保健医療科学　2019　Vol.68 No.1 p.55－60

Topics: Recent topics in public health in Japan 2019

＜ Review ＞

Patient safety: History and recent updates in Japan

Kenichiro Taneda

Department of International Health and Collaboration/Department of Health and Welfare Services, National Institute of Public Health

Abstract

Japan Ministry of Health, Labour and Welfare (MOHLW) hosted the Third Patient Safety Ministerial Global Summit in April, 2018, in Tokyo, Japan. Healthcare quality including patient safety is one of critical aspects to achieve Universal Health Coverage (UHC) under Sustainable Development Goals (SDGs). Japan has been striving for patient safety improvement around the last 20 years. This article describes some of the recent activities including the new reporting system of death cases due to medical accidents, the reform of patient safety management at advanced treatment hospitals. These our experiences in Japan would be useful for other countries.

keywords: patient safety, reporting and learning system, global summit

(accepted for publication, 7th February 2019)

I. Introduction of patient safety measures in Japan

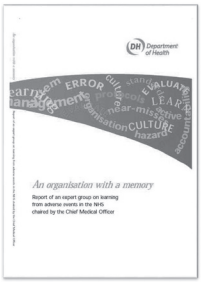
Japan achieved universal health insurance coverage of the nation in 1961. Then Japanese health system was ranked top in overall goal achievement according to WHO World Health Report 2000[1]. However, the quality of healthcare services was not necessary as good as we thought. In 1999 and early 2000, Japan experienced the series of serious patient safety accidents (Table 1). Interestingly, The US and UK also published the reports on patient safety which described similar patient safety issues in 1999 and 2001 respectively (Figure 1, 2).

Table 1 Patient safety accidents which triggered national patient safety measures in Japan

- January, 1999: Yokohama City University Hospital
  Patients for heart surgery and lung surgery were mixed up, and operations were performed for different parts of the bodies.
- February, 1999: Tokyo Metropolitan Hiroo Hospital
  After a surgery, disinfectant, instead of anticoagulants, was administered intravenously by mistake, which resulted in the patient's death.
- February, 2000: Kyoto University Hospital
  Ethanol was put into a humidifier of a respirator/ventilator by mistake, instead of distilled water, and then the patient died of its toxicity.
- April, 2000: Tokai University Hospital
  Oral medication was administered intravenously, due to confusion with enteral nutrition route, , which resulted in the pediatric patient's death.

Health care in the United States is not as safe as it should be--and can be. At least 44,000 people, and perhaps as many as 98,000 people, die in hospitals each year as a result of medical errors that could have been prevented, according to estimates from two major studies. Even using the lower estimate, preventable medical errors in hospitals exceed attributable deaths to such feared threats as motor-vehicle wrecks, breast cancer, and AIDS.

Figure 1 "TO ERR IS HUMAN" US IOM (Institute of Medicine) Report in 1999



"Yet the best research-based estimates we have reveal enough to suggest that in NHS hospitals alone adverse events in which harm is caused to patients:

- occur in around 10% of admissions – or at a rate in excess of 850,000 a year;
- cost the service an estimated £2 billion a year in additional hospital stays alone, without taking any account of human or wider economic costs."

Figure 2 "An organization with a memory" UK DOH (Department of Health) Report in 2001

Corresponding author: Kenichiro Taneda
2-3-6 Minami, Wako-shi, Saitama 351-0197 Japan.
E-mail: taneda.k.aa@niph.go.jp

II. Brief history of patient safety measures in 2000s[1]

In response to these accidents, Japanese government established the office of patient safety promotion within MOHLW in 2001, and then patient safety measure review meeting "National Council for Patient Safety" was held with experts (Table 2).

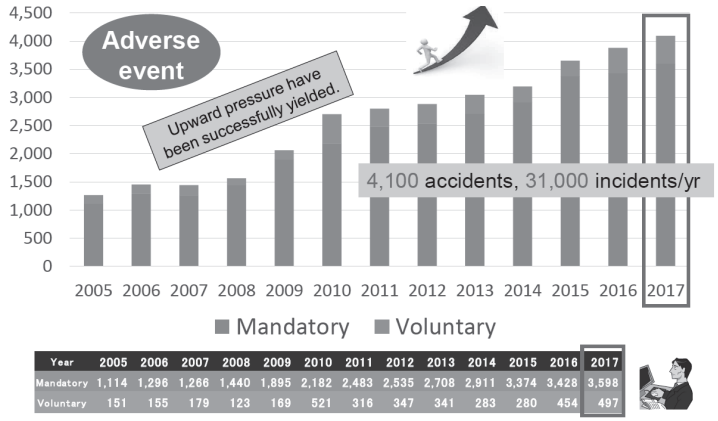
In 2002, the council coordinated the "patient safety promotion comprehensive measures" report. The report described the followings: the patient safety measures at medical facilities, safety improvements on medication and medical equipment, education and training on patient safety, system improvements to promote patient safety such as development of patient consultation services, providing information on patient safety, and scientific research on patient safety. Various patient safety measures were enforced based on this report. In October 2002, the ministerial ordinance mandated medical facilities with inpatient facilities to establish a patient safety management system. In April 2003, advanced treatment hospitals were requred to arrange medical safety management personnel, a patient safety management department, and patient consultation services. In 2004, they were also enforced to report patient safety incidents to the national adverse event reporting and learning system operated by the Japan Council for Quality Health Care (JQ)[2] (Figure 3).

Patient safety has been stipulated through revisions of ministerial ordinances. In the amendment of the Medical Service Act in 2006, patient safety was included in the Act and the all medical facilities were mandated to establish a patient safety management system. All prefectures were also obliged to establish a Patient Safety Support Center to conduct consultations for patients and residents and to support patient safety activities at healthcare facilities.

In 2009, the Japan Obstetric Compensation System for Cerebral Palsy (JOCS-CP) was launched as a novel system of no-fault compensation and investigation/prevention. JQ was appointed to manage JOCS-CP and its financial source is mainly from public health insurance system. Guardians of a patient with cerebral palsy have been provided monetary compensation as well as its investigational report.

Table 2 Overview of Patient Safety measures in 2000s

2001	- Office of Patient Safety at Ministry of Health, Labor and Welfare (MHLW) - National Council for Patient Safety
2002	- The "Patient Safety Promotion Comprehensive Measures" report - Ministerial ordinance: Mandate of Patient Safety management at advanced treatment hospitals, teaching hospitals, general hospitals, and clinics with inpatient facilities
2003	- Ministerial ordinance: Mandate to have patient safety manager, patient safety division, and office of patient complaint at advanced hospitals, etc. - "Urgent appeal of Patient safety accident measures": Patient safety as one of the most important issues of medical policy by the Minister of MHLW
2004	- National Adverse Event Reporting and Learning System - Ministerial ordinance: Mandate of patient safety reporting system at advanced hospitals, etc.
2006	Amendment in Medical Service Act for patient safety: Mandate of patient safety system at all healthcare facilities including clinics without inpatient facilities and midwifery centers, to establish patient safety support centers in each prefecture
2009	The Japan Obstetric Compensation System for Cerebral Palsy (JOCS-CP)



Year	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Mandatory	1,114	1,296	1,266	1,440	1,895	2,182	2,483	2,535	2,708	2,911	3,374	3,428	3,598
Voluntary	151	155	179	123	169	521	316	347	341	283	280	454	497

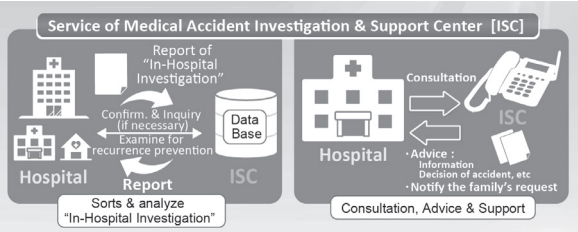
http://www.congre.co.jp/psgms2018/pdf/Day_1/Evening_Session/ES-1_Shin_Ushiro.pdf

Figure 3 The Number of Adverse Events reported to JQ presented by Dr. Ushiro in the Patient Safety Summit

III. Recent Updates

1. Investigation System of death cases due to Medical Accident[3]

In 2015, the Medical Accident Investigation and Support Center (ISC) was established and then operated by the Japan Medical Safety Research Organization (Medsafe Japan) (Figure 4). This new system aims to prevent recurrences of serious events resulting in unforeseen death of patients at all healthcare facilities including small clinics. The ultimate decision of "Medical Accident" is made by a director of a concerned healthcare facility under the concept of "Professional Autonomy and Self-Regulation". The reports "In-Hospital Investigation" submitted to ISC is more than 900 cases in total as of February 5th, 2019. Based on the reports, ISC has published booklets to facilitate preventions of medical accidents, including "Central Venous Catheterization", "Acute Pulmonary Thromboembolism" and "Anaphylaxis caused by injections".



https://www.medsafe.or.jp/modules/en/index.php?content_id=1

Figure 4 Investigation System of Death Cases due to Medical Accidents

2. Local networking on patient safety

In 2018, the MHLW initiated the new financial incentive to facilitate mutual learning and support among local hospitals. The hospitals can receiver better re-imbursement if they could establish local networking to improve patient safety. The hospitals are required to organize meetings and site visits on regular basis to learn patient safety activities from each other.

3. Reform of patient safety management at advanced treatment hospitals

Because of several serious accidents at university hospitals, the MHLW organized the task force committee to improve patient safety management at advanced treatment hospitals such as university hospitals in 2015. Since 2016, the drastic reform of patient safety management proposed by the committee has been implemented at advanced treatment hospitals.

The reform includes the followings:

- A hospital director/president is required to participate in a designated patient safety seminar every year. A hospital director should have experiences on patient safety activities before.
- To have personnel, such as a vice hospital director, who is responsible for the whole patient safety management. The personnel is required to participate in a designated patient safety seminar every year.
- To have personnel who is responsible for medication safety management. The personnel is required to participate in a designated patient safety seminar every year.
- To have personnel who is responsible for medical equipment safety management. The personnel is required to participate in a designated patient safety seminar every year.
- To have a doctor as a full-time patient safety officer
- All death cases should be reviewed to determine whether there is a case which should be reported to the Medical Accident Investigation and Support Center.
- To conduct peer-review including a site visit on patient safety among advanced hospitals
- To have external reviews on patient safety by external experts including a patient representative twice a year
- To have some indicators to monitor patient safety

4. Patient Safety Culture in Japan

In 2001, the committee on human error under MHLW identified particularly important issues for patient safety and then mentioned "safety culture" in the first place. It is essential to foster a culture of safety in healthcare facilities to provide safe care. Therefore, the author translated and administered the validated patient safety culture survey tool developed originally by the Agency for Healthcare Research and Quality (AHRQ) in US[4,5]. The figure 5 shows

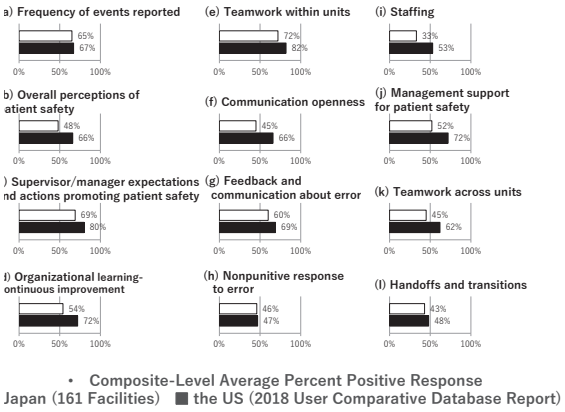


Figure 5 Patient Safety Culture in Japan and the United States in 2018

the recent survey result of patient safety culture in Japan in 2018 (Average response rate: 89%) compared with the one in US in 2018 (Average response rate: 54%). Japan needs to improve patient safety culture in particularly in the following aspects: staffing, communication openness, and management support for patient safety. As one of strategies to improve patient safety culture, we have implemented TeamSTEPPS® in collaboration with US[6].

5. Third Global Ministerial Summit on Patient Safety Tokyo, in April 2018[7]

In 2016 and 2017, the UK and German governments hosted the first two Summits respectively. In 2018, the Japanese Government organized the third Summit in Tokyo, as the first host country in Asia (Figure 6). There were approximately 500 participants including delegations from 44 countries with18 Ministers/Vice-ministers, delegates from international organizations, patient safety experts and other stakeholders. We expected that, through the Summit, the global patient safety movement would spread to all the countries of the world regardless of their region or income level to achieve UHC because UHC requires quality of healthcare services[8]. In the summit, Mr. Katsunobu Kato, Minister of Health, Labour and Welfare, Japan, clearly stated "I stressed sincere hope that UHC and patient safety will be promoted hand-in-hand in a holistic manner, leading to coherent and effective policy measures, tailored to the circumstances of each country."

At the end of the summit, the "Tokyo Declaration" was endorsed by the majority of participating countries. The declaration will facilitate patient safety as an integral element towards the achievement of UHC, and then promote and support "Global action on patient safety" among all countries, including low- and middle- income countries.

Quote from Tokyo Declaration on Patient Safety:

"We reaffirm our commitment to improving patient safety in order to reduce all avoidable harm and the risk of harm to all patients and people during their interaction with health care systems, whoever they are, wherever they live, by 2030"

We hope that our experiences in Japan can contribute to other countries, global patient safety movement, and then Universal Health Coverage ultimately.

References

[1] WHO. The world health report 2000 - Health systems: improving performance. https://www.who.int/whr/2000/en/whr00_en.pdf?ua=1 (accessed 2019-02-07)

[2] Patient Safety Activities at Ministry of Health, Labour and Welfare (MOHLW). https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryou/i-anzen/index.html (accessed 2019-02-07)

[3] The Japan Council for Quality Health Care (JQ). http://www.med-safe.jp/contents/english/index.html (accessed 2019-02-07)

[4] Medical Accident Investigation System. https://www.medsafe.or.jp/ (accessed 2019-02-07)

[5] US AHRQ Surveys on Patient Safety Culture. https://www.ahrq.gov/sops/index.html (accessed 2019-02-07)

[6] 種田憲一郎，奥村泰之，相澤裕紀，長谷川敏彦．安全文化を測る―患者安全文化尺度日本語版の作成．医療の質・安全学会誌. 2009;4(1):10-24.
Taneda K, Okumura Y, Aizawa Y, Hasegawa T. [Reliability and validity of the Japanese version of the hospital survey on patient safety culture.] The Japanese Journal of Quality and Safety in Healthcare. 2009;4(1):10-24. (in Japanese)

[7] The official website of the Military Health System. Patient Safety in Action: Collaboration with Japan Leads to Diffusion of TeamSTEPPS Overseas. https://health.mil/News/Articles/2017/11/01/Patient-Safe-

http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000204000.html

Figure 6　Patient Safety Global Ministerial Summit 2018 in Tokyo

ty-in-Action-Collaboration-with-Japan-Leads-to-Diffusion-of-TeamSTEPPS-Overseas (accessed 2019-02-07)
[8] Patient Safety Global Summit 2018. http://www.congre.co.jp/psgms2018/index.html (accessed 2019-02-07)
[9] 種田憲一郎．SDGsの要であるUHCの必須要素：サービスの質・安全とこれに資する包括的人々中心のサービス．保健医療科学. 2017;66(4):380-386.
Taneda K. [Integrated people-centred health services for healthcare quality and patient safety to contribute to UHC under SDGs.] J. Natl. Inst. Public Health. 2017;66(4):380-386. (in Japanese)

Kenichiro Taneda

患者安全
ー日本における歴史（概要）と近年の取組みー

種田憲一郎

国立保健医療科学院国際協力研究部／医療福祉サービス研究部

抄録

2018年４月に，厚生労働省は第三回の患者安全閣僚級グローバルサミットを東京にて実施した．患者安全を含む医療の質は，SDG（Sustainable Development Goals）で提案されるUHC（Universal Health Coverage）を達成するために重要な要素の一つである．日本は，過去約20年間にわたって患者安全の改善に努めてきた．今回の特集記事では，死亡事故を対象とした医療事故調査制度，特定機能病院における医療安全管理体制の見直しなど，近年の日本における患者安全の活動について紹介する．これらの経験は諸外国においても参考となる取組みと思われる．

キーワード：患者安全，閣僚級患者安全サミット，UHC