Third Global Ministerial Summit on Patient Safety 2018

“Medical Accident Investigation System” in Japan

Apr. 13th. 2018

Tokyo

Sosuke Kimura, MD.PhD.

Medical Accident Investigation and Support Center

Japan Medical Safety Research Organization

[**Medsafe Japan**]

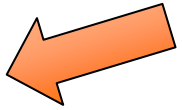
Two systems in Japan

Medical Accident Reporting / Investigation System

1. “Medical Accident Information Reporting System”

- Since 2004
- **“Web reporting system” to collect medical accident information**
- Participating hospitals: Mandatory participation [275*] + Voluntary [718*]
- “Japan Council for Quality Health Care. [jq]” is entrusted the management.

2. “Medical Accident Investigation System”



- Enforced in 2015
- **Consists of two steps : Self investigation [1st] + Third party investigation [2nd]**

  1st Step : “In-Hospital Investigation” with “Supporting Organization”

  2nd Step : “ISC Investigation”, if requested by bereaved family or concerned hospital.

  [ISC : “Medical Accident Investigation and Support Center”]

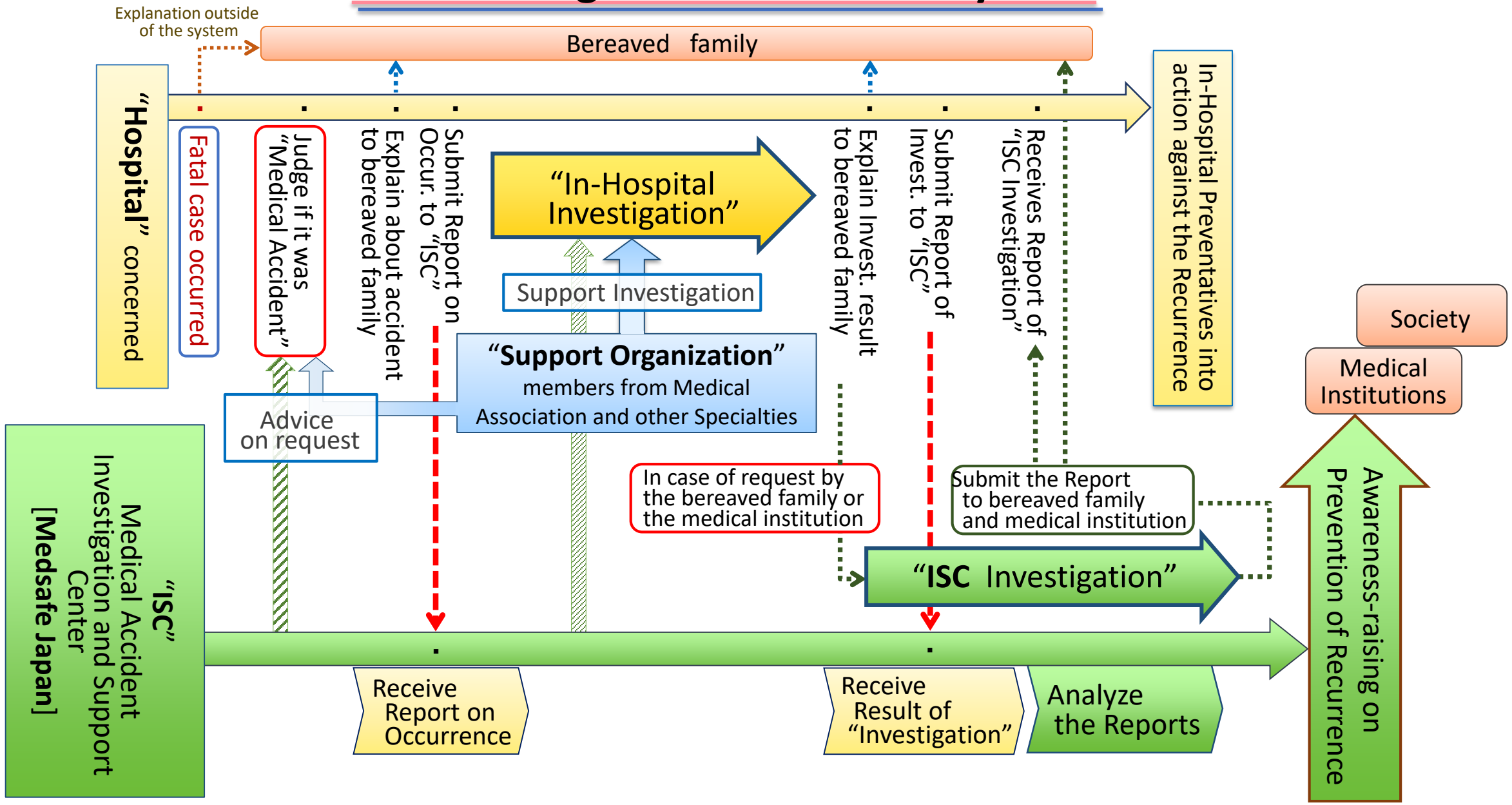
- Participating hospitals: All medical institutions including clinics [110,000*]
- “Japan Medical Safety Research Organization. [**Medsafe Japan**]” is entrusted.

[* : Number of Participating Institutions]

Principles of “Medical Accident Investigation System”

- In 2015, the system was enforced under the Medical Care Act.
- “Trust in medicine” is the premise of the system.
- Purpose is to enhance patient safety and to improve quality of medicine.
- Basis of the Investigation
  - ✓ 1st Step: “In-Hospital Investigation” accompanied by “Supporting Organization”
    - **Voluntary Investigation with Peer Review**
  - ✓ 2nd Step: “ISC Investigation”
    - **A third party Investigation**
    - “ISC” (Medical Accident Investigation and Support Center) manages the investigation.

The Investigation Flow of the System



Definition of “Medical Accident”

“6th Amendment of Medical Care Act” 2014

> “Death or stillbirth which was caused or suspected to have been caused by the care provided by employee of the medical institution, and which was unforeseen by the administrator”.
>
> Official Document [English Version]

Extent of “Medical Accident”

	Death or stillbirth, caused by the **med. care provided by the employee**	Does not meet factors on the left
Death or stillbirth, **unforeseen by the administrator**	“Medical Accident”	
Foreseen by the administrator		

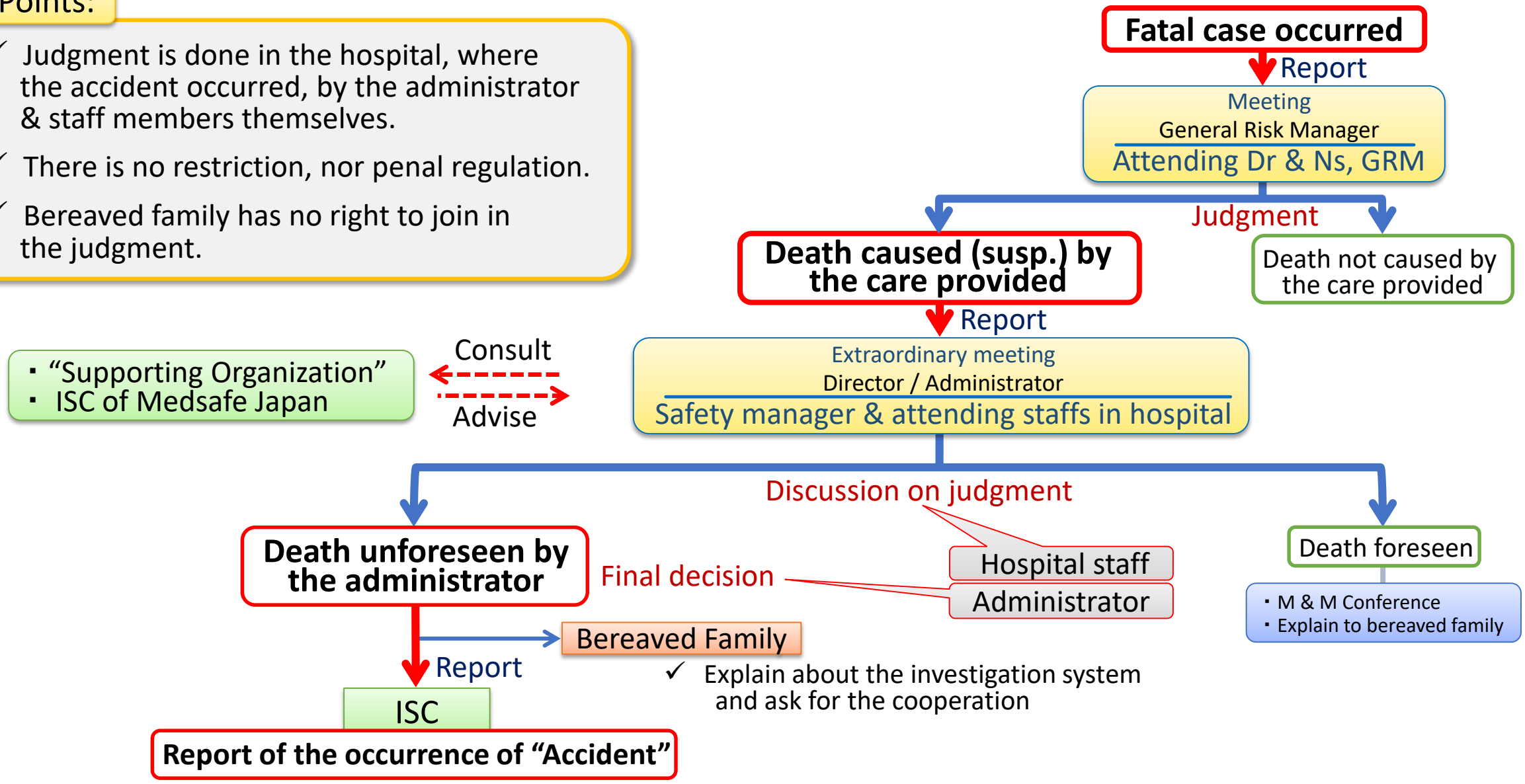
Points:

1. Targets of this system are restricted within the **fatal cases**
2. It **doesn’t matter if it is “Error” or not.** And the definition **includes a wider range as targets, such as undiscovered new findings or phenomenon** related to death.
3. Definition is related that the **administrator should decide** on “Medical Accident”.

Judgment Steps of “Medical Accident”

Points:

- ✓ Judgment is done in the hospital, where the accident occurred, by the administrator & staff members themselves.
- ✓ There is no restriction, nor penal regulation.
- ✓ Bereaved family has no right to join in the judgment.



The Investigation Flow and Images of the System

Accident

Hospital concerned

- Decision on "Medical Accident"
  - By the administrator of the hospital concerned
  - Explains to the family
  - Reports to ISC
- "In-Hospital Investigation"
  - Organizes "In-hospital Investigation Committee"
  - Participation of "Supporting Organization"
  - Investigates the causes of Accident
  - Explains the result to the patient family
- Submits Investigation Result to ISC

"Supporting Organization"
Guarantee of
- Neutrality & Fairness
- Specialty
- Transparency

Submits the Report to ISC

ISC / Medsafe Japan

Investigation & Support Center
Japan Medical Safety Research Organization

- Receives Report from hospital
- "ISC Investigation"
  - If requested by
    - Bereaved family, or
    - Concerned hospital
  - Traces something to its origins with additional investigation
  - Looks deep into the causes of the individual Accident
- Sorts and Analyzes the each Investigation Report
  - Sorts Reports into piles according to the theme, with additional investigation
  - Accumulates the points in common,
  - Draws up preventive measures
- Awareness-raising on Prevention of Recurrence

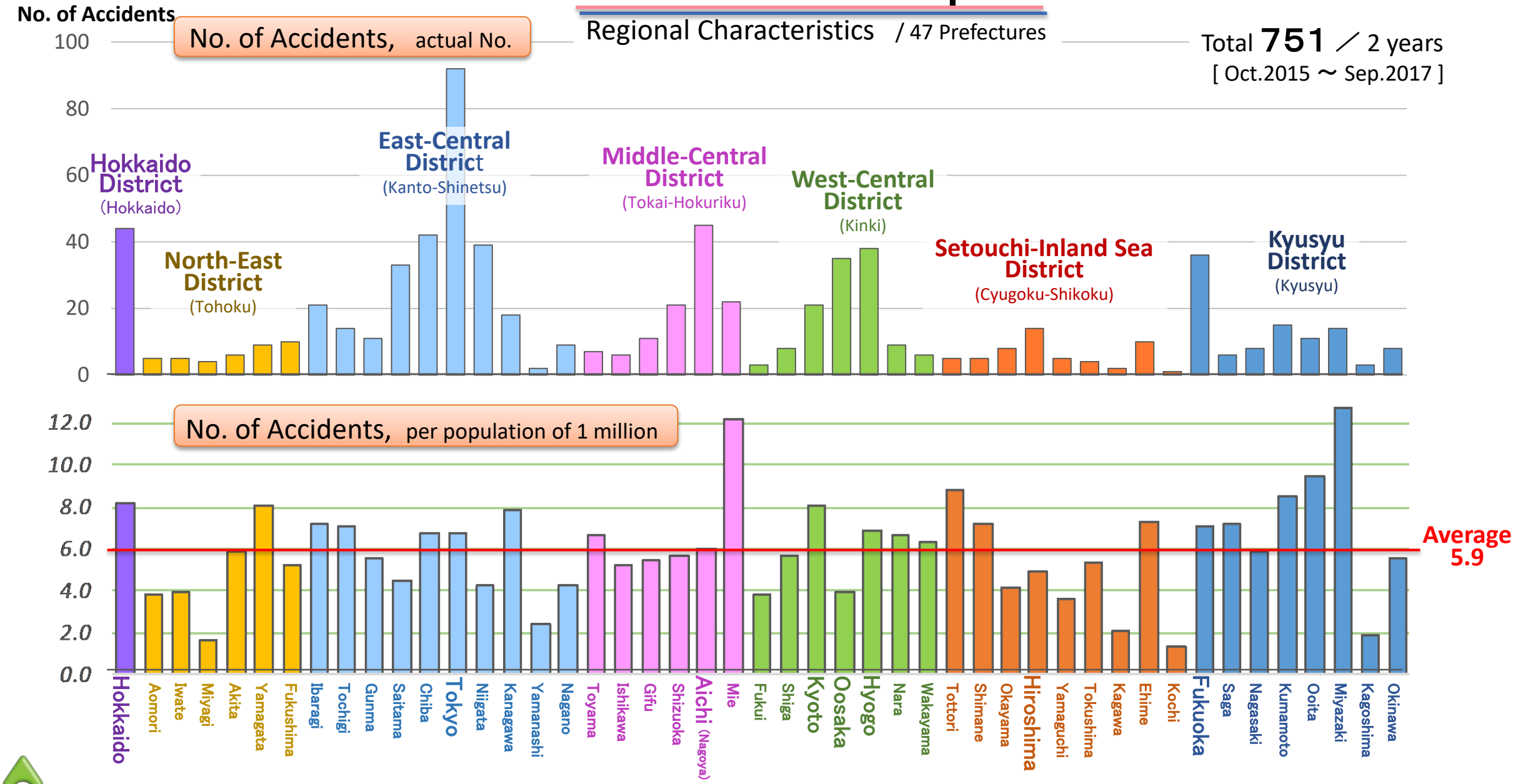
Submits Report to Hosp. and Pt. Family

Publication of the Preventives

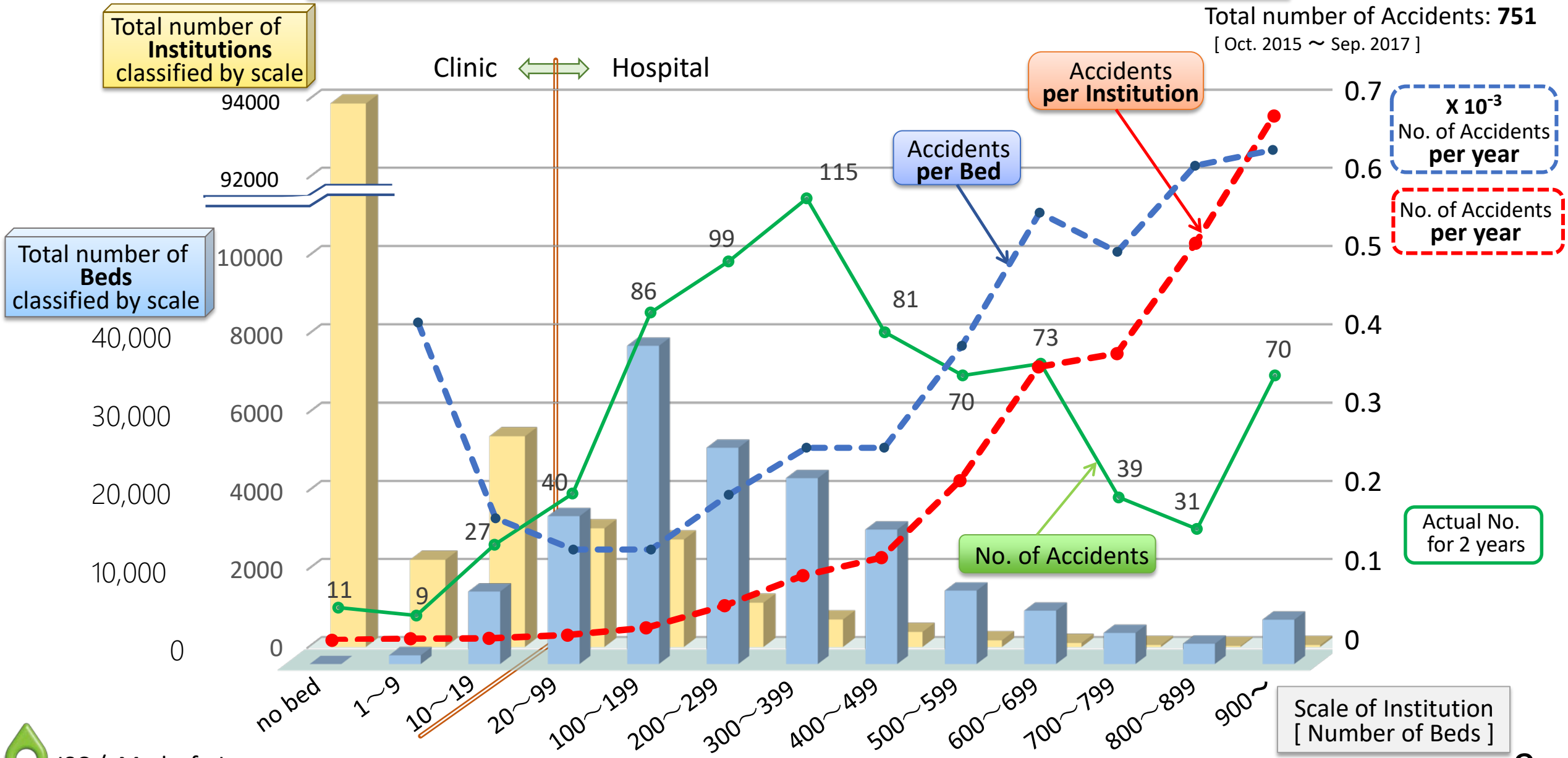
No. of Accident Reports

Regional Characteristics / 47 Prefectures

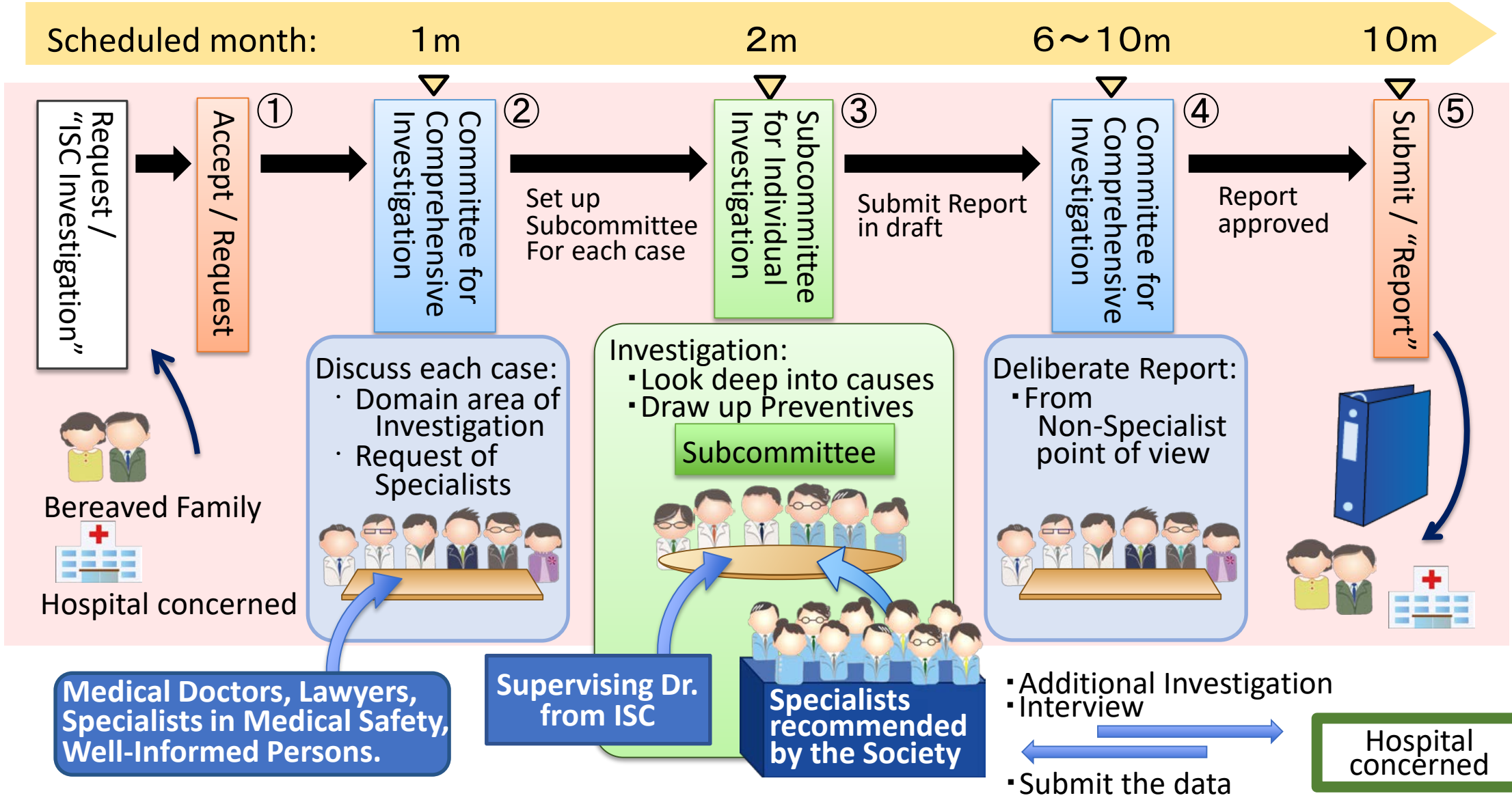
Total **751** ／ 2 years
[Oct.2015 ～ Sep.2017]



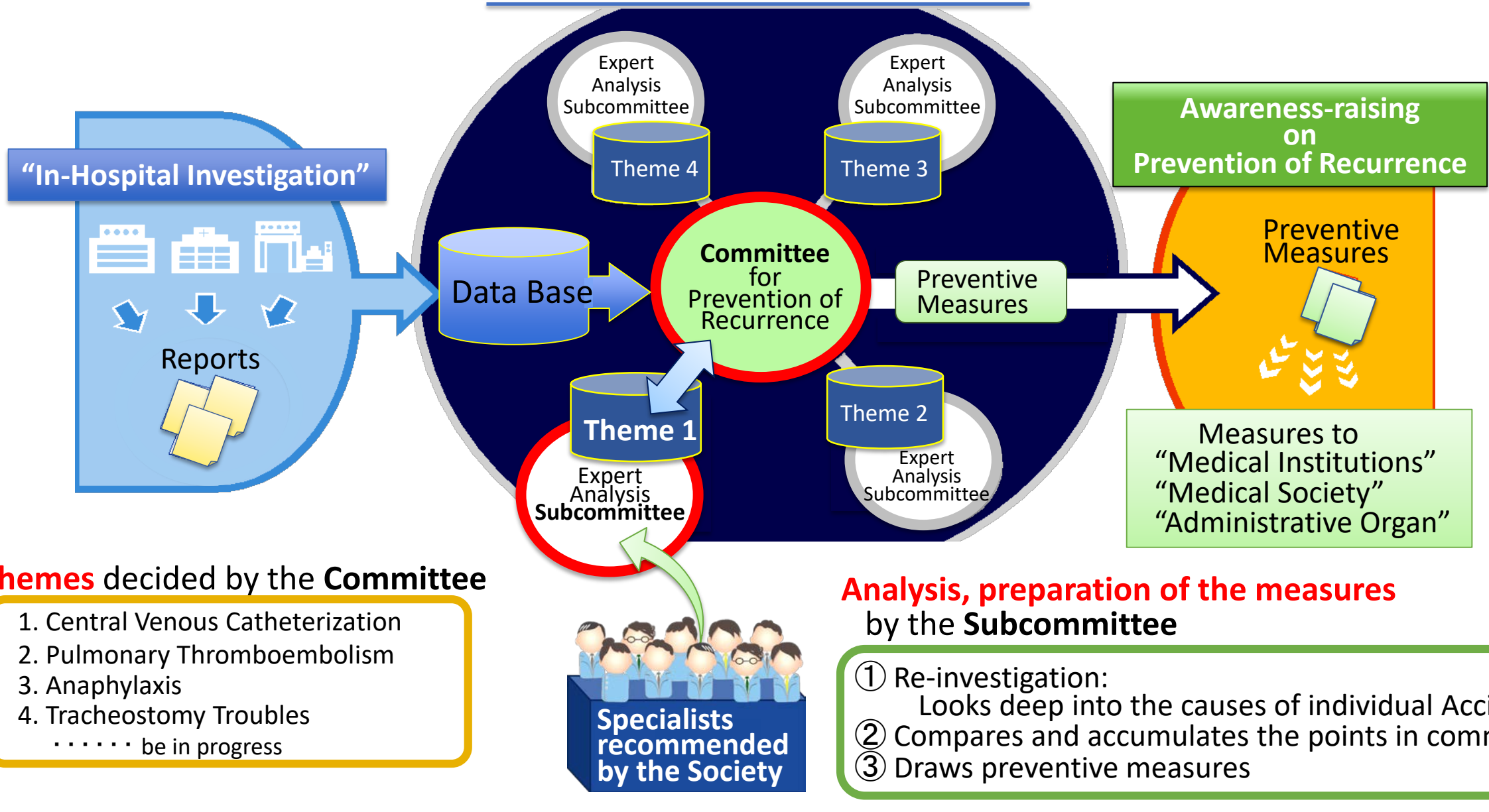
Reported ”Medical Accident” by Hospital Scale for 2 years



"ISC Investigation"



Prevention of Recurrence



Themes decided by the **Committee**

1. Central Venous Catheterization
2. Pulmonary Thromboembolism
3. Anaphylaxis
4. Tracheostomy Troubles

・・・・・・ be in progress

Analysis, preparation of the measures by the **Subcommittee**

① Re-investigation:
Looks deep into the causes of individual Accident
② Compares and accumulates the points in common
③ Draws preventive measures

Analysis of the deaths related to Central Venous Catheterization

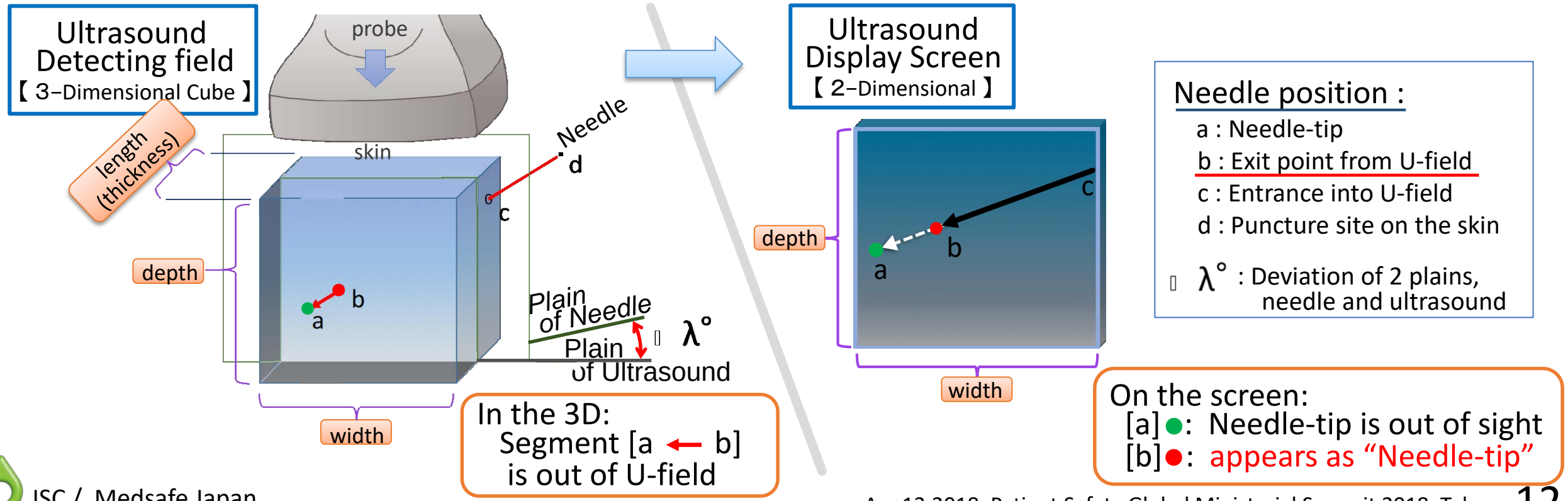
Target cases:

- Among 226 cases of "In-Hospital Investigation", **10 cases** were the deaths related to CVC.
- Bleeding by arterial puncture, Pneumothorax, Hematoma compression to trachea, etc

Investigation point:

Pitfall of Ultrasound-guided intervention

- The fact: "Needle" and "Ultrasound" Plains are not always agreed.
- **The deviation of two plains (□ λ°) makes the "Needle Tip" fade away → insert too deep.**



Recommendations for the safer CVC

1. [Indication of CVC]
2. [Informed Consent]

[Intervention Techniques]

3. **Ultrasound "Pre-Scan" for identifying the vein and its appearance.**
4. **"Real-time ultrasound-guide" is essential but has a "Pitfall".**
   Operator should receive a Simulator training in advance.
5. Needle in "CVC kit" is mostly too long. **[What we expect of company]**
6. Inserted guide wire should not exceed 20cm. **[What we expect of company]**
7. [Verification of place of the catheter]

[Patient Care]

8. Careful observation on hemothorax, pneumothorax, airway narrowing, etc.
9. Prompt responce to the event of complications.

Analysis of deaths related to Acute Pulmonary Thromboembolism [acute PTE]

Target cases:

- Among the Data of 330 cases of "In-Hospital Investigation Report" during 1 year 6 months, 11 cases were decided PTE as the cause of death, and about 25 cases clinically suspected.
- **Eight cases** out of 11, were clearly fixed by any of enhanced CT, Autopsy, or other methods.

Investigation points:

- 8 cases were investigated, focused on the course of clinical events.
- **"Initial Signs" prior to "Shock" were found out retrospectively.**

Risk of PTE

- Risk Factors :
  - # Hemostasis, # Vascular endothelial damage, # Hyper-coagulation.
  - Every patient in hospital comes under the high-risk of PTE (All eight cases):
    [Lie down > 2days, BMI > 25, Operation, Anesthetized, Psychoactive Drug, etc.]

Initial Signs

Dyspnea, Chest Pain, Tachycardia, Tachypnea

[Not Specific, Not Severe]

- Retrospectively, those signs were newly developed in connection with the shock.
- All of the 8 cases were not reminded as PTE at the emergence of those signs.

Time Intervals from "Initial Sign" to "Shock"

- **30 min.～5 hrs.**
  (Operation, Start of Rehabilitation, etc)
- **4 days～2 weeks**
  (Medical Restraint, Stay in bed, etc)

Retrospective

Chance to escape from the Shock

Sudden Onset of Shock

Target 8 cases:

- Rapid progress
- Resuscitation unsuccessful

Death

Acute Pulmonary Thromboembolism [acute PTE]
Rapid Response to the "Initial Signs"

1. **Catch the "Initial Signs" and start treatment** before the onset of Shock.

   But "Initial Signs" are
   - Not Specific and Not so Severe
   - It is difficult to catch them by the Staff, because the patient is not conscious of the signs, its medical meanings, and then does not inform of them to the staff.

2. **Patient Participation to the treatment.** (Ask patient's cooperation)

   (1) **Patient should learn the mechanism of PTE**, and must be convinced to do the preventives

   (2) **If experienced newly appeared signs, such as**
   - **Dyspnea**
   - **Chest Pain**
   - **Tachycardia (Bradycardia in some case)**
   - **Tachypnea**

   Initial Signs

   (3) **Inform the fact to the staff**, if it is severe or not

See the Leaflet !

3. Way to Rapid treatment

   (1) **Staff should be reminded of PTE by the "Initial Signs" information.**

   (2) Examination (enhanced CT, etc) to confirm the diagnosis

   (3) If PTE is confirmed, immediate "Intravenous administration of Heparin"

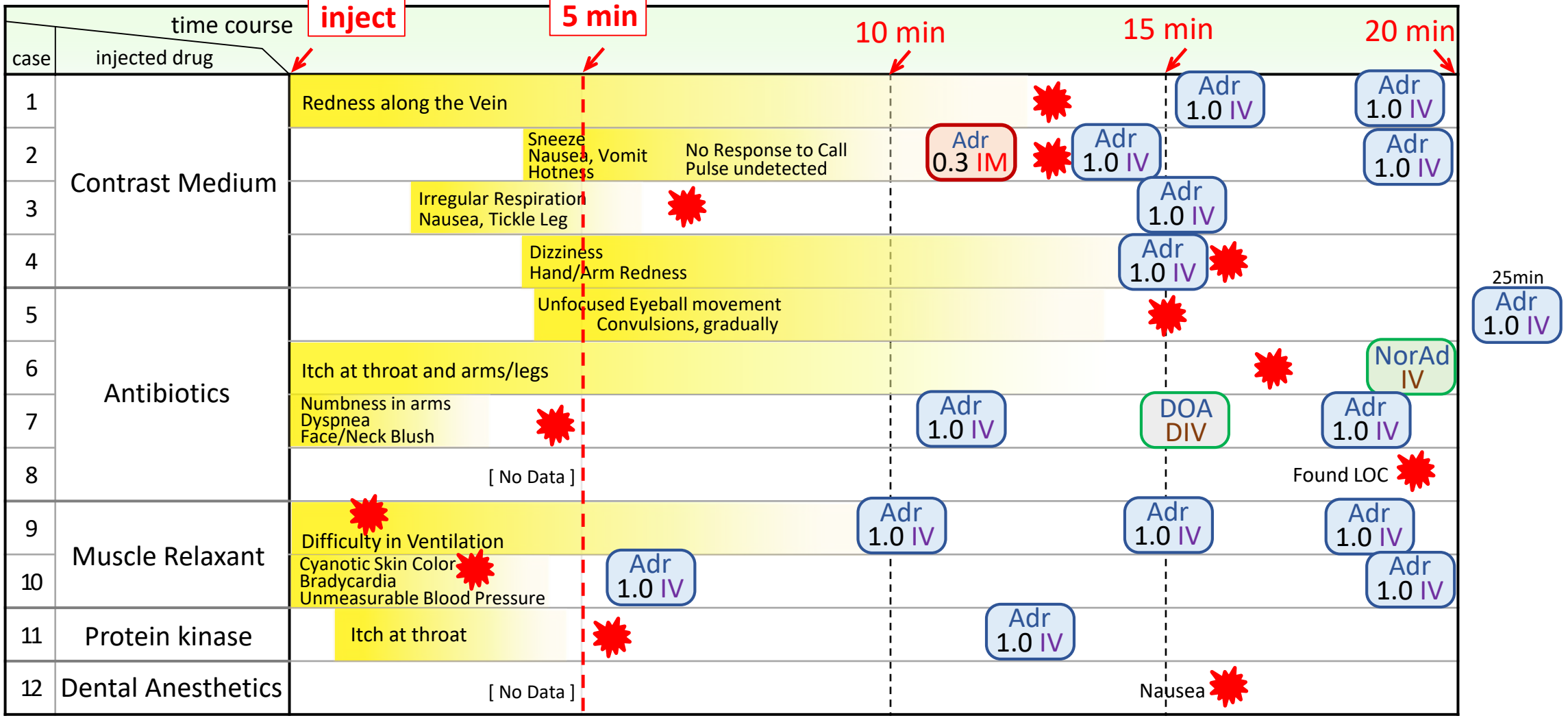
Analysis of deaths related to

Anaphylaxis caused by injections

Target cases:

- Among the Data of 476 cases, 2 years, **Twelve cases** were clearly fixed.

Time course of Signs, provided treatments and resuscitation from the injection of causative drug.



: sign of anaphylaxis, : resuscitation start, Adr 1.0 IV : adrenaline 1.0mg IV, NorAd IV : noradrenaline IV

Analysis of deaths related to Anaphylaxis caused by injections

Target cases:

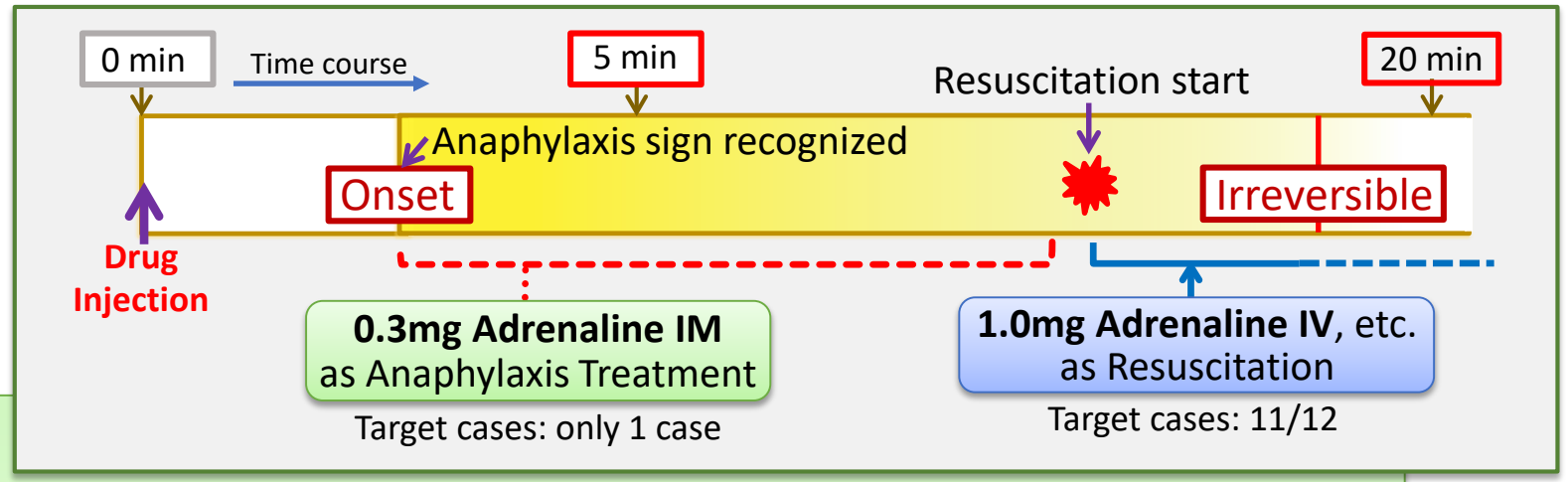
- Among the Data of 476 cases of "In-Hospital Investigation Report" during 2 years, 13 cases were diagnosed clinically Anaphylaxis as the cause of death.
- **Twelve cases** out of 13, were clearly fixed by autopsy and/or clinical course.

Investigation points:

- Anaphylaxis may be caused by any drug injection, esp. contrast medium, antibiotics and muscle relaxant, if it was used safely multiple times in the past, may cause fatal anaphylactic shock.

[Time course]

- Ten cases out of 12,
  signs of anaphylaxis : within 5 min.
  irreversible conditions : by 20 min.
- "0.3mg Adrenaline Intramuscular Inject." was done only in one case before the resuscitation.

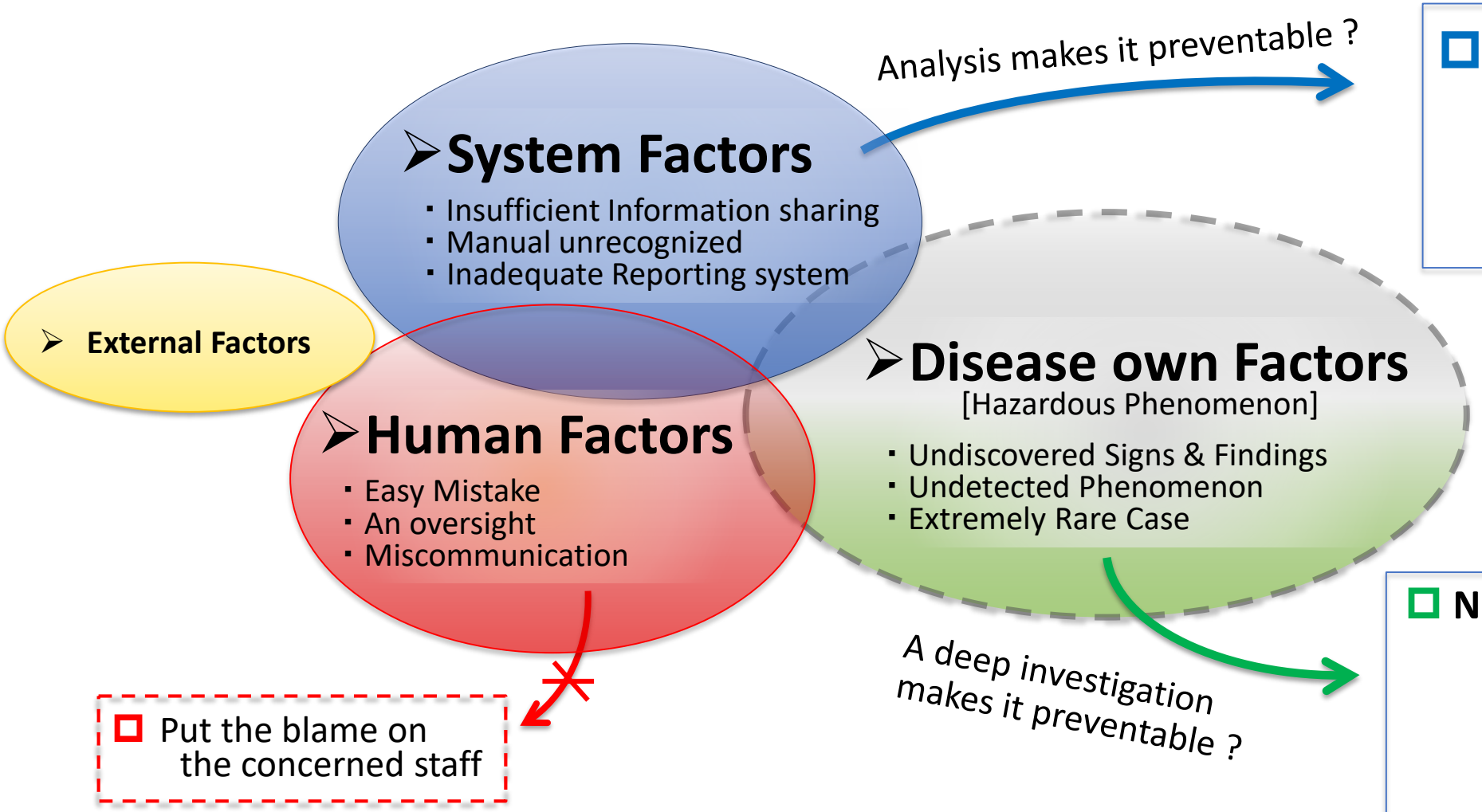


Recommendations

1. **At least 5 minutes, observe the patient** carefully after intra-venous injection of drugs, such as contrast medium, antibiotics, muscle relaxant, etc.
2. If the patient shows **an abnormal sign suspected anaphylaxis**, without waiting for a definitive diagnosis, prepare "0.3mg Adrenaline IM".
3. If suspected, **do not hesitate to inject "0.3mg Adrenaline IM"** into the anterolateral thigh.

Consideration

Factors related to “Medical Accident” including “Unforeseen”



Structural Reform

- System Approach
  - Team Meeting
  - Review Manual over again
  - Ensure the report delivery
- “TeamSTEPPS”

Safety in medicine

Quality in medicine

Newly Detected Knowledge

- Through the investigation, a new knowledge of phenomenon or disease revealed
- The investigation contributes to a new progress in medicine

"Medical Accident Investigation System" in Japan

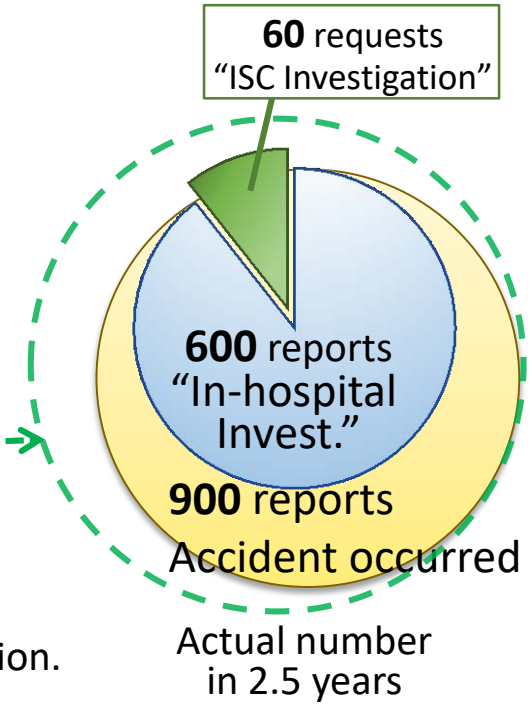
Summary

1. Actual reported numbers, as a result of 2 years and a half operation :

- ✓ Over 900 Accidents reported ＞ About 600 "In-Hospital Investigation" reports ＞ About 60 requested for "ISC Investigation"

- **In 90% cases, "In-hospital Investigation" was accepted with satisfaction**

2. "True number of Medical Accident" :



- ✓ **Actual reported number : 3.2 cases /million people / year**

- ✓ Toward the whole accidents report :
  - ・This system depends on the medical profession's continuing responsibility to self-regulation.

- **The results under mandatory regulation does not work well effectively for the Patient Safety. The physicians initiative participation in the system should be basic, responding to the trust.**

3. Proposal for Preventive Measures against Accidents :

- ✓ Among "In-Hospital Investigation Reports", those cases selected according to the theme, were looked into deeply and investigated again. After comparing each case, they were accumulated the points in common and were drawn up the preventive measures, focusing on the importance of avoiding accidents that may lead to death.

- **From a small number of cases, through the investigation, we could draw valuable preventives.**

- **"Investigation" is essentially important, in cooperation with the "Big-Data of Reporting System".**