal associations of payers and providers, is the ultimate decision-making body, and is independent of the Federal Ministry of Health in Germany (Busse et al., 2009). The Netherlands, on the other hand, had already gone through a period of privatization and establishing autonomous ALBs in the 1980s. In recent years, the focus has been on transferring the responsibilities of monitoring performance, cost and quality of healthcare services from central government to agencies and local authorities (Pollitt & Bouckaert, 2011, p.292). Lastly, the impact of well-publicized medical incidents on these reforms is worth noting. Without anti-practitioner sentiments in the public domain, regulatory changes were made in three Continental countries (European Commission, 2014). This is unlike the cases in the UK and Denmark where national media reports on malpractice scandals instigated anti-practitioner sentiments, which led the changes. The level of politicization of such matters and drivers for change vary across countries. With these international trends in mind, the following two sections will outline the basic health governance structures and mechanisms in Japan.[2]

Patient safety in Japan

Governance arrangements in the Japanese health sector

Health care in Japan is financed through mandatory social insurance schemes, through which patients have universal access to any facility since 1961 (Tatara & Okamoto, 2009). As of December 2016, healthcare providers in Japan include 8,440 hospitals, 101,571 clinics (of which 7,550 have beds, and 94,021 do not) and 68,935 dental clinics (MHLW, 2017). In Japan, a facility with 20 or more beds is defined as a hospital, and one with fewer than 20 as a clinic. Until recently,

[2] Unless otherwise stated, translations of Japanese quotations through the rest of the article are the author's.

patients had freedom of choice, and when choosing a care provider, they largely rely on word-of-mouth, physical distance from home or workplace and rankings published in magazines (Medicarelife, 2014). Patients, when they can, select renowned teaching or national hospitals, based on their geographical location. In April 2016, the government increased the initial consultation fee to 5,000 JPY (approximately 45 USD as of February 2016) at advanced treatment hospitals (*tokutei kinō byōin*) and large hospitals (with more than 500 beds), except in cases where the patient brings a referral from a primary care physician (MHLW, 2017).

Politically, Japan has a unitary, parliamentary system. The Liberal Democratic Party (LDP) has been in power continuously, except for a brief period between 1993 and 1994, and again from 2009 to 2012 (Chiavacci, 2010, Kohno, 2012). In terms of regulatory issues, the national government is responsible for the registration of medical practitioners, as the Ministry of Health, Labour and Welfare (MHLW) administers a national licensing examination (Archer et al., 2016). Locally, prefectures provide licenses for hospitals and monitor their legal compliance benchmarked against guidelines given by the MHLW. Selected large municipalities have the authority to license clinics and pharmacies (Tatara & Okamoto, 2009).

Governance of health delivery in Japan can be characterized by weak political representation of citizens' voices at the ministerial level, combined with a centralized bureaucratic structure. As described below, while there is a close relationship between 'welfare expert' politicians in the governing LDP party and the Japan Medical Association (JMA) (Kondo, 2005; Mizuno, 2005), health ministers have been largely detached from healthcare delivery issues. For many years, there was no channel by which the general public could effectively influence government policy at the national level (Mizuno, 2003). Hospital care is provided primarily through private hospitals (56% of the total number of providers), the proportion of which has increased over time (Figure 2).

Under these arrangements, the healthcare system in Japan does not hold politicians in the Diet (the Japanese *Kokkai*) directly to account for delivery issues; instead, semi-autonomous providers simultaneously have discretion and carry liability in this respect.

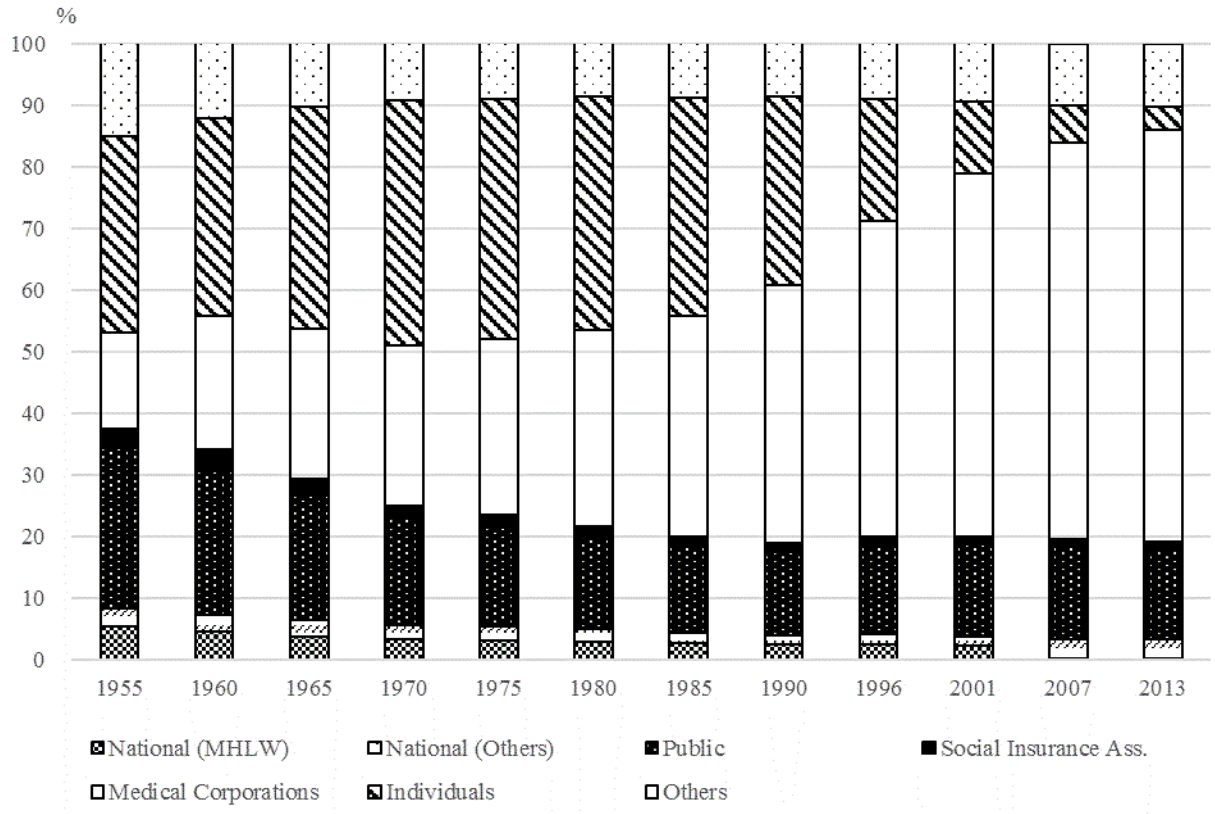

Figure 2. Proportion of healthcare providers by ownership type (Sources: MHLW various years).

In Japan, the JMA was the single largest contributor to the LDP and its candidates over a number of years. Its politically active wing, the Doctors' League, endorsed candidates and fielded former doctors, particularly for the Diet. The LDP's policy-making apparatus, the Policy Affairs Research Council, served as a glue, while the LDP prefectural leagues mediated local interests by formulating policies and lobbying (Nakano, 1998). In health policy, the formalized and closed relationship fostered 'welfare expert' politicians. 'Welfare expert' politicians were expected to

take the ministerial portfolio and play the role of broker between the Ministry of Health and Welfare (MHW, which later merged with the Ministry of Labour, and became the MHLW in 2001) and the JMA, mainly on the issue of the fee schedule[3] (Campbell & Ikegami, 1998). As a ministerial post was awarded based on the number of re-elections, 'welfare expert' politicians, with strong and stable backing, had a higher chance of eventually taking the premiership (e.g. Ryūtarō Hashimoto (Minister for Welfare, 1978-79; Prime Minister, 1996-98) and Junichirō Koizumi (Minister for Welfare, 1988-89, 96-98; Prime Minister, 2001-06)). In exchange for the JMA's electoral support for the LDP, a beneficial package was agreed by both camps at the fee-schedule negotiations, and non-interference from central government was also agreed upon. This is the political mechanism which created and sustained the liberal model of medical practice in Japan.

In terms of provision, the central government has allowed each prefecture (i.e. directly-elected governors) to decide the number of hospital beds**,** while respecting the discretion of private practitioners or university professors over many practical decisions. Technical decisions are often delegated to experts in the councils, which are commissioned by the MHLW. Given the quick turnover of ministers in Japan, policy formulation must rely heavily on civil servants in the relevant ministries. As a result, the influence of each minister over health policy has inevitably been limited. Bargaining for remuneration remains at the national level, however. The government thus does ultimately retain leverage against private providers through the fee-schedule negotiation (Campbell & Ikegami, 1998).

[3] Healthcare fees in Japan are administered on a fee-for-service basis. A complete set of listing for these fees are called the fee schedule (*shinryō hōshū*), and it is revised biannually, and uniform nationwide.

Another interesting feature of the governance structure in Japan is the consistent centrality of ministries, even after public administrative reforms led to the creation of 'independent administrative corporations' modelled on UK-style agencies in the early 2000s (Nakano, 2004). The exception in health services is a third-party body, the JCQHC, which was set up and co-financed by the JMA and the MHW in 1995 for a new and voluntary hospital accreditation scheme. The agency was spawned out of initiatives by the medical professional community, rather than as part of any political reform (Hirose et al., 2003; Kodate, 2012).

The functions of political representation and bureaucratic structure in the health service domain thus display some important differences in Japan and other European countries. How professional interests are mediated and institutionalized within the macro-politics of each can also have considerable impact on policymakers' actions.

Mechanisms of disciplinary procedures and detecting 'bad apples' in Japan before 'the incidents'

In terms of the mechanisms for dealing with malpractice errors, Japan does not have a counterpart to the medical councils in the UK or to the system of medical arbitration boards in Germany. Instead, until June 2014, upon discovering an 'unnatural death', doctors were obliged to report it to the police, based on Article 21 of the Medical Practitioner Law in Japan. When clinical errors were reported, disciplinary measures were, in theory, taken by the Medical Ethics Council (MEC, *Idō Shingikai*) (Komatsu, 2004; Leflar, 2013). The MEC sits within the MHLW and consists of thirty members, including the presidents of the JMA. Conventionally, the MEC waited for judicial verdicts for such cases before deciding to sanction doctors or demand closures of their clinics or hospitals (Tatara & Okamoto, 2009). The independence of the MEC, as part of the MHLW (which

also licenses and regulates physicians), has long been questioned, as has its power to regulate physicians. The MEC biannually examines reported cases lodged against doctors. However, these cases are seldom related to their diagnostic or surgical skills. There has not been a mechanism for detecting doctors who make mistakes repeatedly, apart from the use of medical professional liability insurance (*Mainichi Shimbun*, June 26, 2017).

The lack of openness and responsiveness in these systems was challenged by two serious adverse events that took place in the late 1990s. These cases put safety and quality of care services on the political agenda, generating a series of discussions.

Responding to the incidents, strengthening priority-setting functions at the center

In the late 1990s, the 'Independent Administrative Corporation for National Hospitals' was introduced in Japan as a wholesale public administration reform (of national hospitals). It was intended as a measure to slim down the state and cut down the number of civil servants, a move which was generally regarded as popular among the electorate (*Asahi Shimbun*, April 28, 1999). In October 1999, an administrative inspection and audit conducted by the then Management and Coordination Agency (now part of the Ministry of Internal Affairs and Communications (MIAC)) revealed that half of all national hospitals and sanatoriums were operating under deficit. The MHW provided a briefing on the plan to announce the creation of just a single body, the Independent Administrative Corporation of National Hospitals, rather than a myriad of separate bodies (Nakano, 2004). From 226 hospitals and sanatoriums in November 1999, the plan called for mergers and closures until 2004, at which point there would be 153 hospitals and sanatoriums across the country (143, as of July 2017) (MHLW, 2017). The plan was agreed by the Cabinet in December 2000,

with some amendments such as the introduction of an assessment system for each hospital, rather than the entire agency. This was a compromise between the LDP's Public Administration Promotion Headquarters and the MHW (*Nikkei Shimbun*, December 12, 2000; *Asahi Shimbun*, December 20, 2000). The Independent Administrative Corporation National Hospital Organization Act took effect in April 2004, as the National Hospital Organization (NHO) became a single Independent Administrative Agency.

Against this background, the issue of patient safety was put on the agenda. A serious medical malpractice case at Yokohama City University Hospital (YCU) captured the news headlines on 14 January 1999 (*Asahi Shimbun*, January 14, 1999; *Yomiuri Shimbun*, January 14, 1999). A patient who needed a heart operation was mistaken for another patient who required a lung operation. The two patients died within the year due to complications. This incident was followed by another at Tokyo Metropolitan Hirō Hospital (TMH) one month later (Yoshida, 2004; Nagai, 2007). A nurse injected a patient with disinfectant instead of a physiological salt solution mixed with heparin. The patient died within 2 hours. The two hospitals were publicly-run, well-reputed, regional hospitals.

The cases inevitably sparked huge public concern and media reports, particularly because YCU had been a government-authorized, 'advanced treatment hospital'. An 'advanced treatment hospital' is a large hospital with 500 beds or more, ICUs and more than 10 specialties, with advanced treatments on offer for patients as well as higher training for medical staff. 'Advanced treatment hospitals' were created by the second amendment to the Medical Care Act in 1992. This incident revealed that the MHW had not originally thought about the power to revoke the hospital's status (*Asahi Shimbun*, March 27, 1999; *Mainichi Shimbun*, June 4, 1999).

The YCU scandal immediately prompted a review of the accreditation system by the MHW, and the focus was to strengthen the power of the ministries. In October 1999, the MHW decided to amend the regulation itself, empowering itself to revoke accreditation status as needed (*Nikkei Shimbun*, November 27, 1999). 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, which would require all advanced treatment hospitals to have guidelines for accident prevention and an internal committee for risk management.

The diffused responsibility for the hospital sector in Japan across multiple ministries also meant that other actors had to act quickly to address this issue. Soon after the incident at the YCU in January 1999, the Board of National University Hospital Directors, jointly with the Ministry of Education, Culture, Sports, Science and Technology (MEXT), established a working group for formulating measures to prevent medical errors. In 2002, the National University Hospitals' Patient Safety Assembly was set up under the Permanent Committee of the Board (National University Hospitals' Patient Safety Assembly website). The assembly consists of 42 national university hospitals nationwide, and meets twice every year to discuss patient safety issues (Hirose, 2016).

Within the MHLW, a Patient Safety Unit was also created in April 2001. In May 2001, the government set up a consultative body named the Council on Patient Safety Measures, with several subcommittees. The interim report recommended that every healthcare provider should establish a risk management system. From 2001, the Ministry decided on the final week of November as Patient Safety Promotion Week, which was rolled out nationally (MHLW website). In order to provide an official complaints resolution system, Medical Safety Support Centers (MSSCs) were

also established in every prefecture and major city. However, the decisions regarding crucial and sensitive issues (e.g. the setting up of a judicial body which had power to remedy a situation or penalize hospitals in the case of adverse incidents) were delegated to another set of subcommittees (MHLW, 2002).

Information gathering and transparency: complementary roles between arm's length bodies and private actors

In October 2002, the MHLW amended the Ministerial Ordinance, obliging accredited health providers (including all national hospitals) to ensure safety measures by reporting medical errors (enacted in October 2004). Concerning the task of gathering and analyzing this data, the previously-mentioned third-party body, JCQHC was chosen by the government as an appropriate body to perform this function (Hirose, 2016). Two of the major functions provided by the JCQHC are: hospital accreditation (which is not mandatory, and is independent of the government) and adverse/near-miss event data collection and analysis (approved by the government). However, because the Council only published the names of 'good' hospitals but not those of 'failed' hospitals, the lack of transparency was also pointed out as a weakness in the autonomous nature of the organization (*Asahi Shimbun*, December 15, 2004).

In April 2005, the JCQHC made progress in the area of public access to information by announcing the very first statistics on the medical errors in large hospitals after a three-year pilot study (276 hospitals as of March 2005). 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. Just as with the skepticism over the MEC's self-regulatory function, the recurring question concerning the independence of the JCQHC was raised once more.

Later in the same year, tensions also arose with regard to transparency of data. Following the first publication of adverse incident details in large hospitals, the Council for Regulatory Reform within the Cabinet Office called for the mandatory publication of death rates in hospitals. Yet the MHLW was opposed to this, claiming that crude death rates could be misleading unless the data were modified to accurately reflect the critical status of patients and their disease profiles (*Asahi Shimbun*, October 30, 2005). The lack of political intercession on behalf of patients and the public in all of these issues in Japan point to the absence of channels through which citizens' voices can be translated into policy-making.

However, patient demand pushed forward another trend in the market. Private companies embarked on data gathering to enable them to publish their own hospital rankings. A number of weekly magazines began publishing league tables (*Asahi Shimbun*, December 15, 2004; Kodate, 2010). Data on operations performed, outcomes and various processes aimed at ensuring patient safety were gathered and analysed. Medical records relating to operations from Social Insurance bureaus, and the Law Concerning Access to Information held by Administrative Organizations (enforced in 2001) were used to gather evidence-based data for the publication of clinically-based rankings (Tiessen, 2005).

Therefore, the roles of the arm's length body (JCQHC) and actors in the market are complimentary in information-gathering and dissemination functions. There is also the All Japan Hospital Association, which is a voluntary organization with more than 2,400 hospital members, which publishes mortality rates and patient satisfaction levels. However, only 40 hospitals take part in this, and provide data on mortality rates and patient satisfaction levels. In addition, the NHO collates and analyzes adverse incidents, and has been publishing some of the reviews in their annual 'White Paper on Patient Safety' since 2007 (NHO, 2018).

Government responsibility under scrutiny, with medical professions taking active roles

Although the level of public attention regarding patient safety began to stabilize (or decline in the case of *Nikkei Shimbun*) by 2004, this did not mean that policy solutions were found either for the medical professions or patient groups.

With recognition of the need for a level playing field for public and private providers, illegal practices by doctors came to light and underlined the deeply rooted staff shortage problem. In September 2003, numerous doctors at university hospitals, and qualified postgraduate medical students in particular, allegedly had been receiving remuneration from private clinics or public hospitals in return for 'registering their names' without actually providing any services (*Kōhoku Shimpō*, September 21, 2003; *Asahi Shimbun*, October 10, 2003). This illegal act continued, as each provider desperately needed qualified doctors as their full-time consultants in order to notch up some points for the pay schedule. The government responded to this scandal, with MEXT conducting surveys and inquiries in January 2004. Its findings illuminated the prospective chronic problem of insufficient doctors within the Japanese health system. A shocking revelation showed that out of 79 teaching hospitals, 51 (i.e. 1,161 doctors) were involved in this illegal act. As an immediate response, the three relevant ministries (MHLW, MEXT and MIAC) set up a liaison committee to tackle the insufficient manpower at hospitals (*Sankei Shimbun*, December 23, 2003; *Shikoku Shimbun*, February 1, 2004; *Asahi Shimbun*, April 4, 2004).

There was one further major development in April 2004. The Supreme Court convicted the CEO of TMH for failing to notify police of an 'unnatural death' at the time of another medical incident in 1999. This verdict was a huge blow to the professional community. The incident resulted in the

publication of a report by the independent scientific advisory body to the Cabinet, the Science Council of Japan, and separately a model project was launched for the investigation and analysis of medical practice-associated deaths in four regions the following year (Tahara, 2007). This model project was funded by the MHLW, and initiated by the idea put forward by four medical specialty societies. The four specialty societies include the Japan Surgical Society, the Japanese Society of Pathology, and the Japanese Society of Legal Medicine in addition to the Japanese Society of Internal Medicine. The model project was subsequently expanded to other regions, with mixed reviews in terms of uptakes and cost effectiveness (Leflar, 2013, p.197). However, the unit later grew into an independent body called the Japan Medical Safety Research Organization (JMSRO) in 2010.

In April 2006, the Medical Care Act was revised for the fifth time. The revisions included measures to rectify the shortage of doctors in rural areas, further relaxation of advertisements for healthcare providers, and formalization of the MSSCs. Article 6, Clause 10 in the Act stipulates that administrators of all the healthcare service providers must put in place patient safety guidelines and measures, and offer training for all staff members twice a year. Remedial activities for disciplined practitioners also became mandatory. Article 6, Clause 11 stipulates that the roles of the MSSCs be to provide support and consultations for patients, their families and care providers when they have safety-related issues to discuss. The Medical School of the University of Tokyo was designated as the center for providing training for MSSCs' staff. While this Act (Fifth Amendment) took effect the following year, a new fee schedule was introduced in April 2006, offering each provider financial incentives (the preferential patient safety countermeasure fee (PPSCF)) to implement patient safety measures (Hirose, 2016).

In March 2006, another case of criminalization of medical professionals gained national attention. A gynecologist at Ōno Fukushima Prefectural Hospital was arrested, even though a reconciliation process with the victim and her family was underway. 'Unnatural deaths' became a focal point of ensuing discussions and criticisms yet again, and medical societies and the public protested against the arrest (Leflar, 2009). The lack of gynecologists in Japan and the worsening environment for doctors prompted this public apprehension and led to another outcry, in favor of the professionals. In July 2006, the JMA set up a working group to discuss the possibility of establishing an Alternative Dispute Resolution (ADR) mechanism. The ensuing policy discussions also resulted in the foundation of a no-fault compensation scheme for cerebral palsy, which started in April 2009 (Nagamatsu et al., 2009; Hasegawa et al., 2016).

The issue of the lack of doctors, particularly pediatricians, also hit the NHO (*Asahi Shimbun*, April 6, 2006), echoing the problem which affected other public hospitals (*Asahi Shimbun*, February 17, 2004). With news of scandals featuring the lack of human resources in hospitals across the country erupting, the central government was under heightened pressure, and was required to strengthen its grip over the sector in a more coordinated fashion across the divided ministries. It was media attention rather than party competition that brought the scandalous nature of the issue (doctors' human errors putting patients' lives at risk) to the attention of the public, the health ministry and the politicians. The establishment of the NHO helped to bring the problems out in the open, and under the new set-up, the central government became more exposed and vulnerable to pressure. Therefore, by transforming national hospitals into a government agency, the central government's role of monitoring the agency became clearer. This case exemplifies how creating a new unit helped clarify the accountability of the central government as opposed to medical practitioners and hospitals in the realm of patient safety.

Medical professions began taking a more active role, in 2008 launching the campaign called the Japanese Coalition for Patient Safety (JCPS), modeled on the US-based Institute of Healthcare Improvement (IHI)'s 100,000 Lives Campaign. It was established in partnership with all the medical professions and societies (e.g. the JMA, the Japanese Nursing Association, the Japan Dental Association, and the Japan Association of Clinical Engineers and the Japanese Society for Quality and Safety in Healthcare).[4]

Establishing a new system of reporting and investigating major adverse incidents

In March 2007, the MHLW commissioned a task force and endorsed the basic idea of establishing an ADR mechanism as a solution to the long-standing problem of the criminalization of medical practitioners. This eventually resulted in the Ministry publishing a draft plan in April 2008, and subsequently the resulting Bill was being prepared for submission to the Parliament (*Kokkai*) later that year. However, in the meantime, this process coincided with the waning power of the LDP-led coalition government. In the Upper House election held in July 2007, the LDP was defeated for the first time since 1955 by the Democratic Party of Japan (DPJ).

Opposition to the Bill began to be expressed from well-known medical practitioners on the grounds that the Bill was flawed and would not achieve the intended goal of reduced involvement by the police in malpractice cases. Opponents pointed out that by the time that the Bill was prepared, the sense of acute public criticism of the medical professions had dissipated, and therefore, there was no urgent pressure on policy makers or medical practitioners. In fact, the number of prosecutions began to stabilize after 2008, moderating the trend towards criminalization (Leflar, 2009).

[4] https://kyodokodo.jp/about/aisatsu2/ (accessed July 5, 2018).

The emergence of the 'twisted parliament' (*nejire Kokkai*, which literally means 'contorted Diet') meant that the largest opposition party, the DPJ, was now required to propose its own policies, distinct from the LDP's. A new mode of party competition emerged, with a much clearer emphasis on policy differences between government and opposition. The new type of political dynamics galvanized the voices of maverick-type leaders in the medical professions, which led to a split in opinion among the medical professions and the subsequent demise of the Bill. In particular, the Association of Japanese Healthcare Corporations (AJHC) was opposed to the Bill prepared by the MHLW (*Nikkei Shimbun*, July 14, 2011).

The DPJ, the opposition party in the House of Councilors (Upper House), put forward an alternative proposal, which focused on the abolition of Article 21 and the establishment of a completely new body for investigating unnatural deaths. The obligation to report unnatural deaths to the third-party agency was also eliminated. According to the survey conducted by M3, Inc. (a company offering a portal site for medical practitioners in Japan) in July 2008, 43.1% of the doctors surveyed favored the DPJ's proposal, while only 13.2% supported the MHLW's proposal (M3, July 14, 2008).

In August 2008, the Fukushima District Court passed its judgement regarding the gynecologist at Ōno Fukushima Prefectural Hospital. The Court ruled that the defendant was innocent on all counts (*Yomiuri Shimbun*, September 8, 2008). This underlined the importance of clinical judgment in the prosecution process, while simultaneously antagonizing the relationship between the medical professions and the police/prosecutor. The main newspapers were divided on the issue. *Asahi*, *Yomiuri* and *Nikkei* supported the judgment, criticizing the prosecution, whilst *Mainichi* questioned the validity of the verdict, favoring the medical practitioner over the patients (*Asahi*

Shimbun, August 20, 2008; *Mainichi Shimbun*, August 20, 2008; *Nikkei Shimbun*, August 20, 2008; *Yomiuri Shimbun*, August 20, 2008).

Among many structural problems exposed by the YCU and TMH cases, criminalization of the professionals became the main issue for stakeholders. The subsequent reform process was driven by the professional societies, who feared that their surgical mistakes could become subject to scrutiny by the police as possible criminal acts of manslaughter (Yasunaga, 2008). At the general election in August 2009, the DPJ won a landslide victory.

Change of law under restored political stability, increasing organizational accountability and self-regulation

The change of government was hailed as a radical departure from the long-term dominance of the LDP. The closed decision-making process among stakeholders (lawmakers, bureaucrats and industries/professional groups) was at an end, and medical practitioners were divided between the LDP and the DPJ.

However, the two competing ideas of the DPJ and the MHLW regarding the third-party body for investigating medical incidents became embedded in the parties' political power game, while the priorities for such legislation were also de-escalated. In order to reduce the government's massive budget deficit, the newly-created Administrative Renewal Council decided to introduce a mechanism called *Shiwake* (sorting out), and the successfully-run model project for the investigation and analysis of medical practice-associated deaths became the target for abolition (JMSRO website).

The irony was that the new DPJ government was elected, winning the hearts and minds of the people, under the banner of 'supporting people's lives'. Yet the policy resulting from the change

of government was so adverse to victims of medical incidents and their families that they began campaigning once again, calling for an early establishment of the third-party body, proposed by the MHLW (*Yomiuri Shimbun*, April 11, 2009; *Asahi Shimbun*, May 13, 2010).

In July 2011, the JMA proposed a new policy, outlining that medical incidents be investigated first by an independent committee set up internally in every hospital. Instigated by this move, the MHLW re-commissioned a task force to discuss this issue in February 2012. From April 2012, the PPSCF was revised and financial incentives were offered to healthcare providers for hiring dedicated staff to deal with patient safety (Hirose, 2016).

Due to political infighting and disarray, the DPJ government became extremely unpopular within three years. The government's poor handling of the Fukushima nuclear disaster further contributed to this unpopularity. At the December 2012 general election, the LDP led by Shinzō Abe regained power. Although the 'twisted parliament' continued to exist for several months, the Upper House election in July 2013 cleared up the situation, securing the majority of the LDP-led ruling coalition. As the former policy subsystem was restored, the final report by the task force was submitted to the MHLW in May 2013. In January 2014, the Cabinet finally approved the proposal, and revisions to the Medical Care Law were passed by Parliament in June 2014 (MHLW, 2015).

A new reporting system for deaths resulting from medical care was introduced in October 2015. The Medical Accidents Investigation System (*Iryōjiko Chōsa Seido*) is a non-punitive system which aims to prevent recurrences of medical accidents while ensuring patient safety by learning from mistakes. Unlike in the previous system, all healthcare providers in Japan are mandated to

investigate 'unexpected' cases of patient deaths internally first, regardless of their legal liability. They must also report the results to the next of kin and to the above-mentioned third-party body, the JMSRO. The system is a new departure, avoiding direct involvement of the police and the possibility of criminalization of medical professionals. For patients and their families, the positive aspects of this new system is that healthcare providers are now responsible for covering the cost of postmortem investigations. Yet the greater caveat of this system is that it is up to each provider to decide whether a case meets the criteria of the 'unexpected deaths' (Kodama, 2016). Additionally, the provider is not mandated to share the written reports submitted to the JMSRO with the next of kin (Otake, 2015). As of 2016, one year after its inception, many newspaper articles had already begun to highlight the smaller number of cases reported than predicted (388 cases), and the weakness of the new system (Mitsutake, 2016). Between October 2015 and June 2018, the total number of cases reported to the JMSRO was 1,028. On average, approximately 30 cases have been reported each month since the establishment of the reporting system. Almost 70% of those cases were investigated internally in the hospital where the adverse events took place (JMSRO website).

Discussion and conclusion

Policy decisions relating to how to deal with medical incidents in Japan were deeply 'nested' in governance arrangements (Hill & Hupe, 2006). By analyzing the long-term development of policies, this article illuminates the fact that a seemingly technical policy issue such as regulation of patient safety risks can be influenced not only by the adverse events, but also by the governance arrangements. In the case of Japan, a long tradition of non-interference in the sphere of the medical professional community has been challenged by a series of adverse incidents, which were the key

drivers for regulatory change. This is very similar to many countries, including the UK and Australia.

In 2015, two serious incidents hit the headlines in Japan. The MHLW decided that the status of the two hospitals (Gunma University Hospital and Tokyo Women's Medical University Hospital) as advance treatment hospitals should be revoked (*Nikkei Shimbun*, May 27, 2015). This was just as the Mid-Staffordshire NHS Foundation Trust Public Inquiry Report highlighted the deficiencies in the UK system once again, 12 years after the Royal Bristol Infirmary Report. The key drivers for regulatory change (research question (i)) were primarily public and professional concerns channeled through media attention rather than those mediated by a formal political system in Japan.

However, when examining the degree and direction of changes made to the regulation of risks to patient safety in Japan (research question (ii)), remarkable differences were found between many English-speaking countries and Japan after almost two decades. In Japan, a revalidation system is not yet in place, and the two key ALBs (JCQHC and JMSRO) both originate in medical professional groups. As a result, they remain weak in the areas of data accuracy and representation of patients' voices. Yet as competition amongst healthcare providers becomes even more intense in a predominantly private sector-driven market, pressures are exerted on providers. In a similar way to France, Germany and the Netherlands, where there are not-for-profit private providers, Japanese hospitals have come to bear greater responsibility for their standards of care and possible failures. Market competition and choice appear to be a strong driver in these countries, including Japan (Mossialos et al., 2016; KPMG International, 2017).

With the additional forces of globalization and medical tourism, several hospitals in Japan began to look at global standards, and apply for Joint Commission International (JCI) accreditation (22 organizations including long-term care and ambulatory care institutions, as of February 2016; JCI website), at the expense of accreditation from the JCQHC, which is a national body. There is now clearly an international dimension to the regulation of risks in healthcare in Japan, which will no doubt spill over into the debates around professional licensing and registration in the future.

In European countries with the Bismarckian social insurance model, self-regulation and the liberal practice of medicine still appear to be the norm. The Japanese case is not an anomaly from this perspective. However, the medical professions in Japan have managed to minimize the government's intervention compared with the other countries after all these reforms. Furthermore, there is a legal requirement in Japan that the director of a healthcare provider has to be a doctor. In view of the systemic problem of insufficient doctors and their established link with the dominant political party within the broader political institutions in Japan, they maintained their status as the only actors who control the market of expertise (Freidson, 1970; Bourgeault & Grignon, 2013). Performance evaluation schemes, for example, were built by formal collaboration between civil servants (the former MHW) and professional associations of the JMA.

From the perspective of politicization, the politics of risk regulation in Japan did not produce positive impacts. Party competition hardly existed there, and even where it did, the change of government did not successfully open a channel for citizens' (patients') voices coming through the ballot box. As the LDP-led government returned to power, reforms were led and negotiated by professional groups, although they are not united voices. During the brief period of the two-party

system, party competition fostered and publicly highlighted divisions among medical professions, which indicated the potential for politicization of regulatory issues. However, as the opposition party collapsed, the medical professions have regained their political clout.

Although the reform path in Japan does not signal the emergence of a new accountability regime, increased pressure is now placed on healthcare providers in terms of monitoring performances, collecting information and making decisions on how to act when serious incidents occur. This signifies that medical institutions as a whole need to enhance and demonstrate their capacity to respond to public concerns or redesign the institutional arrangements. The Japanese case demonstrates that the long-term reform outputs were heavily influenced by dominant discourses and proactive actors, which in this case were medical professionals and associations. Unlike the other European countries, Japan does not have a body equivalent to the Medical Council for setting standards, handling medical errors, and determining disciplinary actions and remedial measures for medical practitioners. Given the negative legacy of Article 21, there will be challenges for establishing and embedding a 'just culture' (Dekker, 2016), but an effective mechanism for involving the public and patients and handling patient safety risks in a transparent manner seems desirable. The question is: who will consistently promote transparency and advocate patients' right to know, when democratic channels for patients' voices are rather weak?

Figure 3 is adapted from the original generic diagram (Figure 1), and this demonstrates how key stakeholders and bodies interact with and influence each other within the present Japanese healthcare system.

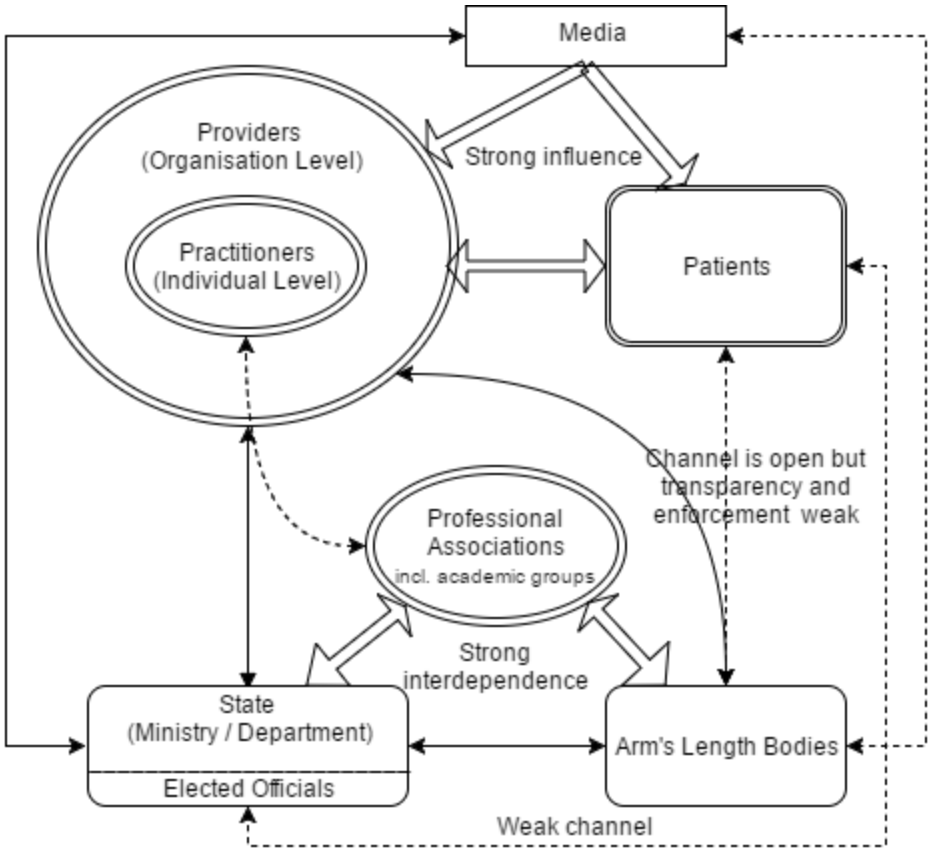

Figure 3. Schematic diagram of post-reform healthcare governance for patient safety regulation in Japan (author).

Dixon-Woods et al. argue that 'scandals need to be understood not as simple determinants of change, but as one performative element in a constellation of socially contingent forces and contexts' (Dixon-Woods et al., 2011, p.1). The impact of an event does not depend solely on the scale of damage or the level of initial shock. It also depends on the existence or absence of institutional mechanisms that provide legitimacy to ideas that encapsulate solutions which will prevent the recurrence of such events. It is worth examining further the long-term policy developments in patient safety regulation from the perspective of comparative institutional design. If self-regulation remains more resilient in the Bismarckian social insurance-based healthcare systems than in English-speaking countries', what are the mechanisms in the former group for

ensuring balanced accountability between individuals and the organizations/professionals? Or is it simply the pace of reform that is different across countries, depending on the level of citizens' trust in medical professions, healthcare organizations and government? As the shift towards preventive medicine and self-care is becoming more common, and as the government rolls back its delivery functions, the power relationships amongst medical professionals, patients, elected and non-elected officials have to be carefully examined in future research. Building a system which is properly balanced between safety and productivity in healthcare is always a challenge. However, seeking consensus over how to regulate medical professionals and healthcare organizations in order to ensure safety is equally challenging. The functions of political and patient representation, together with the economic incentive structure for medical professionals and healthcare organizations, differ across countries. The case of Japan has demonstrated that these factors shaped the dynamics, leaving professional self-regulation almost intact, while testing healthcare organizations' capacity for being transparent and accountable.

Funding details
This research is partly supported by the Japan Society for the Promotion of Science (10101-11-2201-A-0001).

Disclosure statement
There is no potential conflict of interest.

Acknowledgments
This research is partly supported by the Japan Society for the Promotion of Science (10101-11-2201-A-0001). The author would like to thank all the reviewers and colleagues for their feedback and comments, particularly participants at the Political Studies Association Annual Conferences in the UK.

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