COMPLETION REPORT

A Study on Medical Accident Reporting System in Japan for Implementing Improvement Strategies in Malaysia

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Title of Research Project:

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Result of the Research:

Adverse events or "injuries due to medical care" due to practice, products, procedures and systems may emerge at all stages in the process of care-giving. The occurrence of medical error induces adverse events, which may be caused by a combination of human factors and system factors. However, majority of medical errors are considered preventable, particularly, those involving human errors. Therefore, patient safety management requires various institutional initiatives to be taken in order to encourage open disclosure of medical errors, to prevent their re-occurrence and ultimately, to learn from them. Amongst the various patient safety initiatives that have been taken in Japan is implementing a wider use of internal reporting systems for hospitals and building a system to provide and collect information. The Japan Council for Quality Health Care (JCQHC), a third party hospital accreditation organisation, has been tasked to collect 'medical near-miss/adverse event' information for the promotion of patient safety and medical adverse event prevention. In the light of increasing number of adverse events reported to JCQHC in 2014, the amendment to the Japan Medical Care Act was made to establish the Medical Accident Investigation System which is also known as *iryojiko chosa seido.* The new system came into operation on October 1, 2015 and made it mandatory for all medical institutions in Japan to report any 'unexpected deaths' in relation to medical care to a medical accident investigation support centre and perform medical accident investigation to identify the cause of the accident. The number of mandatory reporting medical institutions as of 31st December 2014 is 275 hospitals and the number of reported accidents collected from January 1st to December 2014 is 2911 cases, which include 225 cases resulting in death. According to Articles 6 – 10 of the Medical Care Act, administrators of hospitals, clinics or birthing center shall undertake measures for (i) the establishment of policies to ensure safety in medical care; (ii) the implementation of training for employees; (iii) measures to ensure safety in medical care in other relevant hospitals, clinics or birthing centers. Further, according to Articles 1 - 11(i) of the Act, administrators of the hospitals shall ensure medical safety based on regulations

described in Articles 6 - 10 in (i) preparing guidelines for medical safety control; (ii) holding committee meetings on medical safety control; (iii) training staff in medical safety control; and (iv) taking improvement measures aimed at ensuring medical safety, such as, reporting of medical accidents that occur within medical institutions. Medical accidents subjected to this system are "death or stillbirth which are caused or suspected to have been caused by care provided by employees of the medical institutions, and which are unforeseen by the administrator". Subsequently, the outcome of the investigation will be collected by a private third party institution known as the 'Medical Accident Investigation Support Centre'. This Centre is tasked to analyse the result of the accident with the objective of preventing its recurrence as well as improving the safety and quality of healthcare. They must also explain the results of their investigations to relatives of the deceased and submit a report on each case to the Japan Medical Safety Research Organisation so that they are able to analyse the information and propose steps to avoid similar mistakes. This step is considered very beneficial in making the healthcare institution more transparent and accountable. Overall, the initiative taken by Japan is very much applauded and can provide valuable lessons for many countries, including Malaysia, in ensuring that adverse events in medical institutions are reported, discussed and prevented. In particular, the following strategies implemented in Japan can be further developed in Malaysia to strengthen and improve Malaysia's incident and investigative system namely; (i) To create an incident reporting and investigative system, under a clear legislative framework to provide clear rules and guidance for medical institutions to know clearly their duties on reporting and implications of not reporting on adverse events particularly, those leading to death; (ii) To develop specialized and separate bodies to handle the 'reporting' and 'collection' of adverse events cases, the 'investigation' and 'analysis' of the cases and finally, the 'plan of action' for preventing future recurrence; (iii) To inculcate a culture of transparency in making it mandatory to explain to the affected persons such as the bereaved families on the events leading to the mishap and providing them with the necessary documents as substantial evidence. Implementing these strategies will ultimately, ensure the preservation of public confidence in medical institutions in Malaysia as well as systemic improvements in patient safety and professional discipline.

Publication of the Results of Research Project:

Verbal Presentation (Date, Venue, Name of Conference, Title of Presentation, Presenter, etc.)

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1. Name of Author: **Prof Dr Puteri Nemie Jahn Kassim**

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2. Name of Authors:
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