

Adverse Events



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*Enhancing Quality Assessment and
Performance Improvement Programs
in Transplant Programs and Hospitals*

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CMS Webinar Series

Transplant Centers



1. Introduction to the Transplant QAPI: Regulatory Overview
2. Worksheet Overview
3. Comprehensive Program and 5 Key Aspects of QAPI
4. Objective Measures
5. Performance Improvement Tools and Methods
- 6. Adverse Events**
7. Transplant Adverse Event “Thorough Analysis”
8. QAPI Tools (part 1)
9. QAPI Tools (part 2)
10. Data display
11. Writing an effective Plan of Correction and Other QAPI Resources
12. Interpretive Guidelines

Disclaimer



- This training series will contain concepts, tools and methods used to identify, address, and document adverse events and patient safety systems (as they were originally developed) and regulatory guidance to help transplant programs meet compliance with the Conditions of Participation.
- CMS understands that: 1) Healthcare has various definitions of what an Adverse Event is, 2) There are many methods that can be employed and 3) There are many tools that can be utilized within Adverse Events activities.
- CMS also understands that organizations have leeway to severity rank and define adverse events within their own organization in accordance to what their governing body has established , so long as the activities required under the CMS Adverse Event definition are fulfilled.
- CMS is never prescriptive in the tools/methods required for an organization to meet compliance. This training series does not support or advocate any particular method or tool. This training fully supports that patient safety activities include data driven decisions that lead to improved performance and ultimately the prevention of harm to patients.

Purpose and Objectives

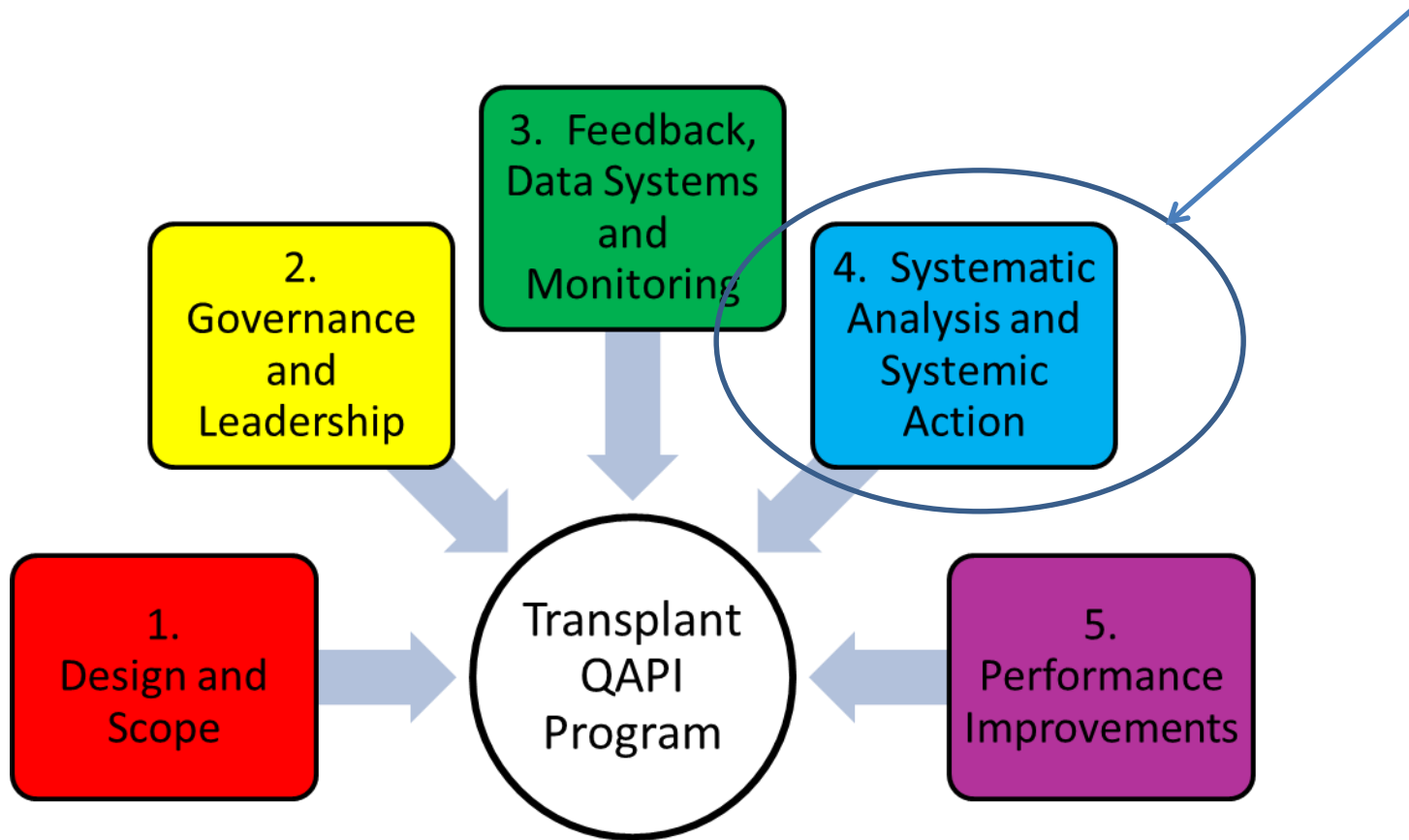
The purpose of this session is to enhance the safeguarding of recipients and living donors through:

- An increased understanding of regulations,
- An understanding of adverse event identification methods,
- The use of analysis techniques / tools, and
- An understanding of documentation practices with QAPI activities.

Upon completion of this session, the participant will be able to:

- Discuss the meaning of an Adverse Event as it applies to a Transplant program utilizing CMS' definition.
- Identify the requirements for Transplant programs in relation to Transplant Adverse Events.
- Specify critical elements of an Adverse Event Action Plan utilizing the results of a 'thorough analysis'.

The 5 Key Aspects of Transplant Quality



Aspect 4: Systematic Analysis and Systemic Action



- Transplant programs must develop **policies and procedures** and demonstrate **proficiency** in conducting a **thorough analysis**.
- The transplant QAPI program must **analyze** collected **data**.
- Analyses must **include, but are not be limited to**, analysis of data related to proactively defined quality indicators and the ongoing use of systemic methods to **assess and analyze adverse events**.

Aspect 4 - Systematic Analysis and Systemic Action



- Transplant adverse events must be **identified, tracked, investigated, analyzed,** and the **results used to prevent recurrence.**
- There must be **evidence** that the transplant QAPI program develops **system-based interventions** to improve quality of care and performance on an ongoing basis to reduce risk of harm to patients.
- Systemic actions look **comprehensively** across all involved systems to **prevent** future negative events and promote **sustained** improvement.
- The transplant QAPI program uses an identifiable **structure, policies and procedures** to address investigation of **root and contributing causes** of transplant quality issues and **document actions** taken toward correction and sustaining change.

TRANSPLANT ADVERSE EVENTS



Adverse Events are components of Hospital Quality activities and the Patient Safety system. Transplant programs have specific requirements under the CoP for QAPI at 482.96 to develop and maintain an Adverse Event Policy, to document any Adverse Event during any phase of transplantation or living donation, to conduct a 'thorough' analysis on any adverse event and to utilize the findings of the 'thorough' analysis to prevent future re-occurrences.

The manner in which adverse events are dealt with within Transplant Programs may be different than how hospitals have dealt with these items in the past.

The best way to think about what an Adverse Event is for a transplant program is to understand **WHO responds** to the patient and **WHO makes changes to the patient's plan of care** when an event that has caused harm or has the potential of causing harm has occurred.

REGULATION STANDARD



482.96 (b) Standard: Adverse Events

TAG X102

IMPLEMENT WRITTEN POLICIES to address ADVERSE EVENTS

*A transplant center **must** establish and implement written policies to address and document adverse events that occur during **any phase** of an organ transplantation case. (Includes Living Donors, where applicable)*

*(1) The policies must address, at a minimum, the process for the **identification, reporting, analysis, and prevention** of adverse events."*

INTERPRETIVE GUIDELINES

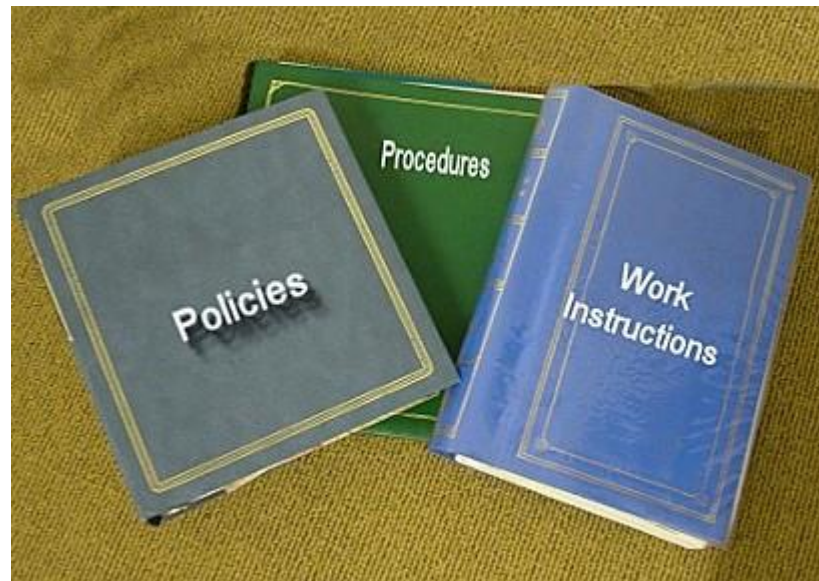


The policy **MUST address** the following and **be implemented** throughout the program:

- a) All organ types (transplant recipients and living donors),
- b) Process for identification of adverse events,
- c) Severity of events that are tracked and analyzed,
- d) Reporting of adverse events ,
 - i. Within the hospital
 - ii. To local or state agencies
 - iii. To the Organ Procurement and Transplantation Network
 - iv. To the Organ Procurement Organization
- e) Disclosure of adverse events to the patient(s) or family,
- f) Analysis of adverse events,
 - i. How will the event be analyzed
 - ii. Who is responsible for conducting the review
 - iii. What types of events will be reviewed and **by whom**
- g) Actions taken to **prevent** similar adverse events.

ADVERSE EVENT POLICY

ESTABLISHING AND IMPLEMENTING



Defining Adverse Events

Compliance with the
Conditions of Participation
will always be based on
CMS definitions.



CMS Definition



42 CFR 482.70 Definitions.

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, **or the risk thereof.**

As applied to transplant centers, **examples** of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended beneficiaries; and unintended transmission of infectious disease to a recipient.

SOURCE: (42 CFR 482.70) STATE OPERATIONS MANUAL (SOM: 2060)

Other Organization Definitions



Institute for Healthcare Improvement (IHI): “Unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization, or that results in death”.

American Society for Quality (ASQ): “Healthcare term for any event that is not consistent with the desired, normal or usual operation of the organization; also known as a sentinel event”.

National Quality Forum (NQF): “An event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient”.

World Health Organization (WHO) [International Classification for Patient Safety (ICPS)]: “A patient safety incident is an event or circumstance that could have resulted, or did result, in unnecessary harm to the patient. The classification system further defines event, error, patient safety and incident”.

Adverse events may take on several names within a facility including:

Incident
Critical Incident
Safety Incident
Near Miss
Close Call
Safety Event
Occurrence
Patient Safety Event
Critical Event
Never Event
Sentinel Event



SECTION SUMMARY



- Surveyors are aware of the many different names and definitions that can be utilized within an organization or transplant program.
- The terminology utilized within the transplant program or hospital organization is not the primary concern. Surveyors will focus on the required components for the adverse event policy, that thorough analyses are being performed and that the results of the analyses are being utilized to prevent future events.
- The CMS definition will always be applied to the survey process for determining compliance with the Transplant Regulations (Tags X102, X103 and X104 specifically).

Identification



Does the Transplant Program's
Adverse Event policy clearly
define the methods and tools
that will be utilized to Discover
or Identify Adverse Events for
Recipients and Living Donors?

Policy Example 1

Non-Compliant



POLICY: XYZ Transplant programs follow the hospital's cause analysis process to identify, track, analyze and report safety events occurring in patients being evaluated, listed and/or transplanted.

PROCEDURE: If an event is deemed to be a serious safety event (SSE) appropriate cause analysis will then occur, led by the Performance Improvement Department. This includes a time line of the events preceding transplant, as well as during the patient's course of care and transplant process. SSEs involving the transplant program would include representatives from the organ specific QAPI program on the stakeholder group for the event.

Reporting a safety event:

1. If any event meets the criteria for a safety event as per the hospital protocol the incident is reported through the Medical Center event reporting system. Events with harm score are specifically reviewed by PI and Risk Management to determine if additional cause analysis is needed.
2. Adverse events for transplantation resulting in death will be reported to the OPTN via UNet.
3. Any infections that may have been transmitted from the donor to the recipient will be reported to the CDC and to the OPTN as well as the Organ Procurement Organizations involved with organ recovery.

Tracking safety event:

1. A log is maintained in the Health System's Performance Improvement Department and transplant related safety event report is presented to the organ specific QAPI sub-committee during the monthly meeting.
2. The case is presented in the QAPI meeting to analyze the safety event using the cause analysis process.
3. Outcome will be tracked in a QAPI process, followed up at the quarterly QAPI steering committee meeting and shared with the organizational leadership.

Policy Example 2

Compliant



PURPOSE: To appropriately identify, report, investigate, and analyze transplant related adverse events as required in the CMS regulations COP 482.70. An adverse event is defined as an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof.

IDENTIFICATION OF ADVERSE EVENTS: As per hospital policy, an Occurrence Report shall be completed immediately in Safeguard by the Associate who first identifies the event. Additionally, transplant-specific adverse events will be reported to Transplant Administration and/or the UNOS Safety Contact by the person who identifies the event. A log of these events will be retained.

Adverse events may include, but are not limited to, the following:

- Transplant of an organ into an unintended recipient.
- Transplant of an organ into an ABO incompatible recipient.
- Patient death within 1 year of transplant.
- Return of a Living Donor to the Operating Room during the peri-operative period.

GENERAL INFORMATION: Adverse event trends, RCA findings, and actions to prevent repeat incidents will be reported to the appropriate organ specific Quality Assessment Performance Improvement (QAPI) committee.

Detection of Safety Hazards



- An institution's picture of patient safety will hinge on which method they emphasize for **error detection**, and a comprehensive picture can only be obtained by integrating multiple methods.
- A seminal study that compared safety data from five separate sources (voluntary error reports, malpractice claims, patient complaints, executive walk rounds, and a risk management database) found that each source identified different types of errors.
- There are no consensus standards on how hospitals or clinics should assess their safety hazards, either prospectively or retrospectively. What is clear, however, is that no single method is comprehensive enough to provide a full picture of patient safety at an institution.

There are many methods and tools that aid in the Discovery, Detection and Identification of Adverse Events

One widely accepted method is the use and application of 'Triggers'

Discoverability and Identification



Traditional efforts to detect adverse events have focused on voluntary reporting and tracking of adverse events (errors).

Conventional attempts to quantify adverse events have included voluntary incident reports, retrospective or concurrent record reviews (sometimes supplemented by “bedside” surveillance), and abstraction of events from observational databases.

The concept of a “**trigger**” (or clue) to identify adverse events in the medical record was introduced in 1974. The use of triggers with manual record reviews was initially developed by the Institute for Healthcare Improvement (IHI) in 1999 to identify only adverse medication events; adaptation of the methodology for other areas of the hospital, such as intensive care, followed. The adoption of triggers will help reviewers by standardizing the review methodology to determine if positive indicators suggest the presence of a potential adverse event.

Adverse Event Triggers



IDENTIFICATION / DISCOVERY / INITIAL AWARENESS

Transplant Adverse Event Triggers

Potential Category Examples

- Medication
 - Over-sedation
 - Anticoagulation issues
 - Constipation/Ileus
 - Allergic reactions
- Infections (Hospital Acquired – HAI's)
 - Surgical Site Infections
 - CAUTI
 - CLABSI
 - Clostridium difficile
- Patient Care
 - Exacerbation of pre-existing conditions
 - Electrolyte disorder
 - Venous Thromboembolism / DVT / PE
 - Poor Glycemic Control / Episodes
 - Wrong Patient / Wrong Procedure
 - Blood Transfusions / Incompatibility
 - Nutritional allergic reactions
 - Re-admissions (preventable)
 - Misinterpretations of medical orders
- Environment of Care
 - Falls
 - Slips/Trips
 - Pressure Ulcers
 - Oxygen Therapy (Toxic Substances in lines)
 - Electrical Shock
 - Burns from any source
- Documentation / Communication
 - Transcribing Errors
 - Order Entry Errors
 - Verbal Orders

Transplant Adverse Event Triggers 1



Examples of potential triggers to check for adverse events

Medication

- Reversal agent documented in medical record
- INR level increasing / decreasing
- Change in medication therapy in physician orders / progress notes
- Medication reconciliation documents do not match
- Constipation noted in nursing notes / care plan
- Benadryl or Epi used to treat patient's condition
- Rapid Response team or other medical interventions

Transplant Adverse Event Triggers 2



Examples of triggers to check for potential adverse events

Patient Care

- Blood sugars increasing / decreasing without intervention
- Patient unstable (vital signs, lab results)
- Dietician note or tag in medical record that patient received an item they were allergic to
- Interview with patient identified a food allergy or medication allergy and this is not noted in medical record.
- Patient re-admitted for fever, dehydration or fatigue
- Pharmacy / Medication Safety minutes discuss orders not followed or order that were not legible

Transplant Adverse Event Triggers 3



Examples of triggers to check for potential adverse events

Infections

- New antibiotic ordered
- Combination therapy of antibiotic
- Fever
- Swelling of surgical site noted in Medical Record
- Positive Lab result from culture

Transplant Adverse Event Triggers 4



Examples of potential or actual adverse events

Environment of Care

- Fall noted in nursing notes
- Change in skin integrity in nursing assessment
- Burn documents in surgical record
- Treatment for burn or skin issues
- Tagged medical equipment still in patient room
- Interview with patient/family indicates there was a problem with equipment
- Incident reports / Quality reports contain information on slips or trips from nursing unit with transplant patients
- Patient Safety or Safety reports with electrical safety issues discussed.
- Patient Safety or Safety reports with oxygen line issues
- Respiratory Therapy notes with oxygen issues noted

Transplant Adverse Event Triggers 5

Examples of potential or actual adverse events

Documentation / Communication

- Transcribing Errors
- Order Entry Errors
- Handwriting issues
- Verbal Orders
- Electronic Health Record
 - Learning to utilize
 - Physician order entry
 - System issues / communication
- Communication
 - Written
 - Spoken
 - Telephone and other devices



Sources of Triggers



Documentation / Reports

- Action Plans
 - Tasks within the Action Plans are marked as complete with no follow-up activities
 - Action Plans leave questions unanswered
 - Action Plans do not involve hospital leadership or other hospital departments
- Meeting Minutes
 - Discussion of an event that occurred to a patient
 - Recommendations from staff generated in routine discussions
 - Concerns documented about patients with no follow up activities
- Audit Reports
 - Financial audit reports – billing / coding concerns
 - Chart audit reports showing incomplete documentation
 - Peer Review audit summaries indicating concerns with provider practices
 - Mortality & Morbidity (M&M) summary reports indicating practice concerns

Transplant Survey Application Triggers



Surveyors will review a Transplant Programs Adverse Event Policy (as well as Hospital policies) to ensure that the methods/processes or tools that will be utilized within a program to identify any adverse event that occurs during any phase of transplantation or living donation has been clearly developed, defined and implemented across the transplant program – including floor nurses and ancillary staff that may come into contact with or care for transplant patients/living donors.

Once a trigger has been identified on survey, a ‘Tracer’ Methodology will be applied. Surveyors will work backwards from the trigger to the point of event origin.

Surveyors are trying to determine if the Transplant program has conducted activities related to adverse events as outlined within the programs adverse event policy and related procedures.

Survey Application Source Documents



- Policy / Procedures / QAPI Program
 - Adverse Event Policy
 - Adverse Event Reporting
 - QAPI program activities
- Medical Records
 - Random Sample of volume
 - Deaths (3 year period)
 - Graft Failures (3 year period)
 - Return to Surgery for complications
 - Re-transplants
- Interviews
 - Transplant Staff
 - Unit Nurses
 - Physician and Surgeon
 - Hospital Quality / Patient Safety
- Event Reporting System
 - Event Reports
 - Annual Reports to committees
 - Data Analysis by severity levels
- Internal Data
 - Coding audits
 - Record Audits
 - Public Reporting (HAC's & POA's)
- External Data
 - SRTR data / TPQR
 - Patient Survival
 - Graft Survival
 - Outcome data
 - Medicare Financial / Coding Reports (if any exist)
 - Hospital Compare website



REPORTING

ACCIDENT or DANGEROUS OCCURRENCE REPORT (SIS) FORM

A. Subject of report: ☐ Accident ☐ Dangerous Occurrence

B. Date of incident: _____ **Time of incident:** _____
Building: _____ **Room/Location:** _____
If off campus, please specify: _____

C. Incident occurred in patient area or non-patient area: ☐ Patient ☐ Non-Patient

Personnel involved: _____
Witnesses: _____
Occupation: _____
Department: _____
Supervisor: _____
Other: _____

D. Describe what led to the report. If health condition or dangerous occurrence indicates all boxes which apply:

Unlabeled or unlabeled	<input type="checkbox"/>	Unlabeled or unlabeled	<input type="checkbox"/>
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E. Other information: _____

University of South Florida Safety Services
Report Learning in a Safe Environment



Internal Hospital Reporting Adverse Events



- There are many methods and tools that can be utilized to report an adverse event.
- The majority of Hospitals today utilize an electronic (on-line) reporting system for staff to enter in event information.
- Other methods include paper reports, hotlines, reporting to immediate supervisor, reporting to attending physicians and weekly/daily safety huddles.

Policy Example 3

Non-Compliant



Purpose: This policy provides a framework under which the Transplant program staff will identify, report, analyze and prevent adverse events.

Policy:

- 1) All safety events will be addressed through the mechanism identified in this policy based on the level of event.
- 2) An Adverse Event is defined as “an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof”
- 3) In order to continuously improve patient care and prevent adverse events, Transplant staff will identify, report and respond to all safety and adverse events occurring in the organization or associated with services that the organization provides. In addition to those events identified per the “Patient Safety Event Reporting and Management – Serious Sentinel Events” policy that automatically trigger an initial Root Cause Analysis (RCA). The Transplant program leadership may also choose to initiate a root cause analysis for any event, including adverse events and ‘near miss’ events.

Policy Example 4

Compliant



POLICY: XYZ Transplant programs follow the hospital's cause analysis process to identify, track, analyze and report safety events occurring in patients being evaluated, listed and/or transplanted.

PROCEDURE: If an event is deemed to be a serious safety event (SSE) appropriate cause analysis will then occur, led by the Performance Improvement Department. This includes a time line of the events preceding transplant, as well as during the patient's course of care and transplant process. SSEs involving the transplant program would include representatives from the organ specific QAPI program on the stakeholder group for the event.

Reporting a safety event:

1. If any event meets the criteria for a safety event as per the hospital protocol the incident is reported through the Medical Center event reporting system. Events with harm score are specifically reviewed by PI and Risk Management to determine if additional cause analysis is needed.
2. Adverse events for transplantation resulting in death will be reported to the OPTN via UNet.
3. Any infections that may have been transmitted from the donor to the recipient will be reported to the CDC and to the OPTN as well as the Organ Procurement Organizations involved with organ recovery.

Notification versus Identification



- Reporting may occur in many different manners. The importance for transplant programs is that events which may have occurred get to transplant leadership so that action may be taken.
- Notification processes are more staff driven where information is pushed from staff to leadership via electronic systems, paper systems or phone reports.
- Identification processes are methods where the transplant leadership pulls information from report sources.
- Identification, Discovery, Detection, Notification, Reporting are just a few names to describe the methods in which Transplant programs become aware of an adverse event. Regardless of the name used, transplant programs need to clearly delineate how Identification and Reporting will occur in their adverse event policy or procedures.

Potential Sources to Discover and Identify Adverse Events



NOTIFICATION EXAMPLES

Staff actions:

- Incident Reporting System
- Electronic System
- Paper System
- Hotlines
- Reports to supervisors

Patient / Family actions:

- Complaints
- Grievances
- Hotlines
- Patient Satisfaction Survey's

IDENTIFICATION EXAMPLES

- Record audits (Retrospective/ Concurrent)
- Complaints / Grievances
- Case management / Reporting activities
- Lawsuits / Legal action
- Peer reviews
- M&M meetings
- Financial audits (POA / HAI's / HAC's)
- Coding audits ('E' and 'V' codes)
- Never Events
- Executive Rounds / Multi-D Rounds
- Staff Rounds / Inspections
- Database analysis
- External reports (CMS)

Transplant Survey Application

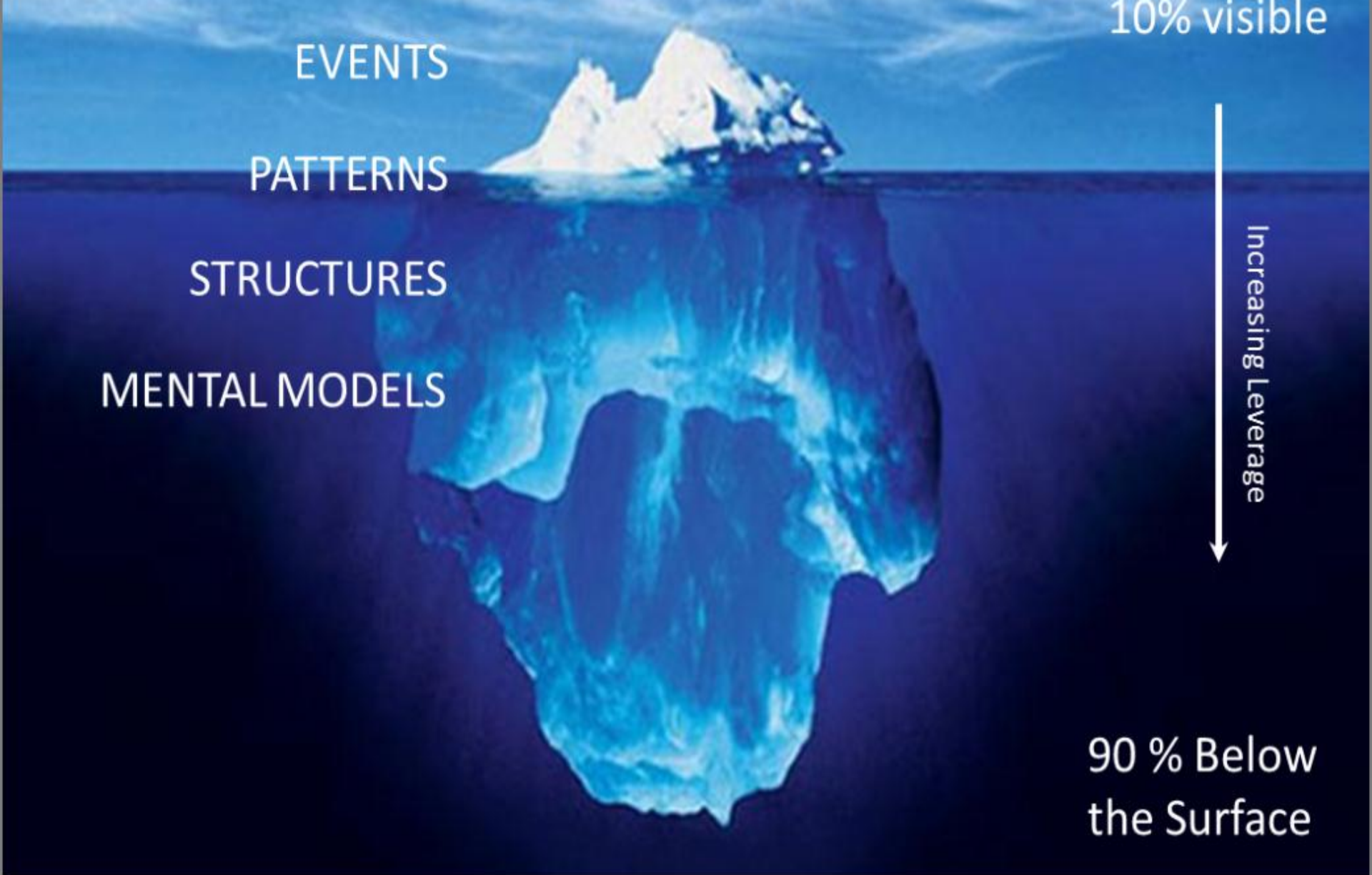


Medical Record examples

- Nursing notes
- Social work notes
- Ancillary care staff notes
- Physician progress notes
- Notes from morning rounds
- Pharmacy reports
- Patient care plan
- I&O tracking sheet
- Medication orders (MAR)
- Handoff Communications
- Laboratory reports of communicable diseases

Facility Document examples

- Safety incident / occurrence reports
- Team discussions
- Risk management reports
- QAPI / Patient Safety committee meetings
- Interviews with staff/patients/family
- Selection committee minutes
- Department of Surgery meeting minutes
- Medical Executive Committee meetings
- Peer Review summaries
- Biomedical reports on medical devices (robotics, pumps, video equipment, surgical equipment)



ANALYSIS

Thorough Analysis



- CMS does not require a Root Cause Analysis to be conducted on all adverse events; CMS does require a **Thorough Analysis** to be conducted on ANY adverse event that may occur during ANY phase of transplantation or living donation.
- CMS understands that adverse events contain different levels of severity and risk.
- Hospital organizations have developed severity and risk ranking systems to classify events.

Thorough Analysis continued



- The Transplant policy should clearly define what a thorough analysis will be for a given type of adverse event.
- Adverse Events with a higher risk level will require a more involved analysis such as a Root Cause Analysis –
- It is up to the transplant program to outline the steps, methods, tools or procedures that will be utilized for any adverse event.

Policy Example 5

Non-Compliant

Policy Statement: Prompt reaction to adverse events enables appropriate departmental response, including assessing for immediate preventive action, complying with reporting requirements of external agencies and conducting timely analyses of systems and processed to identify improvements which will have a positive impact in providing patient care and preventing future adverse events.

Analysis and Prevention: All adverse events will be analyzed for a root cause analysis (RCA) by the involved team within 21 days on having knowledge of the event.

Compliant

Patient Safety Event Report: A person who discovers a patient safety event completed the required on-line report immediately after the event or as soon as possible. The Risk Manager reviews all reports and verifies the event classification.

- 1) Events classified in categories A through C (No harm to patients) will have an investigative report completed within 72 hours of filing.
- 2) Events classified in categories D to F (minimal / temporary harm) will have an apparent cause analysis along with an investigative report to be completed within 7 days of filing.
- 3) Events classified in categories G to I (permanent harm / death events) will have a Root Cause Analysis started within 72 hours of initial awareness – led by the Risk Management Department.

Transplant Survey Application Analysis



- Surveyors are guided by the Transplant programs adverse event policy on what type of analysis is conducted for a given adverse event.
- The policy should clearly define and direct staff how to conduct a thorough analysis for adverse events as defined by the transplant program or hospital.

Transplant Survey Application

Analysis *(continued)*



- While near misses or events with no harm to the patient may have a lower level or breadth of analysis than events with harm, this is not always the case (e.g., near misses could reveal risks to large numbers of patients and require more systemic review and reform).
- Surveyors look for how analyses are defined and carried out in relation to the hospital policies and the nature of the events involved.

Prevention



Taking Action

- The transplant program is required to develop and implement a policy that covers the prevention of future adverse events.
- The policy should clearly define how the results of a thorough analysis will be utilized in the prevention efforts.
- The policy should be developed in such a manner that any staff member will understand:
 - What actions are required and
 - How implementation of remedial action is monitored to ensure that those actions led to improvements or led to the prevention of future re-occurrences.

Policy Example 6

Non-Compliant

POLICY:

(1) Adverse events and/ or complications must be identified, reported, analyzed and prevented using two tracking methods: tracking of individual complications occurring in post-transplant patients based on the Classification of Surgical Complications; and b) institutional tracking of adverse events through the electronic Patient Safety Net.

(2) Review and analysis of complications and adverse events are essential components of the liver transplant-specific QA/PI program. These are reviewed monthly with a biannual review of aggregate data for trends. The results are used to identify system patterns resulting in potential or actual patient harm that needs to be addressed through policy and process changes.

Compliant

Policy:

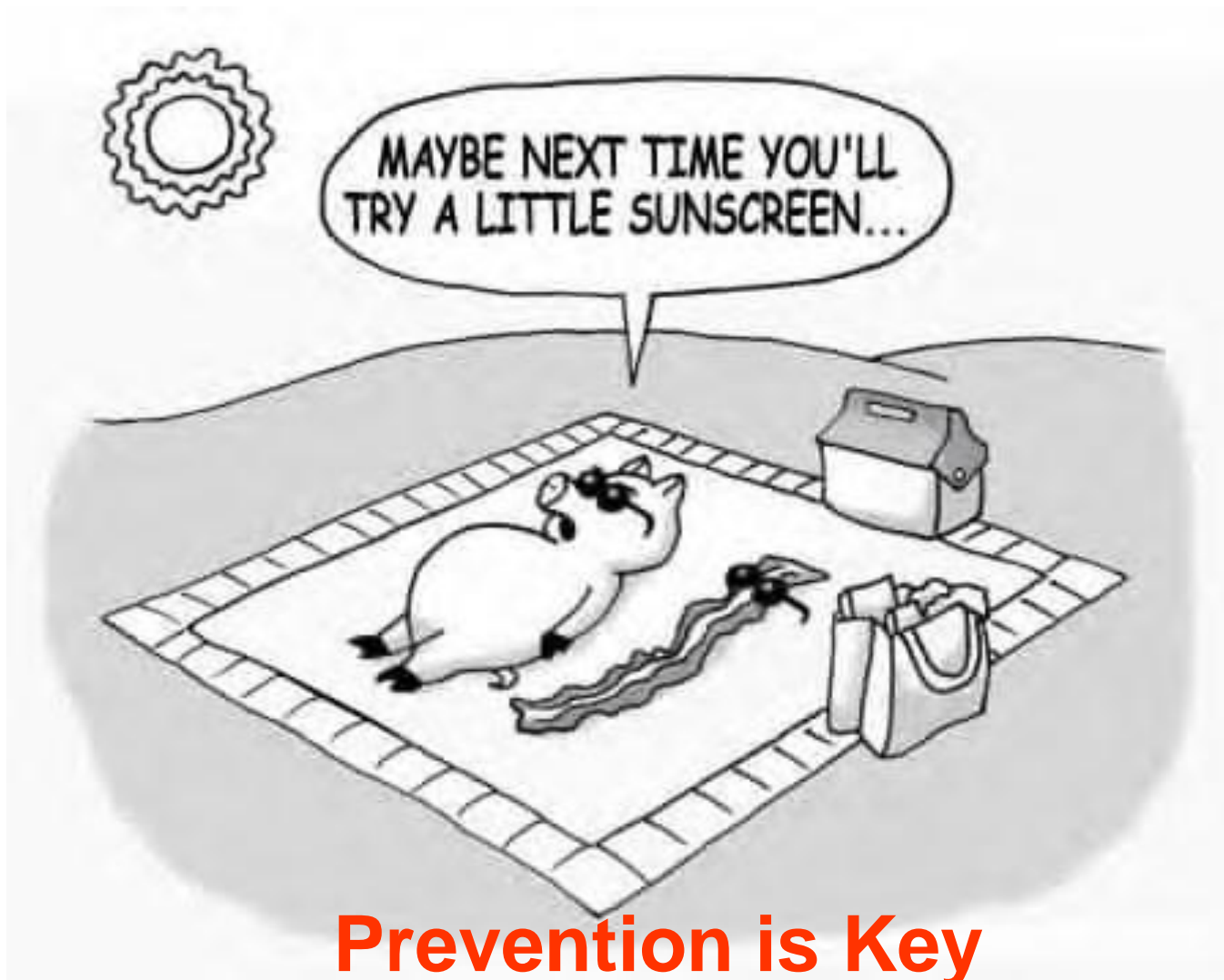
- 1) For those events not deemed reportable, Transplant staff will complete a Quality Issue Monitoring Form and submit to the Committee for review and recommendations.
- 2) For those events deemed reportable, the Quality coordinator will complete a summary and timeline of events, conduct interviews with the staff, complete the causal analysis tool, create fishbone diagram, review with committee, implement actions and report to quality and patient safety, continue monitoring through transplant quality until actions are completed and sustained.

Transplant Survey Application Action



- First, transplant surveyors seek to determine if any actions or recommendations have been identified and documented in response to an adverse event analysis.
- Next, the transplant surveyors seek to determine if the transplant program implemented actions based upon a thorough analysis.
- The actions taken should be appropriate to the level of risk posed by the adverse event(s) and the level of thorough analysis that was conducted.

QUESTIONS



Prevention is Key

Contact Information



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