



Diagnostic safety

System /Team-based approach for improvement

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Japan Council for Quality Health Care (JQ)
Accreditation Council Member,
International Society for Quality in
Healthcare (ISQua)

Kyushu University Hospital (KUH)

- Kyushu University Hospital is a national university hospital, located in Fukuoka City, a gateway to Asia, and a hospital having more than 100 years of history.
- KUH is one of the leading affiliated medical and dental school hospitals in Japan employing nearly 3,500 staffs.
- KUH accepts 3,100 outpatients per day on average and are equipped with the number of bed that exceeds 1,400.



Project line-up of JQ on Quality and Safety Improvement

Hospital Accreditation

Patient Safety Promotion Group of Accredited Hospitals

Education and Training Program on Quality and Safety

EBM Medical Information (Clinical guidelines) Distribution Project (Minds)

Nationwide Adverse Events Reporting System of Medical Institutions

Nationwide Near-miss Event Reporting System of Community Pharmacy

The Japan Obstetric Compensation/Investigation and Prevention System for Cerebral Palsy

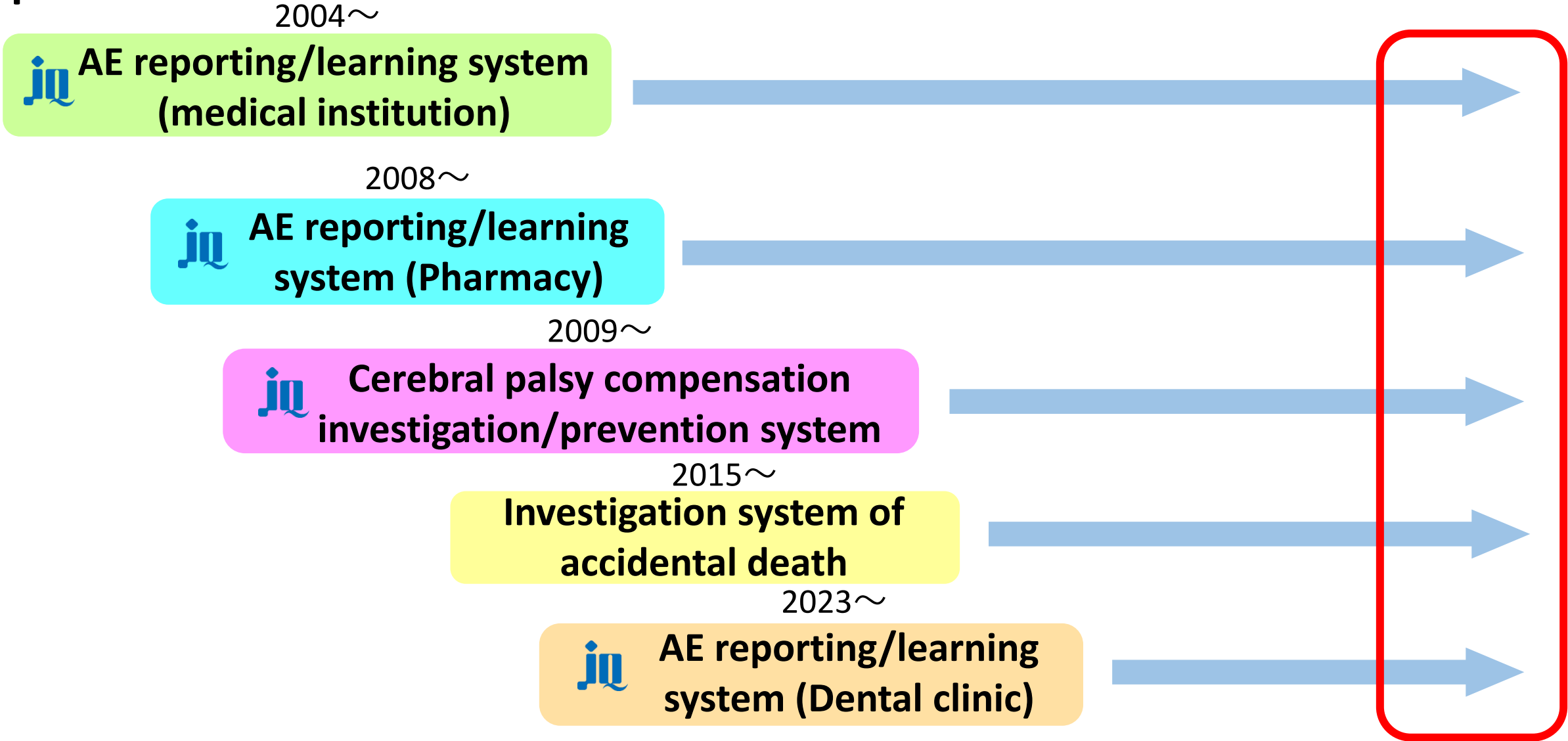
National Quality Indicator (QI) Measurement Project

CBT* platform and contents development for medical education * Computer-based Testing

Financial support program for Covid-19-affected healthcare professional

Patient representatives participate in the operation of most projects.

Nationwide reporting/investigation/learning system with public or quasi public nature 2024



Themes of WPSD 2019-2024



World Patient Safety Day

2024: Improving diagnosis for patient safety

2023: Engaging Patients for Patient Safety

2022: Medication Safety

2021: Safe maternal and newborn care

2020: Speak up for health worker safety!

2019: Speak up for patient safety!

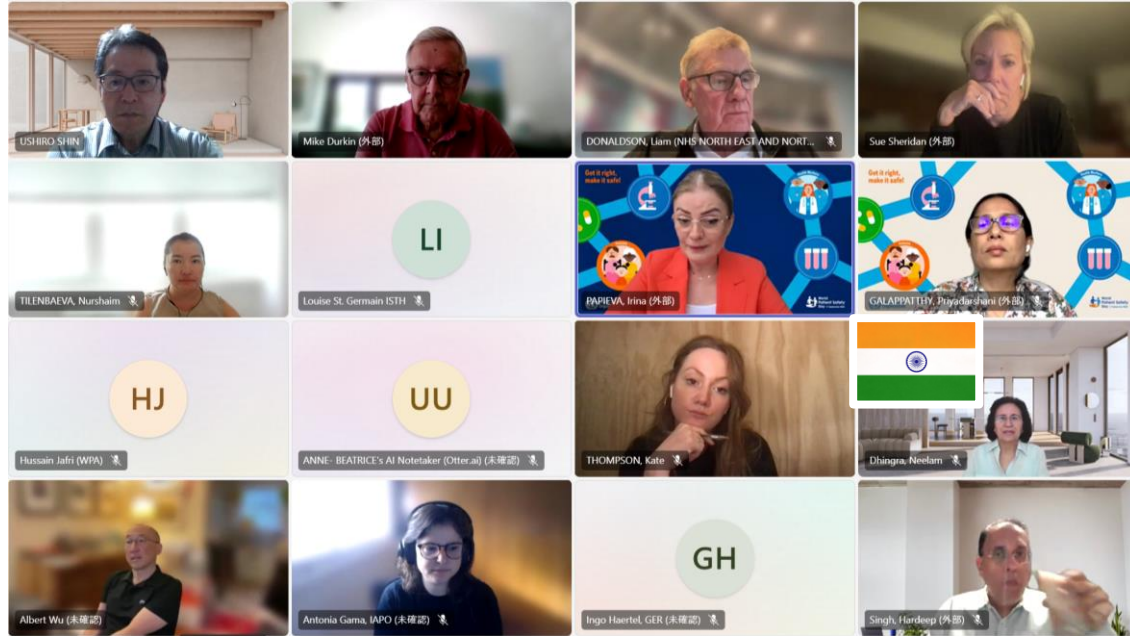


**World Health
Organization**

WHO World Patient Safety Day 2024 Steering Committee, 29th Aug 2024

Agenda

- Opening speech by Sir Liam Donaldson, WHO Patient Safety Envoy
- Draft literature review on diagnostic safety
- Progress report on World Patient Safety Day e.g. campaign materials, light-up
- Discussion
- WHO WPSD 2024 Global Consultation Meeting on 10th-12th September

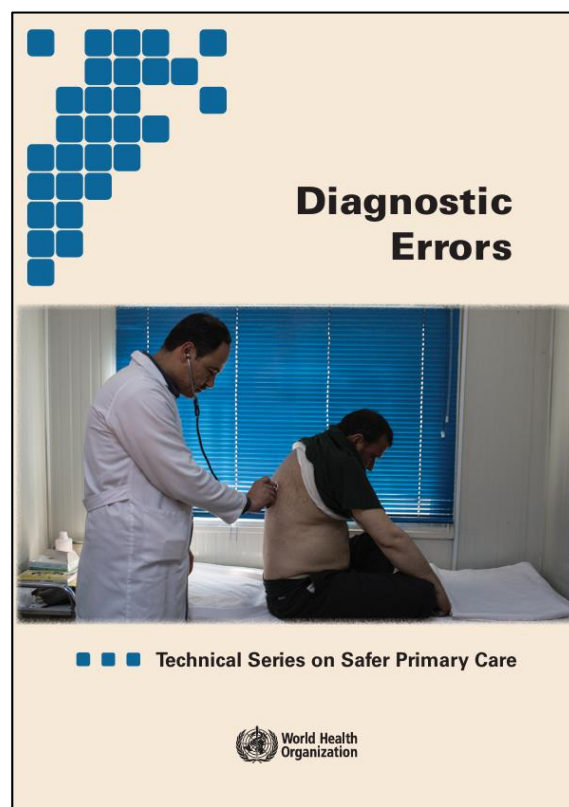


Report and Textbook on Diagnostic Safety

2015



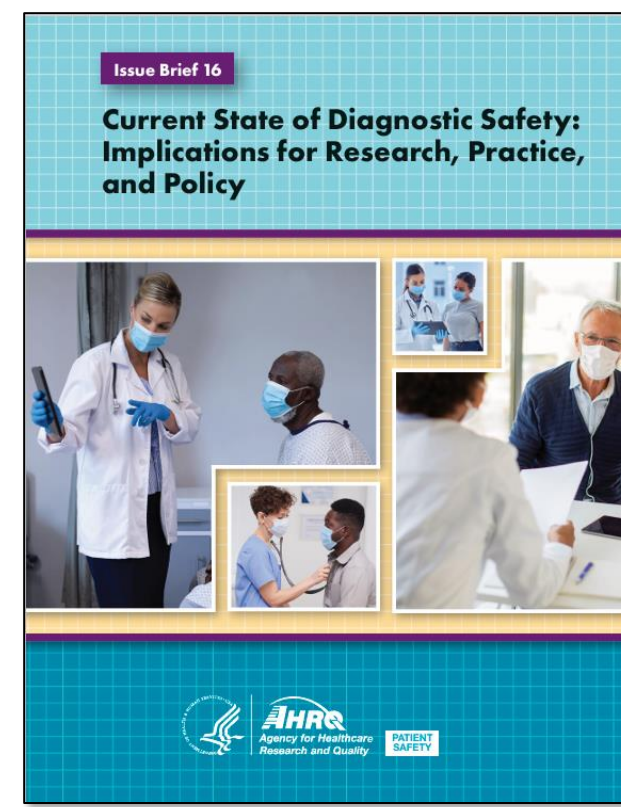
2016



2021



2024



* “Learning of diagnostic error”

Definition of Diagnostic Error

Definition	Defined by
A diagnosis that was unintentionally delayed (sufficient information was available earlier), wrong (another diagnosis was made before the correct one), or missed (no diagnosis was ever made), as judged from the eventual appreciation of more definitive information.	Graber, et al. (2005)
Any mistake or failure in the diagnostic process leading to a misdiagnosis , a missed diagnosis , or a delayed diagnosis . This could include any failure in timely access to care; elicitation or interpretation of symptoms, signs, or laboratory results; formulation and weighing of differential diagnosis; and timely follow-up and specialty referral or evaluation.	Schiff, et al. (2009)
Missed opportunities to make a correct or timely diagnosis based on the available evidence, regardless of patient harm.	Singh, et al. (2014)
The failure to : (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient .	National Academy of Medicine (NAM) report (2015)

Diagnostic process

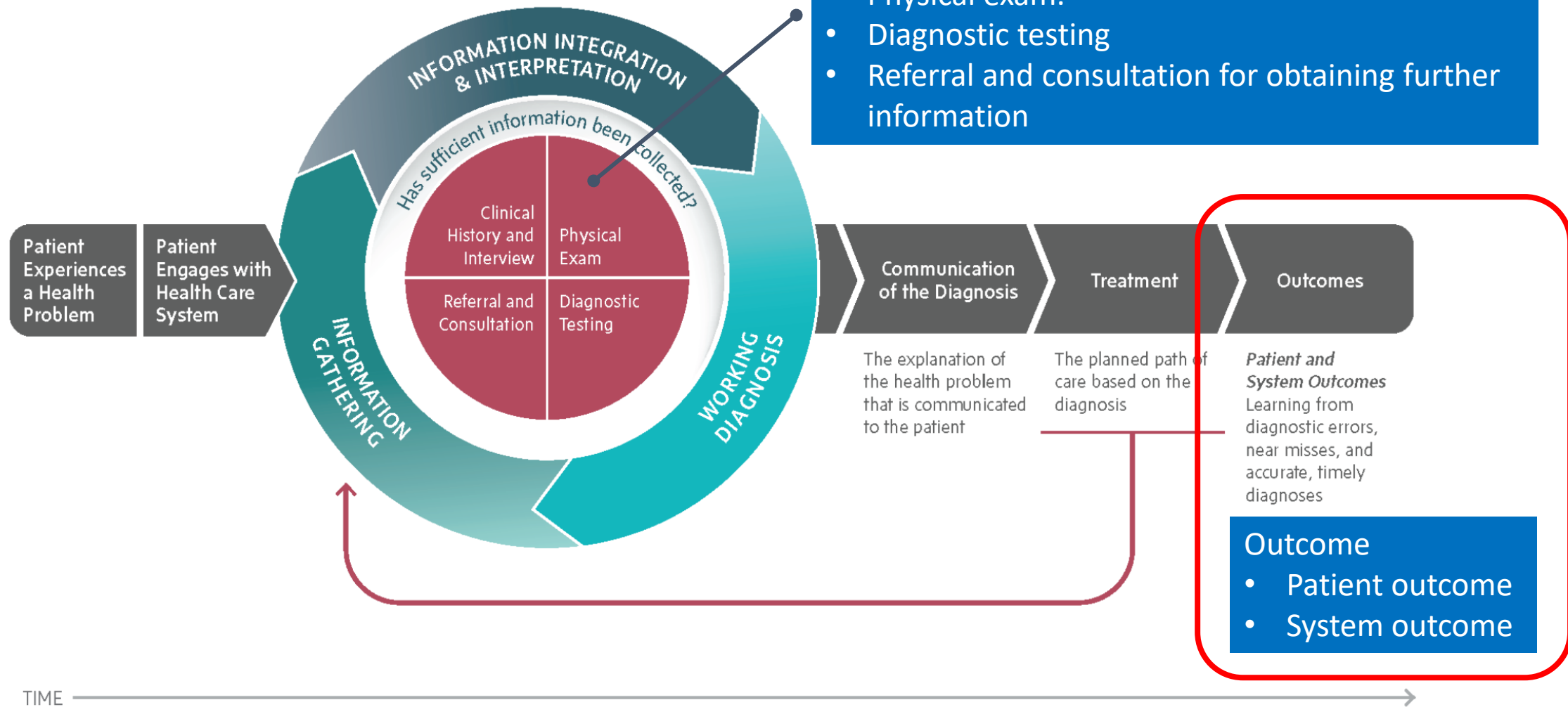


FIGURE S-1 The diagnostic process.

Committee on diagnostic error in health care, The National Academy of Sciences, 2015



The outcome from the diagnostic process

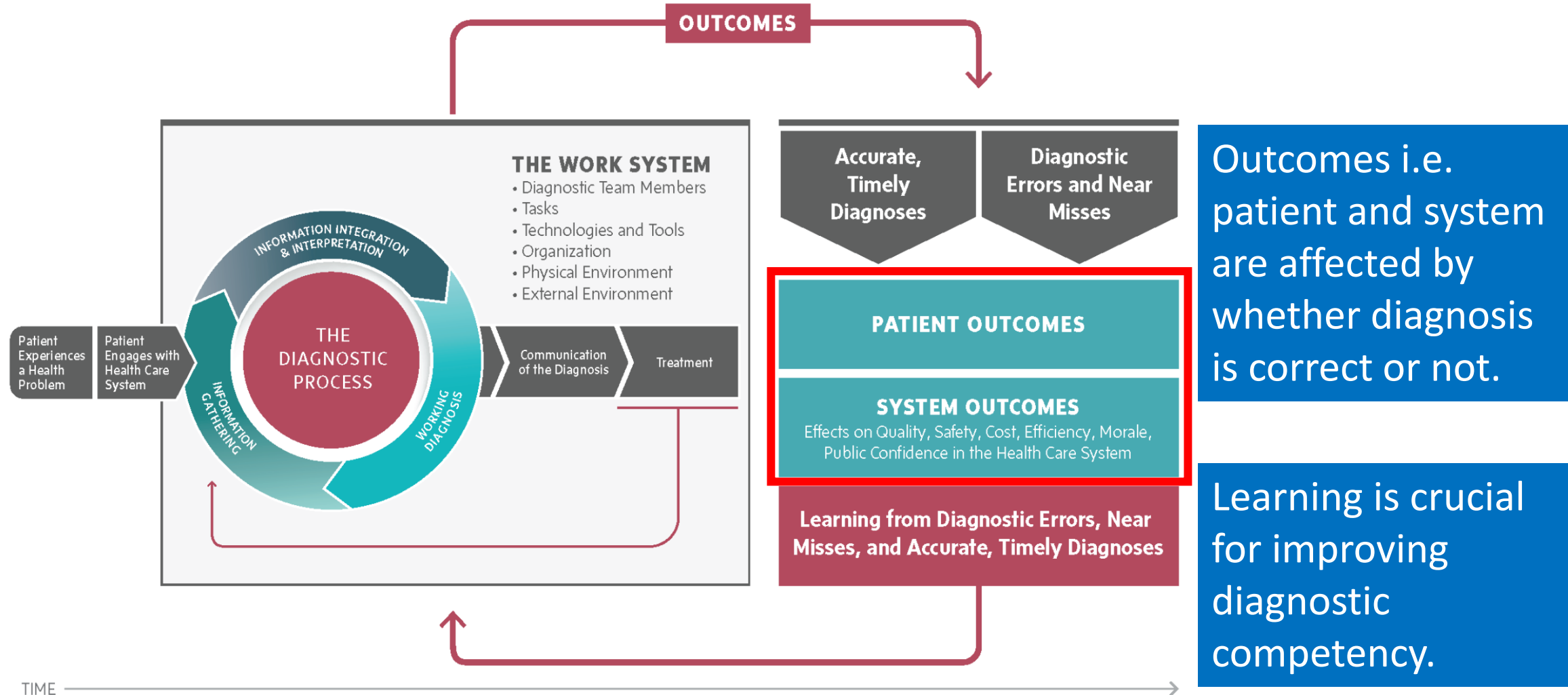


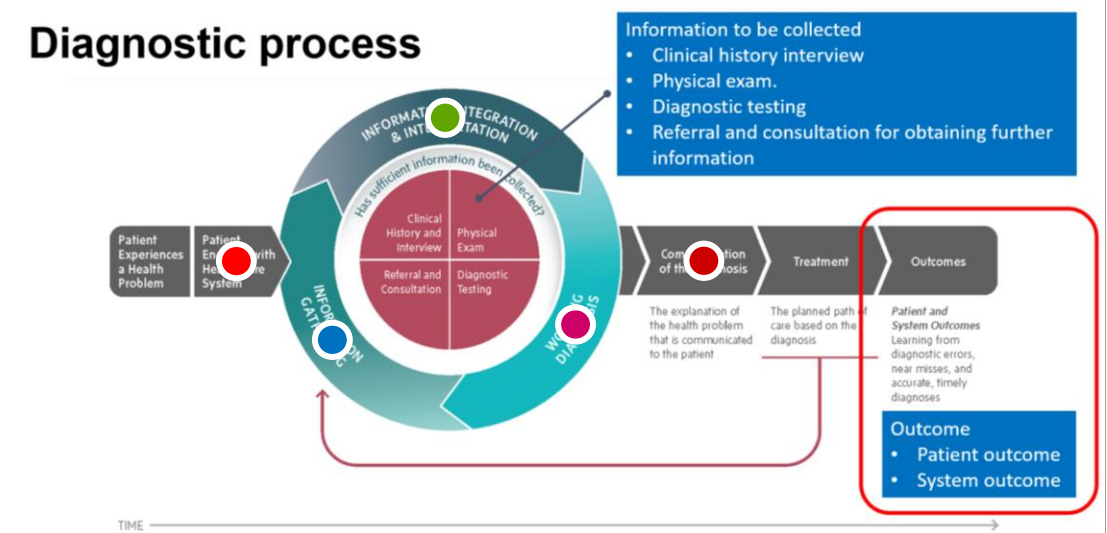
FIGURE S-3 The outcomes from the diagnostic process. “Improving Diagnosis in Health Care”, National Academy of Medicine, US 2015



Where in the diagnostic process failure occurred

- Failure to engage in the health care system or in the diagnostic process ●
- Failure in information gathering ●
- Failure in information integration ●
- Failure in information interpretation ●
- Failure to establish an explanation (diagnosis) ●
- Failure to communicate the explanation to the patient ●

Diagnostic process



“Improving Diagnosis in Health Care”, National Academy of Medicine, US 2015

Disease susceptible to diagnostic error

- Data about the most common conditions involved in diagnostic errors are mainly from high-income countries. A systematic review identified diagnostic difficulties and errors in primary care among people with **cancer, heart attack, meningitis, dementia, iron deficiency anaemia, asthma, tremor in the elderly** and **human immunodeficiency virus (HIV)**.*
- A study of 190 cases of diagnostic errors found that errors were common in patients with **pneumonia (7%), decompensated congestive heart failure (7%), acute renal failure (5%), cancer (5%)** and **urinary tract infection (5%)**.**
- Another study identified errors most commonly involving **infections, trauma** and **malignant neoplasms**.
- Overall, it appears that missed cancer, infections and cardiovascular disease comprise the leading categories of harmful diagnostic errors in primary care. Each of these is explored briefly in turn.

* Kostopoulou O, Delaney BC, Munro CW. Diagnostic difficulty and error in primary care - a systematic review. Fam Pract. 2008;25(6):400-13. 2

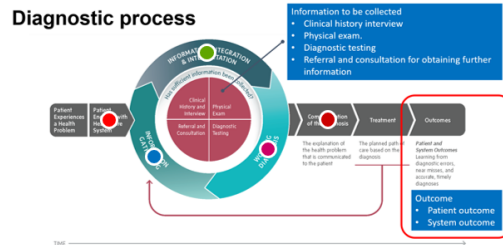
** Singh H, Giardina TD, Meyer AND, Forjuoh SN, Reis MD, Thomas EJ. Types and origins of diagnostic errors in primary care settings. JAMA Intern Med. 2013;173(6):418-25.

“Diagnostic errors_Technical series of primary care” WHO 2016

Diagnostic dilemma/challenges

Where in the diagnostic process failure occurred

- Failure to engage in the health care system or in the diagnostic process ●
- Failure in information gathering ●
- Failure in information integration ●
- Failure in information interpretation ●
- Failure to establish an explanation (diagnosis) ●
- Failure to communicate the explanation to the patient ●



“Improving Diagnosis in Health Care”, National Academy of Medicine, US 2015

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Diagnostic error happen in ordinary practices and settings.

Why diagnostic error happens? - causes of diagnostic errors

Factors

Possible issues contributing to error

Access to high quality

Limited access due to lack of money, remoteness, illiteracy, travel constraints or a limited number of health care facilities.

Availability of health care professionals and specialists

Lack of sufficient, competent health care professionals, for example, due to lack of training, outward migration or a poor employment situation.
Specialty expertise may not exist or may be limited in number or quality.

Teamwork

Poor teamwork, lack of learning and feedback when errors occur.

Availability of diagnostic tests

Diagnostic tests limited in scope, availability or quality.

“Diagnostic errors_Technical series of primary care” WHO 2016

Causes of diagnostic errors (Cont'd)

Factors

Possible issues contributing to error

Communication

Little or no sharing of medical information.

Care coordination

Consultations delayed or test results lost or a lack of health records documenting care.

Follow-up

Limited follow-up reduces the ability for diagnostic impressions to evolve.

Affordability of care

Care unaffordable or compromises other basic needs such as food or housing.

Training of health care providers

Training is suboptimal, in particular lack of training for clinical reasoning; certification and licensure requirements are deficient.

“Diagnostic errors_Technical series of primary care” WHO 2016

Causes of diagnostic errors (Cont'd)

Factors	Possible issues contributing to error
Availability of health informatics resources	Health informatics resources, including internet access, may not be available, especially in remote areas; unaffordable subscription or download fees for medical information.
Culture	Some cultures may be punitive, which discourage sharing and inhibit learning; physician-centric systems limit the value of the team. Patients may feel it is more appropriate to be passive care recipients.
Human factors and cognitive issues	Cognitive issues such as “bias” may lead too early diagnosis, premature diagnosis, groundless diagnosis and more erroneous outcomes.

“Diagnostic errors_Technical series of primary care” WHO 2016

Relevant biases to cause diagnostic error

Premature closure Early conclusion of diagnosis unless necessary exams are carried out thoroughly.

Patient underwent sudden lumber pain for the first time. The physician diagnosed the patient with “Ureterolithiasis (Ureteral stone) without performing ultrasonography and CT scan.

Confirmation bias Focusing only on clinical findings of the physician’s concern.

Physician predicts that ureterolithiasis is likely as diagnosis. He/She favored that urine test revealed hematuria, while ignoring findings of neither dilated ureter nor hydronephrosis in ultrasonography. He/She clung to the notion that the lack of those findings is not enough to reconsider the diagnosis.

“Learning of diagnostic error” NIKKEI Medical 2021

Relevant biases (Cont'd)

Base rate neglect	Intentional estimation of high-likelihood of the diagnosis regardless of the evidence-based incidence.	<i>Physician considers the diagnosis “Pulmonary embolism” most likely for a patient at the age 20 suffering sudden and mild chest pain without any similar symptom in clinical history.</i>
Availability heuristic*	Prioritization of a diagnosis which the physician has frequently diagnose patients with.	<i>Physician instantly diagnose a patient with influenza infection whom he/she sees first, while he/she has seen massive patients contracted with influenza virus in epidemic winter season.</i>

*heuristic: Instinctive decision-making, judgement and assessment instead of those conducted logically.

“Learning of diagnostic error” NIKKEI Medical 2021

Relevant biases (Cont'd)

Overconfidence

Strong conviction on knowledge beyond actual knowledge level and early conclusion without adequate information gathering and integration

Physician cannot provide rationale to periodical fever syndrome of the patient, however, the physician concludes that it is caused by “familial Mediterranean fever” and commences treatment without conducting any test or examination for other diagnoses.

“Learning of diagnostic error” NIKKEI Medical 2021



Potential solutions to diagnostic errors

I. Direct solutions;

- Improving education and skills
- Empowering and Engaging patients/families
- Improving health systems
- Improving testing i.e. access, ordering and processing, result management, closing the loop of entire testing processes
- Health information technology

II. Indirect solutions;

- Learning from errors e.g. learning of biases and generate measures to reduce them
- Further research/closing knowledge gap; sources of data, globally joint action, measurement of diagnostic error, diversity in diagnostic settings i.e. well known in areas as primary care, pediatric care, not known in other areas as surgery, psychiatry and psychology.

“Current State of Diagnostic Safety: Implications for Research, Practice, and Policy ” AHRQ US 2024

“Diagnostic errors_Technical series of primary care” WHO 2016

Collective actions at all levels to address “Delayed diagnosis”

■ Institutional level

- Team-based approach
- Engaging patient/family

■ National level

- National reporting and learning system
- National Investigation system
- No-fault compensation system
- Hospital group i.e. leading hospital approach



Case 1: Delayed Diagnosis of Hepatitis B Virus Reactivation -Institutional level approach



県がんセンターは13日、B型肝炎ウイルスに感染し昨年6月から悪性リンパ腫の治療を受けた70代男性患者に、肝炎の適切な検査と治療をせず、今年1月に死亡させた医療事故があったと発表した。今後、50代男性主治医を処分する方針。同センターによると、男性は昨年6月に悪性リンパ腫の治療で来院し、検査でB型肝炎に感染していると

判明。主治医は7〜10月、抗がん剤治療と並行してB型肝炎のウイルスが増えているか検査し、適切な治療をする必要があったが、怠った。男性は今年1月に肝不全で亡くなった。同センターの岩田広治副院長は「B型肝炎を確認し続けているか確かめる仕組みはなかった」と説明した。今後、遺族と損害賠償の協議を進める。

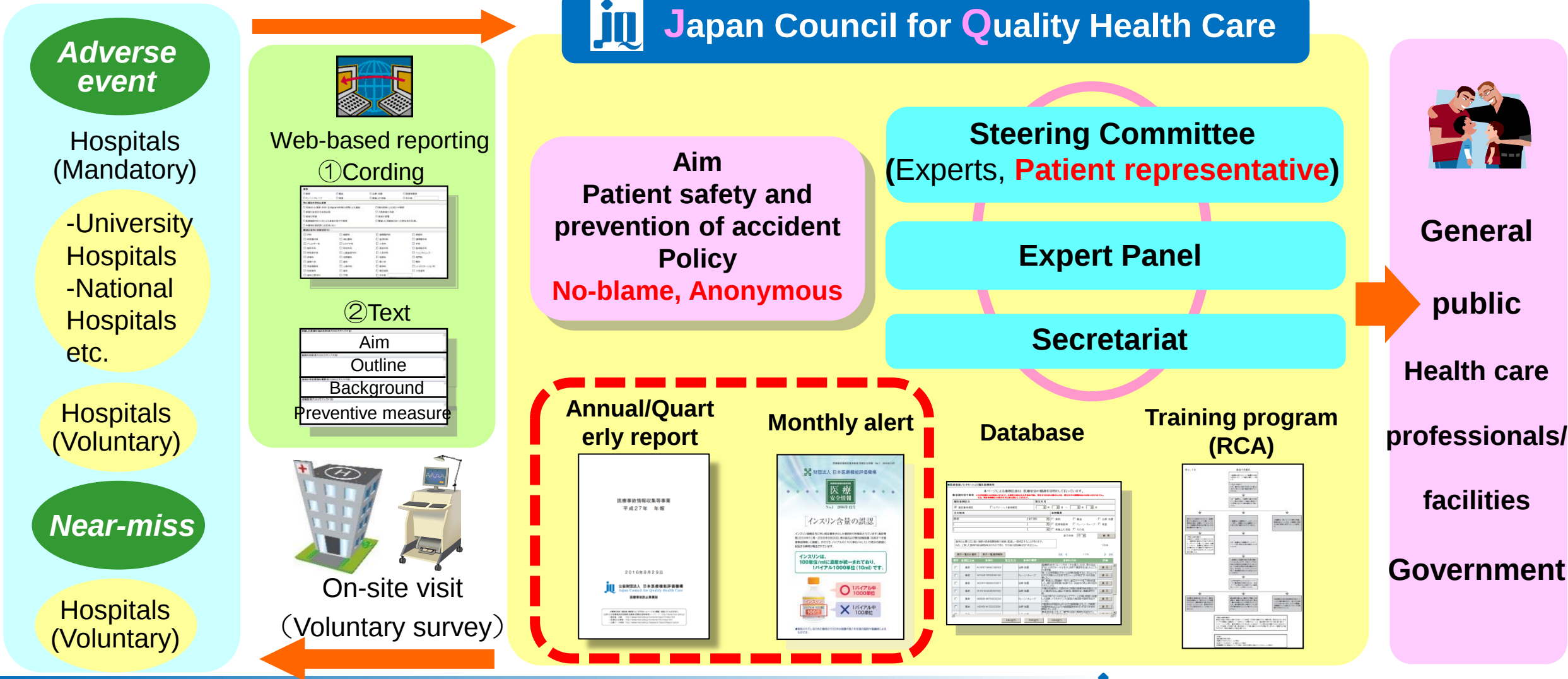
2019.11.14 ASAHI SHIMBUN (Newspaper)

適切な治療せず 70代男性が死亡 県がんセンター

Patient in his 70s died at “AICHI Cancer Center” because he was not provided with appropriate care.

- The patient was diagnosed with malignant lymphoma. He turned to be positive for HBV.
- He underwent chemotherapy during Jul to Oct 2019, while no test was conducted to see if HBV is reactivated.
- The patient finally suffered HVB hepatitis and died due to liver failure.
- The vice president said, “There was no systematic response to the reactivation”.

Overview of the nationwide adverse event reporting/learning system (2004 -)



JQ's Monthly Alert: No.171, Reactivation of Hepatitis B Due to Immunosuppression / Chemotherapy, Feb 2021

Project to Collect Medical Near-Miss/Adverse Event Information

Medical Safety Information

No.171, February 2021

Reactivation of Hepatitis B Due to Immunosuppression/Chemotherapy

Thirteen cases have been reported in which patients were affected by the reactivation of the hepatitis B virus (HBV) due to immunosuppression/chemotherapy as a result of the failure to carry out screening or monitoring, or the halting of administration of nucleos(t)ide analogue preparations (information collection period: from January 1, 2017 to December 31, 2020). This information was compiled on the basis of the content featured in the Recurrence of Events and Occurrence of Similar Events section of the 48th Quarterly Report.

Cases have been reported in which patients were affected by the reactivation of HBV due to immunosuppression/chemotherapy.

Examination/Treatment Process	Factors	Main Background Factors
HBs antigen screening	Not carried out	HBs antigen screening was not carried out before starting immunosuppressants
HBc antibody/HBs antibody test	Not carried out	HBs antigen screening was not carried out, because the patient had a history of using immunosuppressants under their previous physician
HBV DNA quantitative test	Not carried out	The HBc antibody/HBs antibody tests conducted for those who test negative for HBs antigen in screening were not carried out
HBV DNA quantitative level & AST/ALT monitoring	Not carried out	The HBV DNA quantitative test was omitted due to inadequate checks of the outpatient blood collection order
Administration of nucleos(t)ide analogue	Administration halted	Nobody noticed that the HBV DNA quantitative test had not been carried out, as the hospital had no mechanism for checking regular monitoring

Administration was not continued, because the department of gastrointestinal medicine was not contacted at the time of discharge from the otorhinolaryngology department

Project to Collect Medical Near-Miss/Adverse Event Information

Medical Safety Information

No.171, February 2021

Reactivation of Hepatitis B Due to Immunosuppression/Chemotherapy

Case 1
A patient with rheumatoid arthritis since a few years earlier, who had been treated with immunosuppressants, was admitted to the department of hepatobiliary and pancreatic medicine. After a blood test revealed high levels of HBs antigen, the patient was admitted to the department of hepatobiliary and pancreatic medicine. After a blood test revealed high levels of HBs antigen, the patient was admitted to the department of hepatobiliary and pancreatic medicine. After a blood test revealed high levels of HBs antigen, the patient was admitted to the department of hepatobiliary and pancreatic medicine.

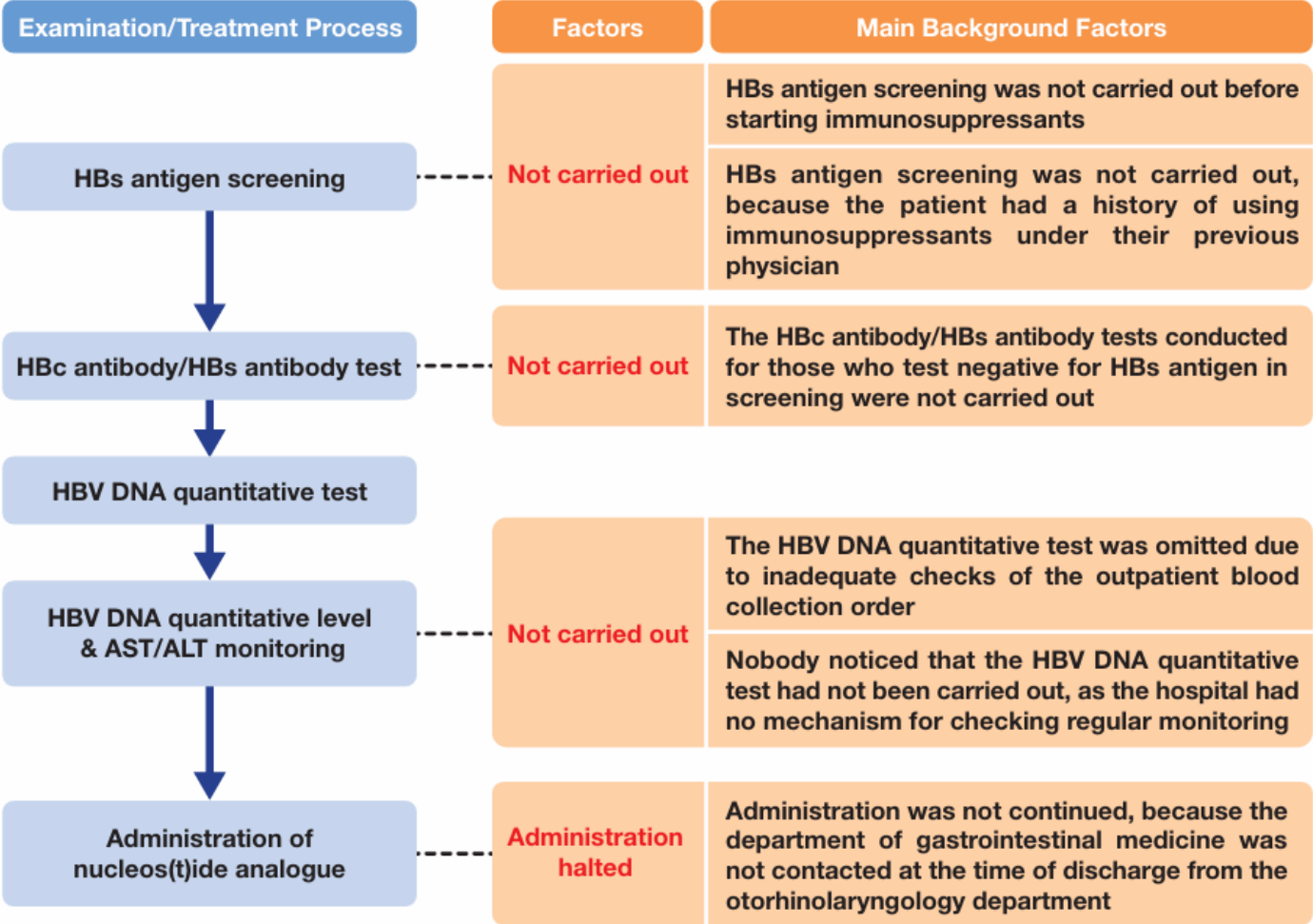
Case 2
A patient with acute lymphoblastic leukemia since a bone marrow transplant for acute lymphoblastic leukemia found the patient to have liver damage. After checking, the patient was found to have liver damage. After checking, the patient was found to have liver damage. After checking, the patient was found to have liver damage.

Medical institutions in which the events occurred
Medical staff are aware that immunosuppression/chemotherapy can lead to the reactivation of HBV. They should inform them of the Guidelines for the Management of Hepatitis B Virus Infection.

Preventive Measures
Require caution in respect of the reactivation of HBV in screening mechanism.
(Comprehensive Evaluation Panel)

Event Information (a Ministry of Health, Labour and Welfare grant project), the information collected in the Project as well as an opinion of the "Comprehensive Evaluation Panel" will be published on the JQ website for details.
The information is for reference only and cannot be guaranteed in the future.
Healthcare providers are to assume certain obligations or responsibilities on them.

Ministry of Health, Labour and Welfare
Japan Council for Quality Health Care
1-1-1, Chiyoda-ku, Tokyo 100-0001 JAPAN
03-3217-0252 Direct Fax: 03-3217-0253
info.jq.jp



HBV reactivation case in Kyushu University Hospital (KUH)

- The patient underwent **living-donor kidney transplantation**. Blood group was matched between donor and the patient.
- Prior to the surgery, the patient proved to be high-risk because Flow Cytometry Cross-matching (FCXM) unveiled that recipient plasma contains anti-donor lymphocyte antibody against both T-cell and B-cell. It was known that immunosuppressant therapy after surgery was difficult in the presence of the anti-donor lymphocyte antibody. Therefore, the patient underwent plasma exchange and administration of **Ritsuxan[®] for immunosuppression**. In addition, the patient began to take such immunosuppression as **Graceptor[®] capsule, Cellcept[®] capsule, Medrol[®] tablet and Simulect** i.v. injection two weeks before the surgery and later.

HBV reactivation case in Kyushu University Hospital (KUH)(cont'd)

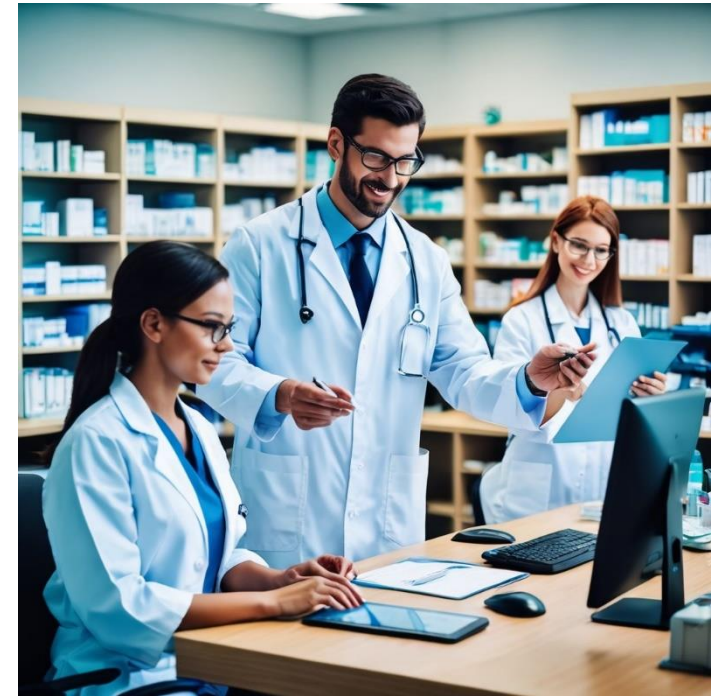
- Hepatitis B blood test in advance of the surgery revealed that;
 - HBsAg (hepatitis B surface antigen); NEGATIVE
 - **HBcAb or anti-HBc (hepatitis B core antibody); POSITIVE**
 - HBV-DNA; NEGATIVE

Past infection and no current reactivation of HBV
- Clinical course after surgery was smooth with **three immunosuppressants** as Graceptor[®] capsule, Cellcept[®] capsule, Medrolr[®] tablet. The patient visited hospital on weekly basis and underwent HBV blood test until four months after surgery. Physician in charge then made the visit interval longer to two weeks. **Eight months after surgery**, the blood test revealed elevated liver enzymes such as AST 79 and ALT 104. Additional test unveiled **HBsAg; POSITIVE and HBcAb; POSITIVE, HBV-DNA; ABOVE UPPER LIMIT**. The patient was urgently admitted to hospital due to probable “de novo reactivation of Hepatitis B virus”.



Launch of the team for prophylactic action to “de novo HBV reactivation”

- The hospital director took the lead in launching a team to tackle with this issue.
- It is joined by experts of;
 - a. Liver disease,
 - b. Laboratory medicine, i.e. physician and technicians trained over hepatitis through prefectural education system under the Comprehensive Hepatitis Control Act.
 - c. Health informatics and electronic health record,
 - d. Patient safety e.g. physician, pharmacist in the division of patient safety,



Development of clinical management from on “de novo HBV reactivation control”

Plan for administering anti-immunosuppressant, anti-cancer drug, anti-rheumatic drug, molecular-targeted drug et cetera.

HBsAg measurement

POSITIVE

NEGATIVE

HBeAg · HBeAb · HBV-DNA
measurement

HBsAb · HBcAb measurement

Either of them
is POSITIVE

ALL NEGATIVE

Liver disease specialist
consultation

HBV-DNA
measurement

Administration of anti-
immunosuppressant etc. are
allowed as planned

Specialist advises;

- Prescription of Nucleotide analogue
- Laboratory test and Interval for monitoring

Monitoring;

- HBV-DNA every 1-3 months
- AST/ALT every 1-3 months

Development of “Alerting system” for positive viral marker on EHR (2017-)

- Message appears when physician opens the patient’s medical chart in question.
- Message “Caution: Patient is at risk of HBV reactivation.” pops up when either HBs Ag, HBs Ab or HBc Ab turn positive.
- The message is removed when the latest test result(s) turn negative.

The screenshot shows a medical software window titled 'エディタ(新規) - テスト カンエン33(0099020334)'. The window has a menu bar with '標準', '重要', '周知', '注意', and a dropdown menu. Below the menu bar, there is a header section with the text '【経過記録】 2017/06/02(金) 15:35' and '免疫感 外来'. Below this, there is a table with the following content:

01版:	2017/06/02(金) 15:35 医師)肝炎勧奨 医師01
作成:	2017/06/02(金) 15:35 作成者:医師)肝炎勧奨 医師01

Below the table, there is a list of items with checkboxes:

- #
- S
- O
- A
- P
- FREE

The main area of the window is labeled 'EHR image'. At the bottom, there is a box with the text 'Caution: Patient is at risk of HBV reactivation.' in blue. A blue arrow points from the text 'Caution: Patient is at risk of HBV reactivation.' in the list to the box.

Development of listing table of patients treated with high-risk medication on EMR (2018-)

Navigation (Dashboard)> VIEW TEST RESULTS> TEST RESULTS & TERS REPORT> FOLLOW-UP OF HBV REACTIVATION

EHR view (Dashboard)



Click “FOLLOW-UP OF HBV REACTIVATION”

肝炎フォローアップ一覧

指定なし 患者ID カナ検索 診療科

検索期間

初回チェック日 最終チェック日 状態更新日

2017/09/22 ~ 2017/09/28

オーダー医師

入院

HBc抗体 ☒ 陽性 ☐ 陰性 ☐ 未検査

HBV-DNA ☒ 陽性 ☐ 陰性 ☐ 未検査

閉じる

一覧印刷 ファイル出力 検索条件

患者ID	患者名	診療科	入院	医師	HBc抗体結果	HBc抗体検査日	HBV-DNA抗体結果	HBV-DNA検査日
0099020598	テスト カンエン59	放射線科	入院	富士通 医師	-	2017/05/01	+	2017/05/01
0099020512	テスト カンエン51	放射線科	外来	富士通 医師	+	2017/05/01	+	2017/05/01
0099020521	テスト カンエン52	放射線科	外来	富士通 医師	-	2017/05/01	-	2017/05/01
0099020539	テスト カンエン53	放射線科	外来	富士通 医師	-	2017/05/01	+	2017/05/01
0099020113	テスト カンエン11	放射線科	外来	富士通 医師	+	2017/05/01	-	2017/05/01
0099020105	テスト カンエン10	放射線科	外来	富士通 医師	+	2017/05/01	+	2017/05/01

Date of test, Test result (positive/negative);

- HBsAg/Ab,
- HBcAb,
- HBV-DNA

Prescription date of high-risk medication

Physician to prescribe high-risk medication

Patient name

Patient's ID

Clinical dept.

Staff education and training on de novo HBV reactivation control through E-learning system

I. Essential subject line (“MUST LEARN”)

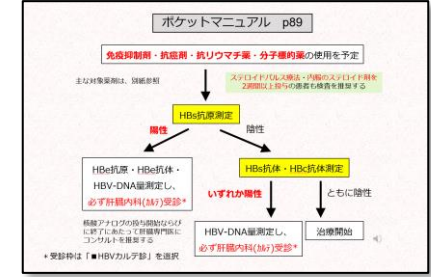
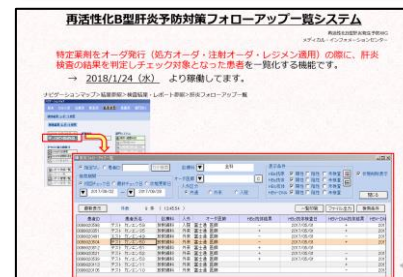
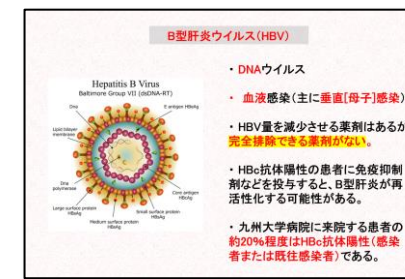
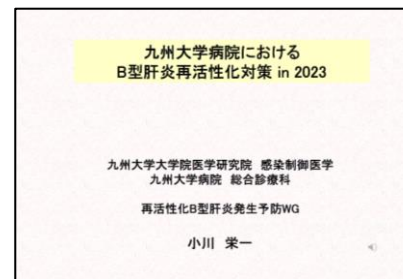
- Patient safety in Kyushu University Hospitals – outlining patient safety manual

II. Selective subject lines (at least one lecture to take)

- De novo HBV reactivation control →
- VTE Prevention
- Response to disputable incident
- Delirium prevention
- Medication safety
- Lessons of recent incidents



E-learning Platform



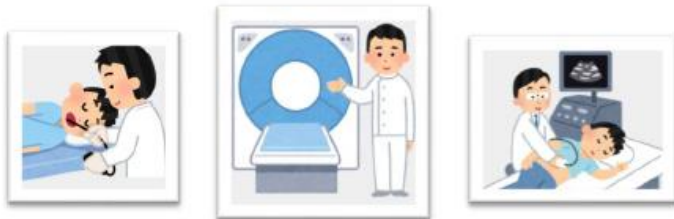
Enlightening and engaging patient/family on sharing test/exam results

検査のあとは、
結果を聞き、診断を受けましょう

“Please be mindful of your test/exam results and ask your doctor about it.”

あなたに関する、大切な情報です。
検査後は、受診してください。
どうしても来院できない場合は、ご相談ください。

“Test/examination results not issued today is vital information for you. Please visit us again for being informed of it, otherwise, please call us on the phone.”



より専門的な診断が必要な検査では
結果が出るまでに数日かかることもあります。

“It would take days to get result of highly specialized test/exam.”



九州大学病院 医療安全管理委員会 2018年9月

Relation to general knowledge on diagnostic error of specific incident:

“HBV reactivation”

- Where in the diagnostic process failure occurred
 - a. Insufficient information gathering
 - b. Failure in information integration
 - c. Failure in information interpretation
- Causes of diagnostic error
 - a. Teamwork
 - b. Care coordination
 - c. Lack of training provider
 - d. Availability of health informatics resources
 - e. Human factors and cognitive issues: Overconfidence e.g. *“Transplantation group have not only surgical skill but knowledge on care and follow-up of patient with previous history of HBV infection.”*





Case 2: Delayed Diagnosis of Cancer due to Failed Confirmation of Imaging Report - National level /Hospital group approach

- CT imaging reports mentioned to “**Cancer**”.
- The physician in charge ignored cancer in organs that he/she did not specialize in.
- **Nine similar cases** including **two fatal cases** were verified through internal investigation.
- Preventive measures should be in place in expedited manner.

Jun 09, 2018 YOMIURI SHIMBUN (Newspaper)

担当医「専門外」目届かず

CT報告書には「がん」

千葉大病院

がんの疑いの指摘が4年余りも見逃され、命が失われた。8日、千葉大医学部付属病院（千葉市中央区）が公表した画像診断の見落とし問題。コンピュータ断層撮影法（CT）検査の結果、治療対象でなかったがんの疑いが浮上しても、担当医が専門外の領域に目が行き届かないという盲点が次々と判明した。「同様のケースは各地の病院に埋もれている」との指摘も出てくる。

△本文記事一面▽

概要	治療への影響
60歳代女性（腎臓で死亡）	あり
70歳代男性（肺がんで死亡）	あり
50歳代男性	あり
60歳代男性	あり
80歳代女性	なし
30歳代女性	なし
50歳代女性	なし
80歳代男性	なし
50歳代男性	なし

CT検査結果を巡って診断の遅れが判明した9人の患者

千葉市中央区で8日午後だった。男性は2016年に行われた記者会見で、山本修一病院長は「患者と家族の皆様にも多大な負担とお心をおかけしたことをおわびする」と述べ、深く頭を下げた。患者や遺族には既に謝罪しており、金銭的な補償も検討するとした。

一連の問題が判明したきっかけは、50歳代の男性が昨年7月、肺がんの疑いで呼吸器内科を受診したこと。病院が全診療科で調査した結果、今年2月末までにCT検査結果を巡って計9人の患者について確認不足があった。

このうち死亡した男女2人は画像診断報告書の見落としの後、病状が判明した。手術もできない状態に悪化。4年余り治療が遅れ、腎臓で死亡した60歳代の女性について、市川智彦副病院長は会見で「その時点で治療したのであれば、経過に大きな違いがあったと考える。（報告書の見落としと死亡）因果関係がはっきりと言われれば、それとおわり」と述べた。

肺がんが死亡した70歳代男性については「死亡が早くなったという意味で因果関係はあった」とした。

CT画像は担当医が確認するとともに、放射線診断専門医に画像診断報告書の作成を依頼する。報告書には、治療対象の患部以外に関する所見も記載されるが、同病院は「担当医は専門領域については画像を見て診断するが、放射線診断専門医の報告書も合わせて確認するという認識が十分だった」と説明する。

同病院は外部の有識者による調査委員会の提言を受け、再発防止策に乗り出す。7月1日に画像診断センターを新設し、放射線診断専門医の常勤を5人増の10人体制にして担当医との連携を強化。患者に対しては画像診断報告書を確認してもらうなど説明を手厚くするほか、担当医による報告書の確認状況の管理を電子カルテのシステムで徹底する。

「他の病院でも起きていると考えるほうが自然」と専門家の間には、今回のような画像診断報告書の見落としは「氷山の一角」との見方がある。関西の大学の放射線科教授は「自分の専門領域以外は熱心に見ない、ということはい面もある。意思疎通の行き違いを防ぐシステム作りが必要だ」と指摘する。

慈恵医大病院は再発防止のため、報告書を主治医が確認し、必要に応じて放射線科事務員が2度に分けて、医師に念押しする仕組みを導入。報告書の内容に患者が誤りがあることを発見した場合、再発防止を徹底したい」としている。

厚労省は「あつてはならないことが、現実には起きている。再発防止を徹底したい」としている。

記者会見で謝罪する千葉大医学部付属病院の山本病院長（8日、千葉市中央区で）

山本修一病院長は「患者と家族の皆様にも多大な負担とお心をおかけしたことをおわびする」と述べ、深く頭を下げた。患者や遺族には既に謝罪しており、金銭的な補償も検討するとした。

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厚労省は「あつてはならないことが、現実には起きている。再発防止を徹底したい」としている。

Thematic analysis

再発・類似事例の分析

「画像診断報告書の確認不足」(医療安全情報 No. 63)

【2】「画像診断報告書の確認不足」(医療安全情報 No. 63)

(1) 発生状況

画像診断報告書の内容が伝達されなかった事例について、第26回報告書(2011年9月公表)において、画像診断報告書を見なかった事例と画像診断報告書の記載内容を見落とした事例に大別して分析を行った。その後、医療安全情報 No. 63(2012年2月提供: 集計期間: 2008年1月~2011年12月)では「画像診断報告書の確認不足」として、画像検査を行った際、画像診断報告書が報告されているにもかかわらず内容を確認しなかったため、想定していなかった診断に気付かず、治療の遅れを生じた可能性のある事例について取り上げた。さらに、第40回報告書(2015年3月公表)の「再発・類似事例の発生状況」において、医療安全情報 No. 63「画像診断報告書の確認不足」について、新たに報告された事例を紹介し、画像検査の目的と画像診断報告書を確認していなかった背景・要因について取りまとめた。

今回、本報告書分析対象期間(2017年7月~9月)においても類似の事例が13件報告されたため、再び取り上げることとした。第40回報告書の集計期間後の2015年1月以降に報告された再発・類似事例は32件であった(図表Ⅲ-3-4)。

図表Ⅲ-3-4 「画像診断報告書の確認不足」の報告件数

	1~3月 (件)	4~6月 (件)	7~9月 (件)	10~12月 (件)	合計 (件)
2015年	3	2	2	4	11
2016年	0	0	3	1	4
2017年	2	2	13	—	17

図表Ⅲ-3-5 医療安全情報 No. 63 「画像診断報告書の確認不足」

医療安全情報 No. 63

「画像診断報告書の確認不足」

画像検査を行った際、画像診断報告書を確認しなかったため、想定していなかった診断に気付かず、治療の遅れを生じた可能性のある事例が報告されています。

「画像診断報告書の確認不足」

事例

主治医は、胸部腫瘍専門医の画像診断報告書も確認し、治療方針の決定を促す。しかし、検査結果は「肺がん」であり、治療方針は「手術」であった。主治医は「肺がん」の診断に気づかず、治療方針を「手術」から「化学療法」に変更した。結果、治療の遅れを生じた。主治医は「肺がん」の診断に気づかず、治療方針を「手術」から「化学療法」に変更した。結果、治療の遅れを生じた。

Medical Safety Information, Project to Collect Medical Near-Miss/Adverse Event Information, No.63, February 2012

Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/Adverse Event Information

Medical Safety Information

No.63, February 2012

Inadequate Checks Concerning Diagnostic Imaging Reports

Three cases have been reported involving a situation in which, although the diagnostic imaging report had been delivered after having conducted imaging examinations, the content was not checked and the physician failed to notice a diagnosis that s/he had not anticipated, thereby giving rise to the possibility that treatment was delayed (information collection period: from January 1, 2008 to December 31, 2011; the information is partly included in "Individual Theme Review" (p.131) in the 26th Quarterly Report).

Cases in which, after having conducted imaging examinations, the physician failed to check the content of the diagnostic imaging report and did not notice a diagnosis that s/he had not anticipated, thereby giving rise to the possibility that treatment was delayed, have been reported.

Objective of the Imaging Examination	Content Not Checked
Thorough examination for the purpose of a catheter ablation	Suspected pulmonary adenocarcinoma
Follow-up after a synthetic blood vessel graft replacement	Suspected primary lung tumor
Follow-up for an internal iliac artery aneurysm	Suspected lung cancer

◆ All three reported cases involved a failure to check the diagnostic imaging report following a CT examination.

Medical Safety Information, Project to Collect Medical Near-Miss/Adverse Event Information, No.138, May 2018

Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/Adverse Event Information

Medical Safety Information

No.138, May 2018

Inadequate Checks Concerning Diagnostic Imaging Reports (1st Follow-up Report)

Information about inadequate checks concerning diagnostic imaging reports was provided in Medical Safety Information No.63 (February 2012). As 37 similar events have been reported since then, information about this issue is provided here again (information collection period: from January 1, 2015 to March 31, 2018). The information is compiled based on "Recurrence of Events and Occurrence of Similar Events" in the 51st Quarterly Report.

Cases have been reported in which treatment was delayed because the physician failed to check the diagnostic imaging report after checking the images, and therefore failed to notice findings other than those associated with the purpose of the examination.

Example of the imaging examination process

Radiology Department

Carry out imaging examination

Prepare images

Prepare diagnostic imaging report

Physician

Order imaging examination

View images

Explain to patient

View diagnostic imaging report

Explain to patient if additional explanation is required

Main Factors Behind the Failure to Check the Diagnostic Imaging Report

When the physician looked at the site that was the focus of the examination on the image and explained it to the patient, the diagnostic imaging report had not yet been prepared and the physician forgot to look at it later

The physician was not in the habit of viewing diagnostic imaging reports

CT and MRI examinations were carried out around the same time and the physician was able to confirm the diagnosis from the results of the MRI examination, so did not look at the diagnostic imaging report for the CT examination

The physician did not view diagnostic imaging reports because they were confident in their ability to interpret images in their field of specialization

The physician mistook a diagnostic imaging report dated the same month of the previous year for that day's report

◆ 36 of the 37 cases involved CT examinations.

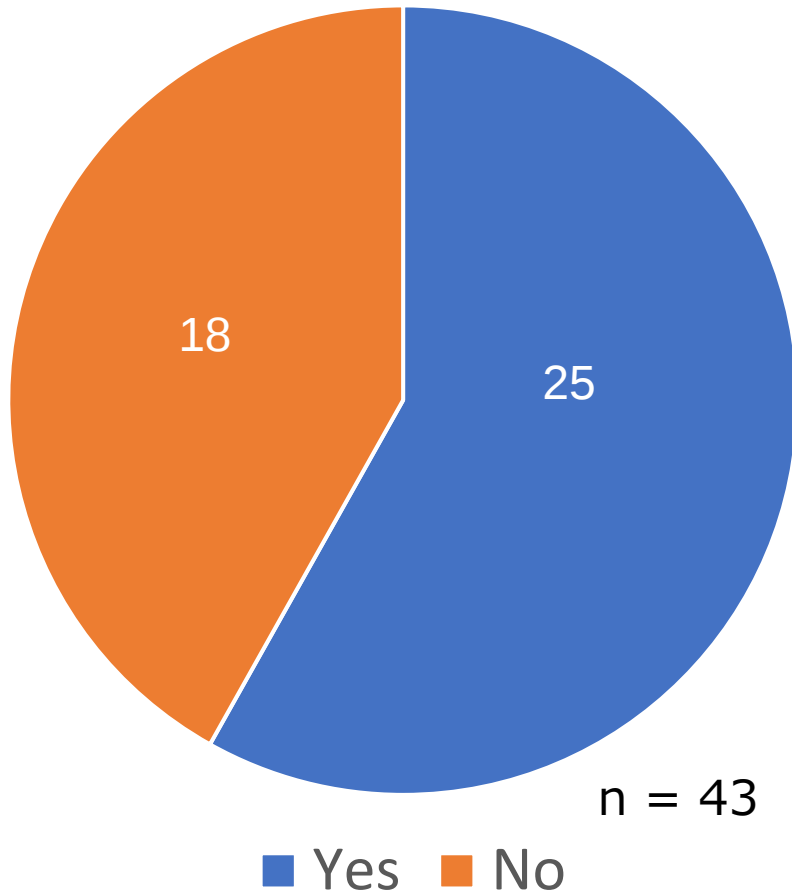
Preventative action by University Hospital Group

Japan **N**ational **U**niversity **H**ospital **A**lliance (**JANUHA**, Chair; Tokyo Medical and Dental University Hospital, Members; 45 National University Hospitals) carried out fact-finding survey; i) and ii) and conducted iii) in relation to physician's failure of confirming radiological imaging report;

- i. Questionnaire survey in 2017
- ii. On-site interim survey program in 2017
- iii. On-site survey program in **2021**



Q; “Is physician in charge reminded of a new imaging report issued by radiologist ?”

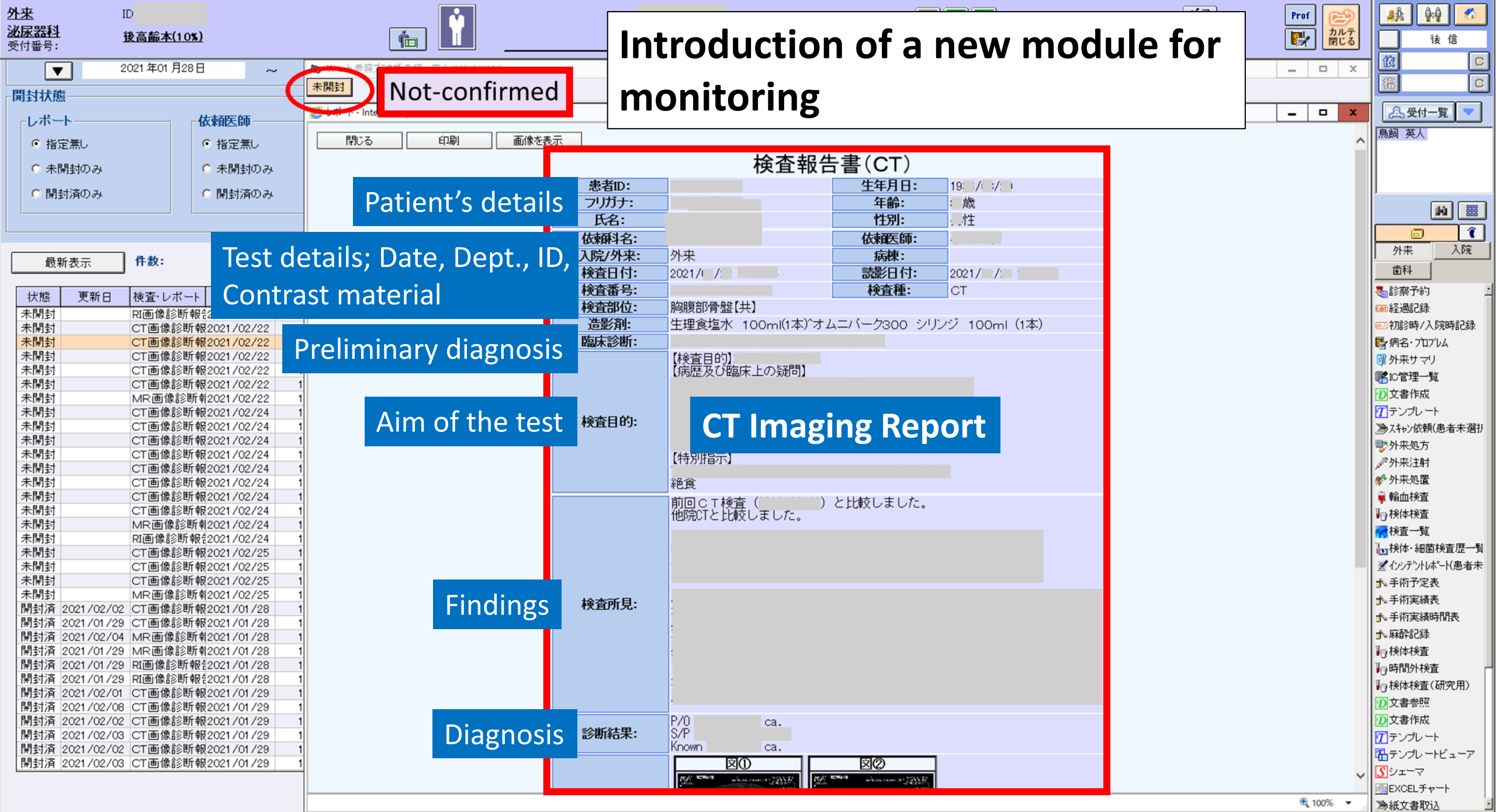


- Only 58% (25/43) institutions are installed with **notification system** on issuance of the imaging report.
- Physicians need to keep in mind that CT was ordered not to fail to refer to the report. **This could cause an error if the memory is lost.**



Notification system rapidly spread in the alliance during 2018-2020.

2017 JANUHA Report on “Patient Safety On-Site Visit Initiative” Report (Steering Committee, Presidents’ Council of National University Hospital, http://www.univ-hosp.net/guide_cat_04_22.pdf)



Introduction of a new module for monitoring

未開封 Not-confirmed

Patient's details

Test details; Date, Dept., ID, Contrast material

Preliminary diagnosis

Aim of the test

Findings

Diagnosis

検査報告書(CT)

患者ID:		生年月日:	19 / /
フリガナ:		年齢:	歳
氏名:		性別:	性
依頼科名:		依頼医師:	
入院/外来:	外来	病棟:	
検査日付:	2021 / /	読影日付:	2021 / /
検査番号:		検査種:	CT
検査部位:	胸腹部骨盤【共】		
造影剤:	生理食塩水 100ml(1本) オムニパーク300 シリンジ 100ml (1本)		
臨床診断:			
検査目的:	【検査目的】 【病歴及び臨床上の疑問】		
【特別指示】	絶食		
検査所見:	前回CT検査()と比較しました。 他院CTと比較しました。		
診断結果:	P/O ca. S/P ca. Known		

CT Imaging Report

Relation to general knowledge on diagnostic error of specific incident:

“Failed Check of Imaging Report”

- Where in the diagnostic process failure occurred
 - a. Insufficient information gathering
 - b. Insufficient information integration
 - c. Failure to communicate the explanation to the patient
- Causes of diagnostic error
 - a. Teamwork
 - b. Communication
 - c. Care coordination
 - d. Lack of training provider
 - e. Culture
 - f. Human factors and cognitive issues: Confirmation bias i.e. focusing only on findings of the physician's concern, Overconfidence *i.e. Physician believes in their competency of interpreting radiological imaging better than that of radiologist.*

Case 3: Delayed Diagnosis of Fetal Distress - National level /No-fault Compensation



No-fault compensation/investigation/ prevention system for cerebral palsy , 2009~)

No-fault compensation (Insurance)

Petition
(Report of CP) → Review → Payment

Proceeding irrespective of negligence

Investigation/Prevention with **Patient Representatives**

Medical chart,
Birth care record,
laboratory data, etc.

Family's Voices

Report

1.
2.
.....
.....
.....
.....
.....

20-30 pages

Prevention, early settlement of conflicts and
Improvement of quality

“Step-wise disciplinary action” to individual facility for quality improvement on condition of anonymity

Procedure which needs improvement is clearly mentioned in the Investigative report.



Report of Case **A**
urged to improve a
specific procedure

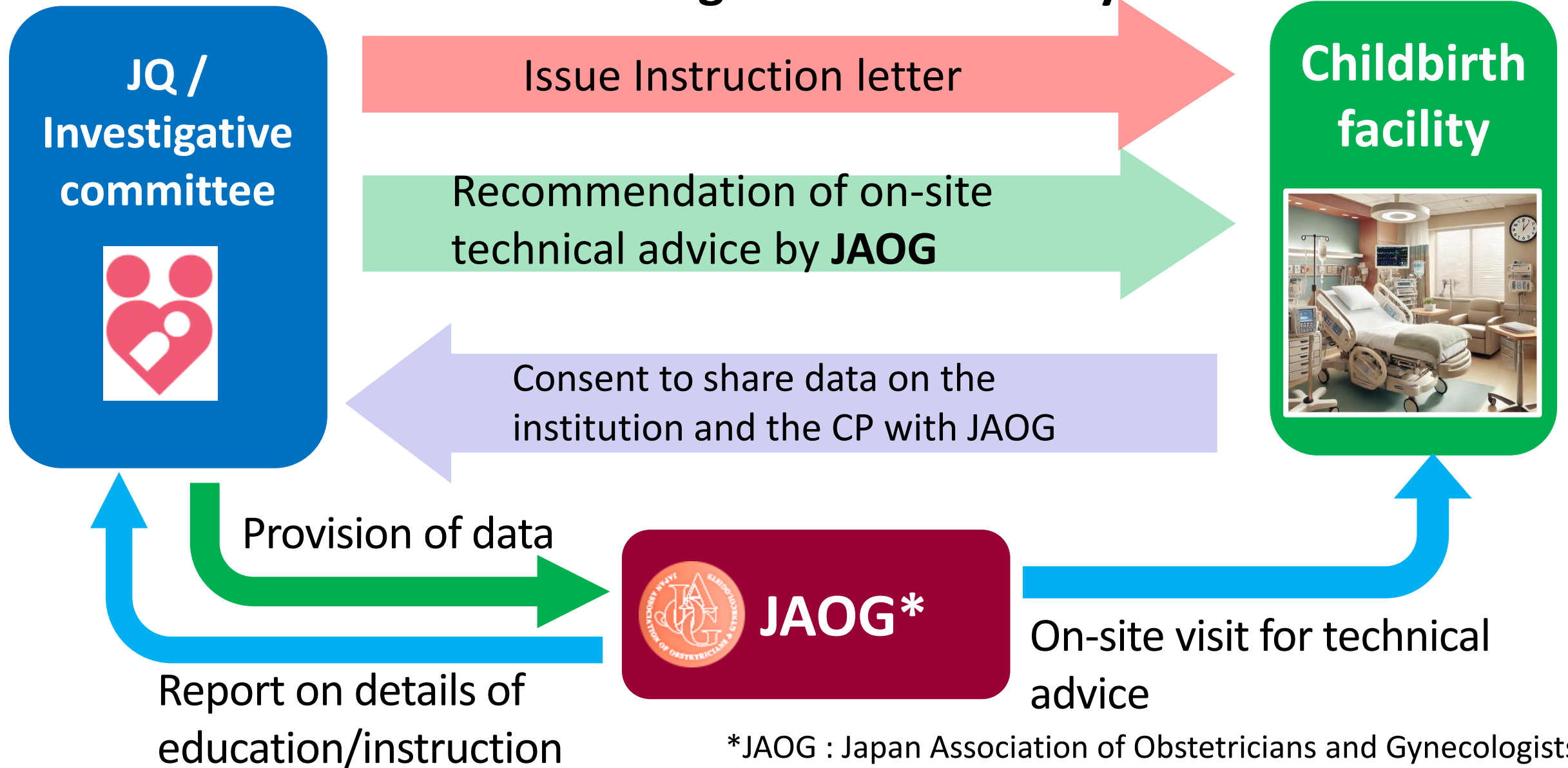
- i. Issue an “**Instruction letter***” to urge facility in question for improvement.
- ii. Request for returning “**Improvement report**” in which the facility describes implementation of improvement plan in detail.



Report of Case **B** also
urged same or similar
procedure for
improvement.

***One hundred and thirty-five** instruction letters were issued to childbirth facilities* (Statistics during Jan, 2009 - May, 2023).
Most frequent comments were made on **Fetal Heart Rate (FHR) monitoring interpretation.**

2020 New scheme for educating childbirth facility



*JAOG : Japan Association of Obstetricians and Gynecologists

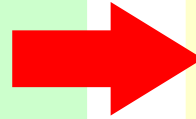
Workflow to publish “Prevention report”

Investigation committee

Report of “Individual case”



- ☐ Cause
- ☐ Appraisal
- ☐ Preventive measures

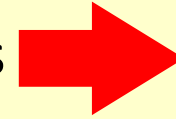


Prevention committee

Report of “Aggregated case reports”



- ☐ Collective analysis
- ☐ Thematic analysis
- ☐ Recommendations,
etc.

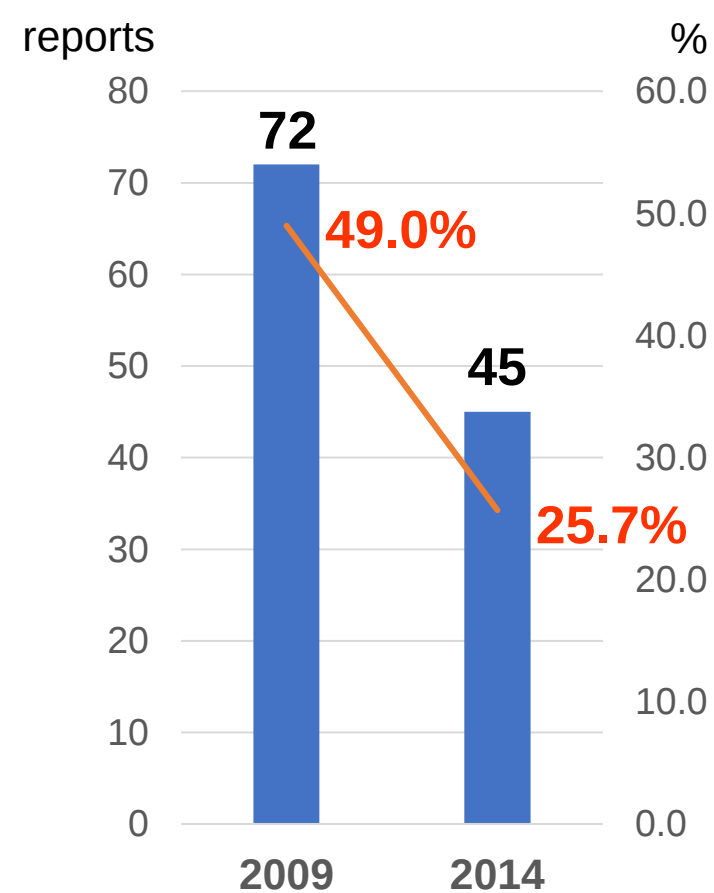


- A) Report; Delivered both to **family** and **childbirth facility**
- B) Synthesized report; Posted on the web
- C) Report with identifiers deleted; Available only for research use through internal ethical process

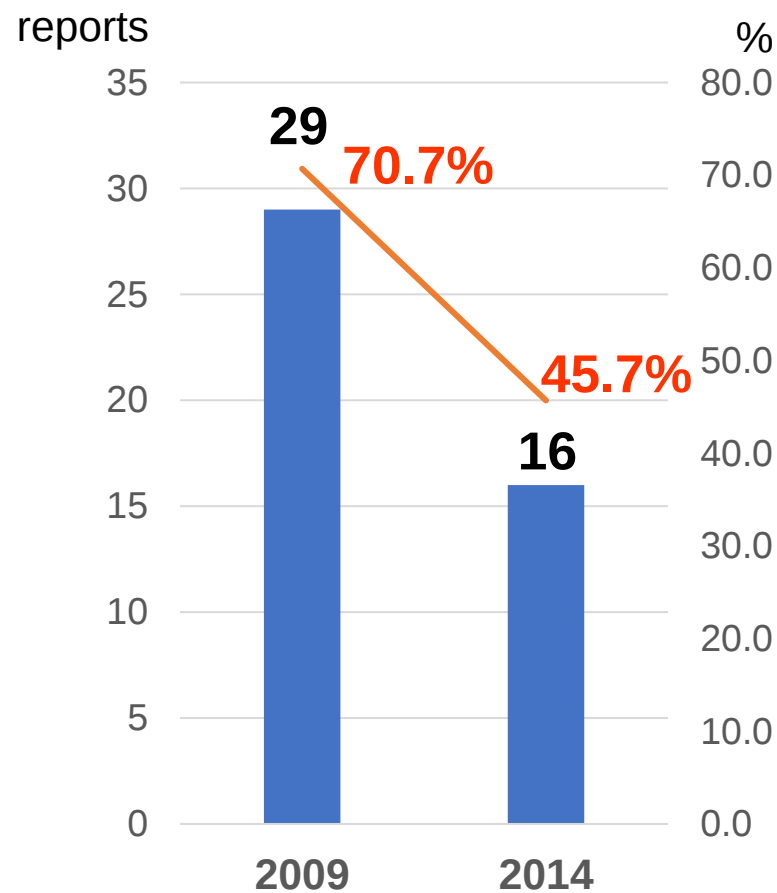
- A) Delivered to **Childbirth facility, Scientific societies, Government, etc.** for education.
- B) Posted on the web open to the public

Improvement of specific practices between 2009 and 2014

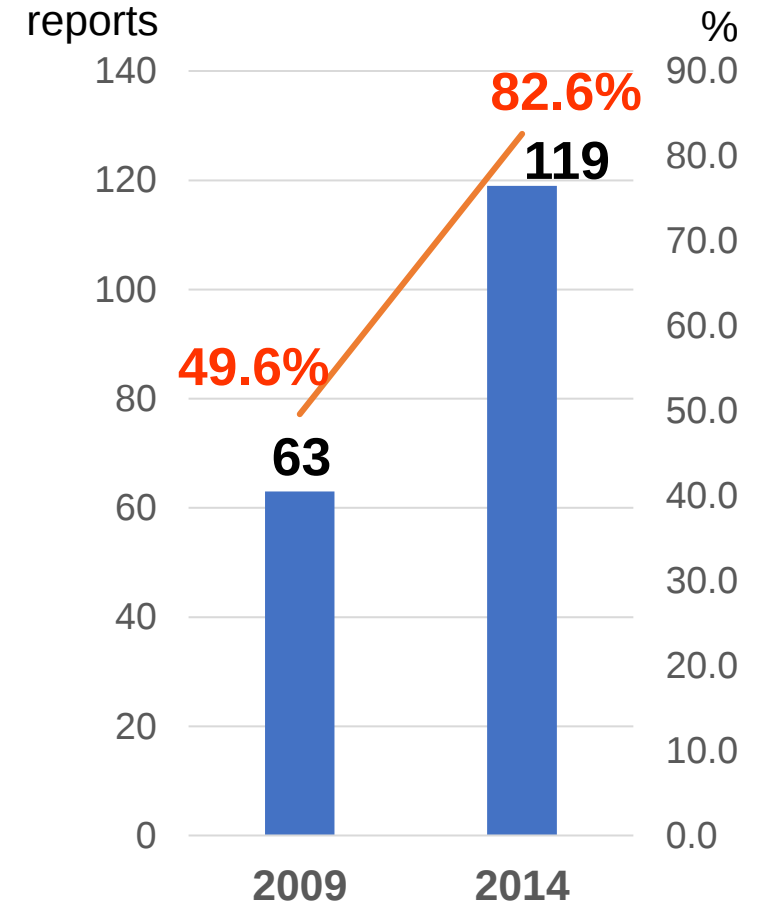
**Comment on FHR monitoring
for improvement**



Excess administration of oxytocin



**Mechanical ventilation
within 1 min after birth**



Educational material on CTG (Mar 2024)

第14回産科医療補償制度再発防止に関する報告書 別冊

脳性麻痺事例の 胎児心拍数陣痛図紹介集

—— 判読と対応を振り返る ——

Cardiotocogram (CTG) pattern on cerebral palsy

2024年3月

事例 1 〈解説〉

子宮収縮薬使用中に子宮頻収縮を認めたが、子宮収縮薬が増量された事例

事例の概要

〈基本情報〉

2 回経産婦

〈妊娠経過〉

血圧 134/93mmHg (妊娠 37 週)、140/89mmHg (妊娠 39 週)
胎児推定体重 2600g 台 (妊娠 37 週 0 日に計測)

〈入院前後の経過〉

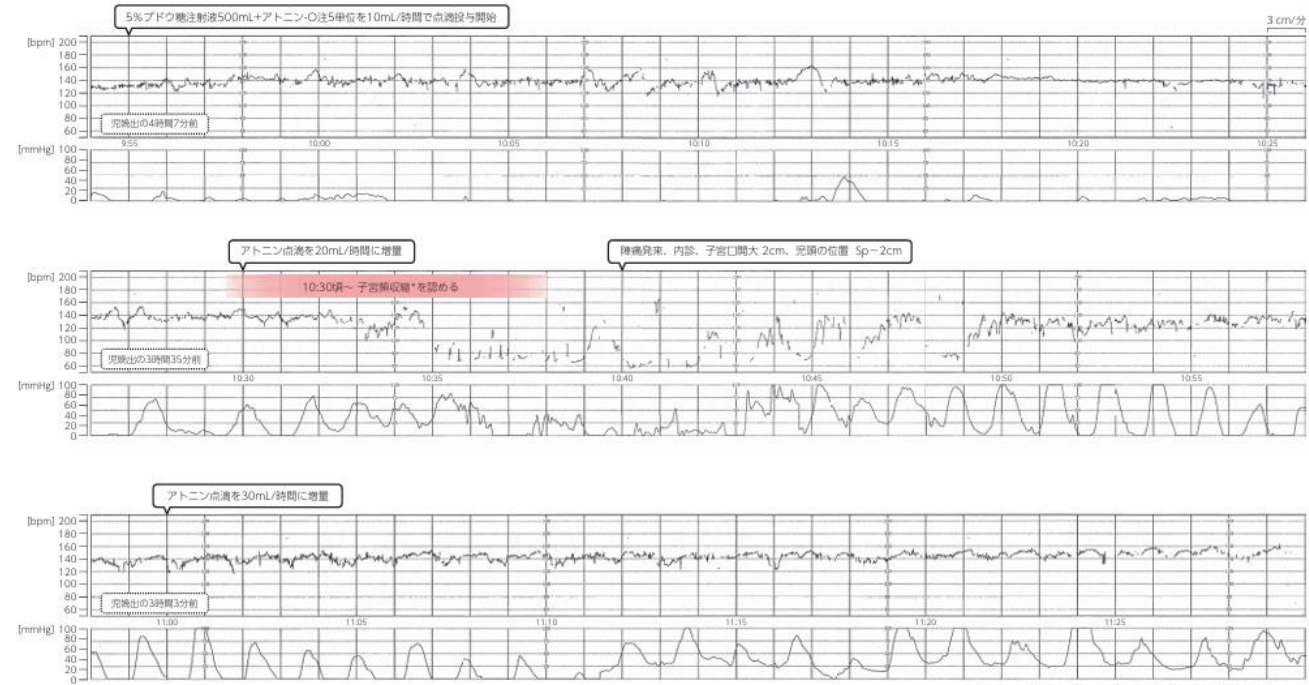
妊娠 39 週 1 日

時刻不明 内診、子宮口開大 3cm

9 時 30 分 妊娠高血圧症候群傾向のため分娩誘発目的で搬送元分娩機関に入院

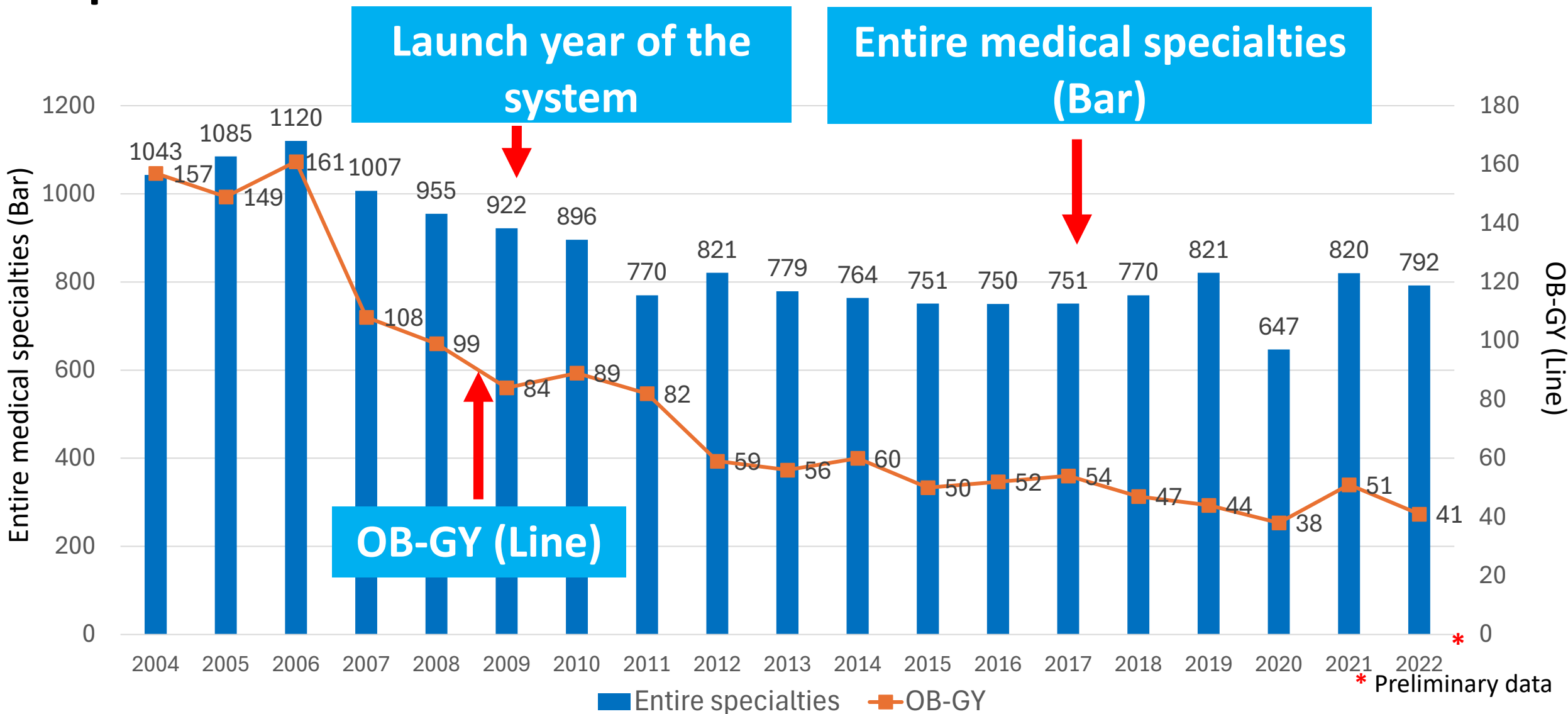
時刻不明 血液検査で白血球 4850/μL、ヘモグロビン 11.6g/dL、ヘマトクリット 36.3%、血小板 11.0×10⁴/μL、CRP 1.78mg/dL

①妊娠 39 週 1 日 (9:54~12:20)



The booklet is shared among academic/professional societies.

Impact on lawsuit statistics on OB-GY

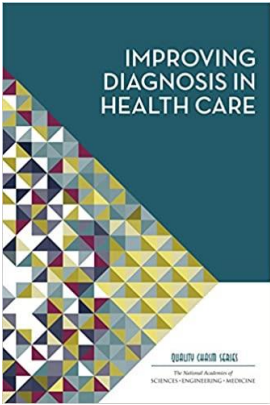


Statistics of lawsuit trend by medical specialties by the Supreme Court.

Relation to general knowledge on diagnostic error of specific incident:

“Fetal Distress”

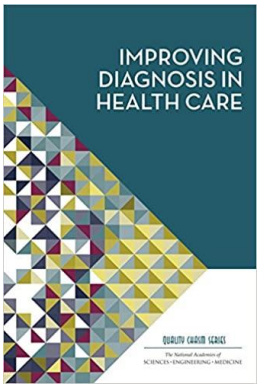
- Where in the diagnostic process failure occurred
 - a. Failure in information integration
 - b. Failure in information interpretation
- Causes of diagnostic error
 - a. Teamwork
 - b. Training of healthcare provider
 - c. Availability of health informatics resources
 - d. Human factors and cognitive issues: Premature closure, Confirmation bias



Diagnostic error reduction

The committee concluded that a sole focus on diagnostic error reduction will not achieve the extensive change necessary; **a broader focus** on improving diagnosis is warranted.

“Improving Diagnosis in Health Care”, National Academy of Medicine, US 2015

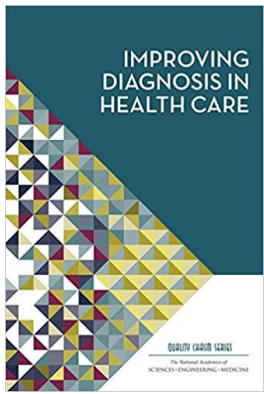


Develop a Reporting Environment and Medical Liability System That Facilitates Improved Diagnosis by Learning from Diagnostic Errors and Near Misses

Reporting

- Conducting analyses of diagnostic errors, near misses, and adverse events presents the best opportunity to learn from such experiences and implement changes to improve diagnosis.
- There is **a need for safe environments**, without the threat of legal discovery or disciplinary action, to analyze and learn from these events.

“Improving Diagnosis in Health Care”, National Academy of Medicine, US 2015



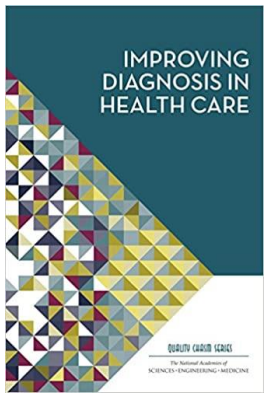
Develop a Reporting Environment and Medical Liability System That Facilitates Improved Diagnosis by Learning from Diagnostic Errors and Near Misses

Medical Liability

- The core functions of medical liability are to compensate negligently injured patients and to promote quality by encouraging clinicians and organizations to avoid medical errors.
- The current approach for resolving medical liability claims sets up **barriers to improvements in quality and patient safety.**
- While medical liability is broader than diagnosis, **diagnostic errors are the leading type of paid medical malpractice claims.**

“Improving Diagnosis in Health Care”, National Academy of Medicine, US 2015





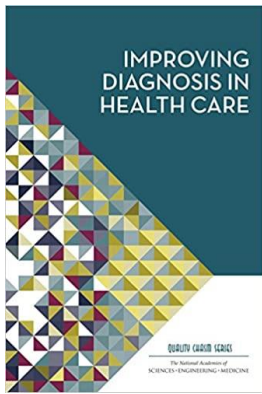
Develop a Reporting Environment and Medical Liability System That Facilitates Improved Diagnosis by Learning from Diagnostic Errors and Near Misses

Medical Liability (cont'd)

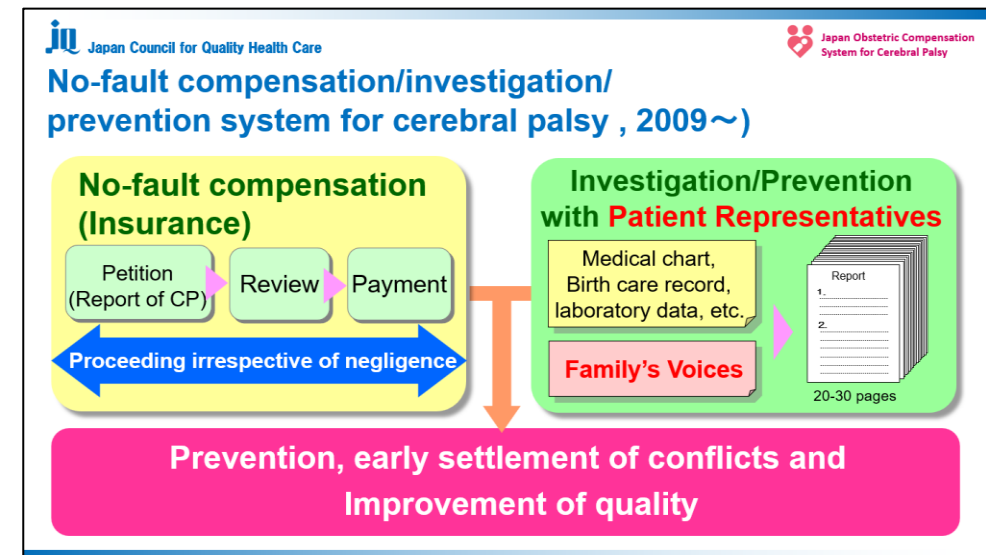
- Traditional medical liability reforms have not been effective in compensating negligently injured patients or deterring unsafe care.
- Alternative approaches are needed that **enable patients and clinicians to become allies** in making health care safer by encouraging transparency and disclosure of medical errors.
- These reforms can enable prompt and fair compensation for avoidable injuries, while **turning errors into opportunities for learning and improvement.**

“Improving Diagnosis in Health Care”, National Academy of Medicine, US 2015





Develop a Reporting Environment and Medical Liability System That Facilitates Improved Diagnosis by Learning from Diagnostic Errors and Near Misses



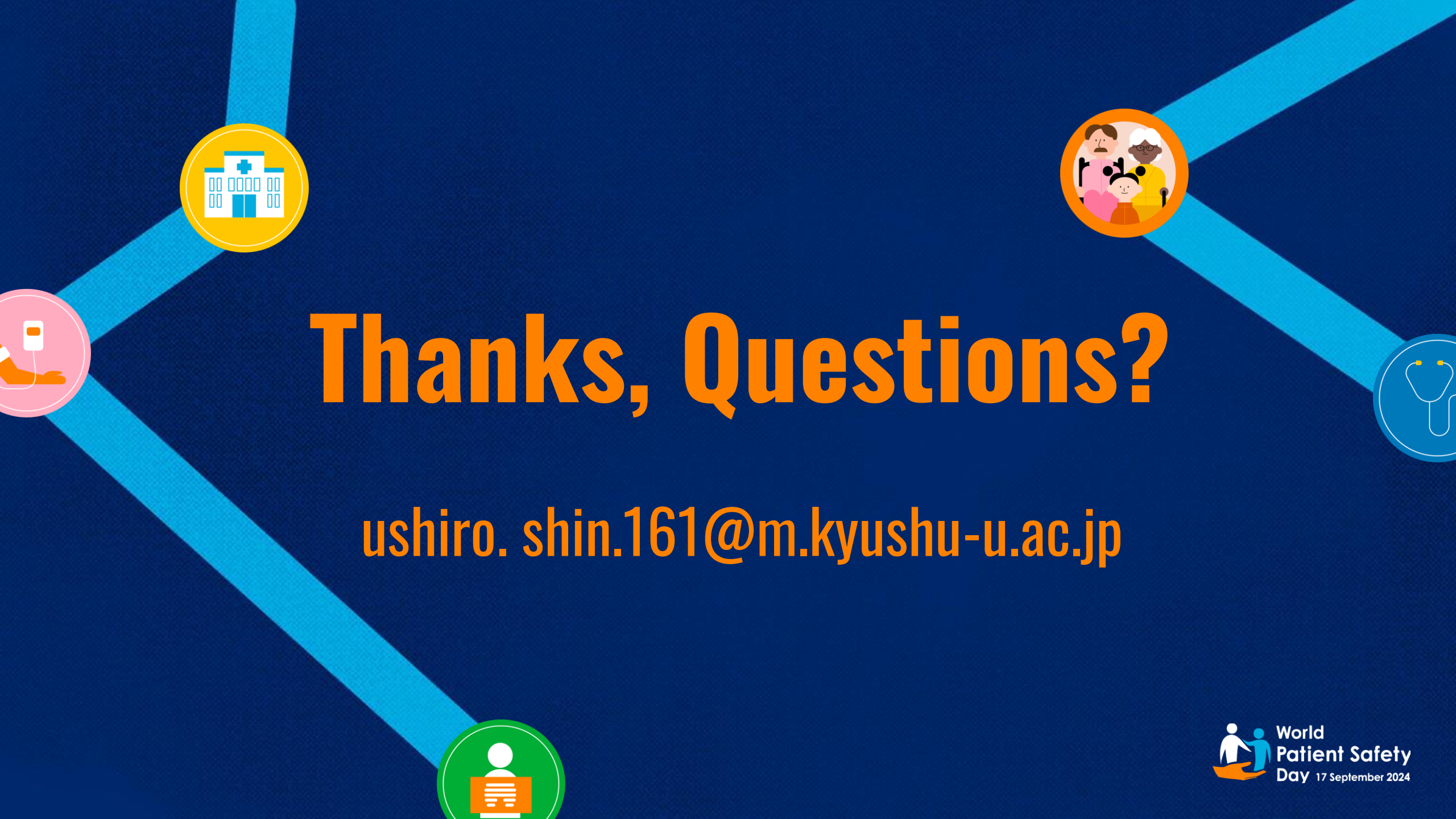
Reporting learning system gives robust foundation to address diagnostic safety.

“Improving Diagnosis in Health Care”, National Academy of Medicine, US 2015

Take away messages



- Wide focuses should be held on learning lessons from diagnostic errors for safer care at all levels.
- Diagnostic error takes place at every step of diagnostic process due to wide variety of reasons. Accordingly, comprehensive approach need to be taken.
- Cognitive error in diagnostic process should be highlighted and addressed through team-based approach.
- Experiences on diagnostic errors in my country such as HBV reactivation, failure to confirm imaging report, failed interpretation of FHR monitoring record and corrective actions at all levels deserve to spread in patient safety community and beyond through international approach.



Thanks, Questions?

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