

HOW CAN WE ENSURE PATIENT SAFETY ON NOVEL AND RISKY SURGERY? - 6-YEAR EXPERIENCE OF STATUTORY INTERNAL REVIEW SYSTEM

Shin Ushiro ^{1, 2}, Satoshi Hamai ^{2, 3} and Committee on public affairs and scientific research, Japan National University Hospital Alliance on Patient Safety (JANUHA-PS)

¹Japan Council for Quality Health Care, Tokyo, ²Division of Patient Safety, Kyushu University Hospital,

³Department of Orthopaedic Surgery, Graduate School of Medicine, Kyushu University, Fukuoka, Japan



Introduction:

In the year 2014 and 2015, Japanese society was stunned at the series of media publicity on high mortality rate in patients who underwent novel and risky laparoscopic surgery conducted by a single surgeon in a prestigious university hospital. The investigation committee was swiftly launched and published in-depth report that demonstrated that there was little or no review process before implementing the surgery which was not well established in terms of evidence on safety. Therefore, the procedures provided was not covered by the public healthcare insurance which has a scope of wide range of cares evidenced as safe and effective through body of research. The central government subsequently revised the ministerial ordinance to mandate university hospitals to install with internal review system for novel and risky surgeries and procedures. We have run the review system in Kyushu University Hospital (KUH) since 2016. Here, in this study, type of surgeries, review comments in implementing novel and risky procedure, challenges and opportunities are analyzed and presented.

Methods:

The internal review and follow-up system was embedded in KUH in 2016. Division of patient safety requested all the clinical departments to submit implementation plan of novel and risky procedure according to definition generated by the Ministry of Health (MoH). It is defined “Surgery or procedure that has never been conducted in the institution and could possibly cause devastating consequences such as death or serious conditions”. Records on the review during 2017-2022 including submitted documents and comments made by the committee were analyzed. In order to assess status quo of the review system of KUH, it underwent peer-review through on-site visit program of the National University Hospital Alliance on Patient Safety (JANUHA-PS). Concurrently, it was also a subject to hospital accreditation survey in 2023 provided by the Japan Council for Quality Health Care (JQ). Therefore, assessment by those external evaluations were also incorporated in the analysis.



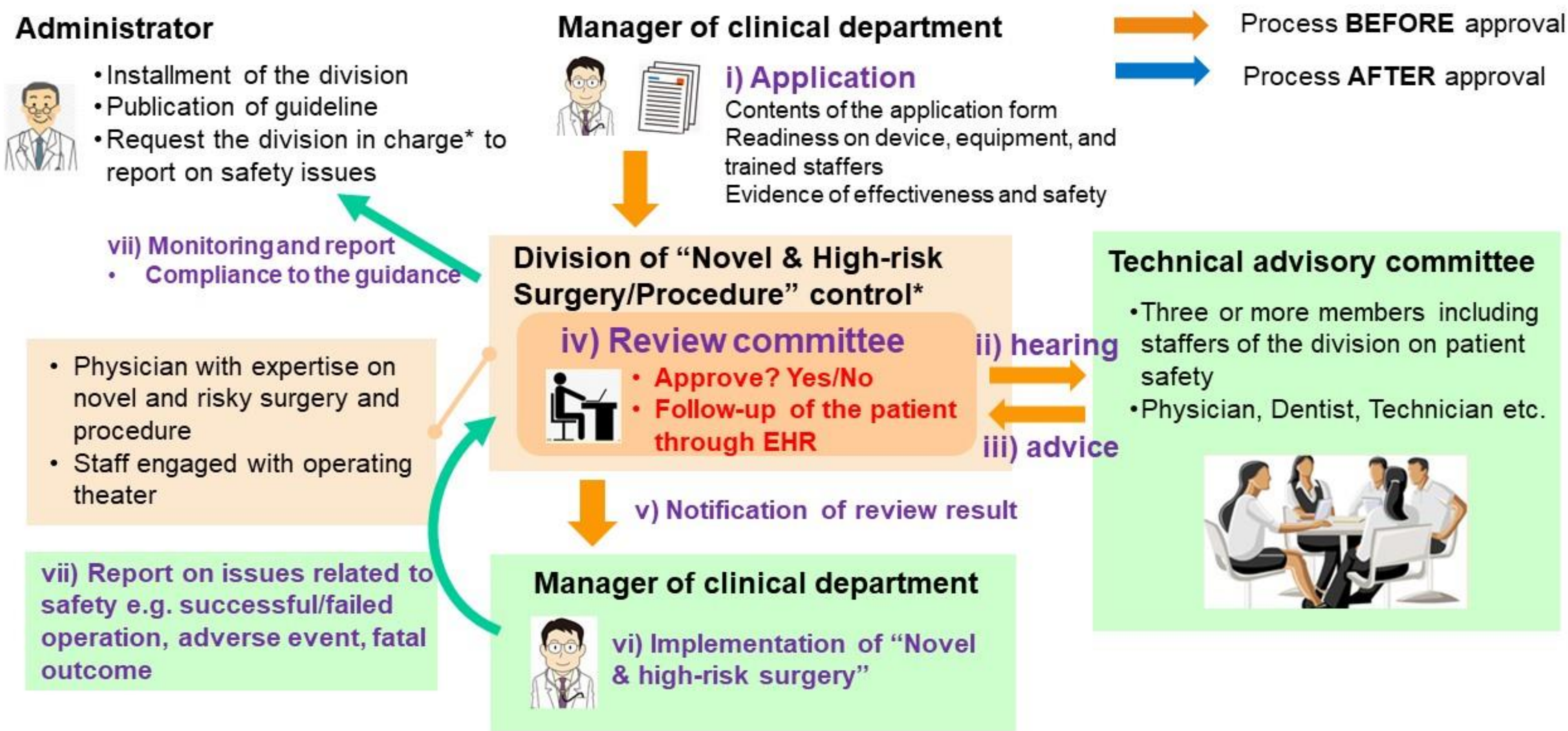
Gunma University Hospital admits negligence in eight surgery deaths



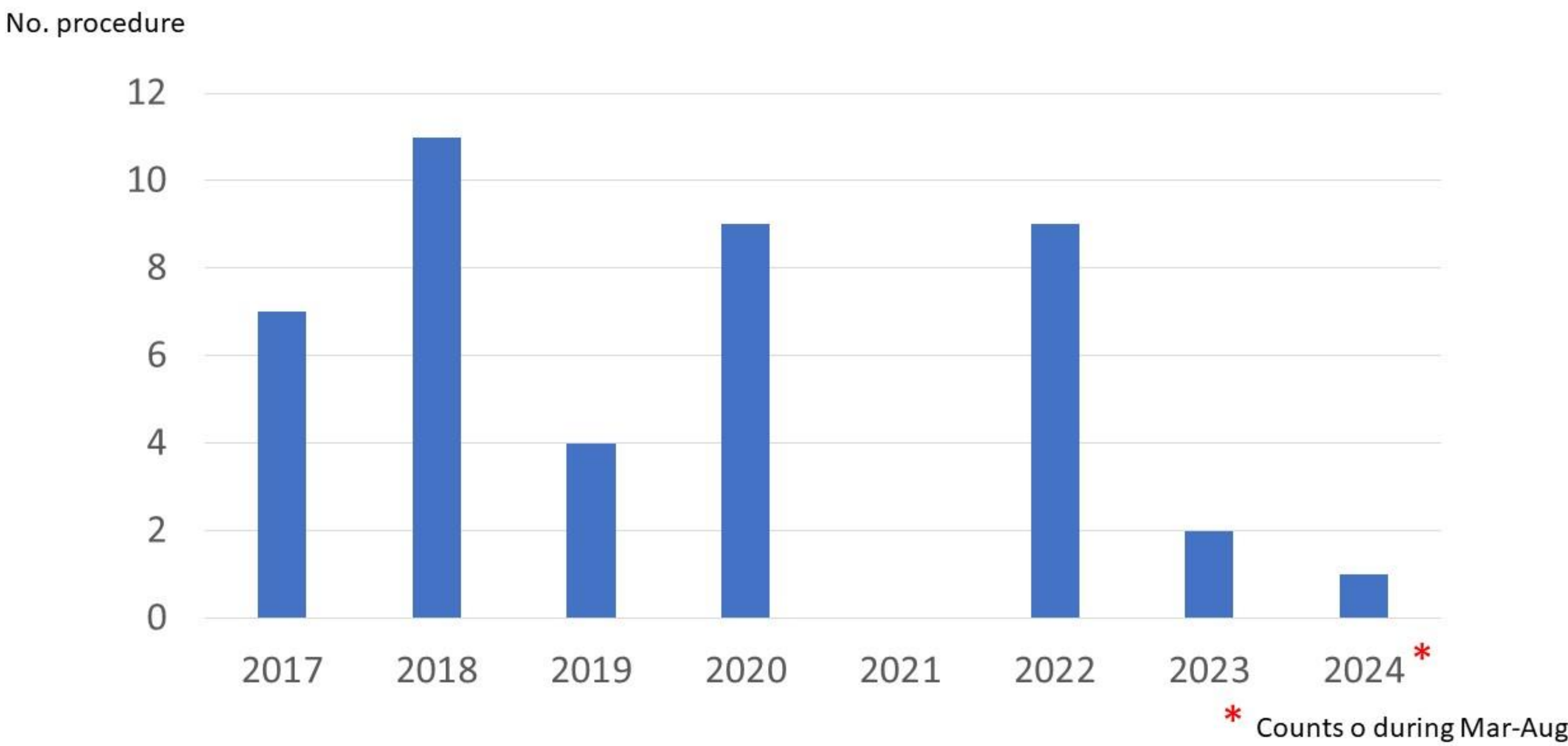
March 3, 2015
MAEBASHI, GUNMA PREF. – Gunma University Hospital on Tuesday admitted negligence in the deaths of eight patients following laparoscopic liver surgery, faulting its staff for failing to look into early deaths and a surgeon for falsifying a record.
Between 2010 and 2014, eight people died within four months of undergoing surgery conducted by laparoscope by one surgeon at the national institution.
Hospital officials told a news conference that in the case of one of the patients who died following surgery to remove what was believed to be a cancerous growth, the tumor turned out to be nonmalignant.
The surgeon falsely reported on a diagnostic report for insurance claims that the patient did indeed have cancer.
The surgeon also failed to inform the patient’s relatives immediately that the patient did not have cancer, which would have been tantamount to admitting the operation was conducted on an erroneous assumption.
The officials said that when questioned for the inquiry, the surgeon replied, “I can’t recall clearly.”
In its final report on the matter, released Tuesday, the hospital noted that four patients died within a year of the procedure being introduced in 2010.
The department “should have been aware of the problem and able to check and implement countermeasures at this early stage following the series of deaths,” the report says.

YOMIURI 15th November, 2014

Review and follow-up system for introducing a “Novel and risky surgery/procedure” (Fig 1)



I. No. approved procedures (2017-2024*) (Fig 2)



II. Type of procedures

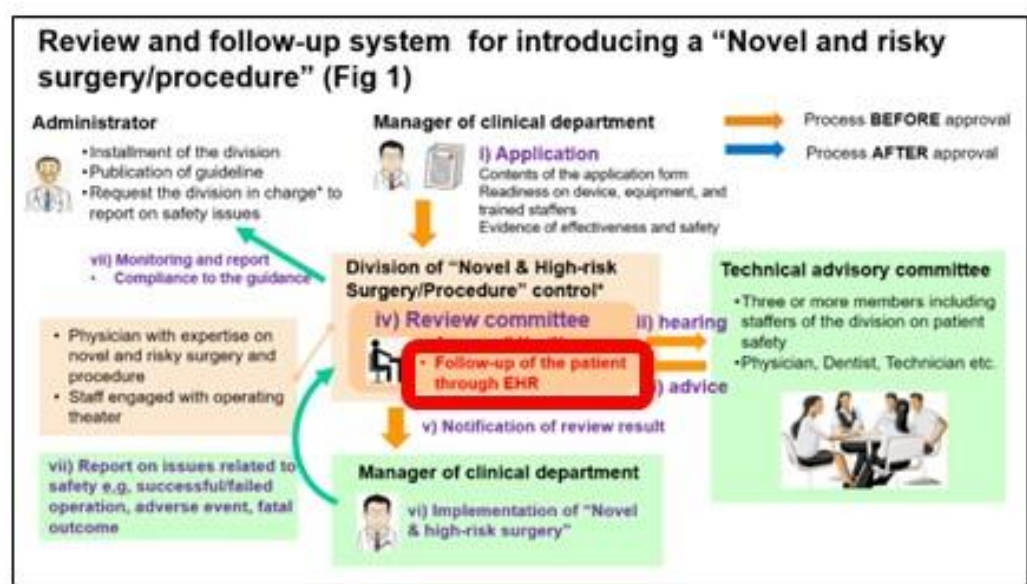
- A) Robotic surgeries ;
- Robot-assisted-thoracoscopic mitral valvoplasty, thoracoscopic atrial septal defect closure, thoracoscopic esophageal cancer resection, thoracoscopic internal thoracic artery graft harvest, thoracoscopic lung cancer resection, thoracoscopic mediastinum cancer resection, pantreatoduodenectomy, laparoscopic pancreatic tail resection, laparoscopic hepatectomy, laparoscopic colectomy, laparoscopic urinary bladder cancer resection, hypopharyngeal cancer resection, laparoscopic nephroureterectomy, laparoscopic adrenalectomy, laparoscopic pyeloplasty.
- B) Other surgical procedures
- Transcatheter aortic valve replacement (TAVR) through carotid approach, Transcatheter pulmonary valve replacement (TPVR), Pediatric heart transplantation, Implantation of left ventricular assist device for pediatric patient, Ross’ procedure for aortic valve repair, Jatene Arterial Switch, Endovascular stent-graft placement for arterial dissection, Endovascular stent-graft placement for aortic arch aneurysm, 3D-mapping and cardiac ablation amid thoracic surgery,

II. Type of procedures (cont’d)

- B) Other surgical procedures (cont’d)
- Pleurectomy/Pulmonary decortication for malignant mesothelioma, Laparoscopic gall bladder (GB) /GB bed resection, Extended right hepatectomy associated with In-situ hypothermic perfusion, total temporomandibular joint (TMJ) replacement, Laparoscopic placement of cervical cerclage
- C) Procedures executed by internal medicine department.
- Endoscopic bronchial thermoplasty, and ultrasonography- guided biliary drainage (EUS-BD).
- D) Non-approved medication
- Cidofovir injection for BK-virus-induced hemorrhagic cystitis
- E) Non-approved medical device
- Corneal transplantation, Dental pulp treatment with MTA (Mineral Trioxide Aggregate)
- F) Use of medical device for extra purpose
- Stent graft placement for right ventricular outflow tract obstruction of “Tetralogy of Fallot”

III. Clinical follow-up protocol and timetable

- The MoH presented a framework of the review system (Fig 1) in which tracing of “appropriate number” of cases e.g. “five cases” in a row and follow-up of the patient at such point as “patient discharge” and more are recommended.
- KUH adopted follow-up of “five consecutive cases” as far as it is medically justifiable and time points such as “patient discharge” for short-term assessment, and “3-months” and “1-year” after discharge for middle and long-term assessment.
- No cases of adverse outcome related to the surgery/procedure have been observed.



IV. Comments made by the review committee in follow-up

- Most comments were made on informed consent or documentation of consent form.
- Suggestion or recommendation were made in such a way of; “Additional staff e.g. nurse needs to be present in meeting with patient/family for informed consent.” “The number of cases treated at the institution with the same surgery/procedure is clearly explained in written format in the consent form.” “Elevated risk which the patient inherently bears when he/she undergoes the surgery/procedure needs to be described in the consent form.”

V. Peer-review and hospital accreditation survey

- KUH underwent two different external evaluations such as JANUHA-PS’s peer-review and JQ’s hospital accreditation survey.
- Experts and surveyors of those programs assessed positively the KUH’s progress of the review system except that JQ’s survey suggested that follow-up need to reach out to patient who cease to visit KUH by being referred to affiliated institutions.

VI. Challenges

- We identified great number of challenges related to the review process such as;
- a. Failure to/nearly failed to submit the plan to the division in charge.
- b. Failure to identify surgery/procedure for the review due to ambiguous definition of the “Novel and risky surgery/procedure”. Accordingly, there was no review in 2021, while new chair took up nine petitions as agenda in 2021.
- c. Review committee/Advisory committee’s timetable i.e. held on monthly basis does not meet physician’s request for expeditious reviewing of the case that patient’s condition is rapidly deteriorating.
- d. Review committee’s follow-up timetable does not meet physician’s request for expeditious reviewing on surgery/procedure due to mounting number of patients.
- e. Careful informed consent must be carried out by multi-professional team because some patients were informed for consent only by physician(s).
- f. The review and follow-up system is peer-reviewed among university hospitals in the framework of the University Hospital Alliance, while no review system is currently in place on mandatory basis in other institutions such as community-hub hospitals where similar surgery/procedure is conducted.

VII. Opportunities

- The review and follow-up system is well ingrained in university hospitals not only by the revision of the government ordinance in 2016 after serial deadly accidents took place, but by private programs such as external evaluation of the JQ and JANUHA-PS.
- The programs will continue to maintain quality of the system and hopefully encourage community-hub hospitals to install with the same system in such a way that it works in their settings.

VIII. Conclusion

- The review and follow-up system for novel & high-risk surgery/procedure serves as a catalyst in bringing cross-sectional vigilant system at institutional level to address siloed healthcare delivery on departmental basis that potentially put it at risk.
- There has never been similar event that provoke scandalous confusion in society by media. The review system for novel & high-risk surgery/procedure have been successful in building confidence on the treatment in our society.
- It is hoped that the review system is embedded in those hospitals in a way that fits local settings.

References:

- 2017-2022 Peer Review Reports by Permanent Steering Committee, Hospital Director Council of National University (http://nuhc.jp/activity/report/sgst_category/safety/safety_management.html), last accessed on Jan 26, 2024, available only in Japanese.