Briefing on Patient Safety Incident Reporting and Learning System for Day Procedure Centres

Office for Regulation of Private Healthcare Facilities

Department of Health

Purpose of the briefing

- To enable operators of day procedure centres ('DPCs') to familiarise themselves with the patient safety incident reporting and learning system ('PSI System') for DPCs, including the reporting criteria and workflow.

Contents of the briefing

Programme
[1] Introduction of the PSI System for DPCs
[2] Details of the PSI System for DPCs
[3] Question & Answer Session

[1] Introduction of the PSI System for DPCs

Background

- According to the Private Healthcare Facilities Ordinance (Cap. 633) ('the Ordinance'), the Code of Practice for Day Procedure Centres ('CoP') is issued by the Director of Health ('the Director') to provide standards for all DPCs licensed under the Ordinance.

- The CoP would be regularly reviewed by the Advisory Committee for Regulatory Standards for Private Healthcare Facilities, which advised the Director to incorporate details of the requirements of the PSI System in the CoP.

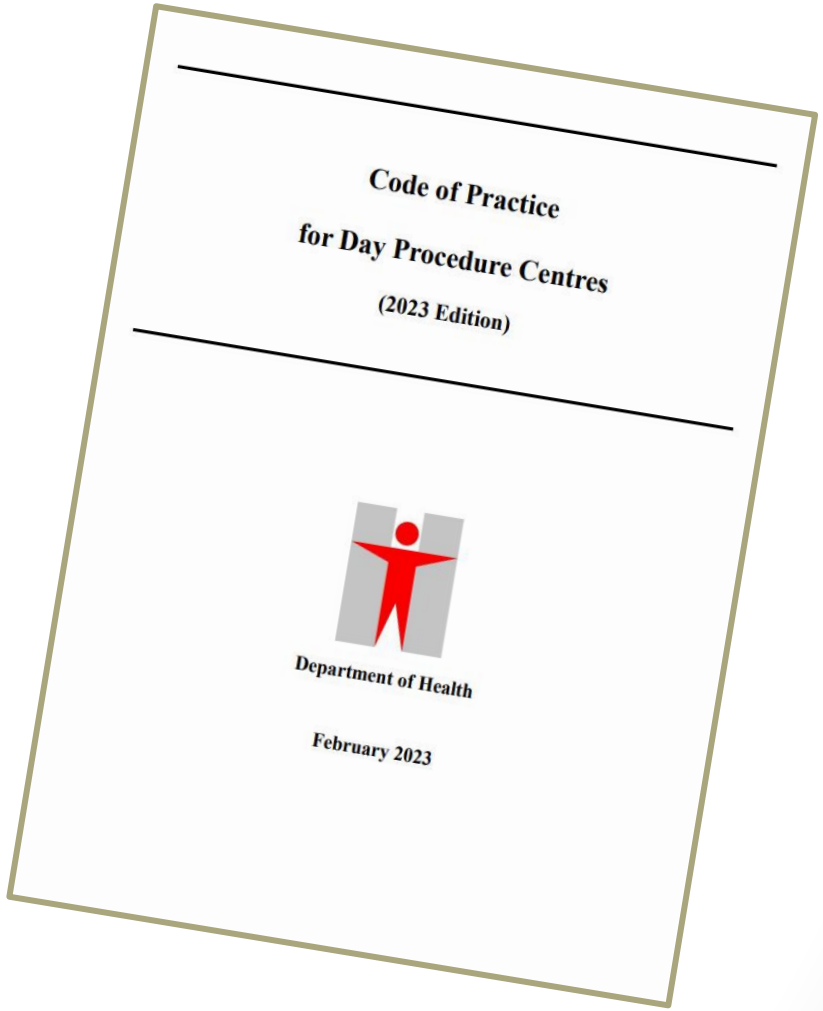
Purpose of the PSI System

- The PSI System aims to enhance patient safety through the identification and reduction of risks.

- It is not for fault finding, but rather to
  - facilitate the understanding of underlying causes of an event
  - reduce the probability of recurrence of the event in the future by changing the organisation's systems and processes
  - learn from experience and disseminate the lessons learnt to other DPCs

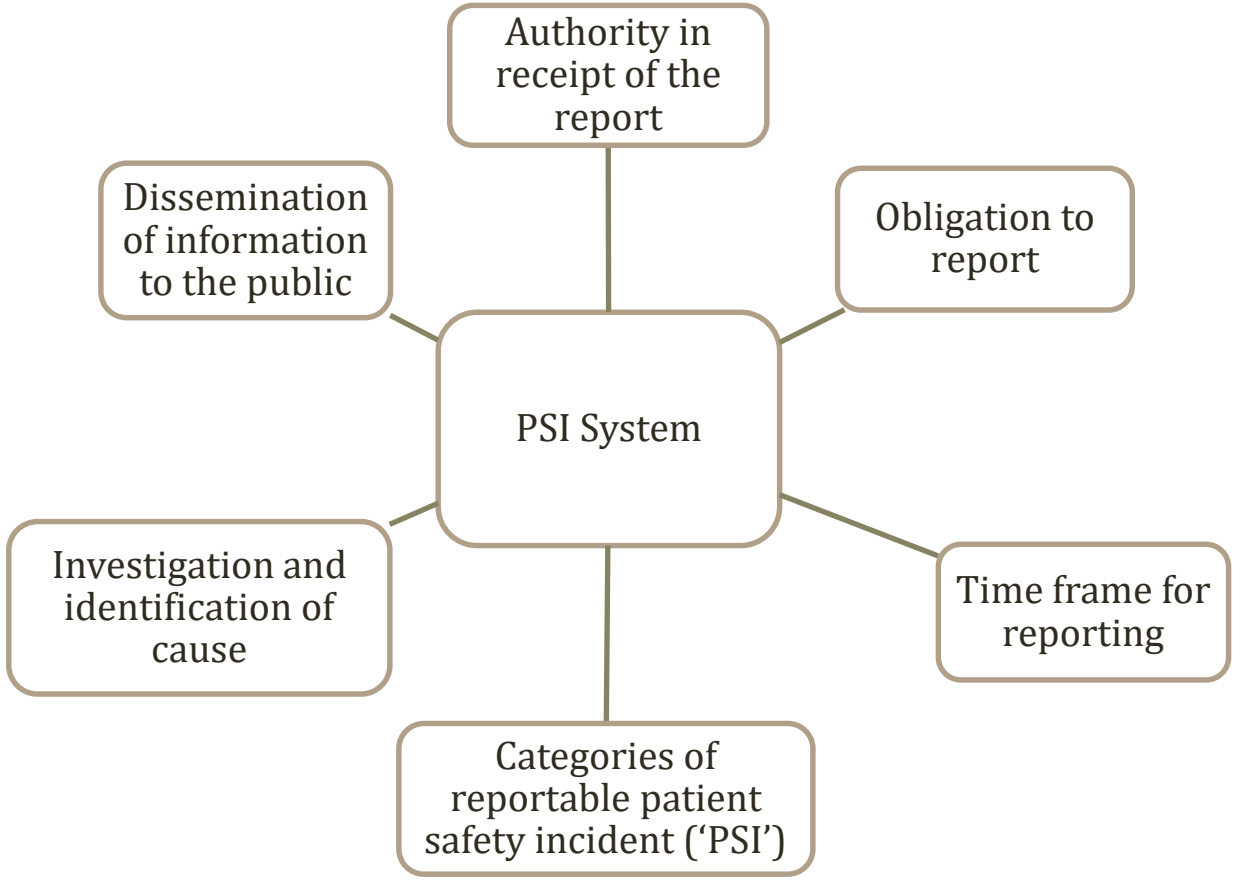
Implementation of the PSI System

- Requirement to report specified reportable events to the Department of Health ('DH') had been stipulated in the previous version of the CoP for DPCs.
- The revised CoP for DPCs, published in the gazette on 6 January 2023, included further details of the requirements of a PSI System in paragraph 1.3.8.
- The requirements shall **take effect on 1 July 2023**.



PSI System for DPCs

- The six key elements:



PSI System for DPCs

Notification to DH

- SE/ SUE: within 24hrs upon identification
- OE: upon identification

Investigation and identification of cause

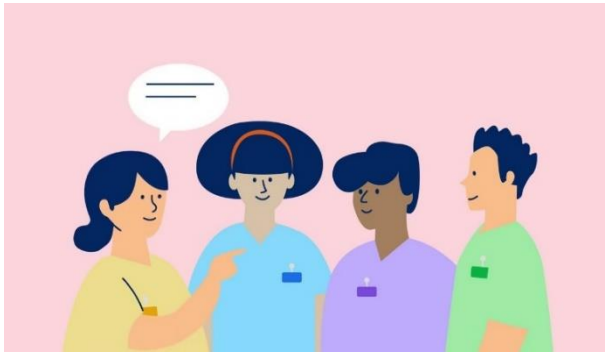
- Identification of contributing factors and causes, focusing on systems and processes

Improvement measure formulation and implementation

- Implementation of a risk reduction action plan
- Report the progress to DH

Dissemination of information

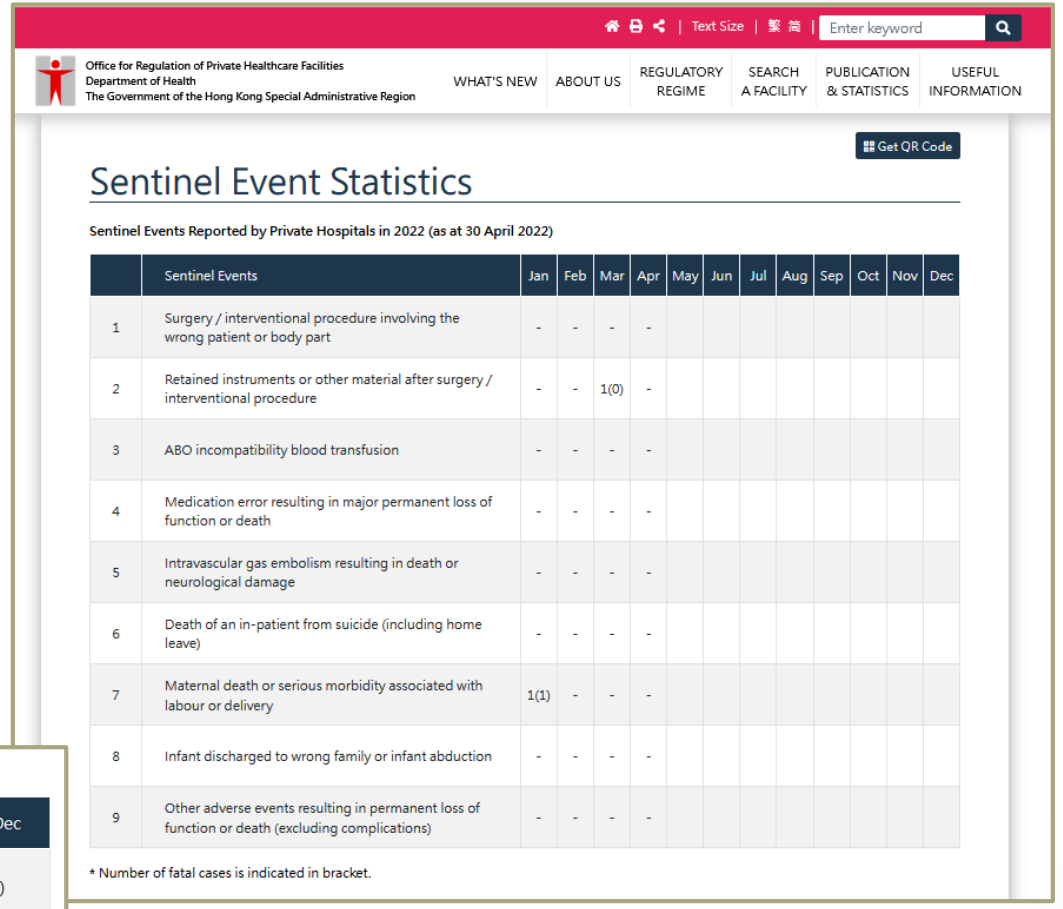
- Formulation of a communication plan to relevant parties such as staff, patient and the public



SE:	sentinel event
SUE:	serious untoward event
OE:	other reportable events

Dissemination of information to the public

- For private hospitals, monthly sentinel event and quarterly serious untoward event statistics are published on the ORPHF website for access of the public.
- A similar approach will be adopted for DPCs.



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Office for Regulation of Private Healthcare Facilities
Department of Health
The Government of the Hong Kong Special Administrative Region

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Sentinel Event Statistics

Sentinel Events Reported by Private Hospitals in 2022 (as at 30 April 2022)

	Sentinel Events	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	Surgery / interventional procedure involving the wrong patient or body part	-	-	-	-								
2	Retained instruments or other material after surgery / interventional procedure	-	-	1(0)	-								
3	ABO incompatibility blood transfusion	-	-	-	-								
4	Medication error resulting in major permanent loss of function or death	-	-	-	-								
5	Intravascular gas embolism resulting in death or neurological damage	-	-	-	-								
6	Death of an in-patient from suicide (including home leave)	-	-	-	-								
7	Maternal death or serious morbidity associated with labour or delivery	1(1)	-	-	-								
8	Infant discharged to wrong family or infant abduction	-	-	-	-								
9	Other adverse events resulting in permanent loss of function or death (excluding complications)	-	-	-	-								

* Number of fatal cases is indicated in bracket.

Serious Untoward Events Reported by Private Hospitals in 2021

	Serious Untoward Events	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec
1	Medication error which could have led to death or permanent harm or carries a significant public health risk	1(0)	2 (0)	3(0)	2(0)
2	Patient misidentification which could have led to death or permanent harm	-	-	-	-

* Number of fatal cases is indicated in bracket.

[2] Details of the PSI System for DPCs

Outline

1. Categories of reportable patient safety incident
2. Notification of an event
3. Investigation
4. Dissemination of information to the public

Categories of reportable patient safety incident

Sentinel Event (SE)	
1	Surgery / interventional procedure involving a wrong patient or body part
2	Retained instruments or other material after surgery / interventional procedure
3	Medication error resulting in major permanent loss of function or death
4	Intravascular gas embolism resulting in death or neurological damage
5	Other adverse events resulting in permanent loss of function or death (excluding complications)
Serious Untoward Event (SUE)	
1	Medication error which could have led to death or permanent harm or carries a significant public health risk
2	Patient misidentification which could have led to death or permanent harm

Categories of reportable patient safety incident

Other Reportable Event (OE)	
1	Unplanned transfer of a patient to a hospital directly from a DPC during or after a planned procedure, which emergency management was required at the hospital
2	Other events of public health significance (for example, radiation health incidents, or serious incidents, such as cessation of water or electricity supply, resulting in harm to patients who are receiving care in the facility)

Categories of reportable patient safety incident

- Explanatory Notes for Reportable Patient Safety Incident
  - Inclusion criteria of SE, SUE or OE
  - Supplementary notes for examples that are intended or not intended to capture

Please refer to Annex I of the PHF(E) 213A Guidance Notes for Reportable SE and SUE of DPC for details

SE 1 : Surgery / interventional procedure involving a wrong patient or body part

- **Inclusion**
  - Any surgery / interventional procedure performed on a patient or a body part that is not consistent with the informed consent
- **Supplementary notes**
  - Surgery / interventional procedure begins at the point of surgical incision, tissue puncture or the insertion of instrument into tissues, cavities or organs
  - Event detected at any time after the start of the surgery / interventional procedure

  - **Not intended to capture**

    Examples:
    - Blood-taking, parenteral administration of drug, or use of otoscope without any intervention
    - Emergency situations that occur in the course of surgery and/or are too urgent to obtain informed consent
    - Unsuccessful procedure as a result of unknown / unexpected anatomy of the patient

SE 2 : Retained instruments or other material after surgery / interventional procedure

- **Inclusion**
  - Unintended retention of foreign objects inside the body discovered at any point after a surgery / interventional procedure ends
  - Foreign objects inserted into a patient's body in surgery / interventional procedure but not removed as planned

- **Supplementary notes**
  - Examples of instruments or other materials
    - Swabs, needles, wound packing materials, sponges, catheter tips, trocars and guidewires

  - **Not intended to capture**
    - Objects that are intentionally left in place
    - Objects known to be missing prior to completion of surgery/interventional procedure and maybe within the patient; but further action to locate and/or retrieve it would not be possible or carry greater risk than retention

SE 3 : Medication error resulting in major permanent loss of function or death

- **Inclusion**
  - Error in the prescribing, dispensing, or administration of a medicine resulting in permanent loss of function or death
    - Wrong drug/dose/patient/time/rate/preparation/route of administration

- **Supplementary notes**
  - **Not intended to capture**
    - Major permanent loss of function or death associated with allergies that could not be reasonably known or discerned in advance of the event
    - Differences in clinical judgement on drug selection, dose and route of administration

SE 4 : Intravascular gas embolism resulting in death or neurological damage

- **Inclusion**
  - Death or neurological damage as a result of intravascular air embolism introduced during intravascular infusion or bolus administration, or through a haemodialysis circuit

- **Supplementary notes**
  - **Not intended to capture**
    - Through surgical site (particularly in ear, nose, throat surgery)
    - During foam scleropathy
    - Deliberately by the patient

SE 5 : Other adverse events resulting in permanent loss of function or death (excluding complications)

- **Inclusion**
  - Any injury related to medical management, in contrast to the natural course of a patient's illness or underlying condition or known complication of treatment, resulting in permanent loss of function and death

- **Supplementary notes**
  - Medical management includes all aspects of care, including diagnosis and treatment, and systems and equipment used to deliver care

  - **Not intended to capture**
    - Event relating to the natural course of patient's illness or underlying condition
    - Event relating to known complication of treatment
    - Death or loss of function following a discharge against medical advice
    - Healthcare-acquired infections

SUE 1 : Medication error which could have led to death or permanent harm or carries a significant public health risk

- **Examples** (for general reference only; not exhaustive)
  - Medication error involving any of the following **high alert medications** that have been unintendedly administered*:
    - Concentrated electrolytes
    - Chemotherapeutic agents
    - Drug associated with known drug allergies (e.g. penicillin, aspirin, NSAIDs)
    - Vasopressors and inotropes
    - Anticoagulants
    - Neuromuscular blocking agents (e.g. atracurium, rocuronium)
    - Oral hypoglycaemics
    - Insulins
    - Narcotics (e.g. fentanyl) and opioids
  - Other adverse events related to medications requiring intervention or extension of monitoring

* For avoidance of doubt, drug dispensed to patient for bringing home are deemed to be administered

SUE 2 : Patient misidentification which could have led to death or permanent harm

- **Examples** (for general reference only; not exhaustive)
  - Misidentification on prescription resulting in a dose of medication (e.g. anticoagulant) given to a patient not requiring the drug which led to intervention or prolonged monitoring
  - Wrong labelling and mix-up of biopsy specimens of two patients resulting in a delay of cancer treatment
  - Wrongly referring to the laboratory report of another patient resulting in wrong administration of syrup potassium chloride (KCl) to a patient with renal impairment which led to an elevated blood potassium level of the patient

OE 1 : Unplanned transfer of a patient to a hospital directly from a day procedure centre during or after a planned procedure, which emergency management was required at the hospital

- **Inclusion**
  - Unplanned transfer of a patient from a DPC to a hospital directly

    AND
  - The patient was receiving or had received a planned procedure at the DPC

    AND
  - The patient required emergency management at the hospital

Examples of emergency management
- cardiopulmonary resuscitation
- use of defibrillator
- use of emergency medications such as adrenaline, inotropes and vasopressors
- airway management such as endotracheal intubation
- emergency operation
- fluid resuscitation for hemodynamically unstable patients
- blood transfusion for massive blood loss

OE 1 : Unplanned transfer of a patient to a hospital directly from a day procedure centre during or after a planned procedure, which emergency management was required at the hospital

- **Not intended to capture**
  - The return of a patient to a hospital after receiving service at a DPC
  - The transfer of a patient with condition that is not related to the planned procedure received at a DPC
  - The transfer of other persons who are not patients of a DPC

OE 2 : Other events of public health significance

- **Inclusion**
  - Radiation health incidents

OR

  - Serious incidents, such as cessation of water or electricity supply, resulting in harm to patients who are receiving care in the facility

- **Supplementary notes**
  - **Not intended to capture**
    - Cessation of water supply in haemodialysis centre not affecting patient care
    - A surgical / interventional procedure was interrupted by cessation of electricity supply, but was able to be completed or ceased safely without harm to patient

Notification of an event

Occurrence of a patient safety incident in DPCs

under the reporting criteria of SE, SUE, or OE

Notify DH for the reportable event

*SE or SUE: Notify **within 24 hours** upon identification*

*OE: Notify **upon identification***

Submit **notification form (PHF 213)** through email or fax.

**For events requiring immediate attention of DH, DPCs should first inform DH by telephone, followed by email*

Inform the **patient and/or patient's relatives/ carer/representative (PHF 215)**

Please refer to the *Guidance Notes for Reportable Sentinel Events and Serious Untoward Events of Day Procedure Centres* for further details

PHF 213 Notification Form for Reportable Events of Day Procedure Centres

Notification of an event

- **PHF 213 Notification Form for Reportable Events of Day Procedure Centres**
- Problem description
  - Date, time, background information of patient, brief description of event
- Type of reportable patient safety incident
  - SE, SUE or OE
- Consequence of event
  - Patient's outcome and current condition, measures taken, etc

PHF 215 Notice to Patient or Relative for Investigation

衞生署展開醫療事件調查 - 病人及/或病人家屬通知書

衞生署接獲_____('日間醫療中心')於_____年_____月呈報一宗涉及你/你家人的個案，衞生署現正了解事件。日間醫療中心可能會徵求你同意向其他醫療機構索取醫療紀錄，如個案涉及死因裁判官的調查，衞生署會要求日間醫療中心提供有關死者的資料，以便跟進調查結果。如欲聯絡衞生署，請致電衞生署私營醫療機構規管辦公室(電話：3107 8451)。

若有關個案屬於醫療風險警示事件或重要風險事件，衞生署會將不具名的個案摘要上載於衞生署的網頁(https://www.orphf.gov.hk/tc/publication_statistics/sentinel_event_statistics)。衞生署將按《個人資料（私隱）條例》及香港特別行政區政府的處理個人資料的政策及指引，處理任何需要發布的資料。

衞生署私營醫療機構規管辦公室
日期：_____

An Investigation of Medical Incident Conducted by the Department of Health – Notice to the Patient and/or Patient's Relatives

The Department of Health ('DH') received notification of a case about you/your relative from _____ ('the day procedure centre') in _____(month), _____(year). DH is now looking into the matter. The day procedure centre may seek your consent to access medical record in other healthcare facilities. If the case involves the Coroner's investigation, DH will request the day procedure centre to provide information of the deceased for follow-up of investigation. If you wish to contact DH, please call the Office for Regulation of Private Healthcare Facilities of DH at 3107 8451.

If the case concerned is classified as a sentinel event or a serious untoward event, DH will upload the anonymous case summary on DH's website (https://www.orphf.gov.hk/en/publication_statistics/sentinel_event_statistics). DH will adhere to the Personal Data (Privacy) Ordinance and relevant policies and guidelines of the Government of the Hong Kong Special Administrative Region on the handling of personal data should relevant information need to be released.

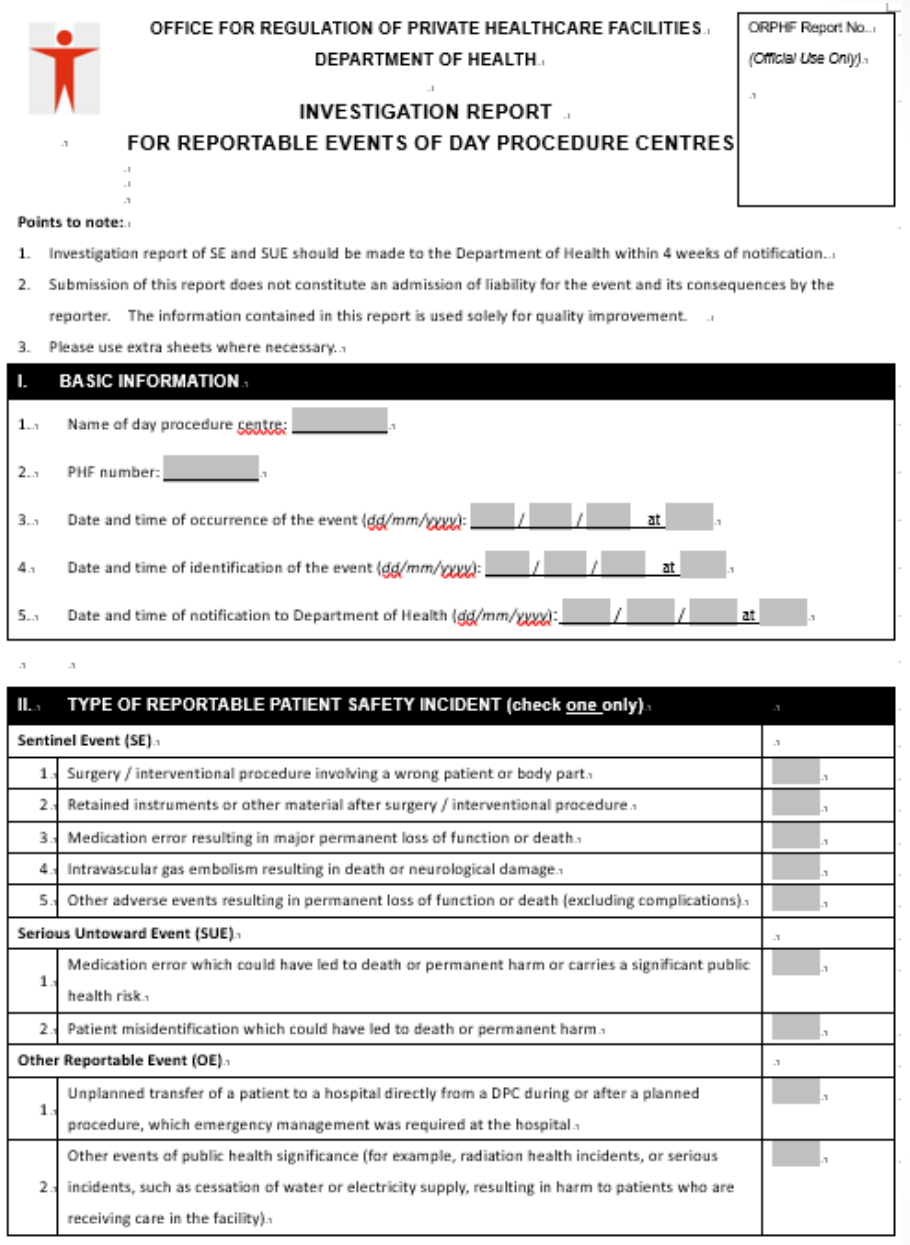
Investigation

- **Investigation and identification of cause** is necessary to guide formulation of improvement measures to avoid recurrence of similar events
  - **Identify the factors** that underlie variation in performance, including the occurrence or possible occurrence of SE, SUE or OE
  - **Focuses primarily on systems and processes**, not on individual performance

- Staff involved in the reported event should avoid participating in the investigation as far as possible to maintain impartiality

PHF 214 Investigation report for Reportable Events of Day Procedure Centres

Submit through email within **4 weeks** of notification



OFFICE FOR REGULATION OF PRIVATE HEALTHCARE FACILITIES
DEPARTMENT OF HEALTH

ORPHF Report No.
(Official Use Only)

INVESTIGATION REPORT
FOR REPORTABLE EVENTS OF DAY PROCEDURE CENTRES

Points to note:

1. Investigation report of SE and SUE should be made to the Department of Health within 4 weeks of notification.
2. Submission of this report does not constitute an admission of liability for the event and its consequences by the reporter. The information contained in this report is used solely for quality improvement.
3. Please use extra sheets where necessary.

I. BASIC INFORMATION

1. Name of day procedure centre: _____
2. PHF number: _____
3. Date and time of occurrence of the event (*dd/mm/yyyy*): ____ / ____ / ____ at ____
4. Date and time of identification of the event (*dd/mm/yyyy*): ____ / ____ / ____ at ____
5. Date and time of notification to Department of Health (*dd/mm/yyyy*): ____ / ____ / ____ at ____

II. TYPE OF REPORTABLE PATIENT SAFETY INCIDENT (check one only)

Sentinel Event (SE)		
1.	Surgery / interventional procedure involving a wrong patient or body part	
2.	Retained instruments or other material after surgery / interventional procedure	
3.	Medication error resulting in major permanent loss of function or death	
4.	Intravascular gas embolism resulting in death or neurological damage	
5.	Other adverse events resulting in permanent loss of function or death (excluding complications)	
Serious Untoward Event (SUE)		
1.	Medication error which could have led to death or permanent harm or carries a significant public health risk	
2.	Patient misidentification which could have led to death or permanent harm	
Other Reportable Event (OE)		
1.	Unplanned transfer of a patient to a hospital directly from a DPC during or after a planned procedure, which emergency management was required at the hospital	
2.	Other events of public health significance (for example, radiation health incidents, or serious incidents, such as cessation of water or electricity supply, resulting in harm to patients who are receiving care in the facility)	

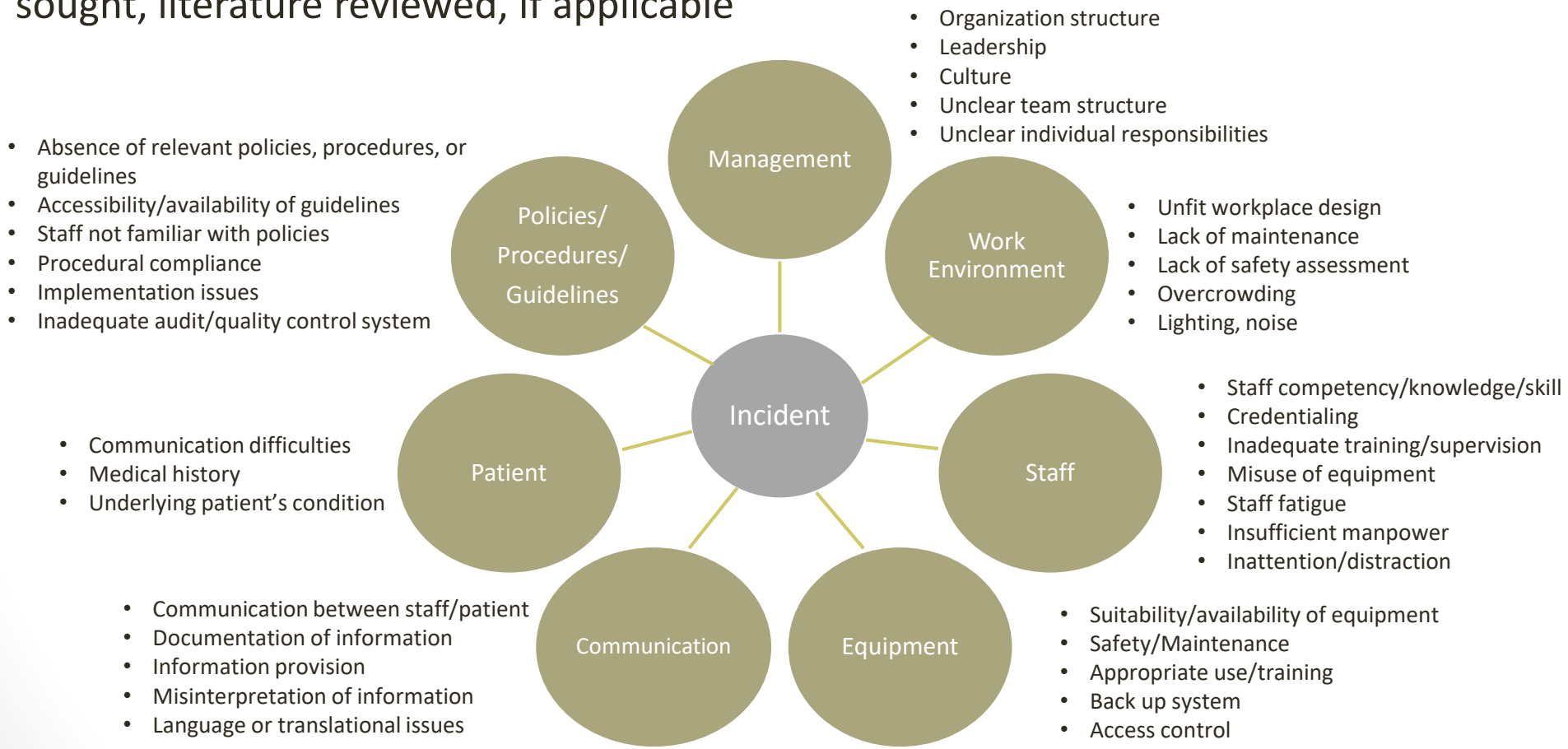
Investigation

PHF 214 Investigation report for Reportable Events of Day Procedure Centres

- Basic information
  - Date and time of the event occurrence, identification and notification
- Type of reportable patient safety incident
  - SE, SUE or OE
- Patient information
  - Patient particulars, past medical history, date and reason of attendance, treatment performed, outcome
- Event Summary
  - What happened, when and where it happened, who was involved, how it happened, what was the outcome
- Chronology of the event
  - Date, time and location of events
- Staffing at the time of the event
  - Role and qualification of the staff involved
- Designated personnel for investigation
  - Name and post of the investigator or investigation team members

Investigation

- Investigation of the event
  - Review all possible contributing factors and causes
  - Description of analysis/methodology adopted, information collected, expert opinion sought, literature reviewed, if applicable



VIII. INVESTIGATION OF THE EVENT

1. Please review all the following possible contributing factors and causes to the reportable event during the investigation:

Please put a √ at the corresponding box in front of your selected option, which is considered as possible contributing factor(s). You can select more than one option of factors.
Please elaborate the details of the contributing factor(s) identified.

☐ **Management**

e.g. Organization structure, leadership, culture, unclear team structure, unclear individual responsibilities, etc.

Details of the contributing factor(s) identified:

☐ **Policies/Procedures/Guidelines**

e.g. Absence of relevant/up-to-date policies, procedures or guidelines, accessibility/availability of guidelines, issues in applying policies, staff not familiar with policies, procedural compliance, implementation issues, inadequate audit/quality control system, etc.

Details of the contributing factor(s) identified:

☐ **Staff**

e.g. Staff competency/knowledge/skill, credentialing, inadequate staff training, inadequate supervision, misuse of equipment, skill gap not recognized, working beyond skill level, staff fatigue, insufficient manpower, staff schedule/rostering issue, inattention/distraction, etc.

Details of the contributing factor(s) identified:

☐ **Patient**

e.g. Communication difficulties, medical history, underlying patient's condition, etc.

Details of the contributing factor(s) identified:

☐ **Communication**

e.g. Communication between staff, communication between staff and patient/family, documentation of information, information provision, misinterpretation of information, language or translational issues, etc.

Details of the contributing factor(s) identified:

☐ **Work Environment**

e.g. Unfit workplace design/layout, lighting, noise, overcrowding, environmental stressors, lack of safety assessments/ evaluation/procedures, lack of maintenance, etc.

Details of the contributing factor(s) identified:

☐ **Equipment**

e.g. Suitability/availability/lack of equipment, safety/maintenance, appropriate use/training, back-up system, access control, etc.

Details of the contributing factor(s) identified:

☐ **Other Factor**

Details of the contributing factor(s) identified:

Investigation

- Referral to other authorities
  - Criminal issue, professional misconduct and etc.
- Risk reduction action plan
  - Risk, cause or learning identified
  - Corresponding action taken or implementation plan with due date of completion
- Communication plan/action
  - Staff, patient/patient's relatives, public/media
- Conclusion
  - Summary of cause of the event
  - Interim actions taken/long term action planned
- Submission
  - CME's endorsement

Investigation

- DH may **conduct site inspection** to the DPCs for investigating the event
- DPCs may also be required to **submit supplementary information**
- DH will request DPCs to **report the progress of implementation of the risk reduction action plan** and submit documents to prove the action taken
- DPCs should **notify other relevant authorities** as necessary, such as the professional boards and councils in case of professional misconduct

Dissemination of information to the public

- DPCs should draw up their **risk communication plan**
- DH will publish **monthly statistics of SE and quarterly statistics of SUE** on DH website.
- If SE involve unanticipated death or serious morbidity, individual private healthcare facilities should have ready communication plan with designated person to respond to media enquiries.
- DH will make a public announcement if there is significant public health impact, ongoing public health risk, or if it is preventable by immediate action

[3] Question & Answer Session

Office for Regulation of Private Healthcare Facilities Department of Health

www.orphf.gov.hk