



Policy and Practice: A Partnership for Better Outcomes
"Accreditation and Patient Safety Right From the Beginning!"

Successes of the national database for Medical adverse events and Pharmacy near misses – Japan experience

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 Kyushu University Hospital
 Japan Council for Quality Health Care (JQ)
 International Society for Quality in Health Care (ISQua)

1



JQ's projects

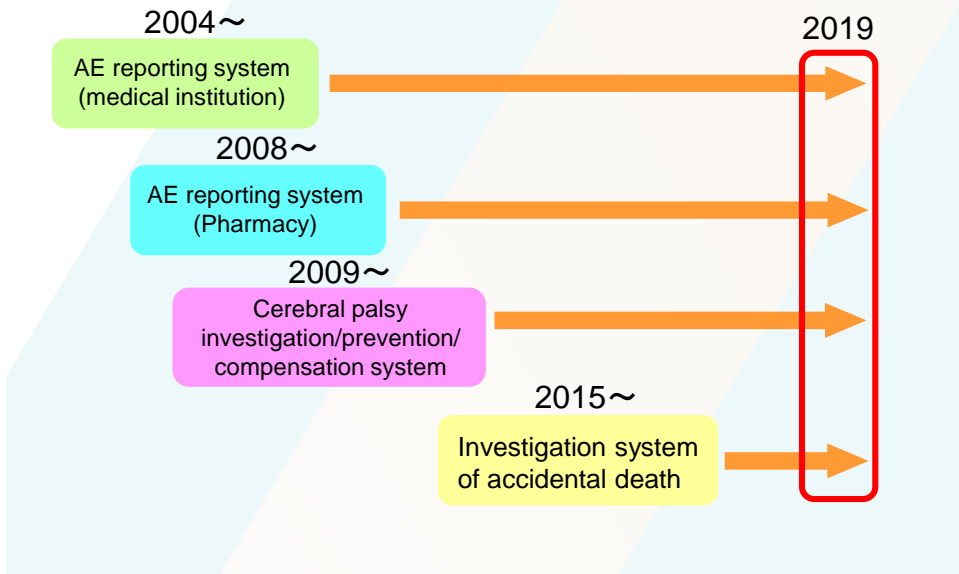


- Hospital Accreditation**
- Patient Safety Promotion Group of Among Accredited Hospitals**
- EBM medical information division**
- Nationwide Adverse Events Reporting System of Medical Institutions**
- Nationwide Near-miss Event Reporting System of Community Pharmacy**
- The Japan Obstetric Compensation/Investigation and Prevention System for Cerebral Palsy**



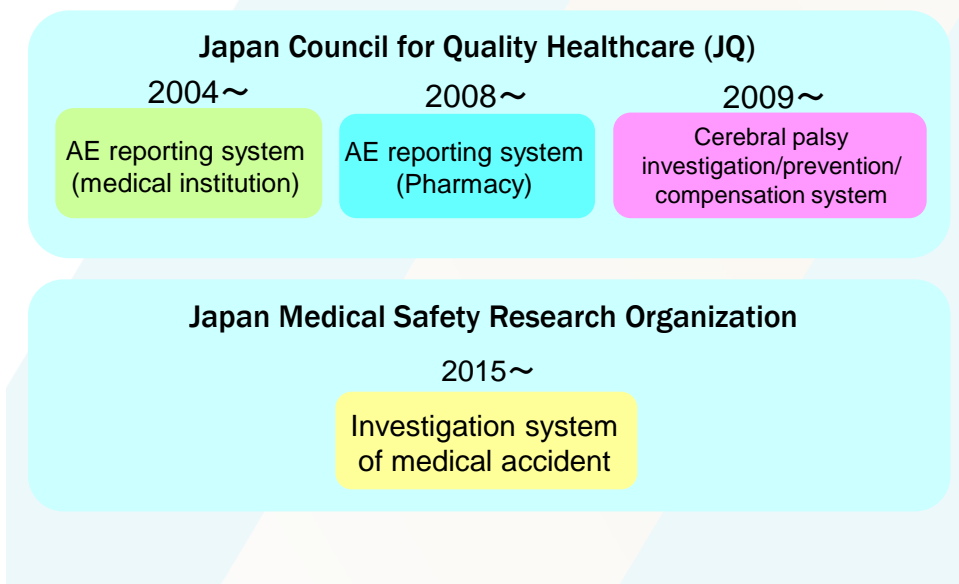
2

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



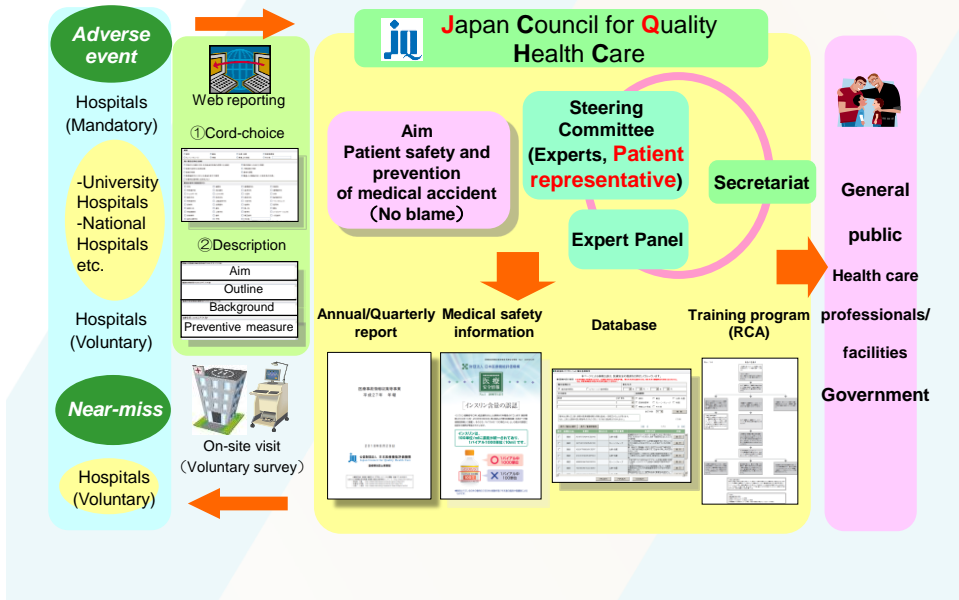
3

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



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



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Number of institutions by registration patterns

Registration type; (A), (B) or both		(B) Near-miss reporting system				Total
		Registered		Not-registered	Total	
		Occurrence and Case Report	Occurrence Report ONLY			
(A) Adverse event reporting system	Mandatory	123	84	67	274	1,080
	Voluntary	372	231			
Not-registered		165	270			435
Total		660	585	270	1,515	
		1,245				

Statistics as of Jun 30, 2019

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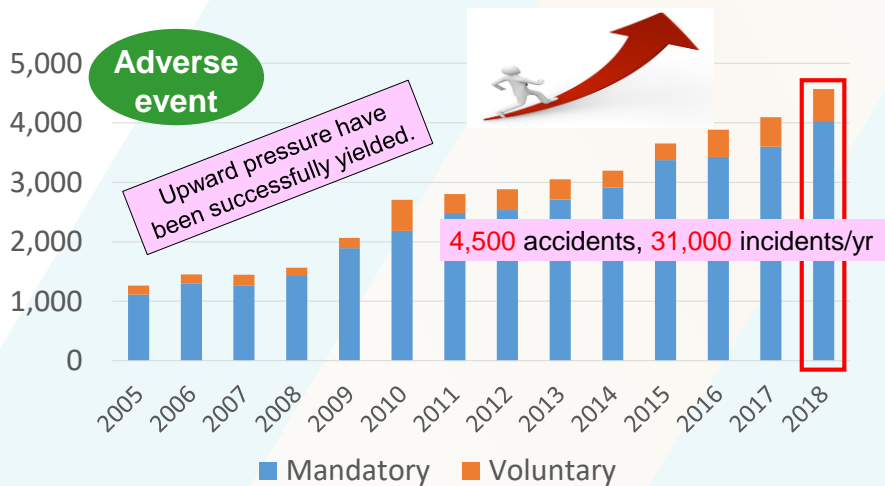
Medical institutions with/without obligation (Mandatory / Voluntary) of AE reporting

Mandatory / Voluntary	institution
Mandatory	274
Voluntary	806
Total	1,080

Ref; Statistics of Japanese hospital	
No. of Hospitals	8,316
No. of Hospital Beds	
i) Mandatory reporting hosp.	139,446
ii) Entire hosp.	1,624,804

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Year-to-year change in the number of AEs

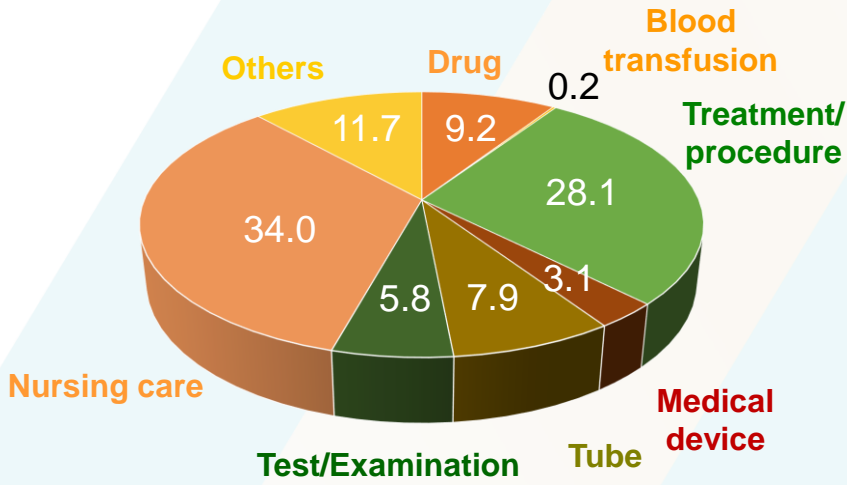


Year	05	06	07	08	09	10	11	12	13	14	15	16	17	18
Mandatory	1,114	1,296	1,268	1,440	1,895	2,182	2,483	2,535	2,708	2,911	3,374	3,428	3,598	4,030
Voluntary	151	155	179	123	169	521	316	347	341	283	280	454	497	535



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Types of Adverse Event



2018 Annual Report of JQ's AE/Near-miss reporting system

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Frequent AEs (10 cases or more / yr)

Summary	Total
Drug	
Overdose administration	60
Wrong drug dispensing	31
Omittance of administration	22
Overdose prescription	20
Wrong method of administration (Wrong injection route, etc.)	19
Faster setting of injection rate	17
Wrong patient	16
Administration of Contraindicated drug	14
Underdose administration	11

(Annual report 2018)

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Frequent AEs (10 cases or more / yr)

Blood transfusion	
Treatment/Procedure	
Wrong procedure/method	206
Wrong management of treatment/procedure	152
Foreign body retention	72
Wrong site	40
Unnecessary treatment/procedure	14
Omittance of treatment/procedure	13
Mixed examination, treatment, procedure etc.	13
Medical device	
Violation of instruction manual	29
Wrong maintenance of devices in use	10

(Annual report 2018)

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Frequent AEs (10 cases or more / yr)

Tubes	
Removal by patient	64
Spontaneous removal	34
Tear/Breakage	28
Blockade of tube	20
Infusion leakage	21
Wrong meintenance of tubes in use	15
Test/Examination	
Wrong procedure/test result	22
Wrong procedure of obtaining test samples	11

(Annual report 2018)

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Frequent AEs (10 cases or more / yr)

Nursing care	
Fall down to floor	889
Drop from bed	100
Aspiration	48
Unnecessary care	13
Collision	13
Restrain	12
Accidental ingestion	11

(Annual report 2018)

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Thematic analysis (~200 themes since 2004)

Wrong Administration of Antineoplastic Agents, Anti-Coagulants etc.

Failure to Confirm CT, MRI Imaging Report

Patient's Falls From a Pediatric Bed

Drug Mix-up Due to Similar Appearance

Tubing Disconnection of Ventilator Circuit

Double Dosing of Medicines Brought in at Hospitalization and Drugs Prescribed in Hospital

Accidentally Ingestion or Aspiration of a Foreign Body During Dental Treatment

Film Dressing Wrongly Affixed to a Permanent Tracheostomy

"Nor-Adrenalin Administration" Instead of "Adrenaline" During Resuscitation

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“Failure to Confirm CT, MRI etc. Imaging Report

- The patient diagnosed as “**Abdominal Aortic Aneurysm**” **underwent CT scanning** for following up the possible growth of it. Vascular physician in charge recorded the finding of the CT image in the medical chart.
- **One year after**, nephrologist, another physician in charge of the patient, learned from other hospital that the patient developed **lung cancer**.
- Reviewing the **CT examination report issued by radiologist** one year ago, it described as “**There is a lesion highly suspicious of lung cancer**”.



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March 3, 2015

Gunma University Hospital admits negligence in eight surgery deaths

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.

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Preventative action by a hospital group

- **Japanese National University Hospital Alliance on Patient Safety (JANUHA-PS, Chair; Tokyo Medical & Dental University Hospital, Members; 45 National University Hospitals)** participated in a program to survey and enhance prophylactic measures to the failure of radiological imaging report by on-site visit and appraisal in 2017 .

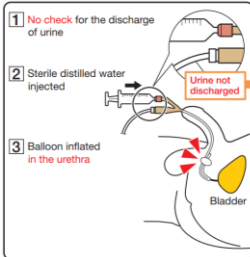
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“Medical Safety Information” (Monthly alert)

The image shows a 'Medical Safety Information' alert from the Japan Council for Quality Health Care, No. 99, February 2015. The document is titled 'Left-Right Mix-Up When Inserting a Thoracostomy Tube'. It contains two case reports (Case 1 and Case 2) and preventive measures. A callout box points to the 'Logo' of the Japan Council for Quality Health Care. Another callout points to the 'Title' of the alert. A third callout points to the 'Case summary' section. A fourth callout points to the 'Key statement' section, which states: 'Cases of left-right mix-up when inserting a thoracostomy tube or performing a thoracentesis have been reported. In all of these cases, the medical staff failed to check the site immediately before the procedure.' A fifth callout points to the 'Preventive measures' section, which includes: 'The physician and assisting nurse will use images and/or the consent form, etc. to check the patient's name, the puncture site, and the position required when carrying out the procedures. The physician will look at the image immediately before the procedure and compare it with the planned insertion site.' A sixth callout points to an illustration showing a patient in a hospital bed with a thoracostomy tube inserted, and a callout box stating: 'Illustration to facilitate better and quick understanding of the key statement'. The illustration shows a patient lying on their left side, and a callout box stating: 'That's a left pneumothorax.' The document also includes contact information for the Department of Adverse Event Prevention, Japan Council for Quality Health Care.

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Image of case



Main Factors Behind the Decision to Inflate the Balloon Without Checking for Urine Discharge	Number of Cases
Thought that the catheter inserted was long enough	27
Felt no resistance when inserting the catheter	15
Thought that there was no urine in the bladder because the patient had just urinated or was on nil by mouth	15

◆ In some cases, more than one of these background factors was involved.

Examination, Treatment, or Procedure	Number of Cases
Head MRI	2
Endoscopy	2
Fluoroscopically guided procedure	2
Cardiac catheterization	1
Cerebral angiography / interventional radiology	1
Chest X-ray	1

Image of case 1



Circumstances of Use of Standby Mode	Number of Cases
Patient transfer	3
Tracheal suction	3
Unknown	1

Example of a check after fitting a ventilator

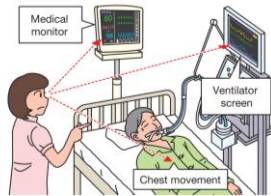
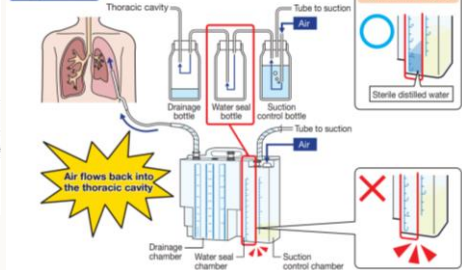
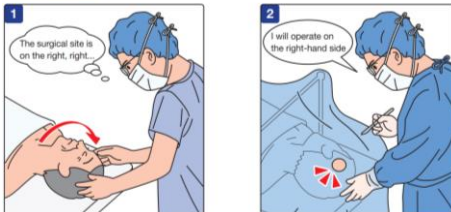


Image of case 1



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Image of case 1



Site of Sample Collection	Examination Result	Treatment Ordered or Carried Out	Background
Left arm	Blood glucose level 656mg/dL	Administration of Humulin R 10 units	• The patient had undergone breast cancer surgery and a sign stating "Do not use the right arm to take blood samples or measure blood pressure" was at the head of the patient's bed
Not specified	Rise in blood glucose level	Excessive insulin therapy	• The staff member was concentrating on taking the blood sample and did not notice that the patient was receiving an infusion
Right arm	Sodium 110mEq/L Potassium 7.8mEq/L	Administration of Calcofol / GI therapy	• The patient had a PIC catheter indwelling in the left arm • The staff members did not know that taking a blood sample from a limb during an infusion could affect the examination results

Image of case 1

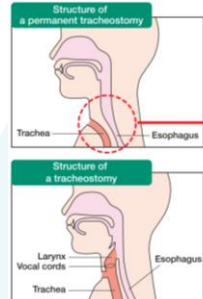


Image of case

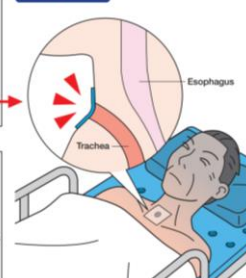
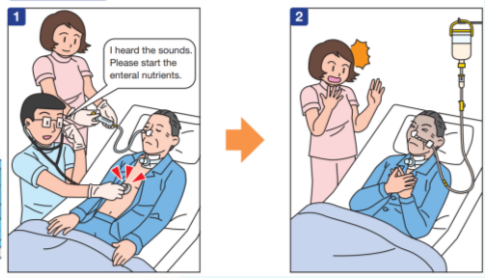


Image of case 1



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HCAC 2019
5th QUALITY HEALTH CARE
CONVENTION & EXHIBITION
11-13 November 2019

公益財団法人 日本医療機能評価機構
Japan Council for Quality Health Care

医療事故情報収集等事業

ホーム | 医療安全情報 | 報告書・年報 | 事例検索 | **English**

事業の内容と参加方法 (PDF) | 参加登録 (医療機関一覧) | 事業要綱 (PDF) | 参加登録 | 事例報告 ログイン

医療安全情報 (PDF) | 医療安全情報 FAX提供 (医療機関一覧) | 医療安全情報 FAX提供 申し込み (PDF)

報告書・年報 | 分析テーマ | 再発・類似事例の分析

集計表 (web公開分) | 報告書・年報 (本文)検索 | 集計表検索

事例検索 | 関連文書 | 利用ガイド | お問合せはこちら

PDF形式のファイルを見るには、Adobe Readerが必要ですが、ダウンロードはこちらから

▼開閉はここから
Facebookのご案内
医療事故情報収集等事業の公式Facebookは [こちら](#) からアクセスできます。
運用ポリシーはPDFをご参照ください。 PDF

2019.09.30 **NEW**
第58回報告書を公開致しました。 PDF

2019.09.17 **NEW**
医療安全情報 [No.154] 「電子カルテ使用時の患者番号誤り」を公開致しました。 PDF

2019.08.19
議案会を開催します。詳しい内容はPDFをご参照ください。
→種め切らせていただきました。

2019.08.15
医療安全情報 [No.153] 「手術時のカーゼの残存数-カーゼカウント-」を公開致しました。 PDF

2019.07.16
医療安全情報 [No.152] 「手術時のカーゼの残存数-カーゼカウント-」を公開致しました。 PDF

2019.07.05
第57回報告書を公開致しました。 PDF

2019.06.17
医療安全情報 [No.151] 「2018年に報告書で取り上げた医療安全情報」を公開致しました。 PDF

2019.05.15
医療安全情報 [No.150] 「産科診断報告書の確認エラー-上部消化管内環境検査-」を公開致しました。 PDF

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HCAC 2019
5th QUALITY HEALTH CARE
CONVENTION & EXHIBITION
11-13 November 2019

Global dissemination of JQ's alert
"Global Patient Safety Alerts"

GLOBAL PATIENT SAFETY ALERTS

cpsj cpsi icsp
Convention Patient Safety Institute
Canadian Patient Safety Institute
International Patient Safety Institute

日本 | 大韓民国 | 中国 | カナダ | アメリカ | メキシコ

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Web-based search system on AE / Near-miss

事例の公表は、医療安全の推進を目的としています。

■ 事例内容で検索 ※ 検索できる事例は、2019年10月1日以前に提出された事例です。
※ 医療安全の推進を促進するために、発生年月での検索はできません。

報告事例区分 医療事故情報 ヒヤリ・ハット事例 発生年月

事例概要
 薬剤 輸血 治療・処置 医療機器等 ドレーン・チューブ

所属診療科 担当医師

全文検索

事例に必須の個人情報や医療機関情報の保護に配慮し一部修正することがあります。
 なお、公表した事例内容は報告時のものと一致しない場合があります。

全て選択 全て選択解除 表示一覧のみ選択 表示一覧選択解除

706 AEs are matched.

選択	事例区分▲	事例ID	発生年月	事例の概要	詳細
<input type="checkbox"/>	事故	A37840C5B0A30CA17		治療・処置	...
<input type="checkbox"/>	事故	AS0ED17E9BA424255		薬剤	...
<input type="checkbox"/>	事故	AFF453E753821FADD		治療・処置	...
<input type="checkbox"/>	事故	A2304D6F8C38C6C0D		職業上の世話	...
<input type="checkbox"/>	事故	A5AS06FC09F2AA22A		ドレーン・チューブ	...
<input type="checkbox"/>	事故	A20804C268A35A35D		その他	...
<input type="checkbox"/>	事故	AA516A8EFC287834		医療機器等	...
<input type="checkbox"/>	高年	A040C709A4344E697D6			...

“Browse” button

“Download” button

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Contribution to scientific research

ORIGINAL ARTICLE

OPEN

Characteristics of Medical Adverse Events/Near Misses Associated With Laparoscopic/Thoracoscopic Surgery: A Retrospective Study Based on the Japanese National Database of Medical Adverse Events

Takashige Abe, MD, PhD,* Sachiyo Murai,* Yasuyuki Nasuhara, MD, PhD,† and Nobuo Shinohara, MD, PhD*

J Patient Saf • Volume 00, Number 00, Month 2017

www.journalpatientsafety.com | 1

The database has been used as a source that provides data for scientific research.

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Alerting document on sound-alike drugs

医療従事者の皆様

アルマールとアマリールの販売名類似による取り違え防止について

2012年1月
大日本住友製薬株式会社

Alert on prescription error of "Almari" and "Amaryl"

取付済みの状況

1	誤読による懸念、処方字にはアルマールと記載したが、処方時にアマリールと入力、処方箋、処方箋裏に「処方箋情報」の記載があるため、処方箋を誤読
2	医師処方間違い、薬局で、患者との確認から疑念発生を行い発見
3	薬局での取り違え、確認を怠った、姓前・手続が未熟だったことによる
4	医師処方間違い、薬局で、患者との確認から疑念発生を行い発見

公益財団法人 日本医療機能評価機構「医療事案」/ヒヤリング報告事例検索
「薬局セマヤハット報告事例検索」システムより(2019年10月末時点)

お問い合わせ先 大日本住友製薬株式会社 くすり情報センター TEL: 0120-034-309
受付時間：月～金9：00～18：30(祝・祭日を除く)

< アルマール, アマリール取り違え事例 3
詳細は下表のとおりです。

No.	施設	内容
1	病院	<p>【事案の概要】 本邦に承認された医薬品の薬名(アマリール)を処方することを嘱託医の依頼でアマリールを処方した。処方3日後の再診時に内服によるめまい・眩暈の訴えがあり、処方確認するとアマリールを処方していた。処方・調剤情報システムで、アマリールの処方を確認した。</p> <p>【薬局の管理業務の概要】 本邦には処方箋(アマリール)と記載、通称、アマリールは、シタキチと記す。22字、32字入力時、欄外に「処方名」で、漢字表示可能。アマリールの場合は、アル、アマ、アム、AM、AM3です。22字以内の漢字を入力し、シタキチで検索、処方情報にアマリール検索結果が表示される。嘱託医の依頼とは異なる漢字の漢字検索結果が表示されており、入力欄にはアマリール(漢字)の漢字検索結果が表示されている。当該事案では漢字検索からめまい・眩暈の訴えがアマリールと入力し、処方時にアマリール(漢字)と処方された。処方した漢字は、処方内容の漢字と漢字検索結果との一致は行われなかった。処方情報について、薬局で処方された処方箋内服薬内服表の処方ありである。薬局の処方箋、処方内容に処方情報となっていた。薬局からの処方箋情報はなかった。</p>
2	病院	<p>【事案の概要】 アマリール錠100mgをアマリール錠100mg錠で処方されていた。患者との確認で処方ミスを確認した。処方情報入力、処方箋変更を行った。</p> <p>【処方要約】 処方名: アマリール錠100mg 剤形: 錠剤 処方量: 1錠 処方期間: 1週間 処方指示: アマリール錠100mgを1錠1回服用する。食事と一緒に飲む。</p>
3	薬局	<p>【事案の概要】 アマリール錠100mg処方したところ、アマリール錠100mg錠を処方してしまった。</p> <p>【処方要約】 処方名: アマリール錠100mg 剤形: 錠剤 処方量: 1錠 処方期間: 1週間 処方指示: アマリール錠100mgを1錠1回服用する。食事と一緒に飲む。</p>

AEs were quoted from the database of JQ's reporting system.

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Sound-alike drugs

“**Almari**” vs “**Amaryl**”

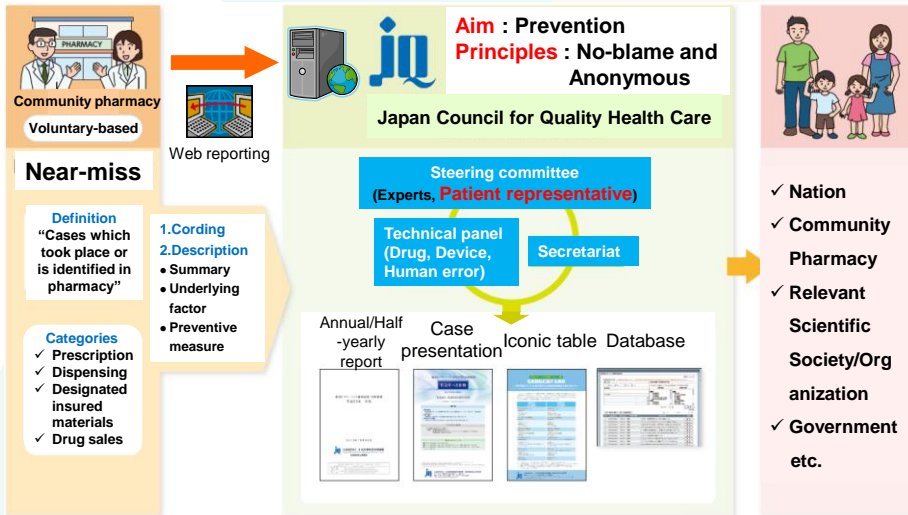


“**Almari**”

The brand was relinquished and replaced with generic name in **2012** by the manufacturer for patient safety reason.

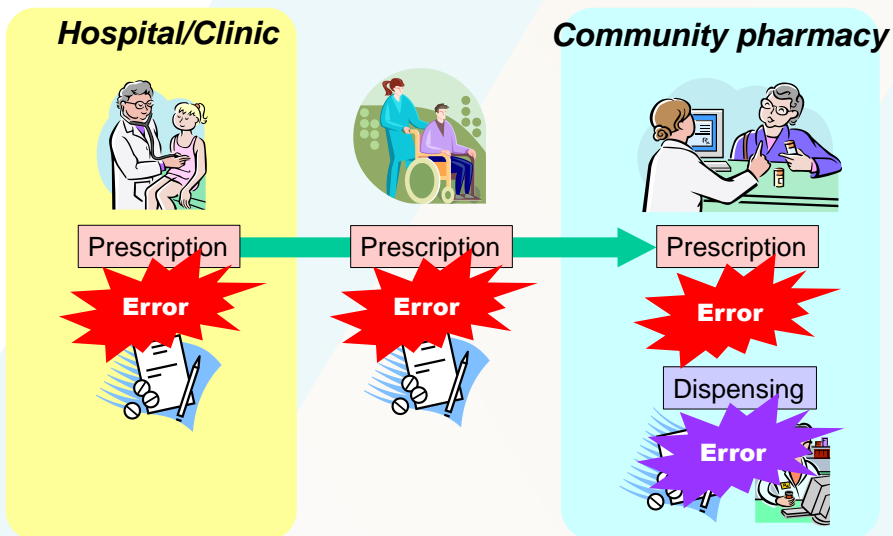
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Reporting and learning system of community pharmacy (2008~)



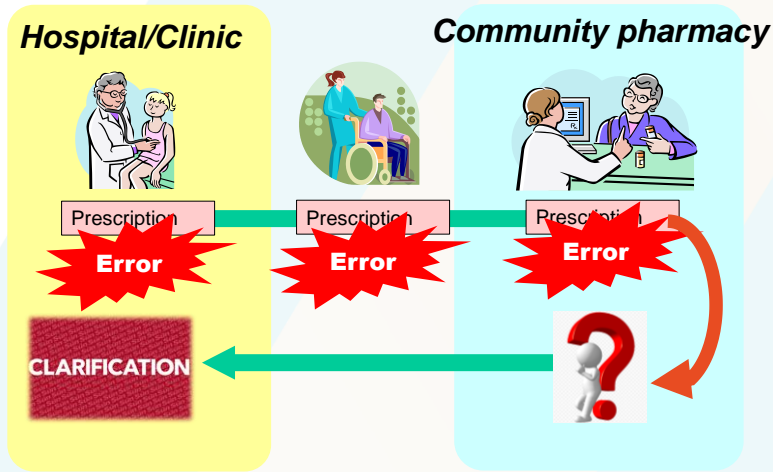
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Structures of medication process in Japanese public healthcare system



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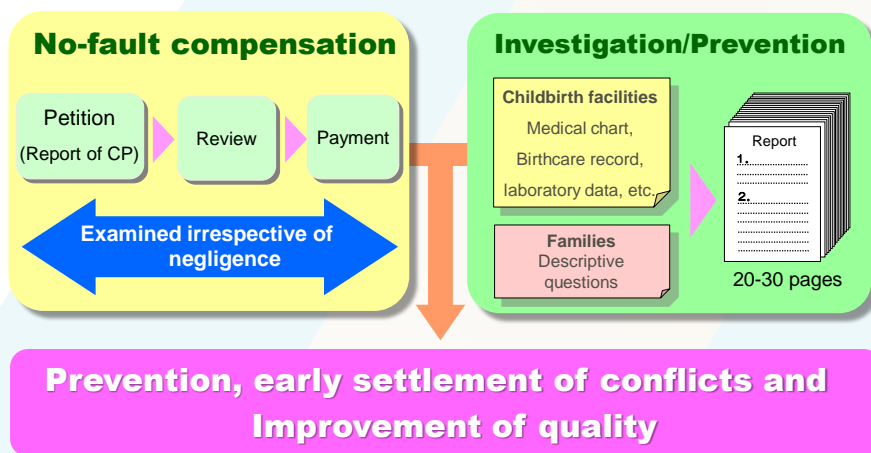
Clarification of questionable prescription by pharmacist



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No-fault compensation/investigation/prevention system for cerebral palsy

~ the Japan Obstetric Compensation System (2009~)~



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Monetary Compensation (30 million JPY = 291,300 USD)

♥ Lump-sum payment

To compensate for expenses on nursing case facilities

**6 million yen
(58,250 USD)**

6 million JPY



♥ Annual installments

To compensate for annual nursing care expenses

total **24 million yen
(233,050 USD)**

+

Annual payment of 1.2 million JPY
× **20 years**



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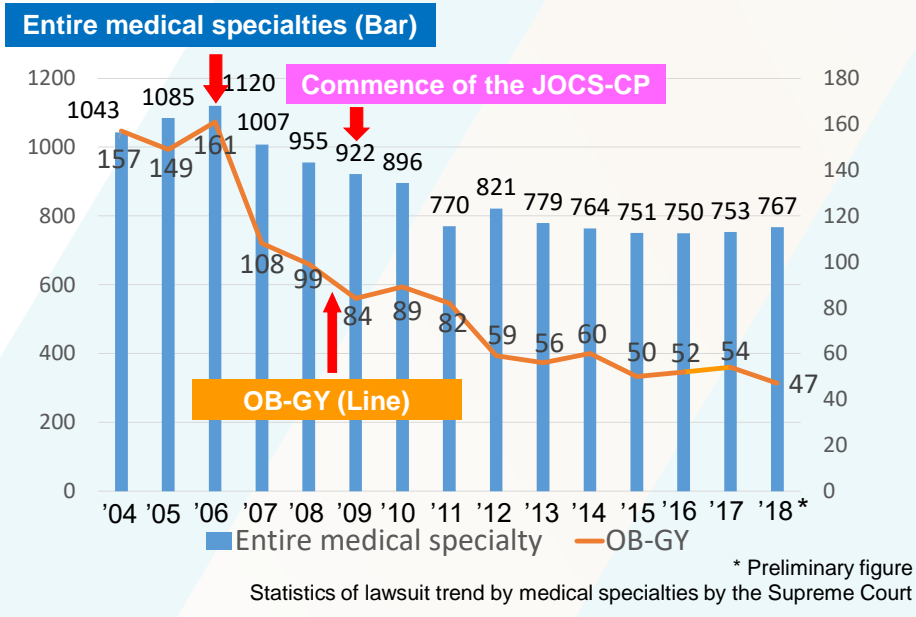
Statistics of eligible case by birth year

(As of Jun 30, 2019)

Birth year	No. case reviewed	No. case by eligibility			
		Eligible	Not Eligible	Preliminary to review	In process
2009	561	419	142	0	0
2010	523	382	141	0	0
2011	502	355	147	0	0
2012	516	361	155	0	0
2013	476	351	125	0	0
2014-2018	1098	887	158	44	9
Total	3,676	2,755	868	44	9

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Possible impact on lawsuit case



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Attention and concern on cerebral palsy in international community on patient safety



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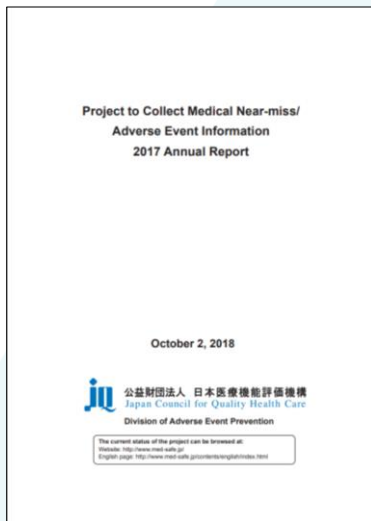
Distribution of knowledge through SNS (2014~)



Quarterly/Annual report,
Thematic analysis
Monthly alert,
etc.

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Disclosure and publicity



- Quarterly report No. 1-58
- Annual report 2005-2018
- Reports are Released at press conference



NHK News (TV News), August 29, 2016

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Take Home Messages

- Learning from error is crucial to ensure patient safety.
- Anonymous nature and no-blame culture are prerequisite for successful reporting and learning system.
- Feedback to the frontline of medicine is vital for constant reporting.
- Transparent operation through products open to public and press conference etc. is helpful to grow trust to the system.
- Incentive such as no-fault compensation effectively works in Japanese system.