TRAINING PROGRAM ON EMPANELMENT CRITERIA UNDER RAJIV GANDHI JEEVANDAYEE AROGYA YOJANA

COURSE MATERIAL

ISSUE: February 2014

TRAINING PROGRAM

ON
EMPANELMENT CRITERIA UNDER RAJIV GANDHI JEEVANDAYEE AROGYA YOJANA

COURSE MATERIAL

Conducted by:

NATIONAL ACCREDITATION BOARD FOR HOSPITALS AND HEALTHCARE PROVIDERS (NABH)

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PREFACE

Patient safety is a fundamental principal of healthcare. There is a widespread awakening all over the globe, about the need to improve the quality of healthcare in terms of actual patient care and patient safety. India has also taken up the cause in full earnest and today private and public hospitals are both showing commitment towards improvement in quality of health services provided. The other driving forces towards ensuring quality of care are the increasing role of health insurance, rise in number of litigations related to patient care, and the increased awareness of patients about their rights.

It gives me immense pleasure in sharing that Government of Maharashtra in consultation with National Accreditation Board for Hospitals and Healthcare Providers (NABH) has finalized the empanelment criteria's under Rajiv Gandhi Jeevandayee Arogya Yojana. These criteria's are applicable for Maharashtra state, in public as well as private sector hospitals.

This program shall help participants to understand the introduction to quality management, patient safety along with background and structure of NABH. Program shall also broadly cover assessment technique, report writing, writing non conformities, how to conduct assessments and prepare the hospital for assessment.

I appreciate the initiative taken by Maharashtra Government.

(Dr. K. K. Kalra)
Chief Executive Officer - NABH

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CODE OF CONDUCT

1. The participants are expected to be punctual for the sessions.

2. The participants are expected to attend every session.

3. The use of cell/mobile phones is discouraged. However, the participants may carry their cell or mobile phone, provided it is in silent (and/or vibration) mode so as not to cause disturbance to fellow participants. The telephonic talk should be outside the programme room, if at all necessary, under emergency situation.

4. A harmonious and cordial ambiance is necessary for the programme. The participants are expected to display team spirit.

5. The participants are expected to actively participate in all the sessions so that the programme becomes interactive.

6. Grievance, if any, shall be communicated to the Tutor, whose decision will be binding.

PROGRAMME OBJECTIVES

1. **To impart understanding to the participants of:**

   a) Introduction to Quality Management and patient safety.

   b) The background and structure of NABH.

   c) The background and structure of the Empanelment criteria.

   d) To deploy the Empanelment criteria, leading towards successful empanelment.

2. **To create awareness among the participants regarding:**

   a) Performing an internal assessment of the organization

   b) Technique of internal assessment

   c) Roles and responsibilities of various people in implementing the criteria.

PROGRAMME SCHEDULE

DAY 1

08.30 to 09.00	Registration
9.00 to 9.15	Inaugural Session
9.15 to 9.30	Pre Test
9.30 to 11.00	Introduction to QMS and NABH
11.00 to 11.20	Tea Break
11.20 to 11.40	Empanelment Standards : Overview
11.40 to 1.30	Empanelment Standards: Chapter HR
1.30 to 2.15	Lunch Break
2.15 to 3.30	Empanelment Standards: Chapter FAC
3.30 to 5.30	Empanelment Standards: Chapter INF

DAY 2

08.30 to 09.00	Recap
9.00 to 11.00	Empanelment Standards: Chapter QPC
11.00 to 11.20	Tea Break
11.20 to 1.30	Empanelment Standards: Chapter QPC
1.30 t0 2.15	Lunch Break
2.15 to 5.00	Empanelment Standards: Chapter MED, EMR & PSI

DAY 3

08.30 to 09.00	Recap
9.00 to 11.00	Empanelment Standards: Chapter SOP
11.00 to 11.20	Tea Break
11.20 to 12.30	Empanelment Standards: Chapter TPI
12.30 to 1.30	Principles of Assessment

1.30 t0 2.15	Lunch Break
2.15 to 3.30	Planning the activities at the hospital for readiness
3.30 to 4.30	Assignment
4.30 to 5.30	Valedictory and Tea

DAY 4

08.30 to 09.30	Wrap up session
9.30 to 10.45	Post Test
10.40 to 11.00	Tea Break
11.00 onwards	Field Visit to Hospital

METHODOLOGY OF THE CONDUCT OF THE PROGRAMME

1. Each participant will be provided with **Programme kit** containing:

    a. Course material.
    b. Stationery
    c. Feedback form

2. The Programme will be **a mix of lecture sessions, discussions and exercises**. The **participants are expected to take part in a constructive and friendly manner** and in case of serious disagreement with any fellow participant or tutor; the decision of the Principal Tutor will be final.

3. **Assessment of performance** of participants

    a. **Continuous assessment by tutor:** Each day the participant's performance will be judged by the tutor (s). The components of this assessment will be:

        i. Adherence to the norms stated in the code of conduct
        ii. Attentiveness
        iii. Level of participation in discussions
        iv. Level of participation in team activities and role as Leader in discussions in each exercise
        v. Attitude towards fellow participants

4. A Pre test and Post test will be held.

5. **Course Duration: 4 days.** The course will be a mix of didactic sessions, group exercise, problem based learning and field visit.

6. **Teaching Site:** The course will be conducted in a class room with maximum of 30-35 participants.

7. **Certification:** A certificate will be provided at the completion of the course, based on attendance and participation in group exercise.

8. The decision of the chairman, NABH shall be final in respect of any grievance of any participants.

ABOUT QCI AND NABH

About QCI

QCI was set up in 1997 as an autonomous body by the Government of India jointly with the Indian industry to establish and operate the National Accreditation Structure for conformity assessment bodies. Indian industry is represented in QCI by three premier industry associations ASSOCHAM, CII and FICCI, QCI is also assigned the task of monitoring and administering the National Quality Campaign and to oversee effective functioning of the National Information and Enquiry Services.

To realise the objective of improving quality competitiveness of Indian products and services, QCI provides strategic direction to the quality movement in the country by establishing recognition of India conformity assessment system at the international level.

About NABH

National Accreditation Board for Hospitals & Healthcare Providers (NABH) is a constituent board of Quality Council of India, set up to establish and operate accreditation programme for healthcare organizations. The board is structured to cater to the much desired needs of the consumers and to set benchmarks for progress of health industry.

QUALITY POLICY

“To continuously improve our quality system and processes through involving all our employees with focus on improving patient safety”

NABH VISION, MISSION AND VALUES

Vision

To be the apex national healthcare accreditation and quality improvement body, functioning at par with global benchmarks

Mission

To operate accreditation and allied programs in collaboration with stakeholders focusing on patient safety and quality of healthcare based upon national/international standards, through process of self and external evaluation.

Values

Credibility: Provide credible and value addition services

Responsiveness: Willingness to listen and continuously improving service

Transparency: Openness in communication and freedom of information to its stakeholders

Innovation: Incorporating change, creativity, continuous learning and new ideas to improve the services being provided

NOTES

RGJAY Quality Standards for Empanelment

WELCOME TO ALL THE PARTICIPANTS

National Accreditation Board for Hospitals and Healthcare Providers

RGJAY Quality Standards for Empanelment

National Accreditation Board for Hospitals and Healthcare Providers

Programme Objectives…

- To impart understanding to the participants of:
  - Introduction to Quality Management.
  - The background and structure of the Empanelment Standards.
- To enhance the ability of the participants to:
  - To deploy the Empanelment Standards, leading towards successful empanelment.
  - Introduce Assessment methodology.

Kindly go through the code of conduct mentioned in the course notes

Kindly adhere to the same

National Accreditation Board for Hospitals and Health Care Providers

Kindly go through the schedule mentioned in the course notes

We shall try to adhere to the same!!!

National Accreditation Board for Hospitals and Health Care Providers

Methodology

- Please check if your kit contains:
  - Copy of RGJAY Quality Standards for Empanelment
  - Course Notes
  - Stationary
  - Feedback form
    - **Kindly fill the same at the end of every session so that you do not forget what you want to say!!**

National Accreditation Board for Hospitals and Health Care Providers

Methodology

- Programme will be *a mix of lecture sessions, discussions and exercises*
- Participants are expected to *take part in a constructive and friendly manner*
- Let us have *interactive sessions*

National Accreditation Board for Hospitals and Health Care Providers

Assessment

1. *Continuous assessment by tutor:* Each day the participant's performance will be judged by the tutor (s). The components of this assessment will be:
    - Adherence to the norms stated in the code of conduct
    - Attentiveness
    - Level of participation in discussions
    - Level of participation in team activities and role as Leader in discussions in each exercise
    - Attitude towards fellow participants
2. *Post Test questionnaire*

National Accreditation Board for Hospitals and Health Care Providers

YOUR INTRODUCTION

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OUR INTRODUCTION

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We hope to see this at the end of the programme!!

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PATIENT SAFETY NEEDS & CONCEPTS

National Accreditation Board for Hospitals and Healthcare Providers

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HISTORY

- Hippocrates recognized the potential for injuries that arise from the well intentioned actions of healers. -drafted the Hippocratic Oath and pledged to:

"prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone."

Since then, the directive *primum non nocere* **("first do no harm**) has become a central tenet for contemporary medicine

- More than 140 years ago, Florence Nightingale warned, "the very first requirement in a Hospital is that it should do the sick no harm" (Nightingale, 1863, preface).

Challenges

- Evolving Public Expectations
  - Doctor no more a god figure – dogmatic and paternalistic figure fading away
  - Increase participation in decision making
- Increased complexity in management of patients
  - Advancements in knowledge and disease management
  - Advanced instrumentations
  - Ageing society
- Lack of concept of Medical errors & Patient safety in medical education curriculum

"The knowledge, skills, and attitudes needed for safe practice are not normally acquired in medical school."

Magnitude of Problem

- Recent studies suggest that:
  - Medical errors occur in 2.9% to 3.7% of hospital admissions.
  - 8.8% to 13.6% of errors lead to death.
  - As many as 98,000 hospital deaths may occur each year as a result of medical errors.
  - Increased LOS of 4.6 days.
  - Increased hospital cost.

The Problem is Large

- In U.S. Healthcare system
  - 7% of patients suffer a medication error [2]
  - On average, every patient admitted to an ICU suffers an adverse event [3,4]
  - 44,000- 98,000 people die in hospitals each year as the result of medical errors [5]
  - Nearly 100,000 deaths from HAIs [6]
  - Estimated 30,000 to 62,000 deaths from CLABSIs [7]
  - Cost of HAIs is $28-33 billion [7]
- 8 countries report similar findings to the U.S.

37 – 51% of AEs are potentially preventable

2 **Bates DW, Cullen DJ, Laird N, et al.,** *JAMA*, 1995
3. **Donchin Y, Gopher D, Olin M, et al.,** Crit Care Med, 1995.
4. **Andrews L, Stocking C, Krizek T, et al.,** Lancet, 1997.
5. **Kohn L, Corrigan J, Donaldson M.,** To Err Is Human, 1999.
6. **Klevens M, Edwards J, Richards C, et al**., PHR, 2007
7. **Ending Health Care-Associated Infections,** AHRQ, 2009.

Call for Action

- Political commitment to make Patient safety a Priority objective in Public health system
- Developing Safety Culture in hospitals
- Involvement of Patient and family by raising effective communication
- Sharing of best practices and data collection

Definitions

Medical Error

The failure of a planned action to be completed as intended or use of

a wrong inappropriate, or incorrect plan to achieve an aim.

Sentinel event

An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function.

- **Medication Error:** A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packing and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (Zipperer, et al)

Definitions

Adverse event

- An unintended injury or complication resulting in death, disability or prolong hospital stay that arise from healthcare management.

Near miss

- *Any event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention.*

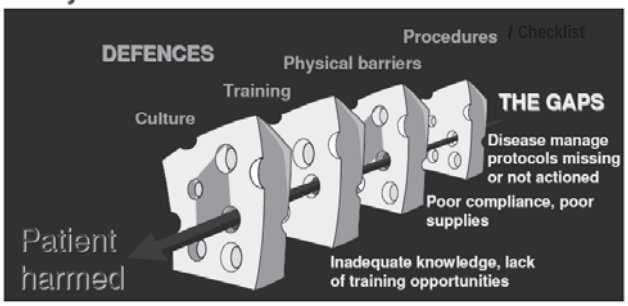
Definitions

Patient safety
The avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of health care.

- Safety emerges from the interaction of the components of the system; it does not reside in a person, device, or department.
- Patient safety is a subset of health care quality

System is a combination of processes, people, and other resources that, working together, achieve an end.

A Systemic Problem that Harms Patients



No clear leadership, no cohesive team structure

Researchers have shown that causes of Medical errors :

- 24% **— Communication problems**
- 20% — Discontinuity of care (includes referrals of existing patients and itinerant/new patients)
- 19% — Lab results (logistics, timing, follow-up)
- 13% — Missing values/charting
- 8% — Clinical mistake (knowledge and skills)
- 8% — Prescribing errors (dosage, choice, allergy or interaction)
- 8% — Other

Type of Errors / Incidence

- Clinical Administration
- Clinical Processes /Procedures
- Documentation
- Healthcare associated infections
- Medication /IV fluids
- Blood /Blood Products
- Oxygen/Gas/Vapor
- Nutrition
- Medical Device /Equipments
- Behavior
- Patient accidents
- Infrastructure /Building
- Resources /Organizational Management

Case scenario # 1

- A plastic wall fan left open in OT complex
- Fan got overheated –starts smoldering & smoke
- Fire alarms –failed to activate in time
- Staff recognize smoke & luckily disaster averted
- Introspect: Sister forgot to switch off fan after duty
- Plastic fan body got heated up and started burning, more of smoke than fire
- all 5 fire alarms sensors were heat sensitive and no smoke sensitive alarm in that area.

Case scenario # 2

- Staff nurse informed resident doctor in ICU that patient on bed no 10 is having tachycardia.
- Resident was half asleep at 1 am and attending another patient ordered digoxin to be given.
- Staff nurse gave 0.125 mg i.v stat.
- Patient died.
- The patient was pediatric patient & she gave adult dose.

Introspect: communication error/memory bias/overwork

Scenario 3

- Scenario-1-During Root Canal Treatment the local Anesthetic, the EDTA liquid, sodium hypochlorite and the saline were all in 5 ml syringes on the tray. The dental surgeon injected EDTA instead of the local anesthetic.
- Introspect: lack of labeling

Scenario-4

- Patient calls the dental office and complains of continuous bleeding after extraction, he had to be admitted to the hospital later on. It was found out he was on anti-coagulant therapy.(adverse event)

Scenario-5

- The dental assistant is mixing the amalgam in a mortar with a pestle THE MERCURY bottle is left opened while mixing and placed at the end of the working platform.

Scenario-6

- After the extraction of left last molar while filling the oral surgeon notices while filling the case sheet that the patient was referred for the right last lower molar.

"Human beings make mistakes because the systems, tasks and processes they work in are poorly designed"

What do we mean by Patient Safety?

A culture that embraces the reduction of medical errors, complications, and other unanticipated adverse events which contributes to improved clinical outcomes through the adoption and management of evidence-based **practices, processes, and systems**

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SEVEN STEPS TO PATIENT SAFETY

Step 1	• Build a safety culture
Step 2	• Lead and Support your staff
Step 3	• Integrate your risk management activity
Step 4	• Promote reporting
Step 5	• Involve and communicate with the patients and public
Step 6	• Learn and share safety lessons
Step 7	• Implement solution to prevent harm –safety designs

Root Cause Analysis

Every adverse event /incident needs detail study

1. Gather the facts.
2. Choose team.
3. Determine sequence of events.
4. Identify contributing factors.
5. Select root causes.
6. Develop corrective actions & follow-up plan.

A Few Simple Rules for Health Care in the 21st Century

Shift from blame & shame culture to system culture

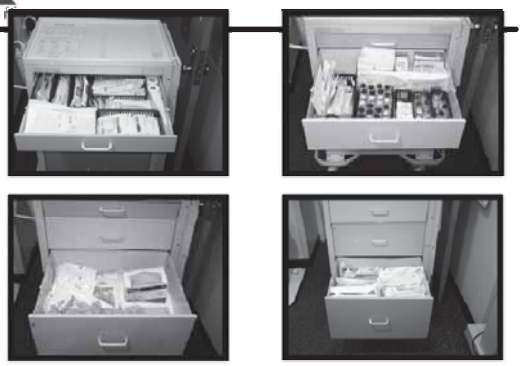
Current Approach	New Approach
• *Do no harm* is an individual responsibility	• Safety is a system property
• Information is a record	• Knowledge is shared and information flows freely
• Secrecy is necessary	• Transparency is necessary
• The system reacts to needs	• Needs are anticipated
• Professional autonomy drives variability	• Decision-making is evidence based

Just Culture -- Mistakes Vs Reckless behavior

How Can We Improve? Understand the Science of Safety

Principles of Safe Design

STANDARDIZE
PROTOCOLS
CHECKLISTS
LEARN WHEN THINS GO WRONG

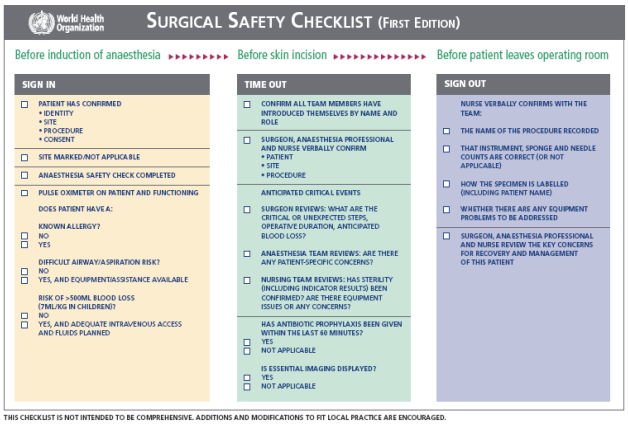


Packaging and Labeling Problems

Look-alike packaging

Hard-to-read labels

L A S A



World Health Organization

SURGICAL SAFETY CHECKLIST (FIRST EDITION)

Before induction of anaesthesia ▸▸▸▸▸▸▸▸▸ Before skin incision ▸▸▸▸▸▸▸▸▸▸▸▸▸ Before patient leaves operating room

SIGN IN

- ☐ PATIENT HAS CONFIRMED
  - • IDENTITY
  - • SITE
  - • PROCEDURE
  - • CONSENT
- ☐ SITE MARKED/NOT APPLICABLE
- ☐ ANAESTHESIA SAFETY CHECK COMPLETED
- ☐ PULSE OXIMETER ON PATIENT AND FUNCTIONING

DOES PATIENT HAVE A:

KNOWN ALLERGY?
- ☐ NO
- ☐ YES

DIFFICULT AIRWAY/ASPIRATION RISK?
- ☐ NO
- ☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
- ☐ NO
- ☐ YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

TIME OUT

- ☐ CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE
- ☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM
  - • PATIENT
  - • SITE
  - • PROCEDURE

ANTICIPATED CRITICAL EVENTS

- ☐ SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?
- ☐ ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?
- ☐ NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?

HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?
- ☐ YES
- ☐ NOT APPLICABLE

IS ESSENTIAL IMAGING DISPLAYED?
- ☐ YES
- ☐ NOT APPLICABLE

SIGN OUT

NURSE VERBALLY CONFIRMS WITH THE TEAM:

- ☐ THE NAME OF THE PROCEDURE RECORDED
- ☐ THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE)
- ☐ HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME)
- ☐ WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED
- ☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

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Training

- Induction training
- Need based training for skill development
- Training for continuous improvement
- Soft skill training

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Key Message…

Based on principles for redesigning care:

- Standardize care processes
- Create independent checks (such as checklists)
- Encourage reporting of events
- Periodic analysis and improvement
- Learn from mistakes
- Regular training
- Have continuous monitoring system

Patient Safety Goals

- Patient' identification
- Improve communication & Handoff
- Medication safety
- Prevent infections
- Identify patient's risk
- Prevent wrong site, wrong patient, wrong procedure
- Falls prevention
- Patient satisfaction

ACCREDITATION PROCESS IN A HOSPITAL

Accreditation Quality

Quality Efforts in Healthcare

- Quality pioneers have different opinions:
  - Dr Joseph Juran – "fitness for use"
  - Philip Crosby – "zero defects"
  - Dr Edwards Deming – "never-ending cycle of continuous improvement"

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Definition of Quality in Healthcare

The IOM stated in 1990 in *Medicare:* "quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (IOM, 1990, p. 21).

Quality can be measured

Healthcare Quality – Keep it Patient Focused

Doing the right thing,
the right way,
at the right time,
in the right amount,
for the right patient
that does not result
in harm to the patient

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Characteristics of a Quality Healthcare System when the Appropriate Systems are in Place

1. It is safe
2. It is effective
3. It is efficient
4. It is patient centered
5. It is equitable
6. It is timely

Institute of Medicine 2001

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Accreditation is interlinked with the Quality of the Healthcare.

- Accreditation is a process of external review of the quality of the Healthcare being provided by the Healthcare organization.
- It also represents the outcome of the review and the decision that an eligible organization meets an applicable set of standards

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National Accreditation Board for Hospitals and Healthcare Providers

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A constituent board of Quality Council of India (QCI)

To provide accreditation services to hospitals and healthcare providers

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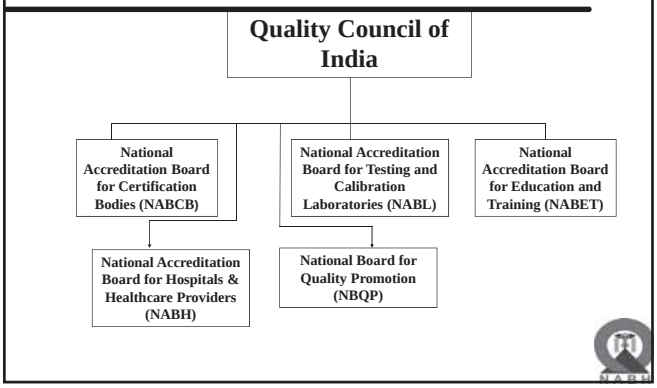
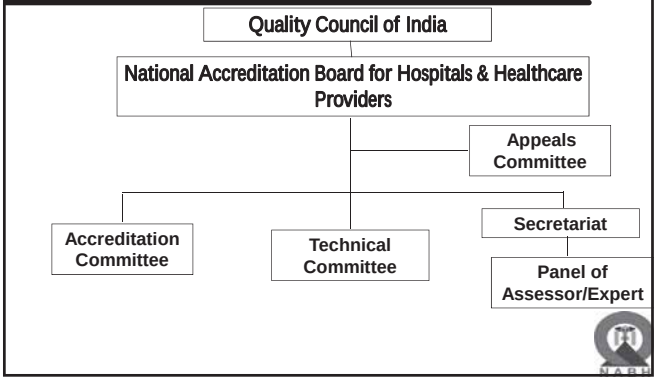
Structure of QCI



Structure of NABH



NABH is an institutional member of the International Society for Quality in Health Care (ISQua) since 2006.

ISQua Accreditation of NABH Standards for Hospitals 3nd edition.

NABH is an ISQua accredited organization

NABH is founder member of Asian Society for Quality in Healthcare (ASQua)

Benefits of Accreditation

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Accreditation benefits Hospital / healthcare organization

- Accreditation to a **hospital** stimulates continuous improvement.
- It enables hospital in demonstrating commitment to quality care.
- It raises community confidence in the services provided by the hospital.
- It also provides opportunity to healthcare unit to benchmark with the best.

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Accreditation benefits Patient

- Although accreditation benefits all stake holders, **patients** are the biggest beneficiary.
- Accreditation results in high quality of care and patient safety.
- The patients get services by credentialed medical staff.
- Rights of patients are respected and protected.
- Patient satisfaction is regularly evaluated.

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Accreditation benefits Staff

- **Staff** in an accredited hospital are satisfied lot as it provides for continuous learning, good working environment, leadership and above all ownership of clinical processes.
- It improves overall professional development of Clinicians and Paramedical staff and provides leadership for quality improvement within medicine and nursing.

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Accreditation benefits to others

- Finally, accreditation provides an objective system of empanelment by insurance and other **Third Parties (e.g. CGHS)**. Accreditation provides access to reliable and certified information on facilities, infrastructure and level of care.

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Framework of Activities

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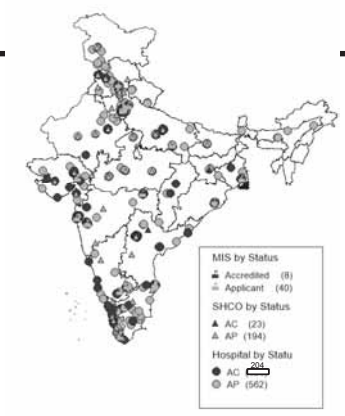
- Accreditation of Hospitals
- Accreditation of Blood Banks
- Accreditation of SHCO/ Nursing Homes
- Accreditation of OST Centers
- Accreditation of Wellness Centers
- Accreditation of PHC/CHCs
- Accreditation of Dental Centers, Medical Imaging Services, Ayurveda Hospitals

NABH status of Health facilities



Hand holding for Govt HCOs--- Road Map

- NABH has been providing handholding to various state run government hospitals
  - Through empaneled consultants
  - Time period for handholding 9 -12months , depend largely on staff
  - Cost to state per hospital 12 -13 lacs
  - Various activities undertaken by the consultants
    - Gap analysis
    - Selection of Priorities
    - POI
    - Training on committee formation,
    - Training on Documentation,
    - Training of staff other than clinicians on NABH standards and their role

Hand holding for Govt HCOs---Road Map (contd)

- Training on legal requirements
- Training on medication safety
- Traning on clinical audit
- Training on Surgical site infection prevention
- Training on Disaster management
- Internal Audit

Principles of TQM and QA in Medical Practice

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NON Quality

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- Hospital stoned .....
- Doctor assaulted .....
- Consumer court fines doctor .....
- Income Tax officials raid hospital.
- Police arrest doctor .....
- Relatives assault hospital staff .....

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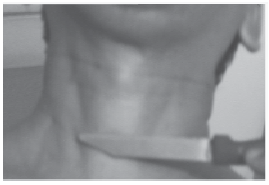
Cost of 'NON' Quality



- C P A - 1986
- Consumer Activism
- Goondaism
- Adverse media publicity
- Re - explorations
- Re - tests
- Lawyers' fees

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What is Quality ? Definitions of Quality

- The totality of characteristics of a medical service that bear on its ability to satisfy stated or implied patients' needs
- Degree to which a set of inherent characteristics fulfils patients' requirements, stated or implied

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MOVEMENT TOWARDS TQM

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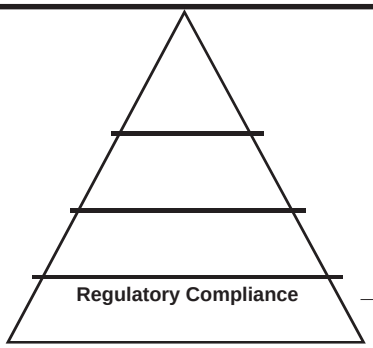
TQM in a Hospital



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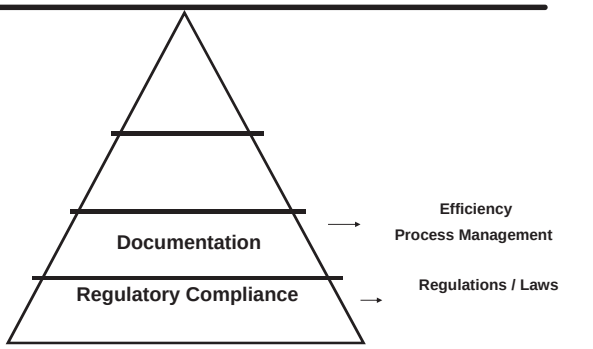
TQM in a Hospital



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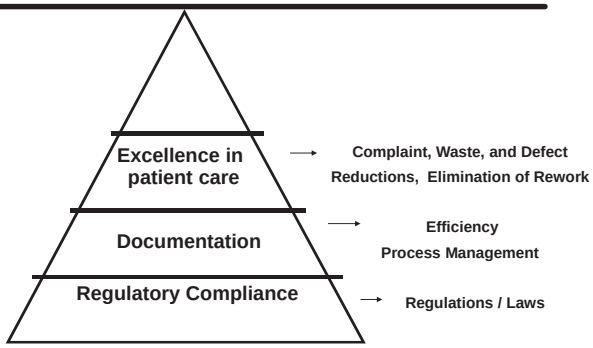
TQM in a Hospital



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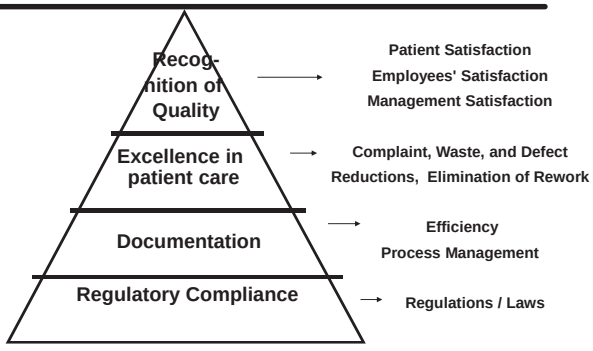
TQM in a Hospital



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8 PRINCIPLES FOR MANAGING QUALITY IN A HOSPITAL

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NABH

8 Management Principles

1. Patient Focus
2. Leadership
3. People involvement
4. Process approach
5. Systems approach
6. Factual approach to Decision Making
7. Supplier Relationships
8. Continual Improvement

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1. Patient Focus…

Hospitals are meant for patients!

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1. Patient Focus…

- SAFETY
- Structure: **C**omfort, **C**onvenience, **C**ommunication
- Process: **C**are, **C**ompetence
- Outcome: **C**ure

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1. Patient Focus

- Hospitals are meant for patients
- Best advertisement: well treated patients
- Loyalty = repeat visits
- Better business
- Patient + Family + Ref. Dr

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2. Management Support & Leadership

- Management has to lead
- Lead by example > followers will learn
- Awareness of hospital's goals.
- No miscommunication.
- Leadership support: resources allocation (infection control, training, research…)
- Hard decisions will need to be taken.

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3. People Involvement

- Everyone (meaning EVERY ONE)
- Everyone must be aware of one's responsibilities towards the patient
- Sense of belonging
- Commitment
- Accountability
- Involvement = hospital's progress

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4. Process Approach

- Process : input > ACTIVITY > output
- If the process is good the service is good
- Consistency
- Predictability of results
- Prioritisation
- Reduce re-work/rejection

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Process Mapping

- Description of activity, patient flow
- Inputs and Outputs
- Responsibility & Authority
- Control measures
- Quality objectives
- Performance evaluation by data analysis of above in records

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Process mapping for Operation Theatre process

inputs > activity > outputs
(O T Process)

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Process mapping for Operation Theatre process

OT list, dept. schedules
fumigation plan
Nurses' & drs' rosters
Credentialing
Emergency stand by
CSSD instrument lists

↘

inputs > activity > outputs
(O T Process)

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Process mapping for Operation Theatre process

OT list, dept. schedules
fumigation plan
Nurses' & drs' rosters
Credentialing
Emergency stand by
CSSD instrument lists

↘

inputs > activity > outputs
(O T Process)

↗

OT Register,
Fumigation record
C & S results, Op notes
Sentinel events,
Implants,
Stock registers

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Process mapping for Operation Theatre process

OT list, dept. schedules
fumigation plan
Nurses' & drs' rosters
Credentialing
Emergency stand by
CSSD instrument lists

OT Register,
Fumigation record
C & S results, Op notes
Sentinel events, Implants,
Stock registers

inputs > activity > outputs
(O T Process)

HOW IS THIS PROCESS PERFORMING ?

(analysis of results, infections, morbidity, utilisation)

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5. System Approach

- 'Inter - departmental approach
- Hospital = inter-related departments
- Systems = inter-related processes
- Output of one dept. (process) = input of another.
- Identification of 'internal' customers
- Focus on key processes.

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6. Factual approach to Decisions

- Key indicators of volume, performance, quality: energy audit, infections, needle sticks, re-opening abdomen / chest / skull
- Evidence based medicine
- Statistical Analysis : morbidity, infections, re-explorations, return to work outcomes (Karnofsky scores), business development

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7. Good Supplier Relationships

- Credentialing & Privileging of Consultants
- Good relationships with suppliers: medicines, equipment, service engineers
- Flexibility & speed of joint responses.
- Optimisation of costs & resources.
- Mutual growth, not parasitism.

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8. Continuous Quality Improvement

- Improve: services, equipment,
- If you are standing still you are going backwards.
- Competition will overtake you.
- If you are not on the road to improvement, you are not on the road to quality

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Take Home Messages

- The practice of medicine is changing
- Every hospital and every person in a hospital has to be involved in delivering quality care to our patients
- Remember there is a cost to NON quality
- Do not follow the Std. for the sake of an expensive piece of paper
- Things will go wrong: focus on minimising errors, then preventing their occurrence

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Questions?

RGJAY Quality Standards

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Objective of these Standards

- Provide a basic framework for structures and processes
- Focus on patient safety and quality of patient care
- Set a roadmap for progressive improvement over 5 grades or levels

Standards in a Nutshell

- 9 Sections
- 96 Standards

Applicable for hospitals

Note: HR Standards are according to different bed strengths

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Standards

- A standard is a **statement** that defines the structures and processes that must be substantially in place in an organisation to enhance the quality of care.

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RGJAY Standards

	Section	Std.
1	Human Resource Quality **(HR)**	10
2	Facilities Management **(FAC)**	15
3	Infection Control Measures **(INF)**	11
4	Quality of Patient Care**(QPC)**	18
5	Monitoring Medication **(MED)**	06

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RGJAY Standards (contd)

	Section	Std.
6	Maintenance of patient Medical Records **(EMR)**	05
7	Patient Satisfaction Indices**(PSI)**	07
8	Standard Operating Protocols **(SOP)**	09
9	Transparency in Pricing **(TIP)**	04
	Total 9 Sections & 85 Standards	**85**

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Rating standards for RGJAY		
Sr No	**Category of Standard**	**% weightage**
1	HR Quality	18
2	Facilities Management	15
3	Infection Control Measures	12
4	Quality of Patient Care	20
5	Monitoring Medication	8
6	Maintenance of Patient Medical Records	7
7	Patient Satisfaction Indices	7
8	Standard Operating Protocols	6
9	Transparency In pricing	7
	Total Weight ages	100

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SECTION 1.

Human Resource Quality (HR)

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Intent: HR Quality

- Intent of this section is to ensure that basic minimum staffing levels are maintained in the hospital for patient care.
- The staff should have adequate qualifications.

There are 10 standards in HR

Standard HR1.

Std UID	Standard Definition	Expected Value	Scoring
HR1	Number of Registered doctors with MBBS Qualification	Average 2 for 50 bed hospital	2

This is a mandatory Standard

Number of beds	Expected	Total	Minimum	Total
30	1 per shift	2	1 per shift	2
50	2 per shift	5	1 per shift	2
100	3 per shift	10	1 per shift	4
200	4 per shift	12	2 per shift	9
300	5 per shift	14	2 per shift	9
400	7 per shift	19	3 per shift	10
500	8 per shift	23	3 per shift	11
1000	10 per shift	23	8 per shift	16

Evidence and data to be maintained

HR-1: Availability of MBBS Doctors:

Norm: Availability of one minimum MBBS qualified doctors per 50 Beds.
Record to maintain: List of the doctors available in the hospital. These minimum data elements should be available in the registers maintained for this purpose by the hospital
Updating of List: List of the doctor should be updated immediately if there is any change.
Frequency of Reporting: Every six month on 1st of January and July of every year. Number of registered doctors with MBBS qualification.

Sr. No.	Name of the Doctor	Qualification	MMC Registration No.	Date of joining

Evidence and data to be maintained
(based on patient load)

1. Data

a) Daily Beds Occupied in Wards
b) A = Daily Attendance of MBBS Drs at time of midnight census
c) X = Number of Occupied Beds in Wards (midnight Census of Wards) divided by 50
d) Y = 2
e) Z = X/Y which is the Number of doctors required
f) Ideal: A should be equal or greater than Z

2. Random Checks in Wards

HR 2. Standard

Std UID	Standard Definition	Expected Value	Scoring
HR2	Number of qualified and registered nurses (GNM, B.Sc. And M.Sc.(Nursing)	Average 4 per shift for 50 bed hospital with one In charge Sister with minimum GNM Qualification excluding 20% leave reserve	2

This is a mandatory Standard

Number of qualified and registered nurses (GNM, B.Sc. and M.Sc.(Nursing)

Number of beds	Expected	Total	Minimum	Total
30	2 per shift	11	1 per shift	10
50	4 per shift	18	2 per shift	16
100	9 per shift	45	7 per shift	33
200	20 per shift	90	15 per shift	66
300	30 per shift	135	25 per shift	100
400	35 per shift	160	30 per shift	133
500	60 per shift	225	40 per shift	166
1000	80 per shift	333	70 per shift	250

HR-2: Availability of Qualified and Registered Nurses:

Norm: Availability of minimum 10 Qualified Nurses (GNM) and one in charge Sister registered with Maharashtra Nursing Council per 50 Beds of the Hospital.
Record to maintain: List of the Nurses and In charge Sister available in the hospital These minimum data elements should be available in the registers maintained for this purpose by the hospital
Updating of List: List of the Nurses should be updated immediately if there is any change.
Frequency of Reporting: Every six month (on 1st of January and 1st of July of every year).

Sr. No.	Name of the Nurse/ In charge Sister	Qualification	Maharashtra Nursing Council Registration No.	Date of joining

Evidence and data to be maintained
(based on patient load)

Evidence and data to be maintained by
Medical Superintendent:

1. **Data**
A = Daily Attendance of Nurses at time of midnight census in wards
X = Number of Occupied Beds in Wards (midnight Census of Wards) divided by 50
Y = 10
Z = X/Y which is the Number of nurses required
Ideal: "A" should be equal or greater than "Z"

2. **Random Checks in Wards**

HR 3. Standard

Std UID	Standard Definition	Expected Value	Scoring
HR 3	Number of qualified and registered and Post graduate degree or diploma	Minimum 1 for particular specialty treated by hospital; Information expected	2

This is a mandatory Standard

HR-3: Qualified and Registered Post Graduate Specialists:

Norm: Availability of minimum 1 specialist for every specialty having Post Graduate qualification of concerned specialty and registered with Maharashtra Medical Council.
Record to maintain: List of the doctors available in the hospital These minimum data elements should be available in the registers maintained for this purpose by the hospital
Updating of List: List of the Specialists Doctors should be updated immediately if there is any change.
Frequency of Reporting: Every six month (on 1st of January and 1st of July of every year).

Sr. No.	Name of the Specialty	Name of the Specialist Doctor	Qualification of the Specialist Doctor	Maharashtra Medical Council Registration No.	Date of joining

HR 3. Standard

Evidence and data to be maintained by Medical Superintendent:

1. Data
a) List of Specialties
b) Name and qualifications of Specialist Doctors

To be Updated as Required or monthly

2. Random Checks in Wards

This is a mandatory Standard

HR-4. Doctor patient ratio in ICU:

Norm: Availability of minimum 1 doctor for 6 Bedded ICU. In case of ICU having more than 6 beds, the doctors should be available in this proportion.

Record to maintain: List of the doctors available in the ICU These minimum data elements should be available in the registers maintained for this purpose by the hospital

Updating of List: List of the Doctors should be updated immediately if there is any change.

Frequency of Reporting: Every six month (on 1st of January and 1st of July of every year).

Sr. No.	Name of the Doctor	Qualification of the Doctor	MMC Registration No.	Date of joining

HR 4. Standard

Std UID	Standard Definition	Expected Value	Scoring
HR 4	Doctor patient ratio in ICU	One Doctor per six bedded ICU in each shift	2

Evidence and data to be maintained by Medical Superintendent:

1. Data

A = Daily Attendance of Doctors at beginning of each shift in ICUs

X = Number of Occupied Beds in ICUs at each shift by 6

Y = 1

Z = X/Y which is the Number of doctors required at each shift

Ideal: "A" should be equal or greater than "Z"

2. Random Checks in ICUs

HR 5. Standard

Std UID	Standard Definition	Expected Value	Scoring
HR 5	Nurse patient ratio in ICU	I : 1	2

Evidence and data to be maintained by Medical Superintendent:

1. Data:

A = Daily Attendance of Nurses at beginning of each shift in ICUs

X = Number of Occupied Beds in ICUs at each shift

Ideal: "A" should be equal or greater than "X"

2. Random Checks in ICUs

HR-5. Nurses patient ratio in ICU per shift:

Norm:

For Ventilated Beds: Availability of minimum 1 Nurse for each ventilated Bed in ICU.

For Non-ventilated Beds: Availability of minimum 1 Nurse for 3 Non-ventilated Beds.

Record to maintain: List of the Nurses available in the ICU These minimum data elements should be available in the registers maintained for this purpose by the hospital.

Updating of List: List of the Nurses should be updated immediately if there is any change.

Frequency of Reporting: Every six month (on 1st of January and 1st of July of every year).

Common list: If Nurses are used in rotation for general duty, then total lists of Nurses for both shift as well as leave reserve should be maintained as a common lists in above format.

Sr. No.	Type of ICU Beds (Ventilated Bed / Non-ventilated bed)	Name of the Nurse	Qualification of the Nurse	Maharashtra Nursing Council Registration No.	Date of joining

HR 6. Standard

Std UID	Standard Definition	Expected Value	Scoring
HR 6	Number of doctors on call with super specialty qualifications according to specialties treated by hospital	Minimum 1	2

Evidence and data to be maintained by Medical Superintendent:

1. Data:

a) List of Super Specialties
b) Name and qualifications of Super Specialist Doctors

To be Updated as Required or monthly

3. Random Checks in Wards

HR-6: Doctors on call with super specialty qualification (Specialty wise):

Norm: Availability of minimum 1 Call specialist for every specialty having Post Graduate qualification of concerned specialty and registered with Maharashtra Medical Council.

Record to maintain: List of the On Call Super Specialist Doctor available in the hospital These minimum data elements should be available in the registers maintained for this purpose by the hospital

Updating of List: List of the Specialists Doctors should be updated immediately if there is any change.

Frequency of Reporting: Every six month (on 1st of January and 1st of July of every year).

Sr. No.	Name of the Super Specialty	Name of the Super Specialist Doctor	Qualification of the Super Specialist Doctor	Maharashtra Medical Council Registration No.	Date of joining

HR 7. Standard

Std UID	Standard Definition	Expected Value	Scoring
HR 7	Number of Qualified and Registered Anesthetist with degree or Diploma.	Minimum 2 on call.	1
	Number of Qualified X-Ray technicians if inhouse facility B.Sc. And trained	Minimum 1	1
	Number of Qualified Lab technician with qualification B.Sc. D.M.L.T. if inhouse facility	Minimum 1	1

Evidence and data to be maintained by Medical Superintendent:

1. Data:

a) List of Staff

To be Updated as Required or monthly

3. Random Checks of call duty registers

HR-7: Other Qualified HR:

Norm:
On Call Anaesthetist: Availability of minimum 2 On Call Registered Anaesthetists.
In-House Pathologist: Availability of minimum one In-house registered Pathologist possessing post graduate degree or diploma in Pathology.
In House X-ray Technician: Availability of minimum 1In-House X-ray Technician.
In House Lab Technician: Availability of minimum 1In-House Lab Technician.
Record to maintain: List of the Other Staff available in the hospital These minimum data elements should be available in the registers maintained for this purpose by the hospital
In case of outsourced lab
Updating of List: List of the Specialists Doctors should be updated immediately if there is any change.
Frequency of Reporting: Every six month (on 1st of January and 1st of July of every year).

Sr. No.	Category of Staff	Name of the Staff	Qualification of the Super Specialist Doctor	MMC Registration No. in case of Doctor	Date of joining
1	Anaesthetist				
2	Pathologist				
3	In House X-ray Technician				
4	In House Lab Technician				

Name of Lab	*Name of Pathologist signing the report*	*Qualification*	*Registration no*	*Timings*
	Name of lab technician	*Qualification*		

HR 8. Standard

Std UID	Standard Definition	Expected Value	Scoring
HR 8	Display of Qualifications of Medical personnel	Should be displayed on signboard	1

Evidence and data to be maintained by Medical Superintendent:

1. Data:

a) List of Staff

To be Updated as Required or monthly

3. Random Checks during rounds

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HR-8: Display of Qualification of Medical Practitioners:

The Specialty wise Qualifications of the Practitioner as well as General Duty Medical Practitioners should be displayed a prominent place of hospital like patient waiting area.

Frequency of Reporting: Reporting of such display should be made every year.

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HR 9. Standard

Std UID	Standard Definition	Expected Value	Scoring
HR 9	Whether qualified and registered Pathologist available if inhouse lab or outsourced		1

Evidence and data to be maintained by Medical Superintendent:

1. Data:

a) List of Staff

To be Updated as Required or monthly

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HR-9: Training Policy:

The Hospital should have Policy for the Training of HR (where ever necessary) along with Calendar and Schedule.

Frequency of Reporting: Training Calendar should be prepared for every year in the month of January.

HR 10. Standard

Std UID	Standard Definition	Expected Value	Scoring
HR 10	Training Policy, Calendar and Schedule	Availibility of Training policy, calender and schedule for all human resources	1

Evidence and data to be maintained by Medical Superintendent:

1. Documents :

a) Training Policy
b) Calendars
c) Schedules
d) Attendance Registers

To be Updated as Required or quarterly

HR: Weightage & Scoring

HR	Score
1	2
2	2
3	2
4	2
5	2
6	2
7	3
8	1
9	1
10	1
Total	18

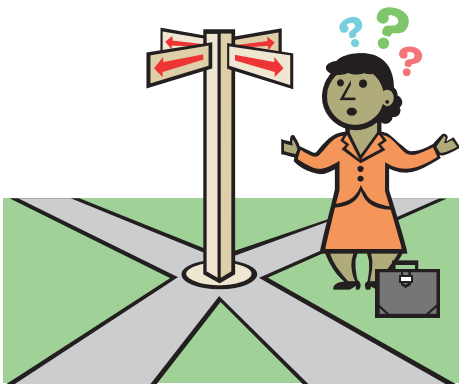
Weightage: 18

Exercise : (Divide Class into 5 groups)

- How will you verify the information for the expected value in the hospital?

Group 1: Std 1 & 2
Group 2: Std 3 & 4
Group 3: Std 5 & 6
Group 4: Std 7 & 8
Group 5: Std 9 & 10

  - What information do you need
  - Who will give this to you
  - Which department/s will you visit
  - Which records will you check
  - How will you verify that the standard is maintained throughout the month/year
  - How will you verify the qualifications of the doctors



SECTION 2.

Facilities Management (FAC)

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Intent: FAC

- Provision of a safe and secure environment for patients.
- Plans for emergencies within the facilities and the community.
- Program for clinical and support service equipment and management.

There are 15 standards in FAC

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Standard: FAC 1

Std UID	Standard Definition	Expected Value	Scoring
FAC1	Sampling by trained Phlebotomist with centralized receiving area	Samples should be collected by trained phlebotomist and received at a centralized area	1

Evidence and data to be maintained by Medical Superintendent:

1. Documents :

a) List of phlebotomists with their training details

To be Updated as Required or quarterly

b) **Physical site visit of Phlebotomy area**

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FAC-1: Trained Phlebotomists for Sampling with centralized receiving Area:

Norm: Availability of Trained Phlebotomists available for sampling with centralized receiving area of Hospital.

Record to maintain: Name of the Phlebotomists available in the hospital These minimum data elements should be available in the registers maintained for this purpose by the hospital

Updating of List: List of the Phlebotomists should be updated immediately if there is any change.

Frequency of Reporting: Every six month (on 1st of January and 1st of July of every year).

Sr. No.	*Name of the Phlebotomist*	*Qualification of the Phlebotomist / Lab technician*	*Training Details*	*Date of joining*

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Standard: FAC 2, 3 & 4

Std UID	Standard Definition	Expected Value	Scoring
FAC2	Whether ambulance Services- in house or available on call	Either inhouse or on call	1
FAC3	Availability of trained personnel with ambulance either BLS or ALS	Ambulance personnel should be minimum BLS trained.	1
FAC4	Avalability of foot suction machine, Emergency tray, Defibrillator/AED, IV Fluids, Oxygen, Stethoscope and BP Apparatus.	For BLS ambulances	1

FAC 2 is MANDATORY

Standard: FAC 2, 3 & 4

Evidence and data to be maintained for Ambulance Services by Medical Superintendent:

1. Documents :

a) Ambulance Papers
b) Training Records of Ambulance Staff
c) Equipment List

To be Updated as Required or quarterly

b) **Physical site visit**

FAC-2: Ambulance Services – In-house or On Call:

Norm: Availability of 1 minimum In-house Ambulance or On-Call Ambulance.
Record to maintain: List of the available In-house or On-Call Ambulance along with the Ambulance No. registered with RTO should be maintained.
Frequency of Reporting: Every Year (on 1st of January of every year).

FAC-3: Availability of Trained Personnel with Ambulance (BLS/ALS):

Norm: Availability of minimum Trained Personnel with Ambulance.
Record to maintain: List of the trained staff on Ambulance in the hospital
These minimum data elements should be available in the registers maintained for this purpose by the hospital
Updating of List: List of the Ambulance personnel should be updated Immediately if there is any change.
Frequency of Reporting: Every six month (on 1st of January of every year).

Sr. No.	Ambulance Number	Name of the Trained Staff on Ambulance	Nature of job on Ambulance	Training details	Date of joining

FAC-4: Availability of Equipments like- Foot Suction Machine, Emergency Tray, Defibrilator/AED, Oxygen, Stethoscope, BP apparatus and IV Fluid:

Norm: Availability of adequate quantity of Foot Suction Machine, Emergency Tray, Defibrillator/AED, Oxygen, Stethoscope, BP apparatus and IV Fluids should be available in Hospital.
Record to maintain: Stock of the inventories should be maintained in inventory stock books of the Hospital in following format. Date of receipt and quantity should be available.
Frequency of Reporting: Once in a Year (on 1st of January of every year).

Sr. No.	*Name of Equipment*	*Date of receipt*	*Quantity Available*
1	*Foot Suction Machine*		
2	*Emergency Tray,*		
3	*Defibrillator/AED,*		
4	*Oxygen,*		
5	*Stethoscope*		
6	*BP apparatus*		
7a	*IV Fluid- Dextrose 5%.*		
7b	*IV Fluid- NSL.*		
7c	*IV Fluid-Ringers Lactate.*		

Open Questions

- How will you ensure that the Ambulance Personnel are BLS trained.
- How will you ensure that the Ambulance Personnel are ACLS trained.
- What is the difference in equipment requirements of BLS and ACLS Ambulance.

FAC 5.

Std UID	Standard Definition	Expected Value	Scoring
FAC5	whether ICU equipped with life saving equipment such as ventilator, defibrillator and Pulse oxymeter	Minimum requirement	1

Evidence and data to be maintained :

1. Documents :

a) Equipment List of ICUs

To be Updated as Required or quarterly

b) **Physical site visit**

FAC 5 is MANDATORY

FAC-5: In ICU availability of Life saving equipments like- Ventilator, Defibrillator and Pulse Oxymeter:

Norm: Availability of adequate quantity of Ventilator, Defibrillator and Pulse Oxymeter should be available in ICU.
Record to maintain: Stock of the inventories should be maintained in Stock books of the Hospital mentioning date of receipt and quantity.
Frequency of Reporting: Once in a Year (on 1st of January of every year).

FAC 6

Std UID	Standard Definition	Expected Value	Scoring
FAC6	Bed occupancy %	Sum of daily census of patients admitted (measured at 12 midnight) x 100 / Number of operational beds x days in month	1

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FAC- 6: % of Bed Occupancy:

Definition: Bed occupancy is defined as percentage of operational beds occupied in a day

Formula: Sum of daily census of patients admitted measured at 12 midnight x 100/ Total number of operational Beds x days in months.

Numerator: Number of daily census of patients admitted measured at 12 midnight.

Denominator: Total number of operational Beds multiplied by number of days in a month.

Work Station: All Wards, Emergency Wards and ICU

Register to capture data:

Frequency of Reporting: Once in a Year (on 1st of January of every year).

Month and Year	Work station (Ward / ICU / Emergency Ward)	Patient Count at 12 midnight

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FAC 7

Std UID	Standard Definition	Expected Value	Scoring
FAC7	Fire Safety Measures. One fire extinguisher per ward with NOC from fire department or licencing agency to be obtained within next one year	Plan exists for exit in case of fire and non fire emergency and drill carried out twice a year	1

Evidence and data to be maintained :

1. Documents :

a) Equipment List of Fire Safety Equipment
b) Fire NOC
c) Fire Exit Plan
d) Records of Emergency Drill

To be Updated as Required or quarterly

b) **Physical site visit & mock drill**

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FAC-7: Fire Safety Measures:

Norm: Hospital should have fire safety plan and availability of one Fire Extinguisher per ward. NOC should be available from Fire Department with Hospital. Hospital should carry out drills twice a year (six months apart).

Record to maintain: Records should be maintained as per requirement of fire department.

The dates of the fire mock drill conducted with details should be recorded and reported every year.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

FAC 8

Std UID	Standard Definition	Expected Value	Scoring
FAC8	Two minimum rounds by treating doctors in a day i.e. Morning and evening	Round book should have record, which should be maintained by nursing incharge	1

Evidence and data to be maintained :

1. Documents :

a) Round Books

To be Updated as Required or quarterly

FAC- 8: Two minimum rounds by treating doctors in a day (morning & evening):

Norm: Hospital should have two rounds, one in morning and one in evening, by treating doctors in which all patients should be examined.

Work Station: All Wards and ICU

Mechanism of Data recording: Indoor papers and round book should mention clinical notes and treatment advised at the time of morning and evening round.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

FAC 9

Std UID	Standard Definition	Expected Value	Scoring
FAC9	Operation theatre	Whether it has Clean, Neutral and sterile zones. Temperature and Humidity monitoring inside operation theater and charting done on a daily basis	1

Evidence and data to be maintained :

1. Documents :

a) Floor Plan of Theatre
b) Daily Records of Temperature and Humidity

To be Updated as Required or quarterly

b) **Physical site visit**

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FAC-9: Clean, neutral and sterile zone in OT and monitoring of Temperature and Humidity:

Operational Definition: Hospital should have clearly demarcated area like clean, neutral and sterile zone in every OT and adhered to guidelines of OT. Daily temperature and humidity monitoring should be done.

Work Station: All OTs.

Mechanism of Data recording: A person shall be designated by the Hospital Authority to observe and record this information on daily basis at all OTs. Person could be in-charge sister of OT. Daily record of temperature and humidity monitoring should be available.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

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OT Zoning

An OT is that specialized facility of the hospital where life saving or life improving procedures are carried out on human body by invasive methods under strict aseptic conditions in a controlled environment by specially trained personnel to promote healing and cure with maximum safety, comfort and economy

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1. Criteria for Zoning:

The aim of zoning is that when staff members, patients or supplies enter the OT suite, the risk factors of carrying the chances of infection with them get lesser and lesser, as they pass from the protective through clean to aseptic zone.

2. General Principles:

1. Clean from dirty traffic-flow within the OT suite should be segregated as best as possible. Spaces in the suite should be arranged in such a way that while moving from one space to another, there is continuous pro-gression of cleanliness from entrance of OT suite to the operating room.

2. Staff working in the OT department should be able to move from one clean area to the other without having to pass through unprotected areas.

2. General Principles (contd):

3. Soiled materials and waste should be removed from the operating rooms without passing through clean areas.

4. OT ventilation should be independent of the air move-ment of the rest of the hospital. Therefore, the direction of airflow within the OT suite should be from cleaner to less clean areas.

OT Zoning

CONSISTS of 4 zones

A. **OUTERZONE**

- Areas for receiving patients messengers, toilets, administrative Function

B. **RESTRICTED ZONE OR CLEAN ZONE**

- Changing room - Patient transfer area- Stores room - Nursing staff room-Anaesthetist room- Recovery room

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OT Zoning

C. **ASEPTIC ZONE**

- Scrub area• Preparation room,• Operation theatre,• Area for instrument packing and sterilization

D. **DISPOSAL ZONE**

- Area where used equipment are cleaned and biohazardous waste is disposed

Recommend further reading about OT Functioning, Infection Control and environment

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FAC 10. Standard

Std UID	Standard Definition	Expected Value	Scoring
FAC10	Doctors Call response time(Difference between the time of receiving the call and the time of physically attending the call by the doctor	Total time interval for all calls / Total number of calls sent	1

Evidence and data to be maintained :

1. Documents :

a) Round Books

To be Updated as Required or quarterly

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FAC-10: Doctors call response time:

Operational Definition: Doctors call response time is defined as the time taken by the doctor to attend the patient from the time of sending the call to the resident doctors and on call doctors.

Formula: Total time call interval of all calls x 100/ Total number of calls sent in a day/month.

Numerator: Total time interval for all calls per day/month

Denominator: Total number of call sent per day/month

Work Station: All Wards and ICU

Mechanism of Data recording: Information available in the doctor's call book at all wards and ICU shall be recorded on daily basis. These minimum data elements should be available in the registers maintained for this purpose by the hospital

Frequency of Reporting: Once in a Year (on 1st of January of every year).

Date and month	Work station (Wards/ ICU)	Name of the Doctor sent call	Time of sending call	Time of attending	Time interval of call	Signature of In-charge Sister

FAC 11

Std UID	Standard Definition	Expected Value	Scoring
FAC 11	Percentage of AMC or CMC of Equipments	Total number of equipments with AMC or CMC / Total number of equipments **x** 100	1

Evidence and data to be maintained :

1. Documents :

a) Equipment Inventory List, with scheduled/completed dates of AMC/CMC
b) Stickers on equipment with dates

To be Updated as Required or quarterly

2. **Random Physical site checks**

FAC-11: % of AMC and CMC of equipments:

Norm: Hospital should have AMC and CMC for all equipments so that equipments are functional by preventive maintenance repairs which will not adversely affect the medical care of the patients. The list of the equipments should be predefined for purpose of AMC and CMC

Record to maintain: List of the equipments having AMC/CMC should be maintained in following date elements such date of AMC / CMC and validity of AMC / CMC

Frequency of Reporting: Once in a Year (on 1st of January of every year).

FAC 12. Standard

Std UID	Standard Definition	Expected Value	Scoring
FAC 12	For purposes of diet, Institution should be registered under Food Safety Act		1

Further reading: Requirements of Food Safety Act

FAC- 12: Registration with FDA for Hospital Diet :

Norm: Hospital should get registered with FDA under food safety Act, since hospital diet is provided to the patients.

Frequency of Reporting: Once in a Year (on 1st January of every year)

FAC 13

Std UID	Standard Definition	Expected Value	Scoring
FAC 13	Uninterrupted power and water supply	Availability at least in critical areas like ICU, OT & Labour ward	1

Evidence and data to be maintained :

1. Documents :

a) Electrical Load and back up system

To be Updated as Required or quarterly

2. **Random Physical site checks**

FAC-13: Un-interrupted Power and Water Supply in ICU, OT and Labour Ward :

Norm: Hospital should ensure un-interrupted Power and Water supply at least in ICU, OT and Labour Ward for which alternative arrangements like generators/ invertors should be in place. Power failure should be recorded from ICU, OT and Casualty should be recorded on daily basis.

Frequency of Reporting: Once in a Year (on 1st January of every year)

FAC 14

Std UID	Standard Definition	Expected Value	Scoring
FAC 14	Oxygen Supply	Contineous availability of either piped oxygen or oxygen cylinder	1

Evidence and data to be maintained :

1. Documents :

a) Oxygen Supply System

To be Updated as Required or quarterly

2. **Random Physical site checks**

***FAC- 14: Oxygen Supply*:**
Norm: Hospital should ensure that continuous Oxygen supply either piped Oxygen or Cylinder should be available. The information about number of cylinders with capacity should be recorded weekly.
Frequency of Reporting: Once in a Year (on 1st January of every year)

FAC 15

Std UID	Standard Definition	Expected Value	Scoring
FAC 15	Signages	Display of various signages	1

Evidence to be maintained :

1. **Random Physical site checks**

FAC-15: Display of Signages :

Norm: Hospital should have displayed various signages for the guidance and ease of patients while seeking medical care. The list of the signages should be predefined for purpose of display.
Frequency of Reporting: Once in a Year (on 1st January of every year).

Weightage & Scoring

FAC Std	Score
1	1
2	1
3	1
4	1
5	1
6	1
7	1
8	1
9	1
10	1
11	1
12	1
13	1
14	1
15	1
Total	15

Weight age:15

Exercise : (Divide Class into 5 groups)

- How will you verify the information for the expected value in the hospital?
  - What information do you need
  - Who will give this to you
  - Which department/s will you visit
  - Which records will you check
  - How will you verify that the standard is maintained throughout the month/year

Group 1: Std 1, 2 & 3

Group 2: Std 3, 4 & 5

Group 3: Std 6, 7 & 8

Group 4: Std 9, 10, 11, 12

Group 5: Stds 13, 14, 15

SECTION 3.

Infection Control Measures (INF)

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Intent: Infection Control Measures

- *Over 1.4 million people worldwide are reported to be suffering from hospital acquired infections.*
- *Significant cause of morbidity and mortality*
- One-third of all such episodes are potentially preventable.

There are 11 standards in INF

Intent

- Infection Control Procedures are in place to minimize risk of Infections
- Focus is on capturing HAI surveillance data, practice of hand hygiene, BMW, and Needle stick Injuries

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Standard: INF 1

Std UID	Standard Definition	Expected Value	Scoring
INF1	Documented Infection control procedures	Air quality monitoring done at least monthly with the help of simple air settle plate or air sampling for OT, Fogging of O.T., Labor room, Burn ward and NICU.	1

Evidence and data to be maintained by Medical Superintendent:

1. **Records of Monitoring**
2. **Random Checks in OTs**

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Operational Definition: Air sample contamination is defined as the evidence of bacteriological growth in the culture subjected to air sample collected from defined sites (OT, Labour Room, Burn ward and NICU).

Formula: Number of Air Samples found contaminated from defined site per month x 100/ Total number of Air samples tested from OT per month.

Numerator: Number of Air Samples found contaminated from OT per month.
Denominator: Total number of Air samples tested from OT per month.
Frequency of monitoring: Monthly
Workstations: All Operation Theaters, Labour Room, Burn ward and NICU.

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Significance:

Service provider factors: Regular disinfection of OT

A. Institutional factors

A.1. Architectural design of OT facilitating proper air conduction

A.2. Availability and adherence to Standard infection control practices (SOPs)

A.3. This indicator reflects the extent of Hospital Acquired Infections (HAI) [Nosocomial infections] and is associated with extent of infection control practices, including improved operating room ventilation, sterilization methods, barriers, surgical technique, and availability of antimicrobial prophylaxis. Most commonly the infection is inoculated in Operation Theatre.

B. Monitoring mechanism:

B.1. Evidence of growth of micro-organism in culture.

B.2. Records to be kept as per format indicated in **Table 1**.

B.3. Information of the denominator will be available from Micro-biology laboratory.

Table 1: INF3 Monitoring Format:

Sr. No.	Work Station (OT/LR/Burn ward/NICU)	Date of collection of Air sample	Microbial growth reported (Yes/No)	Name of organism grown	Signature of OT/ward In-charge

Standard: INF 2

Std UID	Standard Definition	Expected Value	Scoring
INF2	Infection control committee and regular meetings with minutes	Meeting register should be available for monthly meeting with minutes of meeting documented	1

Evidence and data to be maintained by Medical Superintendent:

1. **Records of Meetings**

This is a mandatory Standard

INF- 2: Infection Control Committee (ICC):

Infection Control Committee should meet once in a month to discuss the issues of hospital infections and should maintain a register of minutes of meeting.

Question

- Who should Chair the ICC, and who should eb secretary/coordinator?
- Who should be the members?
- What are the responsibilities of this committee?

Standard: INF 3

Std UID	Standard Definition	Expected Value	Scoring
INF 3	Availability of Surveillance of Hospital acquired infections with record-SSI	1. For surgical facility - Surgical site infections	2
INF4	Availability of Surveillance of Hospital acquired infections with record-VAP	ICU - Ventilator Associated Pneumonia	2
INF5	Availability of Surveillance of Hospital acquired infections with record-Catheter related UTI	Wards - Catheter related Urinary Tract Infections	2

SSI

Surgical Site Infection rate is defined as the number of Surgical Site Infection per 100 surgical procedures. Surgical Site Infection is defined as any infection occurs within 30 days after the operation if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operation and infection involves only skin and subcutaneous tissue of the incision or deep soft tissue (e.g. fascia, muscle) of the incision or any part of the anatomy (e.g., organs and spaces) other than the incision which was opened or manipulated during an operation involves

Further Reading: CDC Guidance on SSI

SSI

Formula for Rate Calculation	Total number of reported SSIs/Total number of surgical procedures *100
Significance	Hospital Acquired Infection are preventable cause of patient harm which are associated with high rate of mortality & morbidity. Measuring the hospital acquired infection rate helps in planning the strategy to prevent the occurrence of them
Exclusions	Stitch abscess /Cellulitis/ Stab wound infection/ Infected circumcision site/ Infected burn wound/ Episiotomy Infection

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INF - 3: % of surgical site infections:

1.Operational Definition: Surgical site infections are defined as clean planned major surgeries developing infections post surgery and indicated by presence of pus and/ or wound gaping
2.Formula: Number of clean planned major surgeries developing infections x 100/ Total number of clean planned major surgeries
3.Numerator: Number of patients developing SSI of clean planned major surgeries within period of hospital stay
4.Denominator: Total number of clean planned major surgeries
5.Frequency of monitoring: Monthly
6.Workstations:
- •General surgery wards,
- •Obstetric and Gynaecology ward
- •Orthopedic ward
- •ENT
- •Ophthalmology
- •Super specialty (CVTS, Neuro, Paediatric, Plastic, Urology, gastroenterology, etc.)
- •ICU

INF - 3: % **3.3.7** *Reference:http://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdfhttp://digitallibrary.srmuniv.ac.in/dspace/bitstream/123456789/2287/1/4041.pdf*

1.Significance:
2.Service provider factors
1.Prolonged surgery leads to increased chances of infection
2.Skill of surgeon
3.Patient factors
1.Immunity
2.Age
3.Pre-exisiting illnesses/ co-morbidity such as diabetes
4.Institutional factors
1.Adequate man-power
2.Availability and adherence to Standard infection control practices (SOPs)
3.This indicator reflects the extent of Hospital Acquired Infections (HAI) [Nosocomial infections] and is associated with extent of infection control practices, including improved operating room ventilation, sterilization methods, barriers, surgical technique, and availability of antimicrobial prophylaxis. Most commonly the infection is inoculated in Operation Theatre.
5.Monitoring mechanism:
6.At level of all workstations
1.Examination of wound
2.Evidence of pus formation and gaping of wound
7.Records to be kept as per format indicated in **Table 1**.
8.Information of the denominator will be kept in the OT in existing register with additional column.

Table 1: INF3 Monitoring Format

	Workstation (Wards & ICU)							
Month & Year	**General Surgery, Gynaecology, Orthopedic, Super Speciality, ICU**	**Patient name**	**Patient UID**	**Name of surgical procedure**	**Date of surgery**	**Date of detection of SSI**	**Evidence of pus/ gaping of wound**	**Signature of Sister-In-charge**
1	2	3	4	5	6	7	8	9

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VAP

Ventilator-associated pneumonia (VAP) rate is defined as the number of ventilator-associated pneumonias per 1,000 ventilator days. Ventilator-associated pneumonia (VAP) is defined as pneumonia in a patient intubated and ventilated at the time of or within 48 hours before the onset of the event.

Further Reading: CDC Guidance on VAP

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VAP

Formula for Rate Calculation	Total number of reported VAPs/Total number of ventilator days *1000
Significance	Hospital Acquired Infection are preventable cause of patient harm which are associated with high rate of mortality & morbidity. Measuring the hospital acquired infection rate helps in planning the strategy to prevent the occurrence of them

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1.Operational Definition: Ventilator-associated pneumonia (VAP) is defined as pneumonia in a patient intubated and ventilated at the time of or within 48 hours before the onset of the event.
2.Formula: Total number of VAP cases per month x 1000/ Total ventilator days per month
3.Numerator: Number of VAP cases per month
4.Denominator: Total number of patient ventilator days per month
5.Frequency of monitoring: Monthly
6.Workstations: All ICUs
7.Reference:
http://www.apic.org/Resource_/EliminationGuideForm/18e326ad-b484-471c-9c35-6822a53ee4a2/File/VAP_09.pdf

http://www.ihi.org/knowledge/Pages/Measures/VentilatorAssociatedPneumoniaRateper1000VentilatorDays.aspx

1.Service provider factors:
1.Hand washing before application of intubation and ventilator
2.Adherence to prescribed dose of sedation
3.Cleaning ventilator accessories
4.Raising head-end to 30 degrees
5.Improper mouth hygiene
2.Patient factors
1.Pre-existing RI will accelerate onset of VAP
2.Pre-existing diabetes m
3.Pre-existing immune-compromised condition
3.Institutional factors
1.1:1 Nurse to patient ratio not maintained
2.Adherence to standard infection control protocols
4.Monitoring mechanism:
5.ICU:
1.Examination of patient blood & x-ray
1. Blood examination of ventilated patients showing fever, low body temperature, new purulent sputum, and hypoxemia
2. X-ray chest
3. Records to be kept as per format indicated in **Table 2**.

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Table 2: INF4 Monitoring Format

	Workstation (ICUs)								
Month & Year	**Medical, Surgical, Super Speciality**	**Patient name**	**Patient UID**	**Diagnosis**	**Date of putting patient on ventilator**	**Date of removal of ventilator**	**Date of onset of pneumonia as indicated by chest X-ray/ blood examination**	**Number of ventilator days**	**Signature of Sister-In-Charge**
1	2	3	4	5	6	7	8	9	10
Jan-14									

CAUTI

- Proportion of Catheter-Associated Urinary Tract Infection (CAUTI) developed in patients that had an indwelling urinary catheter at the time of or within 48 hours before onset of the UTI Catheter associated urinary tract infections (CA-UTIs) are defined as symptomatic urinary tract infection or asymptomatic bacteremic urinary tract infection., clinical manifestations of infection (i.e., fever, chills, loin pain), and no apparent source for the urinary tract infection except the catheter.

Further Reading: CDC Guidance on CAUTI

CAUTI

Significance	Hospital Acquired Infection are preventable cause of patient harm which are associated with high rate of mortality & morbidity. Measuring the hospital acquired infection rate helps in planning the strategy to prevent the occurrence of them
Formula for Rate Calculation	Total number of reported CAUTIs/Total number of Catheter days *1000
Exclusions	• Patient admitted with UTI • Patient diagnosed with UTI before 48 hours of admission in the hospital

INF- 5: Rate of Catheter Associated Urinary Tract Infection (CAUTI):

1.Operational Definition: Urinary tract infections associated with insertion of a catheter. To be identified by symptoms of fever with chills and WBC count more than 50 per high power field) at the time of or within 48 hours before onset of the UTI Catheter associated urinary tract infections (CA-UTIs)
2.Formula: Total number of CAUTI cases per month x 1000/ Total Catheter days per month
3.Numerator: Number of CAUTI cases per month
4.Denominator: Total number of catheter days per month
5.Frequency of monitoring: Monthly
6.Workstations: Wards, ICUs
7.Reference:
http://www.cdc.gov/nhsn/pdfs/pscmanual/7psccautiicurrent.pdf
http://emedicine.medscape.com/article/2040035-overview

Acquired Infections (HAI) [Nosocomial infections] and is associated with extent of infection control practices and sterilization methods.

2.Service provider factors:

1.Proper handwashing before catheterization
2.Using smallest possible size catheter
3.Proper catheter care
4.Maintaining unobstructed urine flow

3.Patient factors

1.Pre-existing UTI
2.Pre-existing diabetes m
3.Pre-existing immune-compromised condition
4.Duration of catheterization/ frequency of changing of catheter
5.More common in females

4.Institutional factors

1.Availability and adherence to standard infection control protocols

1.Monitoring mechanism:

2.Wards (Surgical, Gynaecology, Orthopedics, Super Speciality)

1.Examination of Urine
1.Pyuria= more than 50 white blood cells (WBCs) per high-power field (HPF).
1.Records to be kept as per format indicated in **Table 3**.

1.ICU:

1.Examination of Urine
1.Pyuria= more than 50 white blood cells (WBCs) per high-power field (HPF).
2.Records to be kept as per format indicated in **Table 4**.

Table 3: INF5 Monitoring Format

	Workstation (ICU)								
Month & Year	**Medical, Surgical, Super Speciality**	**Patient name**	**Patient UID**	**Diagnosis**	**Date of insertion of foley'scath-eter**	**Date of removal of foley'scat her**	**Date of developing UTI (more than 10**	**Total catheter days**	**Signature of Sister-In-Charge**
1	2	3	4	5	6	7	8	9=7-6	

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CLABSI

Proportion of catheter related bloodstream infections developed in patients that had a central line within the 48-hour period before the development of the bloodstream infections Catheter-related bloodstream infections (CR-BSIs) are defined as bacteremia / fungemia in a patient with an intravascular catheter with at least one positive blood culture obtained from a peripheral vein, clinical manifestations of infection (i.e., fever, chills, and/or hypotension), and no apparent source for the bloodstream infection except the catheter.

Further Reading: CDC Guidance on CLABSI

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Formula for Rate Calculation	Total number of reported CRBSIs/Total number of Central line days *1000
Significance	Hospital Acquired Infections are preventable cause of patient harm which are associated with high rate of mortality & morbidity. Measuring the hospital acquired infection rate helps in planning the strategy to prevent the occurrence of them
Exclusions	• Patient admitted with Blood stream infection • Patient diagnosed with BSI before 48 hours of admission in the hospital

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Standard INF 6

Std UID	Standard Definition	Expected Value	Scoring
INF6	Incidence of Needle stick injuries with PEP as per standard protocol	Number of Health care providers given PEP	1

Evidence and data to be maintained by Medical Superintendent:

1. **Records of Staff with PEP**

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INF- 6: % of Health care providers given PEP as per protocol:

3.6.1 Operational definition: Post-exposure prophylaxis (PEP) is short-term antiretroviral treatment to reduce the likelihood of infection after potential exposure, either occupationally or through sexual intercourse.

Within the health sector, PEP should be provided as part of a comprehensive universal precautions package that reduces staff exposure to infectious hazards at work. PEP should be taken within 72 hours of exposure.

According to BMW rules 1998 Form 3 (Rule12) it is mandatory to keep record of accident reporting and Post Exposure Prophylaxis's (PEP) as under:
- Date and time of accident
- Sequence of events leading to accidents
- Waste involved in the accident
- Assessment of effects of accident on human health and environment
- Emergency measures taken
- Steps taken to alleviate effect of accident
- Steps taken to prevent recurrence of such accidents

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1.Formula: Total number of health care providers receiving PEP as per protocol per month x 100/ Total number of health care providers reporting needle-stick injury per month

2.Numerator: Total number of health care providers receiving PEP as per protocol per month

3.Denominator: Total number of health care providers reporting needle-stick injury per month

4.Frequency of monitoring: Monthly

5.Workstation: Casualty

6.Reference:

http://www.who.int/hiv/topics/prophylaxis/en/
http://aids.gov/hiv-aids-basics/prevention/reduce-your-risk/post-exposure-prophylaxis/

1.Significance:

2.Service provider factors:

1.Precaution to be taken while invasive procedures

3.Institutional factors

1.Availability and adherence to PEP protocols

4.Monitoring mechanism:

5.Records to be kept as per format indicated in **Table 5**.

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Table 5: INF6 Monitoring Format

	Exposure Type								
Month & Year	**Needle-prick, Blood and other body fluid in eyes and mouth, Blood and other body fluid on exposed skin**	**Health care provider UID (OPD Number) / Employee code**	**ECS Code – ECS 1, 2, 3**	**HIV Status Code – HIV SC 1/2**	**Date and time of exposure**	**Date and time of reporting to casualty**	**Date and time of giving PEP**	**Type of PEP given Basic/ Expanded**	**Signature of Casualty Medical Officer**
1	2	3	4	5	6	7	8	9	10

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Standard INF 7

Std UID	Standard Definition	Expected Value	Scoring
INF7	Availability of hand hygiene guidelines and facility	Basin with elbow cock and liquid soap and alcohol based handrub in OT and NICU	0.5

Evidence:

1. **Physical site checks**
2. **Availability of water, hand rub, soap, wiping towels/dryers**

INF-7: Hand Hygiene Guidelines and Facility:

Norm: Hand Hygiene Guidelines and Facility should be available at all working stations including OT of the hospital.
Frequency of Reporting: Once in a Year (on 1st of January of every year).

Guidelines for Hand Washing

- WHO Guidelines on Hand Hygiene in Health Care-2009
- Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force-2002

Standard INF 8

Std UID	Standard Definition	Expected Value	Scoring
INF8	If CSSD exists with sterilizer monitoring	Autoclave register with evidence of signolac strip monitoring or Chemical disinfectant monitoring with strip or any other process used in CSSD should be monitored appropriately	1

Evidence:

1. **Physical site checks**
2. **Records in CSSD**

INF- 8: CSSD monitoring strips:

Norms: Central Supply Sterilization Department is a main integrated place where sterilization of various consumables and equipments occurs, which is used not only in OT and ICU but also in medical, surgical, maternity and pediatric wards for various procedures like catheterization, wound stitching and bandaging. Thus perfect autoclaving is a crucial part of whole process. The evidence of autoclaving and achievement of sterilization is a CSSD Monitoring strips or signolac strips which should be preserved as a record.

Work stations: All OT and CSSD.

Monitoring mechanism: This information is usually available in CSSD and OT. The person responsible for supervision over CSSD will record the information in the following format. The strip should be duly signed by a person who has carried sterilization process and should be fixed on this register as evidence.

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Date/ Month/Yr	Working station (CSSD/OT)	Description of articles/Equipments / linen to be Sterilized	Name & Design. of person performed sterilization autoclaved	Attach Sterilization strip	Signature of In-charge of CSSD

Frequency of Reporting: Once in a Year (on 1st of January of every year).

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Standard INF 9

Std UID	Standard Definition	Expected Value	Scoring
INF 9	Whether registered with MPCB under BMW Rules 1998	Date, authorization number and date of expiry.	0.5

Evidence:

1. **Physical site checks**
2. **Records**

This is a mandatory Standard

INF- 9: Registration with MPCB:

Norms: Registration with MPCB and disposal of hospital waste including bio-medical waste in a proper manner as per provision in Act is mandatory.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

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Standard INF 10

Std UID	Standard Definition	Expected Value	Scoring
INF10	Hepatitis B vaccination for health care providers should be ensured	Protection levels should be monitored	0.5

Evidence:

1. **Records**

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INF -10: Health care Provider given Hepatitis Vaccine:

Norms: As an bio-safety measures the health care providers are supposed to be protected from the occupational hazards and acquiring infections from the patients. Therefore it is mandatory to provide prophylactic Hepatitis B vaccine to Health care at risks providers.

Monitoring mechanism: The person and department should be identified for keeping the record related to this indicator. It is usually kept in Casualty or Medicine Department of the Hospital.

List of at risk Health Care Providers (HCP): It is mandatory to enumerate the HCP who are at risk and need to provide Hepatitis B vaccine. These minimum data elements should be available in the registers maintained for this purpose by the hospital.

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Frequency of Reporting: Once in a Year (on 1st of January of every year)

Name of Health care provider	Designation	Working station (Ward/Casualty/ICU/OT/Inj. Room/OPD/CSSD/etc)	Date of Hepatitis B vaccine given	Vaccine Batch No./manufacturer	Signature of Suptd. of Hospital

Standard INF 11

Std UID	Standard Definition	Expected Value	Scoring
INF11	Rational use of Antibiotics	Hospital to formulate and implement policy	0.5

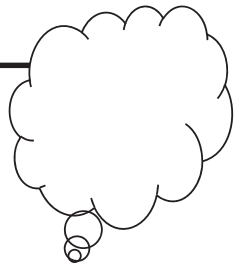
Evidence:

1. **Records**

INF: Weightage & Scoring

INF	Score
1	**1**
2	**1**
3	**2**
4	**2**
5	**2**
6	**1**
7	**0.5**
8	**1**
9	**0.5**
10	**0.5**
11	**0.5**
Total	**12**

Weightage: 12



Q and A

Exercise

- List the applicable requirements for waste management as per the Bio-Medical Waste management rules 1998.

Exercise

- Identify 5 policies that should be part of the Infection Control manual.

NOTES

RGJAY Quality Standards for Empanelment

RGJAY Quality Standards for Empanelment

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RGJAY Standards

	Section	Std.
1	Human Resource Quality **(HR)**	10
2	Facilities Management **(FAC)**	15
3	Infection Control Measures **(INF)**	11
4	Quality of Patient Care**(QPC)**	18
5	Monitoring Medication **(MED)**	06

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RGJAY Standards (contd)

	Section	Std.
6	Maintenance of patient Medical Records **(EMR)**	05
7	Patient Satisfaction Indices**(PSI)**	07
8	Standard Operating Protocols **(SOP)**	09
9	Transparency in Pricing **(TIP)**	04
	Total 9 Sections & 85 Standards	**85**

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SECTION 4.

Quality of Patient Care(QPC)

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Intent: QPC

- Encourage an environment of continuous quality improvement, by monitoring key indicators of patient care

There are 18 standards in QPC

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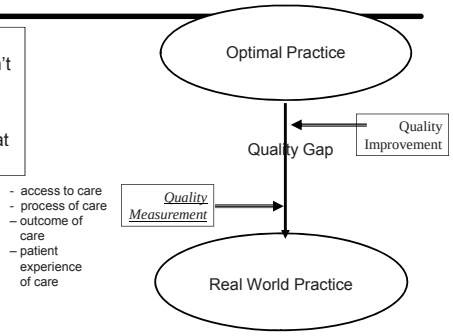
The ultimate goal is to manage quality, but you cannot manage it until you have a way to measure it, and you cannot measure it until you can monitor it.

Florence Nightingale

Why Measure?

What we don't measure, we don't know…….

……And we can only improve what we know



Significance

- Monitoring health care quality is impossible without the use of **clinical indicator**s.
- To make comparisons (benchmarking) over time between places (e.g. hospitals).
- To support accountability, regulation, and accreditation.
- They are used to assess, compare and determine the potential to improve care.

Indicator characteristics

- **Validity** is the degree to which the **indicator** measures what it is intended to measure, i.e. the result of a measurement corresponds to the true state of the phenomenon being measured.

- **Reliability** is the extent to which repeated measurements of a stable phenomenon by different data collectors, judges, or instruments, at different times and places, get similar results. A valid **indicator** must be reproducible and consistent.

Types

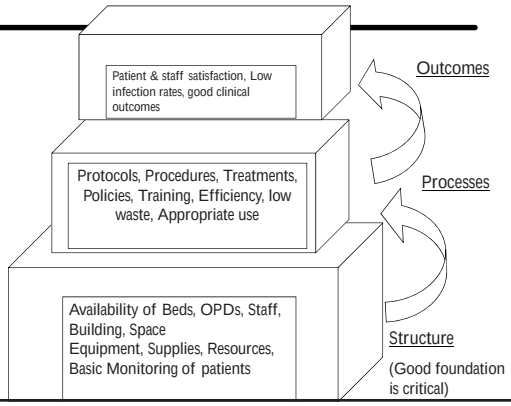
Rate Based

provide a quantitative basis for quality improvement

Incident Based

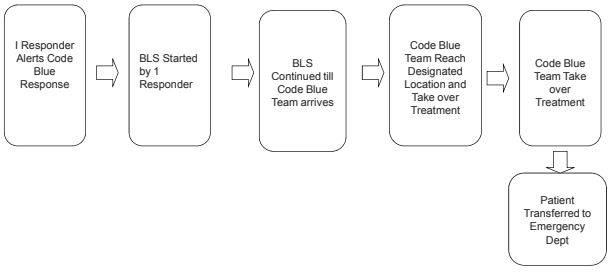
Identify incidents of care that trigger further investigation

(represent poor performance and they are generally used for risk management)



Sample Process for Code Blue

Patient suddenly collapses in Corridor



Measures

Structure	Process	Outcome
• Availability of medicines/crash carts • % staff trained in CPR	• Response time to Code blue	• Mortality

A new indicator now in use

- Appropriateness of Care
  - Antibiotic use
  - Overuse of Investigations
  - Overstay in hospitals
  - Underuse of Specialists
  - Number of appendicectomies done vs number showing positive histopathology

Risk adjustment

- Risk adjustment may be most important for outcome **indicator**s.
- In most cases, multiple factors contribute to a patient's survival and health outcomes.

Factors determining Outcome of Care

- The patient:
  - Demographics: Age, Sex, Height
  - Lifestyle: Smoking, dietary habits, alcohol, physical activity, weight
  - Psychosocial Factors: Social Status, Living conditions, Education
  - Compliance

- The Illness
  - Severity
  - Prognosis
  - Co morbidity

Factors determining Outcome of Care

- The Treatment (prevention, diagnostics, care, rehab, therapy):
  - Technical equipment
  - Evidence based Clinical practice

- The Organization
  - Quality Management and review
  - Use of Clinical Guidelines
  - Safe Practices
  - Efficiency

Process vs Outcome

- Comparisons of process data are easier to interpret and more sensitive to small differences than comparisons of outcomes data.
  - A process indicator can measure whether or not a stroke patient receives the right medication,
  - whereas 30-day mortality rates from stroke patients may be difficult to interpret.

Process vs Outcome

- Process indicators are especially useful when:
  - quality improvement is the goal of the measurement process;
  - an explanation is sought for why specific providers achieve particular outcomes;
  - short time frames are necessary;
  - performance of low volume providers is of interest;
  - and when tools to adjust or stratify for patient factors are lacking.

- Outcomes data are useful if:
  - Outcomes can be measured that are affected by health care
  - Long time-frames are possible
  - Performance of whole systems should be studied
  - Or if a high volume of cases is available.
  - Risk adjustment scoring models are to be used

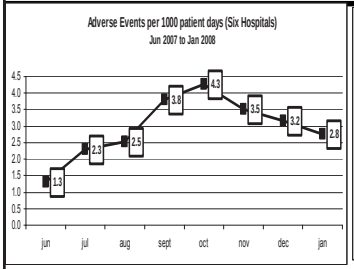
- Regardless of whether structural, process or outcome indicators are chosen, feasibility of measurement is always a key consideration.

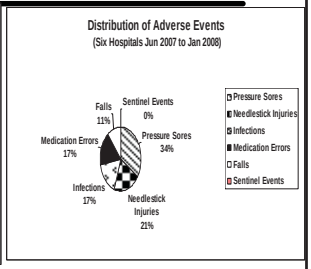
Measurement Levels

- Hospital
- Department specific
- Individual specific

Hospital Level

- Volume Indicators
  - Volume of procedures
  - Bed Occupancy
  - ALOS
- Gross Mortality
- Patient Satisfaction
- Infection surveillance
- Safety
  - Medication Errors
  - Sentinel events
  - Bed Sores
  - Patient Falls
  - Needlestick Injuries
  - Other Adverse Events

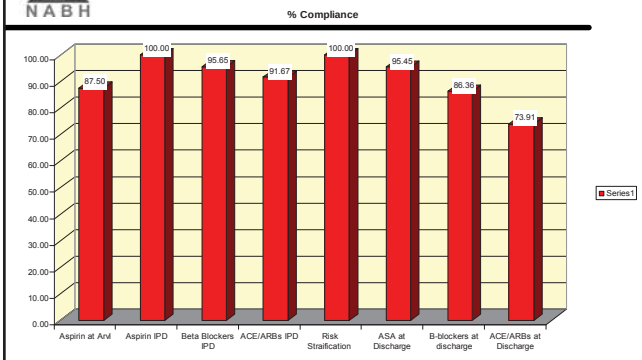




Department Specific- e.g. Cardiology

- Volume Indicators
  - Procedure specific: CABG, PTCA
  - Procedure specific ALOS
- Procedure specific Mortality
- Disease specific care indicators: e.g. Chest pain protocol
- ICU infection rates

Acute MI



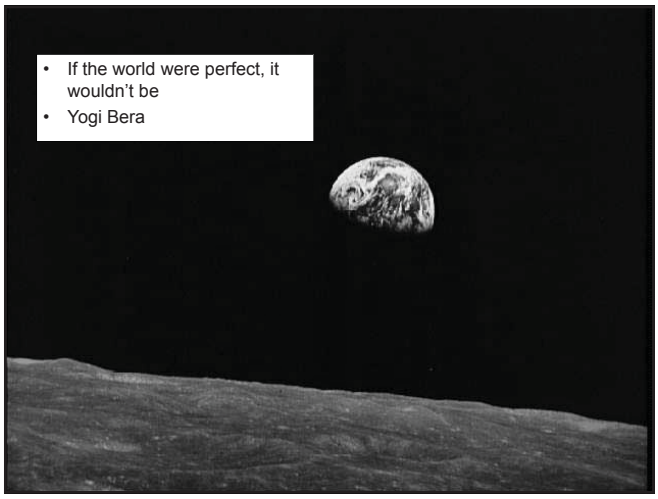
Indicators

Pharmacy

- Delivery to external customers
- % of Times Substitutes delivered
- Time to deliver to Depts
- Errors in delivery to Depts (wrong medicines)
- Waiting time at pharmacy counter

Critical success factors

- Transparency
- Mutual trust within clinicians and staff
- Unbiased
- Indicator should be: Reliable and valid
- Culture of continuous improvement
- Openness to change
- No Blame games
- Must show improvement over time
- Review indicators and targets for current relevance



To be filled within 12 hours of Incident & submitted to Nursing Supervisor/TL within 24 hours

List of Incidents to be reported (Please tick the desired option)

- ☐ Patient Fall
- ☐ Medication Errors
- ☐ Pressure Sores
- ☐ Hypoglycemia (Less than 70mg/dl)
- ☐ Nosocomial Infection
- ☐ Infection Out break
- ☐ Needle Stick Injury
- ☐ Readmission within 14 days
- ☐ Return to OT within 7 days
- ☐ Return to ICU within 7 days
- ☐ Return to Emergency within 7 days
- ☐ Mortality
- ☐ Adverse Drug Reactions
- ☐ Sentinel Events
- ☐ Blood Transfusion related errors

Other Adverse Events

- ☐ Patient Identification Error
- ☐ Acute Limb ischemia
- ☐ Discrepancy in Sponge/gauge count
- ☐ Cautery Burns
- ☐ Needle left inside Porta Cath
- ☐ Others

.....

Near Miss

- ☐ Patient Fall
- ☐ Medication Error

Incident Details

☐ Inpatient ☐ Out -patient ☐ Relative

Patient's Admission Diagnosis:

Admitting Consultant/Consultant in charge:

Name of witness / first person to attend:

Ward/Dept: Exact Location:

Date & Time of the Incident:

Describe what happened and the kind of incident

Impact on the Patient (e.g description of any injury/harm sustained to patient)
Mention category : minor, major or near miss

Intent: QPC

- Encourage an environment of continuous quality improvement, by monitoring key indicators of patient care

There are 18 standards in QPC

Standard QPC 1

Std UID	Standard Definition	Expected Value	Scoring
QPC 1	Reporting of Adverse Events	1. Total medication errors x 100 / Total no of in patient days	1
		2. No of Blood Transfusion reactions x 100 / No of Blood Units issued	1
		3. Total Drug reactions x 100/ Total No of in patient days	1
		4. Total Wrong patient surgery or wrong side surgery(Absolute number)	1

QPC 1.1: % of medication errors:

1.Operational definition: Medication errors in prescribing, transcribing, dispensing and administering medication

2.Formula: Total medication errors in prescribing, transcribing, dispensing and administering the medication per month x 100/ Total number of Total in-patient days per month

3.Numerator: Total medication errors in prescribing, transcribing, dispensing and administering the medication per month

4.Denominator: Total in-patient days per month

5.Frequency of monitoring: Monthly

6.Workstations: Wards, ICU

7.Reference:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000570.jsp

1.Significance:
2.Service provider factors:
3.Prescribing errors include:
- •Not prescribing appropriate drugs according to STP (standard treatment protocol). For example Malaria, Tb, Leprosy, Dengue, Leptospirosis and other Vector borne and water borne diseases
- •Improper dose and route

4.Transcription errors include:
- •Writing verbal orders in an incorrect/ illegible manner by person transcribing the orders

5.Dispensing errors (IPD) include:
- •Dispensing insufficient quantity of medicines than prescribed
- •Not explaining patient regarding dosage and duration

6.Administering errors:
- •Not confirming consumption of medicines by patients
- •Not following route and frequency of administration of medicine

1.Patient factors
- Quality of care
- Morbidity
- Mortality
- Cost of treatment

2.Institutional factors
- •Availability and adherence to standard prescribing, transcribing, dispensing and administering protocols

3.Monitoring mechanism:
- Records to be kept as per format indicated in **Table 6.**

	Workstations (Wards, ICU)					
Month & Year	**General Surgery, Gynaecology, Orthopedic, Super Speciality, ICU**	**Name of patient**	**Patient UID**	**Error detected Prescribing / Transcribing / Dispensing / Administering**	**Description of error**	**Action taken**
1	2	3	4	5	6	7

QPC 1.2: % of blood transfusion reactions:

1.Operational Definition: Blood transfusion reactions present as adverse signs or symptoms during or within 24 hours of a blood transfusion.
2.Formula: Number of blood transfusion reactions per month x 100/ Total number of blood transfusion units per month
3.Numerator: Number of blood transfusion reactions per month
4.Denominator: Total number of transfusion units per month
5.Frequency of monitoring: Monthly
6.Workstations: Wards, casualty, OT, ICU, day care units
7.Reference:
http://emedicine.medscape.com/article/206885-overview

1.Significance:
Transfusion reactions such as hemolytic reaction, febrile reactions, allergic reactions, post transfusion purpura, transfusion associated lung injury, infection should be treated after discontinuing the blood. Blood transfusion should be in presence of a doctor and any reaction should be attended by a doctor and reported to concerned blood bank as per FDA guidelines.
All transfusion reactions should be thoroughly audited and measures should be taken to avoid recurrence.
2. Monitoring mechanism:
•Records to be kept as per format indicated in Table 7.
•FDA format to be included

Table 7: QPC 1.2 Monitoring format

	Workstation						
Month & Year	**Wards, casualty, OT, ICU, day care units**	**Patient name**	**Patient UID**	**Date and time of blood transfusion**	**Date and time of onset of reaction**	**Type of reaction, if applicable**	**Signature of MO in-charge**
1	2	3	4	5	6	7	8

QPC 1.3: % of drug reactions:
1.Definition: Adverse reactions to drugs/ medicines administered
2. Types of reactions:
• Ingestion: Anaphylactic, allergic skin reaction etc.
• Parentral administration: anaphylactic, allergic skin reaction etc.
Adverse reactions should be reported in this indicator. Known side effects of drugs such as nausea, vomiting, diarrhea, should not be considered as drug reactions.
3. Formula: Total drug reactions per month x 100/ Total in-patient days per month
4. Numerator: Total drug reactions per month
5. Denominator: Total in-patient days per month
6. Frequency of monitoring: Monthly
7. Workstations: Wards, ICU, OT, Casualty
8. Reference:

http://www.bmj.com/content/316/7143/1511

Significance:

1.Service provider factors:

- Undertake sensitivity testing (benzathine penicillin, procaine penicillin, ASV, xylocaine)

2. Institutional factors

- Appropriate storage
- Precautions to avoid contamination
- Sub-standard quality
- Availability of facility to treat drug reaction

3. Monitoring mechanism:

Records to be kept as per format indicated in **Table 8**.

Table 8: QPC 1.3 Monitoring format

	Workstations					
Month & Year	**Wards, ICU, OT, Casualty**	**Name of patient**	**Patient UID**	**Type of drugreaction**	**Corrective Action taken**	**Signature of In-charge Sister**
1	2	3	4	5	6	7

QPC 1.4: % of wrong side/ wrong patient surgery:

1.Definition: Surgery performed on wrong patient, wrong side

2.Reporting: In absolute number(Reporting of sentinel event)

3. Workstations: OT and Wards

Frequency of monitoring: Monthly

Reference:

http://www.ncbi.nlm.nih.gov/books/NBK2678/

1.Significance:

2.Service provider factors:

- Adherence to checklist by operating surgeon, OT In-charge, Anesthesiologist, Ward in-charge sister

3.Patient factors

- Financial

4.Institutional factors

- Legal implications +
- Financial
- Availability and adherence to surgical SOPs

5. Monitoring mechanism:

- Records to be kept as per format indicated in **Table 9**.

Table 9: QPC 4 Monitoring format

	Workstations					
Month & Year	OT, Wards	Name of patient	Patient UID	Type of surgery indicated	Surgery actually performed	Name of patient undergone surgery
1	2	3	4	5	6	7

Standard QPC 2

Std UID	Standard Definition	Expected Value	Scoring
QPC 2	Regular Discussion of Adverse Events with corrective measures	Record of Monthly Meetings in meeting register.	1

Adverse Event

An injury related to medical management, in contrast to complications of disease (4). Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable.

Ref: WHO Draft Guidelines for Adverse Event Reporting and Learning Systems

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Sentinel Event

A relatively infrequent, unexpected incident, related to system or process deficiencies, which leads to death or **major and enduring loss of function** for a recipient of healthcare services.

Major and enduring loss of function *refers to sensory, motor, physiological, or psychological impairment not present at the time services were sought or begun. The impairment lasts for a minimum period of two weeks and is not related to an underlying condition*

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76-year-old woman

1. In hospital recovering well from a chest infection
2. Assessed as a risk for falls, should mobilise only with staff assistance
3. Rang buzzer - no response
4. Got out of bed, slipped on a wet floor, fractured hip
5. Needed surgery and longer hospital stay

These events are:

- traumatic
- often tragic
- distressing
- costly for the health care system

Onus is on all of us to learn from them

Sentinel Events

1. Surgical events

- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- Wrong surgical procedure performed on the wrong patient
- Retained instruments in patient discovered after surgery/procedure
- Patient death during or immediately post-surgical procedure
- Anesthesia-related event

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Sentinel Events

2. Device or product events

Patient death or serious disability associated with:

- the use of contaminated drugs, devices, products supplied by the organization
- the use or function of a device in a manner other than the device's intended use
- the failure or breakdown of a device or medical equipment
- intravascular air embolism

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3. Patient protection events

- Discharge of an infant to the wrong person.
- Patient death or serious disability associated with elopement from the healthcare facility.
- Patient suicide, attempted suicide, or deliberate self-harm resulting in serious disability.
- Intentional injury to a patient by a staff member, another patient, visitor, or other.
- Any incident in which a line designated for oxygen or other came to be delivered to a patient and contains the wrong gas or is contaminated by toxic substances.
- Nosocomial infection or disease causing patient death or serious disability.

4. Environmental events

Patient death or serious disability while being cared for in a healthcare facility associated with:

- a burn incurred from any source
- a slip, trip, or fall
- an electric shock
- the use of restraints or bedrails

5. Care management events

- Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products
- Maternal death or serious disability associated with labour or delivery in a low-risk pregnancy
- Medication error leading to the death or serious disability of patient due to incorrect administration of drugs, for example:
  - omission error
  - dosage error
  - dose-preparation error
  - wrong-time error
  - wrong rate of administration error
  - wrong administrative technique error
  - wrong-patient error
- Patient death or serious disability associated with an avoidable delay in treatment or response to abnormal test results

6. Criminal events:

- Any instance of care ordered by or provided by an individual impersonating a clinical member of staff
- Abduction of a patient
- Sexual assault on a patient within or on the grounds of the healthcare facility
- Death or significant injury of a patient or staff member resulting from a physical assault or other crime that occurs within or on the grounds of the healthcare facility.

QPC 2: Meetings to address adverse events:

Norm: As best practices, it is necessary to address the adverse events taking place in the hospital promptly and discuss the issues for identifying the problems and planning to administer the remedies and preventive measures. The meeting for this purpose should be regularly held every month and if required immediately.

Maintenance of record: The proceedings and minutes of decisions of such meeting should be recorded in register duly approved and signed by person authorized.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

Standard QPC 3

Std UID	Standard Definition	Expected Value	Scoring
QPC 3	Use of Surgical Safety Check lists	Whether displayed and followed in all Operation Theatres, ICU, SNCU, Casualty and wards	1

Evidence:

1. **Records**
2. **Physical Site Checks**

Surgical Safety Checklist

World Health Organization | Patient Safety

Before induction of anaesthesia (with at least nurse and anaesthetist)

- Has the patient confirmed his/her identity, site, procedure, and consent?
  - ☐ Yes
- Is the site marked?
  - ☐ Yes
  - ☐ Not applicable
- Is the anaesthesia machine and medication check complete?
  - ☐ Yes
- Is the pulse oximeter on the patient and functioning?
  - ☐ Yes
- Does the patient have a:
- Known allergy?
  - ☐ No
  - ☐ Yes
- Difficult airway or aspiration risk?
  - ☐ No
  - ☐ Yes, and equipment/assistance available
- Risk of >500ml blood loss (7ml/kg in children)?
  - ☐ No
  - ☐ Yes, and two IV/central access and fluids planned

Before skin incision (with nurse, anaesthetist and surgeon)

- ☐ Confirm all team members have introduced themselves by name and role.
- ☐ Confirm the patient's name, procedure, and where the incision will be made.
- Has antibiotic prophylaxis been given within the last 60 minutes?
  - ☐ Yes
  - ☐ Not applicable
- Anticipated Critical Events
- To Surgeon:
  - ☐ What are the critical or non-routine steps?
  - ☐ How long will the case take?
  - ☐ What is the anticipated blood loss?
- To Anaesthetist:
  - ☐ Are there any patient-specific concerns?
- To Nursing Team:
  - ☐ Has sterility (including indicator results) been confirmed?
  - ☐ Are there equipment issues or any concerns?
- Is essential imaging displayed?
  - ☐ Yes
  - ☐ Not applicable

Before patient leaves operating room (with nurse, anaesthetist and surgeon)

- Nurse Verbally Confirms:
  - ☐ The name of the procedure
  - ☐ Completion of instrument, sponge and needle counts
  - ☐ Specimen labelling (read specimen labels aloud, including patient name)
  - ☐ Whether there are any equipment problems to be addressed
- To Surgeon, Anaesthetist and Nurse:
  - ☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged. Revised 1 / 2009 © WHO, 2009

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QPC 3: Surgical check list:

Norm: In Hospital, standard surgical check lists should be available with all levels of personnel like surgeon, OT assistants, health care personnel related with pre operative preparation and post operative care. The strict adherence to such check lists reduces postoperative complications as well as deaths.
Work stations: OT, ICU, SNCU, Casualty and Wards.
Maintenance of record: The work stations where these surgical check lists made available should be recorded.
Frequency of Reporting: Once in a Year (on 1st of January of every year).

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Standard QPC 4

Std UID	Standard Definition	Expected Value	Scoring
QPC 4	Postoperative complications	Record of documentation and corrective actions should be available. No of cases in each complication grade for each category of complication needed.	1

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QPC 4.1: % of post operative complications due to surgery

Definition: All major operations developing complications after surgery of any specialties

Complications include:

Immediate:

1.Primary haemorrhage: either starting during surgery or following postoperative increase in blood pressure - replace blood loss and may require return to theatre to re-explore the wound.
2.Basal atelectasis: minor lung collapse.
3.Shock: blood loss, acute myocardial infarction, pulmonary embolism or septicemia.
4.Low urine output: inadequate fluid replacement intra-operatively and postoperatively.

- **Early:**
- Acute confusion: exclude dehydration and sepsis.
- Nausea and vomiting: analgesia or anaesthesia-related; paralytic ileus.
- Fever- 'Postoperative fever more than 38 deg c after 48 hours.
- Secondary haemorrhage: often as a result of infection.
- Pneumonia.
- Wound or anastomosis dehiscence.
- DVT.
- Acute urinary retention.
- Urinary tract infection (UTI).
- Postoperative wound infection.
- Bowel obstruction due to fibrinous adhesions.
- Paralytic Ileus
- Post spinal headache and meningitis

1.Formula: Number of emergency and planned major surgeries developing post operative complications due to surgery per month x 100 / Total number of emergency and planned major surgeries per month
2.Numerator: Number of emergency and planned major surgeries developing post operative complications due to surgery per month
3.Denominator: Total number of emergency and planned major surgeries per month
4.Frequency of monitoring: Monthly
5.Workstations: All OTs, Wards and ICU
6.Reference: http://www.patient.co.uk/doctor/common-postoperative-complications
http://www.webmd.com/healthy-aging/features/common-surgery-complications

1.Significance:

- **Service provider factors**
  - Adherence to SOPs
- **Patient factors**
  - Co-morbidity
- **Institutional factors**
  - Availability of HR
  - Availability of logistics
  - Availability of SOPs
- **Monitoring mechanism:**
  - Records to be kept as per format indicated in **Table 10.1**.

Table 10.1: QPC 4 Monitoring forma
Format for postoperative surgical complication

Sr No	Name of patient	Age	Diagnosis	Surgery description	Description of surgical complication	Outcome of complication – Tick which is applicable				
						No treatment	Medical treatment	Surgical Intervention	ICU admission	Death

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QPC 4.2: % of post operative complications due to anesthesia

Definition: All major operations developing complications after surgery of any specialties due to anaesthesia. These include:

- Pain
- Nausea and vomiting
- Damage to teeth
- Sore throat and laryngeal damage
- Anaphylaxis to anaesthetic agents - figures such as 0.2% have been quoted
- Cardiovascular collapse
- Respiratory depression

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- Aspiration pneumonitis - up to 4.5% frequency has been reported; higher in children
- Hypothermia
- Hypoxic brain damage
- Nerve injury
- Awareness during anaesthesia
- Embolism - air, thrombus, venous or arterial
- Backache
- Headache
- Idiosyncratic reactions related to specific agents, eg. malignant hyperpyrexia with suxamethonium, succinylcholine-related apnoea
- Iatrogenic, eg pneumothorax related to central line insertion

Death

Numerator: Number of emergency and planned major surgeries developing post operative complications due to anesthesia per month

Denominator: Total number of emergency and planned major surgeries per month

Frequency of monitoring: Monthly

Workstations: All OTs, Wards and ICU

Reference:

http://www.patient.co.uk/doctor/important-complications-of-anaesthesia

Significance:

1.Service provider factors

Adherence to SOPs

2.Patient factors

Co-morbidity, Smoking, obstructive sleep apnea, Obesity, High blood pressure, Diabetes, Other medical conditions involving your heart, lungs or kidneys, Medications, such as aspirin, that can increase bleeding, History of heavy alcohol use, Drug allergies,

History of adverse reactions to anesthesia

3.Institutional factors

Availability of HR, Availability

Table 10.2: QPC 4 Monitoring format
Format for postoperative Anesthetic complication

Sr No	Name of patient	Age	Diagnosis	Surgery description	Description of Anesthetic complication	Outcome of complication – Tick which is applicable				
						No treatment	Medical treatment	Surgical Intervention	ICU admission	Death

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Standard QPC 5

Std UID	Standard Definition	Expected Value	Scoring
QPC 5	Average Length of stay	Total In patient Days * 100/Total IPD patients	QPC 5

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QPC-5: Average length of stay (ALS):

Definition: Average length of stay is defined as an average number of days patient is hospitalized for the medical care. The period is measured from the day of hospitalization till the day of discharge. It is one of the indictor suggestive of quality of care of the hospital and influenced by several factors like availability of specialists, standard procedures, adherence to SOPs, quality of nursing care etc**.**

Formula: Total in-patient days in a month/Total IPD patients discharged in a month.

Numerator: Total in-patient days in a month

Denominator: Total IPD patients discharged in a month.

Work Station: All Wards, Emergency Wards and ICU

Register to Capture data:

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Register to Capture data:
Frequency of Reporting: Once in a Year
(on 1st of January of every year).

Date/ Month/ Year	Work station (Ward/ICU/Emergency Ward)	Total inpatient days (No. of pts discharged x length of stay)	Total patients discharged	ALS for the day	Signature of in-charge sister

Standard QPC 6

Std UID	Standard Definition	Expected Value	Scoring
QPC 6	ICU care	APACHE (Acute Physiology and Chronic Health Evaluation) admission score of patients in ICU: number of patients with APACHE II scores between 20 and 24 (inclusive) as a proportion of the total ICU admissions and their mortality rate.	1

- If it exceeds 40%, the hospital should get a '0' score and if it is less than 40%, the hospital should get a '1'.

QPC 6: % of patients with APACHE II (Acute Physiology and Chronic Health Evaluation) score between 20 and 24 succumbing to death:

Operational definition: Patients admitted in ICU with an APACHE II score between 20 and 24 succumb to death. The score is calculated from 12 routine physiological measurements:

- Age
- Temperature (rectal)
- Mean arterial pressure
- pH arterial
- Heart rate
- Respiratory rate
- Sodium (serum)
- Potassium (serum)
- Creatinine
- Hematocrit
- White blood cell count
- Glasgow Coma Scale

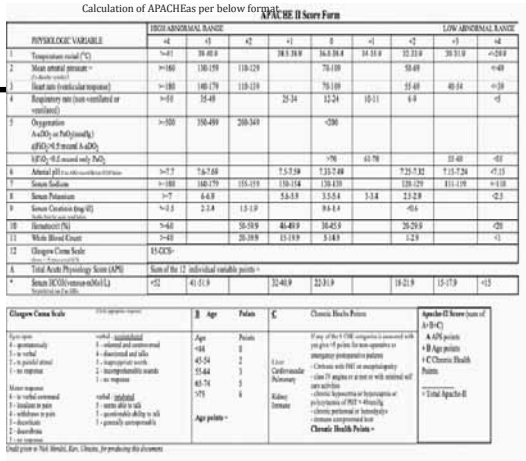
Formula: Number of ICU patients with APACHE II score between 20 and 24 per month x 100/ Total number of ICU patients per month
Numerator: Number of ICU patients with APACHE II score between 20 and 24 per month
Denominator: Total number of ICU patients per month
Frequency of monitoring: Monthly
Workstations: All ICUs
Reference:
http://www.tzuchi.com.tw/file/DivIntro/ER/APACHE%20II%20Score%20Form.htm

Calculation of APACHEas per below format

Significance:

1.Service provider factors
1.Adherence to SOPs
2.Patient factors
1.Co-morbidity
3.Institutional factors
1.Availability of HR
2.Availability of equipment
3.Availability of SOPs

Calculation of APACHEas per below format


APACHE II Score Form

PHYSIOLOGIC VARIABLE	HIGH ABNORMAL RANGE				LOW ABNORMAL RANGE				
	+4	+3	+2	+1	0	+1	+2	+3	+4
1 Temperature rectal (°C)	>=41	39-40.9		38.5-38.9	36.9-38.4	34-35.9	32-33.9	30-31.9	<=29.9
2 Mean arterial pressure =	>=160	130-159	110-129		70-109		50-69		<=49
3 Heart rate (ventricular response)	>=180	140-179	110-139		70-109		55-69	40-54	<=39
4 Respiratory rate (non-ventilated or ventilated)	>=50	35-49		25-34	12-24	10-11	6-9		<=5
5 Oxygenation A-aDO2 or PaO2 (mmHg) if FiO2 >0.5 record only A-aDO2 if FiO2 <0.5 record only PaO2	>=500	350-499	200-349		<200				
					>70	61-70		55-60	<55
6 Arterial pH (no abnormal Rx)	>=7.7	7.6-7.68			7.5-7.59	7.33-7.49		7.25-7.32	7.15-7.24	<7.15
7 Serum Sodium	>=180	160-179	155-159		150-154	130-149		120-129	111-119	<=110
8 Serum Potassium	>=7	6-6.9			5.5-5.9	3.5-5.4	3-3.4	2.5-2.9		<2.5
9 Serum Creatinine (mg/dl) (double for acute renal failure)	>=3.5	2-3.4	1.5-1.9			0.6-1.4		<0.6		
10 Hematocrit (%)	>=60		50-59.9	46-49.9		30-45.9		20-29.9		<20
11 White Blood Count	>=40		20-39.9	15-19.9		3-14.9		1-2.9		<1
12 Glasgow Coma Scale: Score = (15-actual GCS)	15 GCS=									
A Total Acute Physiology Score (APS)	Sum of the 12 individual variable points =									
* Serum HCO3 (venous mM/L) Not if Arterial Blood Gas (ABG)	<15		41-51.9		32-40.9	22-31.9		18-21.9	15-17.9	<15

Glasgow Coma Scale (Add appropriate response)		B Age	Points	C Chronic Health Points
Eye open	verbal - assessment	Age	Points	If any of the 6 CHC categories is assessed with one point. If a non-operative or emergency postoperative patient
4 - spontaneously	5 - oriented and communicated	<=44	0	
3 - to verbal	4 - disoriented and talks	45-54	2	Liver
2 - to painful stimuli	3 - inappropriate words	55-64	3	Cardiovascular
1 - no response	2 - incomprehensible sounds	65-74	5	Pulmonary
	1 - no response	>75	6	- Cirrhosis with PHT or encephalopathy
Motor response				- class IV angina at rest or with minimal self care activities
6 - to verbal command	verbal - inhibited	Age points =		- chronic hypoxemia or hypercapnia or polycythemia of PHT or dyspnea
5 - localizes to pain	3 - words alter to talk			- chronic peritoneal or hemodialysis
4 - withdraws to pain	2 - unintelligible sounds			- immune compromised host
3 - decorticate	1 - generally unresponsive			Chronic Health Points =
2 - decerebrate				
1 - no response				

Apache-II Score (sum of A+B+C)
A APS points
+ B Age points
+ C Chronic Health Points
= Total Apache-II

Credit given to Prof. Wendel, Kerr, Ulmann, for producing this document

	Workstations					
Month & Year	All ICUs (Medical, Surgical, Super Speciality)	Name of patient	Patient UID	APACHE II Score on admission	Date of death	Signature of Sister In-charge
1	2	3	4	5	6	7

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Standard QPC 7

Std UID	Standard Definition	Expected Value	Scoring
QPC 7	Gen Surgery	Number of patients requiring repeat surgery within 30 days *100/ No of major planned and emergency surgeries for a month	1

Evidence:

1. **Records with MS**

National Accreditation Board for Hospitals and Health Care Providers

QPC 7 : % of Patients requiring repeat surgery within 30 days:

Operational definition: Patients requiring repeat surgery for same purpose or for complications arising from initial surgery**.** In general repeat surgery is required for:

- ✓Foreign body left behind in cavities
- ✓Post operative infection causing gaping
- ✓Leakages in anastomosis
- ✓Burst abdomen
- ✓Post operative perforation and gangrene of viscera
- ✓In trauma cases improper debridement and suturing may harbor the infection leading to repeat surgery

Formula: Number of patients who underwent repeat surgery within 30 days of planned surgery per month x 100/ Total number of major planned surgeries per month

Numerator: Number of patients who underwent repeat surgery within 30 days of planned surgery per month

Denominator: Total number of major planned surgeries per month

Frequency: Monthly

Workstations: All Ots
Significance:
Service provider factors: Adherence to SOPs, Proper surgical technique of operating surgeon, Acts of commission and omission
Patient factors: Financial implications, Co-morbidity, Pre-existing immune-compromised condition
Institutional factors: Availability of skilled HR, Availability of SOPs

	Workstation							
Month & Year	**All OTs**	**Name of patient**	**Patient UID**	**Date of initial surgery**	**Type of initial surgery performed**	**Indication of repeat surgery**	**Date of repeat surgery**	**OT In-charge sister**
1	2	3	4	5	6	7	8	9

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Standard QPC 8

Std UID	Standard Definition	Expected Value	Scoring
QPC 8	Gen Surgery	Number of Post-operative Deaths *100/ Total no of major planned and emergency surgeries in 30 days	1

Evidence:

Register in Medical Records to have the data:

National Accreditation Board for Hospitals and Health Care Providers

Standard QPC 9

Std UID	Standard Definition	Expected Value	Scoring
QPC 9	Pre Anesthesia Checkup conducted in surgeries	Number of PAC conducted in elective and emergency surgeries per month X100/ total number of elective and emergency surgeries per month	1

Evidence:

Anesthesia Record

National Accreditation Board for Hospitals and Health Care Providers

QPC 9: % of Pre Anesthesia Checkup conducted in surgeries:

Definition: Perform various pre anesthesia checks required before conducting surgery.
Formula: Number of PAC conducted in elective and emergency surgeries per month X 100/ Total number of elective and emergency surgeries per month
Numerator: Number of PAC conducted in elective and emergency surgeries per month
Denominator: Total number of elective and emergency surgeries per month
Frequency of monitoring: Monthly
Work stations: All wards, OT
Significance:
Service provider factors: Skill of service Provider, Adherence to SOPs
Institutional factors: Availability of SOPs

Monitoring Mechanisms: Records to be kept as per format indicated in Table

	Workstation						
Month & Year	All Ward, ICU, OT	Name of patient	Patient UID	Date of Pre Anaesthesia Checks done	Pre Anesthesia checks completely done – Yes/N0	Total elective and emergency surgery in corresponding month*	Signature of Ward In-charge sister
1	2	3	4	5	6	7	8
Jan-14							

Drop Down Option in software

Total operations data to be retrieved from All OT

Standard QPC 10

Std UID	Standard Definition	Expected Value	Scoring
QPC 10	Avg Door to Needle or door-to-balloon times in acute STEMI	Average time taken in minutes for patients with acute ST elevation myocardial infarction to receive fibrinolytic therapy after arrival in hospital, or primary PCI after arrival in hospital. Timings to be given in minutes.	1

Evidence:

Time of arrival to ER
Time of Needle
Total Time of all patients/ number of patients = average door to needle time

QPC-10: % of Door-to-balloon time less than 90 minutes for STEMI patients:

Definition: Door-to-balloon time is the time taken to perform balloon angioplasty on STEMI patient after his arrival at the hospital.
Formula: No. of STEMI patients who underwent balloon angioplasty within 90 minutes of arrival at the hospital per month x 100/ Total no. of STEMI patients per month.
Numerator: No. of STEMI patients who underwent balloon angioplasty within 90 minutes of arrival at the hospital per month
Denominator: Total no. of STEMI patients per month
Frequency of monitoring: Monthly
Workstations: CATH LAB

Significance
Service provider factors: Skill in angiography and angioplasty
Patient factors: Awareness about the condition of MI (age, underlying risk factors, etc.)
Institutional factors: Availability of interventional cardiologist, IEC of NCD specially MI, Availability of CATHLAB, Availability of Stents, Efficiency of the hospital in investigation & management of STEMI patients thereby reducing morbidity and mortality

Table 16: QPC 12 Monitoring format

	Work station							
Month & Year	CATHLAB	**Name of patient**	**Patient UID**	**Date and Time of arrival in hospital**	**Time of undertaking Angiography**	**Time of performing balloon angioplasty**	**Door-to-Balloon Time**	**Signature of CATHLAB In-charge sister**

Standard QPC 11

Std UID	Standard Definition	Expected Value	Scoring
QPC 11	Use of dual antiplatelet therapy and statins in acute coronary syndromes	Total No of patients discharged with a diagnosis of acute coronary syndrome (including ST elevation MI) receiving both dual antiplatelet therapy (i.e., aspirin and clopidogrel/prasugrel/ticagrelol) AND statin at discharge * 100/ Total MI patients discharged	1

Evidence:

Medical Records to Collate from Discharge summary

QPC-11: % of Patients of acute coronary syndrome given dual anti-platelet therapy and stains:

Definition: Patients of acute coronary syndrome given dual anti-platelet therapy and stains at the time of discharge

Formula: Number of Patients of acute coronary syndrome given dual anti-platelet therapy and stains at the time of discharge per month x 100/ Patients of acute coronary syndrome discharged per month

Numerator: Number of Patients of acute coronary syndrome given dual anti- platelet therapy and stains at the time of discharge per month

Denominator: Total number Patients of acute coronary syndrome discharged per month

Frequency: Monthly

Workstations: Ward / ICU

Reference:

http://www.sign.ac.uk/guidelines/fulltext/93/section7.html
http://emedicine.medscape.com/article/1910735-treatment

Significance

Service provider factors: Adherence to SOPs

Patient factors: Awareness about the condition of MI (age, underlying risk factors, etc.), Co-morbidity

Institutional factors: Availability of SOPs

	Workstation						
Month & Year	Wards, ICU	Name of patient	Patient UID	Diagnosis	Dual antiplatelet therapy given on discharge	Statins given on discharge	Signature of ICU / Ward In-charge sister
1	2	3	4	5	6	7	8

Standard QPC 12

Std UID	Standard Definition	Expected Value	Scoring
QPC 12	In-hospital mortality for CABG surgery	Percentage of patients undergoing CABG surgery who died before discharge	1

Evidence:

Medical Records to Collate from Discharge/death summary

National Accreditation Board for Hospitals and Health Care Providers

QPC -12: % of CABG surgery deaths before discharge:

Definition: Patients who underwent coronary artery bypass graft surgery and died before discharge

Formula: Number of Patients who underwent coronary artery bypass graft surgery and died before discharge per month x 100/ Total number of patients who underwent CABG per month

Numerator: Number of Patients who underwent coronary artery bypass graft surgery and died before discharge per month

Denominator: Total number of patients who underwent CABG per month

Frequency of monitoring: Monthly

Workstations: Cardiac Ward and Cardiac ICU

Reference:

http://www.medicinenet.com/coronary_artery_bypass_graft/article.htm#1whatis

National Accreditation Board for Hospitals and Health Care Providers

Significance

Service provider factors: Adherence to SOPs

Patient factors: Awareness CABG (age, underlying risk factors, etc.), Co-morbidity

Institutional factors: Availability of SOPs

	Workstations					
Month & Year	Cardiac ward, Cardiac ICU	Name of patient	Patient UID	Date of CABG surgery	Date of death	Signature of Sister In-charge
1	2	3	4	5	6	7

National Accreditation Board for Hospitals and Health Care Providers

Standard QPC 13

Std UID	Standard Definition	Expected Value	Scoring
QPC 13	Use of Left Internal Mammary artery grafts	Percentage of patients undergoing CABG surgery who received a left internal mammary artery graft	1

Evidence:

Medical Records to Collate from Discharge summary

National Accreditation Board for Hospitals and Health Care Providers

QPC-13: % of patients undergoing CABG surgery who received a left internal mammary artery graft:

Definition: Patients undergoing CABG surgery who received a left internal mammary artery graft

1.Formula: Number of CABG patients receiving a left internal mammary artery graft per month x 100/ Total number of CABG patients per month

2.Numerator: Number of CABG patients receiving a left internal mammary artery graft per month

3.Denominator: Total number of CABG patients per month

4.Frequency of monitoring: Monthly

5.Workstations: CVTS OT

6.Reference:

http://drsvenkatesan.wordpress.com/2008/11/06/why-is-lima-graft-superior-than-saphenous-venous-graft/

http://www.heartfixer.com/CHC%20-%20Treatments%20-%20CABG.htm

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1.Significance

2.Service provider factors:

1.Using left internal mammary artery as long term patency (less chances of thrombosis) of this artery thereby reducing chances of repeat CABG

3.Institutional factors

1.Availability of SOPs

	Workstation					
Month & Year	CVTS OT	Name of patient	Patient UID	Date of surgery	CABG with or without internal mammary artery	Signature of CVTS OT In-charge sister
1	2	3	4	5	6	7

National Accreditation Board for Hospitals and Health Care Providers

Standard QPC 14

Std UID	Standard Definition	Expected Value	Scoring
QPC 14	In-hospital mortality for valve surgery	Percentage of patients undergoing valve surgery who died before discharge	1

Evidence:

Medical Records to Collate from Discharge /death summary

National Accreditation Board for Hospitals and Health Care Providers

QPC 14: % of patients undergoing valve surgery who died before discharge

Definition: Patients undergoing valve surgery who dies before discharge
Numerator: Number of patients who have undergone valve surgery per month
Denominator: Total number of patients who have undergone valve surgery per month
Formula: Number of Patients undergoing valve surgery per month who died before discharge x 100/ Total number of patients who have undergone valve surgery per month
Frequency of monitoring: Monthly
Workstations: Cardiac ward and cardiac ICU
Reference:
http://www.annalscts.com/article/view/2885/html
http://www.annalscts.com/article/view/1397/2015

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Significance
Service provider factors: Adherence to SOPs
Patient factors: Co-morbidity
Institutional factors: Availability of SOPs

	Workstations					
Month & Year	Cardiac ward, Cardiac ICU	Name of patient	Patient UID	Date of valve surgery	Date of death	Signature of Sister In-charge
1	2	3	4	5	6	7

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Standard QPC 15

Std UID	Standard Definition	Expected Value	Scoring
QPC 15	Post Operative Sternotomy infection	Percentage of patients undergoing sternotomy (for CABG or valve surgery) who developed sternal wound infection	1

Evidence:

Incident Reports

National Accreditation Board for Hospitals and Health Care Providers

QPC-15: % of patients undergoing sternotomy (for CABG or valve surgery) who developed sternal wound infection:

Definition: Patients transferred out by treating hospital to other hospital

Formula: Number of patients undergoing sternotomy (for CABG or valve surgery) per month who developed sternal wound infection x 100/ Total number of patients undergoing sternotomy (for CABG or valve surgery) per month

Numerator: Number of patients undergoing sternotomy (for CABG or valve surgery) per month

Denominator: Total number of patients undergoing sternotomy (for CABG or valve surgery)

Frequency of monitoring: Monthly

Workstations: Cardiac ward and Cardiac ICU

National Accreditation Board for Hospitals and Health Care Providers

Significance

Service provider factors: Adherence to Infection Control SOPs, Adherence to Surgical SOPs

Patient factors: Co-morbidity

Institutional factors: Availability of Infection Control SOPs, Availability of Surgical SOPs

	Workstation						
Month & Year	Cardiac ward, Cardiac ICU	Name of patient	Patient UID	Date of surgery	Date of detection of infection	Nature of complications	Signature of Ward/ICU In-charge sister

National Accreditation Board for Hospitals and Health Care Providers

Standard QPC 16

Std UID	Standard Definition	Expected Value	Scoring
QPC 16	Post PCNL percentage calculi	No of post PCNL patients with residual Calculi *100/ No of operated PCNL patients	1

Evidence:

Incident Reports

National Accreditation Board for Hospitals and Health Care Providers

QPC 16: % of Patients undergoing PCNL requiring re-treatment for residual calculi:

Definition: Patients undergoing percutaneous nephrolithotomy who require re-treatment for residual calculi

Formula: Number of patients undergoing PCNL per month requiring re-treatment for residual calculi x 100/ Total number of Patients undergoing PCNL per month.

Numerator: Number of patients undergoing PCNL per month requiring re-treatment for residual calculi

Denominator: Total number of Patients undergoing PCNL per month

Frequency of monitoring: Monthly

Workstations: OT

National Accreditation Board for Hospitals and Health Care Providers

Significance

Service provider factors: Adherence to SOPs

Institutional factors: Availability of Infection Control SOPs, Adherence to Surgical SOPs

Table 22: QPC 18: Monitoring format

	Workstation					
Month & Year	OT	Name of patient	Patient UID	Date of initial PCNL	Date of repeat PCNL	Signature of OT In-charge sister
1	2	3	4	5	6	7

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Standard QPC 17

Std UID	Standard Definition	Expected Value	Scoring
QPC 17	Orthopedics	Number of patients with fracture nonunion or delayed union requiring repeat surgery *100/ No of surgeries for open reduction of fracture(>9 months for Non-union and >3 months for delayed union)	1

Evidence:

Incident Reports

National Accreditation Board for Hospitals and Health Care Providers

QPC - 17: % of patients with fracture nonunion (more than 9 months) or delayed union (more than 3 months) requiring repeat surgery who have undergone open reduction and internal fixation

Definition: Patients with fracture nonunion (more than 9 months) or delayed union (more than 3 months) requiring repeat surgery who have undergone open reduction and internal fixation

Formula: Number of patients with fracture nonunion or delayed union requiring repeat surgery who have undergone open reduction and internal fixation x 100/ Total No of surgeries for open reduction of fracture over corresponding period who have undergone open reduction and internal fixation

Numerator: Number of patients with fracture nonunion or delayed union requiring repeat surgery who have undergone open reduction and internal fixation

Denominator: Total No of surgeries for open reduction of fracture over corresponding period who have undergone open reduction and internal fixation

Frequency of monitoring: Monthly

Workstations: Orthopedic OT

Significance

Service provider factors: Skill of service provider, Adherence to SOPs

Patient factors: Adherence to prescribed post-operative care

Institutional factors: Availability of SOPs

	Workstation							
Month & Year	*Orthopedic OT*	Name of patient	Patient UID	Date of initial surgery	Date of repeat surgery	Total no. Cases in correspondi ng period*	Reasons: Non union/ Delayed union	Signature of ICU/ Ward In-charge sister
1	2	3	4	5	6	7	8	9

Reference:

http://annals.edu.sg/pdf_nov98/heeht.pdf

http://cal.vet.upenn.edu/projects/saortho/chapter_38/38mast.htm

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Standard QPC 18

Std UID	Standard Definition	Expected Value	Scoring
QPC 18	Gynae	Number of Post-operative Deaths in Gynae Surgery *100/ Total no of major planned and emergency Gynae surgeries(Obstetrics cases not included)	1

Evidence:

Medical Records to Collate from Discharge /death summary

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QPC 18: % of Post operative deaths in General surgery & Gynaec surgeries (Obstetrics cases not included):

Definition: Post operative deaths in planned major general surgery and elective and emergency Gynaec surgeries (Obstetrics cases not included)

Formula: Sum total of Number of Post operative deaths in planned major general surgery and elective as well as emergency Gynaec surgeries (Obstetrics cases not included) per month x 100/ Total number of planned major general surgery and elective as well as emergency Gynaec surgeries (Obstetrics cases not included) per month

Numerator: Number of Post operative deaths in planned major general surgery and elective as well as emergency Gynaec surgeries (Obstetrics cases not included) per month

Denominator: Total number of planned major general surgeries and elective as well as emergency Gynaec surgeries (Obstetrics cases not included) per month

Frequency of monitoring: Monthly

Workstations: Gynaecology ward, ICU, and Gynaecology OT,

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Reference:
http://laparoscopy.blogs.com/prevention_management_3/2010/07/complications-of-laparoscopic-gynecologic-surgery.html

Significance

Service provider factors: Skill of service provider, Adherence to SOPs

Patient factors: Co-morbidity, Immuno-compromised condition

Institutional factors: Availability of SOPs

	Workstation								
Month & Year	*Gynaecology, Gen Surgery Ward, ICU, OT*	Name of patient	Patient UID	Date of planned major general surgery	Date of elective and emergency gynaec surgery	Date of death	Total planned major general surgery in corresponding month*	Total elective and emergency gynaec surgery in corresponding month**	Signature of Ward In-charge sister
1	2	3	4		5	6		7	8

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Weightage & Scoring: QPC

QPC Std	Score
1	4
2	1
3	1
4	1
5	0
6	1
7	1
8	1
9	1
10	1
11	1
12	1

FAC Std	Score
13	1
14	1
15	1
16	1
17	1
18	1
Total	20

Weightage:20

GROUP EXERCISE

- Group Work on APACHE II score

SECTION 5.

Monitoring Medication (MED)

National Accreditation Board for Hospitals and Healthcare Providers

Intent: MED

- Intent of this section is to ensure that basic standards for storage and ordering of medications are in place.

There are 06 standards in MED

National Accreditation Board for Hospitals and Health Care Providers

Standard MED 1.

Std UID	Standard Definition	Expected Value	Scoring
MED1	Storage of medicines	Medications are stored in clean, secure environment as per FDA recommendations	2

Evidence and data:

1. **Physical On Site Checks**

This is a mandatory Standard

National Accreditation Board for Hospitals and Health Care Providers

MED 1: Storing Medicines as per FDA recommendations:

Norm: Medicines used in the hospital should be stored as per recommendations of FDA. The medicine stores of the hospital should be as per accordance of the FDA. Hence, it is mandatory to get the medicine stored approved by FDA. The Pharmacists handling the medicine should be qualified as per the requirements of FDA.

Record keeping: The approval certificate of the Medicine stores from FDA should be kept as record.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

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Standard MED 2.

Std UID	Standard Definition	Expected Value	Scoring
MED 2	Whether Sound Inventory control practices followed	Stock register mentioning receipts and expenditures	2

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MED2: Sound inventory Practices:

Norm: Medicines used in the hospital should be stored as per recommendations of FDA. The medicine stores of the hospital should be as per accordance of the FDA. Hence, it is mandatory to get the medicine stored approved by FDA. The Pharmacists handling the medicine should be qualified as per the requirements of FDA.

Record keeping: The approval certificate of the Medicine stores from FDA should be kept as record.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

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Standard MED 3.

Std UID	Standard Definition	Expected Value	Scoring
MED 3	Whether look alike and sound alike medicines are stored separately in order to prevent drug mishaps	Whether such medications are stored separately	1

Evidence and data:

1. **List of Sound Alike and look Alike Drugs**
2. **Separate Storage and labeling**

National Accreditation Board for Hospitals and Health Care Providers

MED3: Separate storage for lookalike and sound alike medicines (MLASA):

Norm: Medicines which are lookalike and sound alike should be stored separately in the medicine stores, so as to reduce the unpleasant events. The staff handling such medicines should also be well trained.

Mechanism of monitoring and record keeping: Once the medicine storing system as suggested above is established, a quality assurance person or any other person should be given the task of supervision over the store. During supervisory visit he/she will observe whether the medicines lookalike and sound alike are stored separately or not. The visits frequency should be weekly and at times surprise also. The observations should be recorded in following format.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

Date of Visit	Name of Supervisor	Designation of Supervisor	Observations (MLASA stored separately Yes/No	Signature of Supervisor

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Standard MED 4.

Std UID	Standard Definition	Expected Value	Scoring
MED 4	Whether Medical store approved by FDA	Registration number with date and date of expiry	1

Evidence and data:

1. **Licenses**
2. **Conditions of License**

This is a mandatory Standard

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MED 4: Medical Store approved by FDA

Norm: The medicine stores of the hospital should be as per accordance of the FDA. Medicines used in the hospital should be stored as per recommendations of FDA. Hence, it is mandatory to get the medicine stored approved by FDA. The Pharmacists handling the medicine should be qualified as per the requirements of FDA.

Record keeping: The approval certificate of the Medicine stores from FDA should be kept as record.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

National Accreditation Board for Hospitals and Health Care Providers

Standard MED 5.

Std UID	Standard Definition	Expected Value	Scoring
MED 5	Medication orders	Whether medication orders on OPD and IPD papers contain name of medicine, dosage, route of administration and frequency in legible handwriting	1

Evidence and data:

1. **Review of Medical Records and OPD Records**

This is a mandatory Standard

National Accreditation Board for Hospitals and Health Care Providers

MED5: Legible handwriting of medication over OPD papers

Norm: The medicine prescribed by the doctor should be written in a clear and legible handwriting so that correct medicine in correct doses is dispensed to the patient by pharmacists.

Mechanism of monitoring and record keeping; Considering the large numbers of OPD patients, it is instructed that the handwriting checks of medication over the OPD papers should be made on sampling basis every week by a designated supervisory personnel. Minimum 10 OPD papers should be checked from each sections of OPD like medicine, surgery, gynaec, etc.

The observations should be recorded in following format.

Date of Observation	Name of Observer	Designation of Observer	Observations Medication legibility (Yes/No)	Signature of Observer

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Standard MED 6.

Std UID	Standard Definition	Expected Value	Scoring
MED 6	Adequacy of refrigeration facilities with temperature monitoring.	Temperature monitoring record should be available.	1

National Accreditation Board for Hospitals and Health Care Providers

MED6: Monitoring temperature of refrigerator **:**

Norm: To ensure the efficacy of the drugs and vaccines stored in the refrigerator, the inside temperature of the refrigerators should be recorded twice a day i.e in morning and in evening.

Mechanism of monitoring and record keeping: This task should be delegated to fixed person who frequently handle the refrigerator. The timing of power failure should also be monitored. The temperature observations should be recorded in following format.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

Date/M/Y	Temperature at 9 am	Temperature at 9 pm	If power failure- - time from to	Signature of Sister in-charge

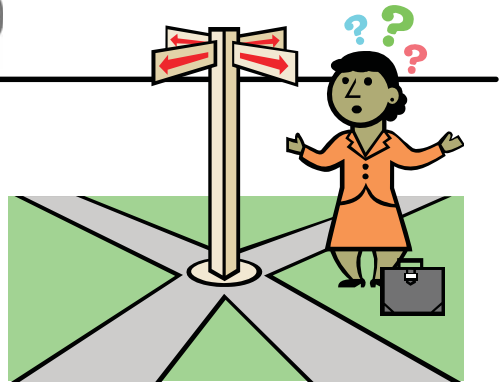
MED: Weightage & Scoring

MED	Score
1	**2**
2	**2**
3	1
4	1
5	1
6	1
Total	**8**

Weightage: 08

Exercise :

Please make a checklist of all points that are to be verified to assess compliance to MED standards.



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SECTION 6.

Maintenance of Patient Medical Records(EMR)

National Accreditation Board for Hospitals and Healthcare Providers

Intent: EMR

- To ensure basic standards of Medical Records are maintained, along with the reports.

There are 05 standards in EMR

National Accreditation Board for Hospitals and Health Care Providers

Standard: EMR 1

Std UID	Standard Definition	Expected Value	Scoring
EMR 1	Whether Patient UID generated	Every OPD and IPD paper should have number.	1

Evidence and data:

1. **Review of Medical Records and OPD Records**

This is a mandatory Standard

National Accreditation Board for Hospitals and Health Care Providers

EMR 1: % of OPD/IPD papers with patient UID:

Norm: For the convenience and ease of patients as well as health record retrieval by health care provider, the UID to each patient is quite useful. Hence every patient should be given UID which should be mentioned in the OPD/IPD paper.

Mechanism of monitoring and record keeping: This mechanism has to be established in the hospital. Hospital authority can ensure existence of it from time to time.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

National Accreditation Board for Hospitals and Health Care Providers

Standard: EMR 2

Std UID	Standard Definition	Expected Value	Scoring
EMR 2	Record of IPD prescription	Whether record of prescription kept	1

Evidence and data:

1. **Review of Medical Records department**

This is a mandatory Standard

National Accreditation Board for Hospitals and Health Care Providers

EMR 2: Keep Record of IPD prescription:

Norms: The prescriptions mentioned in IPD papers should be kept as a hospital record. Thus all in patient's prescriptions should be preserved for a period of 5 years.
Work station: Hospital Record Room
Mechanism of monitoring and record keeping: This mechanism has to be established in the hospital. Hospital authority can ensure existence of it from time to time.
Frequency of Reporting: Once in a Year (on 1st of January of every year).

Standard: EMR 3

Std UID	Standard Definition	Expected Value	Scoring
EMR3	Arrangements made for transmitting information during shifts, transfer in shifts and between treating departments	Documentation should be available	1

Evidence and data:

1. **Review of Medical Records and OPD Records**

EMR3: Arrangements of transfer of information during shift, transfer in shifts and between treatment:

Norms: The information about the changes about in-patient's treatment, transfer in, inter departmental treatment has to be handed over (transferred) to Staff Nurses as well as Doctors when the shift of duty changes. During such exchange of information the papers should be transferred and signature of relieving and joining along with time and date should be obtained.
Work station: All wards, ICU, Casualty Wards.
Mechanism of monitoring and record keeping: This mechanism has to be established in the hospital. Hospital authority can ensure existence of it from time to time by conducting monthly internal audits.
Frequency of Reporting: Once in a Year (on 1st of January of every year).

Standard: EMR 4

Std UID	Standard Definition	Expected Value	Scoring
EMR 4	Whether reporting of Medical Certification of Cause of Death carried out.	100% reporting of Medical Certification of Cause of Death (MCCD) (41 for Govt & 41A for Private Hospitals) is expected.	2

Evidence and data:

1. **Review of Medical Records**

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EMR4: Reporting of medical certification of cause of death (MCCD)

Norms: Regular reporting of hospital deaths is an essential because, it is required for calculating the death rates and incidence rates of various diseases. The exact cause of death and proper certification of cause of death is crucial. Therefore, Hospital should report all deaths as per guidelines of MCCD.

Work station: Medical record Room.

Mechanism of monitoring and record keeping: The MCCD reporting system has to be established in the hospital and a copy of monthly report should be preserved as a record.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

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Standard: EMR 5

Std UID	Standard Definition	Expected Value	Scoring
EMR 5	Morbidity and Mortality statistics with ICD Classification	Morbidity statistics and Mortality statistics with ICD Classification should be available	2

Evidence and data:

1. **Review of Medical Records Department**

National Accreditation Board for Hospitals and Health Care Providers

EMR5: Morbidity and Mortality statistcs with ICD classification:

Norms: It is mandatory to classify the all illnesses (morbidity) as well as deaths (mortality) that are occurring in the hospital as per ICD 10 and the statistics related to it should be available at Hospital.

Work station: Medical record Room.

Mechanism of monitoring and record keeping: The mortality and morbidity data thus analysed every month should be available in the hospital. The analysis can be performed on the characteristics of the patient like- sex, age, religion, place etc. A copy of monthly report should be preserved as a record.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

EMR: Weightage & Scoring

EMR	Score
1	1
2	1
3	1
4	2
5	2
Total	**7**

Weightage: 07

SECTION 7.

Patient Satisfaction Indices (PSI)

National Accreditation Board for Hospitals and Healthcare Providers

Intent: PSI

- To ensure patients rights are respected, and patient satisfaction is in focus

There are 09 standards in PSI

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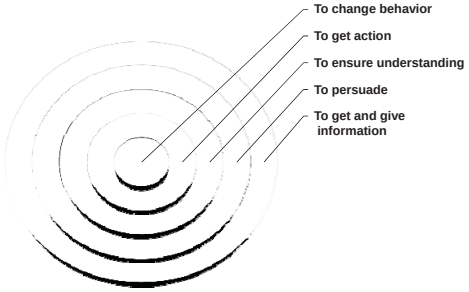
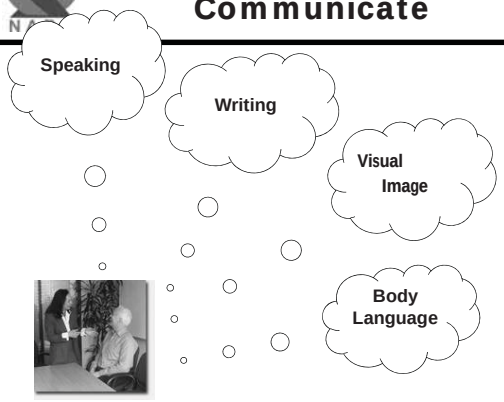
IMPORTANCE OF COMMUNICATION

National Accreditation Board for Hospitals and Healthcare Providers

Communication Goals



Most Common Ways to Communicate



Concepts

- Words Mean Different Things to Different People.
- The Initiation of a Message Provides No Assurance It Has Been Received.
- Communications Often Become Distorted as They Are Transmitted.

It is estimated that 80% of a message gets distorted or lost as it travels through an organization.

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Distorted Message

- There is an old story that, in the first world war, the front line sent a message via runners to the general. The message said: "Send reinforcements, we are going to advance". By the time the message reached the general it said "send three and fourpence, we are going to a dance".

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Communication skills in a healthcare setting include the way you use to:

Greeting the patient and introducing yourself and your role. Putting the patient and the family at ease, cooperative, and under control during the medical encounter.

•Gather information from the patient; history taking.

•Explaining to the patient what are you doing during a physical examination.

•Explaining to the patient the possible diagnosis, investigation and treatment.

•Involving the patient in the decision-making about his health.

•Counseling the patient. Communicating with patients' relatives.

Contd.

- Breaking bad news.
- Seeking informed consent/clarification for an invasive procedure or obtaining consent for a post-mortem.
- Dealing with difficult patients or relatives.
- Giving instructions on discharge.
- Giving advice on lifestyle, health promotion or risk factors.
- Communicating with other health care professionals.

Basic Interpersonal Communication Skills

- Avoid Barriers to Communication.
- Send Understandable Messages: Effective communication.
- Actively Listen.
- Utilize Non-verbal Signals.
- Give and Solicit Meaningful Feedback.
- Adapt to Diversity of Communication Styles... try multiple channels

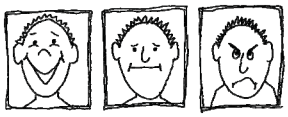
SENDING MESSAGES

Effective Verbal Messages

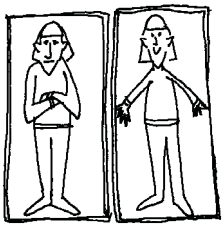
- Are brief, succinct, and organized
- Are free of jargon
- Do not create resistance in the listener

Nonverbal Messages

Nonverbal messages are the primary way that we communicate emotions

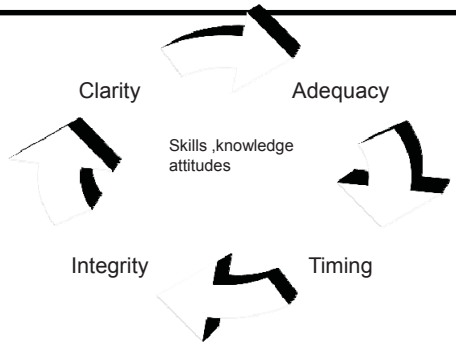


Facial Expression



Postures and Gestures

What makes a good communicator?



Communication models

Engage

- Build rapport based on trust and credibility.
- Pay attention to what you say and how you say it.
- Listen to all presenting complaints, and ask about the clients' goals for the visit.

Empathy

- Invest in gaining an understanding of the client's perspective.
- Communicate this understanding to the client through reflective listening and empathic statements.

Educate

- Assess client's understanding and preferences (ask).
- Provide information in a clear and thorough manner (tell).
- Assess client's understanding (ask).
- Keep complete records. Written communication is just as important as verbal communication.

Enlist

- Communicate with clients as partners in their horse's care.
- Keep all parties informed.
- Follow up (e.g., letter to the client reiterating treatment options and repeating other information you may have discussed).

Tips to good communication skills

- Maintain eye contact with the audience
- Body awareness
- Gestures and expressions
- Convey one's thoughts
- Practice effective communication skills

Why Communication skills?

- Increasing patient dissatisfaction
- Rising number of complaints
- Claims for malpractice
- Problem is Communication Gap rather than Competence.

Prognostication

- Patient generally expect you to cove 5 Ds
  - Disease, discomfort, disability, dissatisfaction and death.
  - Prognostication is an analytical process, based on past experience. It can never be accurate because of inbuilt uncertainty, bioligical variables and risks of therapeutic interventions
    - Is rather like whether –forecasting – uncertain but based on scientific principals.

Hope

- Hope, Healing and Health
  - Promote healing
  - Facilitate coping process
  - Enhance quality of life
  - Hope is a psychological state and has little to do with biostatistics.

Religion, faith & culture in Health care

Faith based Healing factors

- Faith in medicine (placebo effect)
- Faith in a doctor / institute
- Faith in nature, God or Onself (spiritual factor)

Standard: PSI 1

Std UID	Standard Definition	Expected Value	Scoring
PSI 1	Appointment	Whether appointment scheduling possible on phone/internet	1

Evidence and data:

1. **Review of OPD Section**

National Accreditation Board for Hospitals and Health Care Providers

PSI 1: Scheduling appointment on phone/internet:

Norms: With the advent of fast IT growth, some of the patient will opt to have appointment of consultation or check-ups on phone and internet, Therefore, it is necessary to have facility of scheduling appointments on phone/internet in the Hospital.

Work station: Reception/Registration Section.

Mechanism of monitoring and record keeping: A separate section for scheduling appointments of consultation or check-ups should be established in hospital, for which the contact details should be appropriately either by display at prominent place of hospital or any other suitable means. Appointment scheduling register should be preserved as a record.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

Standard: PSI 2

Std UID	Standard Definition	Expected Value	Scoring
PSI 2	Percentage of DAMA / LAMA patients. All patients discharged against medical advice should be given day wise details of treatment given.	Total number of patients who left against medical advice x 100 / Total number of admissions	1

Evidence and data:

1. **Medical Records Discharge Summary review**

PSI 2: % of LAMA patients:

1.Definition: Patients who left against medical advice
2.Formula: Total number of patients who left against medical advice x 100 / Total number of admissions
3.Numerator: Total number of patients who left against medical advice per month
4.Denominator: Total number of admissions per month
5.Frequency of monitoring: Monthly
6.Workstations: All wards, ICU
7.Reference:
http://www.ncbi.nlm.nih.gov/pubmed/17319342
https://secure.cihi.ca/free_products/LAMA_aib_oct012013_en.pdf

1.Significance:
2.Service provider factors:
1.Actual quality of care
3.Patient factors
1.Perceived quality of patient care
4.Institutional factors
1.Presence of responsive feedback mechanism
5. Monitoring mechanism:
1. Records to be kept as per format indicated in **Table 25**.

	Workstation						
Month & Year	*Wards, ICU*	**Name of patient**	**Patient UID**	**Date of admission**	**Date of leaving against medical advise**	**Reason for LAMA**	**Signature of Ward/ ICU In-charge sister**
1	2	3	4	5	6	7	8

Standard: PSI 3

Std UID	Standard Definition	Expected Value	Scoring
PSI 3	% of re scheduling or cancellation of surgeries	Total number of postponed or cancelled surgeries x 100 / Total number of scheduled elective surgeries	1

Evidence and data:

1. **OT Appointment/Scheduling Records**

PSI 3: % of postponement or cancellation of surgeries:

1.Definition: Planned surgeries that are postponed or cancelled
2.Numerator: Total number of postponed or cancelled surgeries
3.Denominator: Total number of scheduled elective surgeries per month
4.Formula: Total number of postponed or cancelled surgeries x 100 / Total number of scheduled elective surgeries
5.Frequency of monitoring: Monthly
6.Workstations: All OTs
7.Reference:
http://www.ncbi.nlm.nih.gov/pubmed/20522351
http://www.sciencedirect.com/science/article/pii/S0952818010000991

1.Significance:
2.Service provider factors:
1.Realistic OT list as regards time factor and priority in patient selection
3.Patient factors
1.Co-morbidity
2.Altered vital parameters
4.Institutional factors
1.Availability HR
2.Availability of logistics
3.Availability and adherence to SOPs
4.TAT (Turn around time) for pre-authorization
5. Monitoring mechanism:
1.Records to be kept as per format indicated in **Table 26**.

	Workstation						
Month & Year	All OTs (Genral surgery, Ortho, Gynaec, ENT, Opthal, Super Speciality)	Name of patient	Patient UID	Date of scheduled elective surgery	Date on which surgery conducted	Reason for postponement / cancellation	Signature of Ward In-charge sister
1	2	3	4	5	6	7	8

Standard: PSI 4

Std UID	Standard Definition	Expected Value	Scoring
PSI 4	Informed consent before surgery/Procedure	Informed consent of patient taken at the time surgery is planned in patient's own language.	1

Evidence and data:

1. **Review of Medical Records**

This is a mandatory Standard

National Accreditation Board for Hospitals and Health Care Providers

IPS 4: Informed consent before surgery/procedure:

Norms: Informed consent of the patient before undergoing surgery or any procedure is pre-requisite. Details of surgery/procedure have to be explained well to the patient in benefit and welfare of patient. The informed consent should be obtained in the language patient understands.

Work station: Wards, ICU, OT and other stations like imaging centers.

Mechanism of monitoring and record keeping: Informed consent in patients own language should be recorded and preserved as a record. As an internal audit a person designated by hospital authority should conduct exit interviews on sample basis, at least 5% discharged patients underwent surgery/procedure, every month to confirm whether the patients are explained in their language to their fullest satisfaction and record in this regard should be preserved.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

National Accreditation Board for Hospitals and Health Care Providers

Standard: PSI 5

Std UID	Standard Definition	Expected Value	Scoring
PSI 5	Feedback form made available at the time of discharge in patients own language	Total number of feedback forms made available at the time of discharge x 100 / Total IPD	1

Evidence and data:

? tracking

National Accreditation Board for Hospitals and Health Care Providers

IPS 5: % of feedback form made available at the time of discharge:

Norms: A patient's feedback regarding medical care rendered by Hospital during his stay in hospital is an indication about quality of health care as well as other perspectives of the patient. Therefore, a feedback form in the language of patient should be made available to the patient at the time of discharge and their feedback should be obtained.

Formula: Total number of feedback forms issued to in-patients at the time of discharge per month x 100 / Total number of in patients per month.

Numerator: Total number of feedback forms issued to in-patients at the time of discharge per month.

Denominator: Total number of in patients per month.

Work station: Wards and ICU.

Mechanism of monitoring and record keeping: Number of feedback forms issued to the in-patients at the time of discharge should be recorded. The denominator will be obtained from indoor register.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

Standard: PSI 6

Std UID	Standard Definition	Expected Value	Scoring
PSI 6	Citizen's Charter and Suggestion Box available	Availability of Citizen's charter at prominent place and Suggestion box with authorized person.	0.5

Evidence and data:

1. **Physical site Check**

IPS 6: Citizen's Charter and Suggestion Box available:

Norms: As a right to information a citizens charter should be displayed at the prominent place like patients waiting place of Hospital. Similarly a suggestion box should be made available at the prominent place of the Hospital.

Work station: OPD patients waiting hall.

Mechanism of monitoring and record keeping: A person should be designated by the hospital authority to collect the suggestions every weekly from the Suggestion Box and presented in the meeting called by Hospital Authority so that the necessary corrective measures can be taken by Hospital Authority on relevant suggestions. The proceedings of such meetings should be maintained as record.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

Standard: PSI 7

Std UID	Standard Definition	Expected Value	Scoring
PSI 7	Patient's Rights and Education.	Patient's record should be accessible to patient and authorized patient's relative on request	0.5

Evidence and data:

1. **Procedure for Issue of Records to patient**

National Accreditation Board for Hospitals and Health Care Providers

PSI 7: Patient's Rights and Education:

Norms: As a right to information on request of a patient or an authorized relative of a patient hospital authority should provide the patient's record of the services provided in the Hospital.
Work station: Admin section**.**
Mechanism of monitoring and record keeping: A person should be designated by the hospital authority to respond to such requests from patients or authorized relative of the patients. The requests received and information provided should be recorded in following format.
Frequency of Reporting: Once in a Year (on 1st of January of every year).

Name of the Pt/Patient's relative	Address of the Pt/Patient's relative	Date of request	Date of record provided	Reasons if not provided	Signature of Authority

National Accreditation Board for Hospitals and Health Care Providers

PSI: Weightage & Scoring

PSI	Score
1	1
2	1
3	1
4	1
5	1
6	1
7	1
Total	7

Weightage: 07

National Accreditation Board for Hospitals and Health Care Providers

RGJAY Quality Standards for Empanelment

RGJAY Quality Standards for Empanelment

National Accreditation Board for Hospitals and Healthcare Providers

RGJAY Standards

	Section	Std.
1	Human Resource Quality **(HR)**	10
2	Facilities Management **(FAC)**	15
3	Infection Control Measures **(INF)**	11
4	Quality of Patient Care**(QPC)**	18
5	Monitoring Medication **(MED)**	06

National Accreditation Board for Hospitals and Health Care Providers

RGJAY Standards (contd)

	Section	Std.
6	Maintenance of patient Medical Records **(EMR)**	05
7	Patient Satisfaction Indices**(PSI)**	07
8	Standard Operating Protocols **(SOP)**	09
9	Transparency in Pricing **(TIP)**	04
	Total 9 Sections & 85 Standards	**85**

National Accreditation Board for Hospitals and Health Care Providers

SECTION 8.

Standard Operation Protocols (SOP)

National Accreditation Board for Hospitals and Healthcare Providers

Intent: SOP

- To ensure Standardized protocols are uniformly used across the hospital.

There are 09 standards in SOP

National Accreditation Board for Hospitals and Health Care Providers

Standard: SOP 1

Std UID	Standard Definition	Expected Value	Scoring
SOP 1	SOP for Diagnosis of top 20 common diseases		1

Evidence and data:

1. **Copy of SOPs**

National Accreditation Board for Hospitals and Health Care Providers

SOP 1: Availability of SOPs:

Norms: Hospital should have SOPs for following:

1. SOPs for top 20 common diseases
2. SOPs for Admission and discharge
3. SOPs for medicine storage and dispensing
4. SOPs for OT
5. SOPs for ICU
6. SOPs for Emergency Services
7. SOPs for Laboratory Services
8. SOPs for Radio-diagnostic services

These should be available at work stations and should be available to the health care providers like doctors, nurses and paramedics concerned.

Work station: OPD, Ward, ICU, Casualty, Laboratory, Radio diagnostic center.
Mechanism of monitoring and record keeping: A person should be designated by the hospital authority to make available of these SOPs to all concerned and should ensure availability of it from time to time.
Frequency of Reporting: Once in a Year (on 1st of January of every year).

Standard: SOP 2

Std UID	Standard Definition	Expected Value	Scoring
SOP 2	SOP for Admission and Discharge		0.5

Evidence and data:

1. **Copy of the SOP**

This is a mandatory Standard

Standard: SOP 3

Std UID	Standard Definition	Expected Value	Scoring
SOP 3	SOP for medicine storage and dispensing		0.5

Evidence and data:

1. **Copy of SOP**

National Accreditation Board for Hospitals and Health Care Providers

Standard: SOP 4

Std UID	Standard Definition	Expected Value	Scoring
SOP 4	SOP for Operation Theatre work flow		0.5

Evidence and data:

1. **Copy of SOP**

National Accreditation Board for Hospitals and Health Care Providers

Standard: SOP 5

Std UID	Standard Definition	Expected Value	Scoring
SOP 5	SOP for ICU(Admission and discharge criterion, putting patient on ventilator and weaning from ventilator)		1

Evidence and data:

1. **Copy of SOP**

National Accreditation Board for Hospitals and Health Care Providers

Standard: SOP 6

Std UID	Standard Definition	Expected Value	Scoring
SOP 6	SOP for Emergency services(20 most common emergencies and how they are managed)		1

Evidence and data:

1. **Copy of SOP**

National Accreditation Board for Hospitals and Health Care Providers

Standard: SOP 7

Std UID	Standard Definition	Expected Value	Scoring
SOP 7	SOP for Laboratory services. (SOP for sample collection, receiving, processing, transport and internal & external validation of results		0.5

Evidence and data:

1. **Copy of SOP**

National Accreditation Board for Hospitals and Health Care Providers

Standard: SOP 8

Std UID	Standard Definition	Expected Value	Scoring
SOP 8	SOP for Radio diagnostic services (For patient and technician safety)		0.5

Evidence and data:

1. **Copy of SOPs**

National Accreditation Board for Hospitals and Health Care Providers

Standard: SOP 9

Std UID	Standard Definition	Expected Value	Scoring
SOP 9	Use of ICD Code for diseases and procedures		0.5

Evidence and data:

1. **Copy of SOPs**
2. **Medical Records**

National Accreditation Board for Hospitals and Health Care Providers

SOP2: Use of ICD Code for diseases and procedures

Norms: Hospital should use ICD code for diseases and procedure. These codes should be available at all working stations and health care providers.

Work station: Wards, ICU, casualty, OT, Labour Room, Laboratory, Radio diagnostic centers.

Mechanism of monitoring and record keeping: A person should be designated by the hospital authority to make available of these ICD codes to all concerned and should ensure availability and applications of it from time to time

Frequency of Reporting: Once in a Year (on 1st of January of every year).

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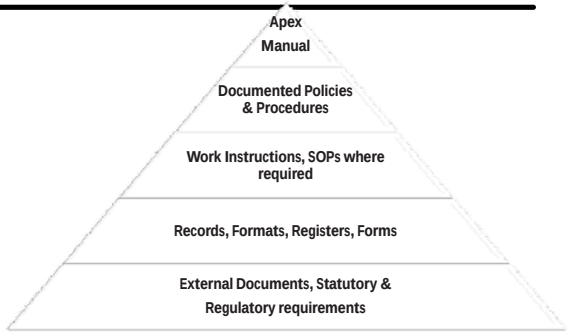
Levels of Documentation



National Accreditation Board for Hospitals and Health Care Providers

Essential Documentation

- Apex manual.

National Accreditation Board for Hospitals and Health Care Providers

Apex Manual….

- Introduction of the HCO
- Management including ownership, vision, mission, ethical management etc.
- Quality policy and objectives including service standards
- Scope of services provided by the HCO and the details of services provided by every department

National Accreditation Board for Hospitals and Health Care Providers

Apex Manual

- Composition and role of various committees
- Organogram
- Statutory and regulatory requirements
- Chapter wise documentation
- Annexure (if any)

National Accreditation Board for Hospitals and Health Care Providers

Required Objective Elements

- Procedure

National Accreditation Board for Hospitals and Health Care Providers

Procedure

- A specified way to carry out an activity or a process (Para 3.4.5 of ISO 9000: 2005).
- A series of activities for carrying out work which when observed by all help to ensure the maximum use of resources and efforts to achieve the desired output.
- **Note 1:** Procedures can be documented or not.
- **Note 2:** When a procedure is documented, the term "written procedure" or "documented procedure" is frequently used. The document that contains a procedure can be called a "procedure document".

National Accreditation Board for Hospitals and Health Care Providers

Required Objective Elements

- Procedure
- Policy

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Policy

- They are the guidelines for decision making, e.g. admission, discharge policies, antibiotic policy, etc.

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Policy, Process & Procedure

- Policies: *"What to do?"*
- Processes: *"How it happens?*
- Procedures: *"How to do it?"*

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Policy Vs. Procedure

Policy	Procedure
• Guide decision making.	• Drive actions.
• Leave some room for managerial discretion.	• Are detailed and rigid.
• Are an integral part of organizational strategies	• Are tactical tools.
• Are generally formulated by top management.	• Are laid down at lower organizational levels in line with policies

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Document adequacy

- Detailing
- Verify if the documentation matches good clinical practice
- Check the linkages

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Document adequacy

- Detailing
- Verify if the documentation matches good clinical practice
- Check the linkages
- Look for the small details!!!

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SOP: Weightage & Scoring

SOP	Score
1	1
2	0.5
3	0.5
4	0.5
5	1
6	1
7	0.5
8	0.5
9	0.5
Total	**6**

Weightage: 06

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SECTION 9.

Transparency in Pricing (TIP)

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Standard: TIP 1

Std UID	Standard Definition	Expected Value	Scoring
TIP 1	Whether pricing information on bed prices, room prices, nursing care, standard procedures available at the help desk		1

Evidence and data:

1. **Availability of Price list**

This is a mandatory Standard

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TIP 1: Pricing information available at help desk:

Norms: Information of prices for the various procedures charged by the hospital should be available at help desk and should be provided in written or verbal form on request by citizen..

Work station: Help Desk/ Enquiry

Mechanism of monitoring and record keeping: A person should be designated by the hospital authority to make available the information of prices of various procedures charged by the hospital. Similar information can also be displayed at prominent place of the hospital. Hospital Authority should ensure about its availability every week through designated person and should maintain the record.

Frequency of Reporting: Once in a Year (on 1st of January of every year).

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Standard: TIP 2

Std UID	Standard Definition	Expected Value	Scoring
TIP 2	Whether bill of discharge gives break up of all the above		2

Evidence and data:

1. **Random Checks of Bills**

This is a mandatory Standard

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TIP 2: Bill formats having break-up of items charged:

Norms: Hospital should provide the Bill with breakup of items charged to the patients. As an instance, the bill should necessary contains the details like price and specification of stents.
Work station: Admin/Billing section
Mechanism of monitoring and record keeping: This system should be established and as an internal audit, hospital should have a mechanism to conduct weekly exit interview of 1% discharged patients on sampling basis. The observations of such exit interviews should be maintained as record in following formats.
Frequency of Reporting: Once in a Year (on 1st of January of every year).

Date of Exit interview	No. of pts. exit interview conducted	No. of Bills checked	No. of Bills found item-wise details.	No. of pts. satisfied	Signature

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Standard: TIP 3

Std UID	Standard Definition	Expected Value	Scoring
TIP 3	Whether patient provided list of items used in his case at time of discharge (list of consumables, medicines and investigations done)		2

Evidence and data:

1. **Random checks of Bills**

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TIP 3: Whether patient provided list of items used in his case at time of discharge (list of consumables, medicines and investigations done):

Norms: Hospital should provide the lists of items used in his case such as list of consumables, medicines and investigations done.
Work station: Admin/Billing section
Mechanism of monitoring and record keeping: This system should be established and as an internal audit, hospital should have a mechanism to conduct weekly exit interview of 1% discharged patients on sampling basis. The observations of such exit interviews. These minimum data elements should be available in the registers maintained for this purpose by the hospital
Frequency of Reporting: Once in a Year (on 1st of January of every year).

Date of Exit interview	No. of pts. exit interview conducted	No. of Discharge cards checked	No. of pts provided list of items used.	No. of pts. satisfied	Signature

Standard: TIP 4

Std UID	Standard Definition	Expected Value	Scoring
TIP 4	For consumables, whether patient informed of choices available before surgery as per hospital purchase policy		2

Evidence and data:

1. **Random checks**

TIP 4: Informing the choices available of consumables before surgery as per hospital purchase policy:

Norms: As per hospital purchase policy, in the Hospital every patient undergoing surgery should be informed about the choices of the consumables available before undergo surgery. As an example if patient is undergoing coronary procedures, the different types of stents available with their manufacturing company and priced should be informed. A choice should be given to the patient/or relative and it should be recorded at suitable place like IPD case paper. .
Work station: Admin/Billing section

TIP: Weightage & Scoring

TIP	Score
1	1
2	2
3	2
4	2
Total	7

Weightage: 07

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ASSESSMENT TECHNIQUES

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Assessment techniques

- Functional Interviews
- Visits to Patient Care Areas
- Visits to Selected Departments
- Facility Tour
- Patient record review

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Various Techniques

- Interview
- Observe
- Review documentation
- Examine records and reports
- Conduct mock drills
- Silence can be useful!!!

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Patient record review

- Sample of **discharged (closed)** patient records for review during the interview.
- Should include a diverse set of records
- Examine records and reports
  - Traceable to activity
  - Complete, correct
  - Legibility, understandable
  - Filing, storage, archiving
  - Management system and clinical records

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Types

- Horizontal assessment
- Vertical assessment
- Combined approach

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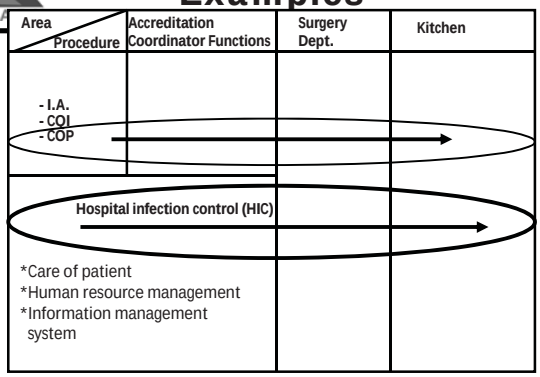
Horizontal Assessment

- Is an assessment of one system across several functional groups within the organization.
- Detailed assessment of one or more elements of the quality system.

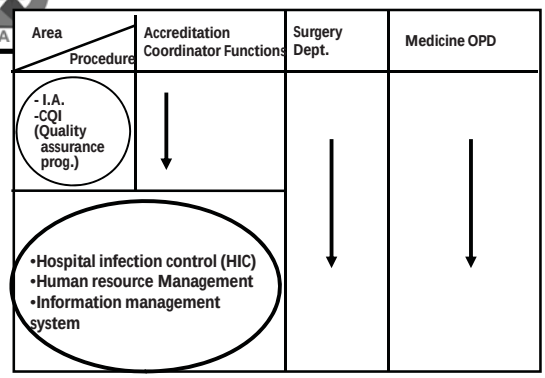
Horizontal Assessment Examples



Vertical Assessment

- Looks at many controls applied within a single functional group.
- Detailed assessment of all elements of an actual case in which the accreditation procedure is implemented.

Vertical Assessment Examples



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Checklist

- Good or bad?

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Purpose

- Assist in keeping the assessment on track.
- Assist with time management.
- Provide a structured approach to the assessment.
- Provide evidence of a full system assessment.
- Reduce workload on assessor during assessment.

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Disadvantages

- Can become a tick list
- May be full of yes-no questions
- If not on checklist, will not look at area
- May stifle initiative and process analysis

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REPORT WRITING

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Objective Evidence

- The observations and statements of fact and the information contained in records that can be verified.

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Objective Evidence

- Evidence which exists
- Uninfluenced by emotions or prejudices
- Can be stated
- Can be documented
- Can be verified
- Relevant to standards

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Remember

➢ If it is not written down it did not happen!!!

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Non-conformity

- How to write?
- Which form to use?

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Preparing the assessment report

- The assessment team leader is responsible for the preparation of the assessment report which should be **complete, accurate, concise and clear**.
- Collective responsibility.

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Contents...

- The assessment objectives
- The assessment scope (organizational and functional units and the time period covered)
- The identified assessment client
- The assessment team composition (with leader)
- Dates and places of assessment

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Contents

- The assessment criteria
- The assessment findings
  - compliance as well as non-compliance.
  - what was examined
  - what was found
  - if non-compliant, specific details.
- The assessment plan
- List of assessee representatives

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Following are the optional elements

- Areas not covered
- Any unresolved divergent opinion between the assessment team and the assessee
- Recommendations for improvements (optional for compliance by the assessee)
- Follow-up action plan, if any
- Any other information

WRITING NON CONFORMITIES

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Non-conformity

- What is this?

- a condition adverse to Quality
- the non-fulfillment of a requirement

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Identifying Non-Conformities

Non-conformities can be :

- Related to the management system
- Related to clinical functions
- Related to statutory requirements
- Failure to do some thing required
- Difference between work practices and documented instructions
- Documentation gaps

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Expressing Non-Conformities

Statements of non-conformities **must be**

- Non-blaming statements of fact
- Based on recorded objective evidence
- Directly related to accreditation standard or specific documented requirement

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Purpose

- Inform the assessee how the system has failed to meet a requirement
- Are the starting points for effective corrective action
- Record on which an assessor bases his or her assessment conclusions

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Parts

- A clear statement of the non-conformance.
- The requirement or specific reference to the requirement.
  - **If you cannot express the problem in the words of the procedure/standard then there is no non-conformance.**
- And finally, objective evidence that supports the statement of non-conformance; based on the requirement.

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Statement

- Should be self-explanatory and related to the process.
- Be unambiguous and concise.
- Not be a restatement of the assessment evidence.
  - Evidence must be traceable to the NC.

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Statement

- Record the requirement against which the NC was detected.
  - If possible, write out the exact text of the requirement.
- The assessment evidence must support the assessment finding.
  - The evidence must be specific to the violated requirement.

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A good NC

- **Observation**
  - what, why, who, where, which patient, unique number (please remember scope issue!)
- **Explanation**
  - why do you say it is a non-conformance?
  - Please do not compare with your own organization or any other organization that you have visited.
- **Attribution**

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INTERVIEWING IN ASSESSMENTS

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Interviewing in Assessments

- Assessment involves an extensive and intensive exercise of finding facts and not faults.
  - Important that the assessee is placed at ease and thus fulfill the purpose of assessment.
- This can be done by interviewing the HCO personnel in which questioning and asking for records and other evidences are involved.

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How to go about?

- **Purpose of asking questions**
  - Should always explain the purpose before putting a question.
  - Strengthens the bond of communication between the Assessor and the Assessee.

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Type of questions

- Direct or Open Questions
- General Questions
- Sarcastic Questions
- Multiple/ Chain Questions
- Probing Questions
- Closed Questions

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Open questions

"I keep six honest serving men, they taught me all I knew, their names are *What* and *Why* and *When* and *How* and *Where* and *Who*."

Rudyard Kipling

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Open questions

- Will elicit more than just Yes or No answers
- Takes longer to answer such a question than it does to ask
  - auditor also gets some thinking time!
- Can control the tone of discussions to their advantage with the use of these questions since the questions demand meaningful answers.

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Different types

- Themed questions
- Expansive questions
- Opinion questions
- Investigative questions
- Repetitive questions
- Hypothetical questions

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Closed questions

- Have a ‘yes’ or ‘no’ response
- Should only be used in audits where the Yes and No answer can quite definitely be given because of what has gone before.
- Should be used to verify that the assessor has clearly understood what has been explained.
- Have their place in an assessment but the assessor must not rely on them.
- Let the assessee do the talking!!

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When to Use ‘Open’ and ‘Closed’ Questions?

- Use ‘open’ questions to search and probe for the unknown.
  - New practices
  - Changes to existing processes
  - Failures (or indeed successes)
- Use ‘closed’ questions to check known or expected facts such as:
  - A stage in a procedure being complete
  - Compliance with a standard

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Interviewing in practice…

- Plan the sequence of your interviews.
  - remember that what you find during the course of one interview may affect who you interview next
- Analyse the procedures to make sure that you are going to assess relevant personnel.
- Don’t barge in and start questioning!
  - Put your assessees at ease
- Use a checklist to structure each interview

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Interviewing in practice…

- Never get distracted with how you think something should be done
- Take one input to a procedure or process and follow it through
- Reassure them that non-conformances are just problems to be corrected.
- Make a good first impression!

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Interviewing in practice

- Your assessees may have (or feel that they have) little time to spare.
  - Keep their attention with short questions.
  - Don't let them distract you by their wanting to leave.
- Keep it focused.

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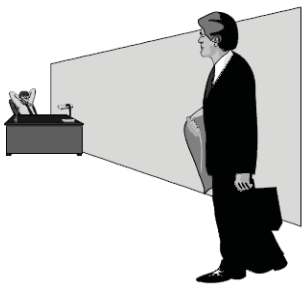
Personality Types: Remote



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Personality Types: Antagonistic

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Personality Types: Reserved

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COMPETENCE OF ASSESSORS

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Competence of Assessors

- Competence is based on
  - personal attributes and
  - the ability to apply the knowledge and skills gained through the education, work experience, assessor training and assessment experience.

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Personal Attributes of Assessors

- **Ethical** – fair, truthful, sincere, honest and discreet
- **Open minded** – willing to consider alternative ideas or points of view
- **Diplomatic** – tactful in dealing with people
- **Observant** – actively aware of physical surroundings and activities
- **Perceptive** – instinctively aware of and able to understand situations

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Personal Attributes of Assessors

- **Versatile** – adjusts readily to different situations
- **Tenacious** – persistent and focused on achieving objectives
- **Decisive** – reaches timely conclusions based on logical reasoning and analysis
- **Self reliant** – acts and functions independently while interacting effectively with others

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Why is this required?..

- Obtain and assess objective evidence fairly;
- Remain true to the purpose of the assessment without fear or favour;
- Evaluate constantly the effects of assessment observations and personal interactions during an assessment;
- Treat concerned personnel in a way that will best achieve the assessment objective;

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Why is this required?..

- React with sensitivity to the regional conventions of the area in which the assessment is performed;
- Perform the assessment process without deviating due to distractions;
- Commit full attention and support to the assessment process;

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Why is this required?

- React effectively in stressful situations;
- Arrive at generally acceptable conclusions based on objective evidence collected during assessments;
- Remain true to a conclusion despite pressure to change that is not based on objective evidence.

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Knowledge and Skills

- Knowledge of and skills in applying
  - accreditation criteria
  - assessment and quality principles, practices and techniques
- Technical Knowledge of Hospital Practices.

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Knowledge and Skills

- Knowledge of and skills in applying
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Knowledge of and skills in applying accreditation criteria

- Assessors should understand the NABH standard and the accreditation body's policies applicable to the desired scope of accreditation;
- Assessors should also appropriately interpret and apply the criteria to actual assessment situations.

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Knowledge and Skills

- Knowledge of and skills in applying
  - accreditation criteria
  - assessment and quality principles, practices and techniques
- Technical Knowledge of Hospital Practices.

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Generic knowledge and skills

- Planning
- Preparing
- Performing
- Reporting
- Following up on issues
- Verifying closure of non compliances from previous assessments
- Closing the assessment

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Generic knowledge and skills

- Skilled in assessment performance techniques
  - interviewing
  - audit trails
  - [illegible]
  - listening
  - auditing
  - communicating
  - collecting assessment evidence and
  - analyzing assessment observations and drawing appropriate conclusions

Maintaining the confidentiality and security of assessment information

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Generic knowledge and skills

- General knowledge of quality systems and processes applicable to a hospital.
- Able to understand hospital's organizational functioning and interface between various disciplines.
- Familiar with the regulatory requirements applicable to HCO, regional, national and international.

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Knowledge and Skills

- Knowledge of and skills in applying
  - accreditation criteria
  - assessment and quality principles, practices and techniques
- Technical Knowledge of Hospital Practices.

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Technical Knowledge of Hospital Practices

- The assessor should have domain knowledge on processes in HCO by virtue of qualification and experience.
- Terminology used in NABH Standards in particular and hospital activities in general.
- Common management tools and their application.

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Additional Skills for a Principal Assessor…

- Preparing the assessment plan and making effective use of resources during the assessment;
- Leading the assessment team;
- Providing direction and guidance to observers and technical experts;
- Preventing and resolving conflicts;

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Additional Skills for a Principal Assessor

- Making decisions relating to the assessment;
- Leading the assessment team to reach conclusions;
- Representing the assessment team with the management; and
- Drafting, coordinating and submitting the assessment report.

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IS THAT ALL?

Soft Skills

Personal Qualities + Interpersonal skills = Soft skills

- Personal Qualities
  - Self esteem
  - Responsibility
  - Integrity
  - Self management
  - Honesty
  - Sociability
- Interpersonal skills
  - Participates as a member of the team
  - Teaches others
  - Serves clients/customers
  - Exercises leadership
  - Accepts other views
  - Negotiates

Why are soft skills important for assessors?

Scenario 1: Little soft skill auditing
- Focus on assessment work step
- Ask basic questions
- Focus is on reviewing documentation and not people or the process

⇨ **Results**
- Assessee is frustrated
- Little co-operation
- Assessee is defensive
- "Vanilla" assessment findings

Scenario 2: Soft skill auditing
- Engage in conversation
- Prepare for the assessment
- Ask intelligent questions
- Present with enthusiasm

⇨ **Results**
- Get information easier
- Reduce follow up
- Gain additional insights
- Value added assessment

Remember

Mind } Your "Competency Factor"

Face
Body
Voice
} Likeability Factors*

*Your personal style.... How you choose to present your message

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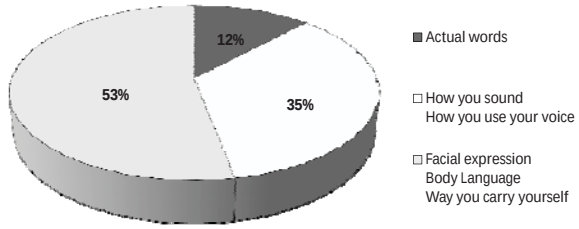
Communicating a message



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How can soft skills help you during assessment?

- First impressions
- Instilling trust and confidence in your team
- Delivering a tough message!!
- Giving compliments
- Projecting a positive demeanor
- Not being intimidated
- Providing unique perspectives/insights

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How can not having soft skills harm you during assessment?

- When your emotions overrule the facts
- Reacting to other's poor soft skills
- Talking too much
- Unprofessional conversations
- Not delivering on your commitments
- Compromising your standards
- Lack of professional skepticism
- Presenting unclear concepts/ideas

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What soft skills am I good at?

• Communicating • Listening • Presenting • Managing • Leading • Responsiveness • Planning • Problem solving	Traditional Non traditional	• Sharing • Visioning • Helping • Learning • Facilitating • Maintaining composure • Complimenting • Exhibiting passion

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How do I improve my soft skills?

- Training
- Understanding people's reactions

- Practice
- Practice
- Practice

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Soft skills in practice during assessment…

- Listening skills
  - focus on speaker
  - avoid physical, mental distractions
  - reassure verbally, visually
  - maintain appropriate eye contact
  - project appropriate body language

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Soft skills in practice during assessment…

- Reduce tension
  - put people at ease
  - reassuring them frequently
  - just being human

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Soft skills in practice during assessment…

- Keep assessment flowing
  - systematic sequence
  - avoid back-tracking
  - orderly flow of questions
  - avoid long periods of silence
  - plan your approach

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Soft skills in practice during assessment…

- When things seem wrong…
  - remain calm, friendly, professional
  - examine all the facts
  - make the person a partner in the discovery
  - explore options for correction

Soft skills in practice during assessment…

- Conduct a thorough assessment but at the end of it still be Friends!!
  - Don't Exhibit Your Supremacy
  - Don't Try to Find Out Faults

Soft skills in practice during assessment…

- Professional approach
  - preparation
  - personal presentation
  - project right image
  - stay on track
  - thorough and persistent

Soft skills in practice during assessment…

- Teamwork
  - work as a team
  - don't interrupt, disagree
  - be ready to support
  - respect one another's viewpoints

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Soft skills in practice during assessment…

- Learn about the process prior to speaking with the owner.
- In the initial few minutes try to gauge the assessee.

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Soft skills in practice during assessment…

- Don't be overly confident or arrogant.
  - Remember, the folks who do this everyday probably know more about their operation than you do.
  - As an assessor, hopefully you will be able to add value by making suggestions on how things can be done better, but this should be done with tact.
  - Assessors should not have a "gotcha" attitude.

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Soft skills in practice during assessment…

- When asking tough questions, try to phrase them in a way that is non-confrontational and does not lead the response.
  - For example, instead of saying "you review the XYZ report weekly, correct?" say something like "could you help me understand how often you review the XYZ report?".
- Ask open-ended, non-threatening questions and then ask for clarification.

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Soft skills in practice during assessment…

- Show true interest in what the assessee is telling you.
- One critical point to keep in mind: don't forget to **LISTEN to what they have to say. Try to clear your mind of any** preconceived notions as to the outcome or response.
- Work with the assessee to show them that you are only interested in the facts. You are not there to judge them or their work.

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Soft skills in practice during assessment…

- Don't be an alarmist.
- Sticking solely to the facts and proven impact of a situation can help keep things from getting out of control.

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NABH criteria

- **Education and work experience for NABH Assessors:**
  - **For clinician:** MBBS with 10 years of experience of which 5 – years should be in a hospital.
  - **For administrator:** PG in Management or Hospital Administration with minimum of 10 years of experience of which 5- years being in the hospital administration.
  - **For Nursing assessor:** B. Sc. / M. Sc. Nursing with 10 – years of experience or diploma in general nursing & midwifery with 15 – years of experience. In both the cases, minimum of 5 – years experience should be in supervisory capacity in a hospital.
- Successful completion of 5-day assessor training course.

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Demonstration of Assessor Competence

- Examination/testing/training evaluation
- Demonstration
- Formal evaluation
- Casual observation

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Maintenance and Continual Improvement of Competence..

- **Continual professional development**
- Can be achieved through additional
  - work experience,
  - training,
  - private study,
  - coaching,
  - attendance at meetings and seminars and conferences, etc.

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Maintenance and Continual Improvement of Competence

- **Maintenance of assessment ability** – by regularly participating in assessment activities.
- Tutoring
- Mentoring

CODE OF CONDUCT

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Assessor Code of Conduct

1. Integrity
2. Objectivity
3. Confidentiality
4. Competency
5. Professionalism

1. Integrity: Assessor shall

- ✓ disclose to NABH any current or prior working or personal relationships that may affect the neutrality of the assessment;
- ✓ not enter into any activity which may be in conflict with the best interests of the NABH or would prevent the performance of duties in an objective manner;
- ✓ perform their work with honesty, diligence, and responsibility;
- ✓ follow high standards of fairness, integrity and ethical conduct;

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1. Integrity: Assessor shall

- ✓ not knowingly be a party to any illegal activity, or engage in acts that are discreditable to the profession of auditing or to NABH;
- ✓ not communicate false, erroneous or misleading information that may compromise the integrity of any assessment;
- ✓ not market their services or promote any business in which they may have an interest;

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1. Integrity: Assessor shall

- ✓ not promote or represent any business interests, whilst conducting assessment;
- ✓ not provide consultancy at any time during the assessment process.

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2. Objectivity: Assessor shall

- ✓ perform the assessment as laid down by NABH (based on the standards and using guidebook and checklist as reference) without bias, prejudice, variance or compromise in relation to both NABH and the assessee organization and any other organization involved in an assessment performed by them;
- ✓ be honest, impartial, independent, discrete, objective and transparent in all their dealings. They shall not discriminate against those to whom, for whom and with whom they provide services but are guided entirely by professional and ethical principles;

2. Objectivity: Assessor shall

- ✓ remain free of any influence, interest or relationship that impairs professional judgment, independence or objectivity while performing assessment;
- ✓ act objectively, accurately, and report findings in a consistent and an unbiased manner, and in accordance with NABH requirements;

2. Objectivity: Assessor shall

- ✓ report honestly, ensuring that judgements are fair and reliable;
- ✓ be able to act professionally under adverse circumstances;
- ✓ not accept any inducement, commission, gift, favours or any other benefit from any interested party.

3. Confidentiality: Assessor shall

- ✓ treat in a confidential and private manner all information gained in relation to any of the organization's identified activities of accreditation. Such confidential information remains the property of the source from which it was obtained; the assessor shall not disclose it, or allow it to be disclosed to a third party or parties, unless that disclosure is required by law or has been authorized by NABH;

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3. Confidentiality: Assessor shall

- ✓ be discrete and use due care and diligence in fulfilling the functions of an assessor;
- ✓ not use assessment information for any personal gain or in any manner that would be contrary to the law or detrimental to the legitimate and ethical objectives of NABH;
- ✓ take all reasonable steps to protect the confidentiality of the assessment results, data collected and the anonymity of interviewees.

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4. Competency: Assessor shall

- ✓ engage only in those services for which they have the necessary knowledge, skills, and experience;
- ✓ not misrepresent their qualifications, competence or experience, nor undertake assignments beyond their capabilities ;
- ✓ strive to continually improve their proficiency and the effectiveness and quality of their assessment skills;
- ✓ be consistent and accurate in their evaluations of data obtained through documentation, interviews and observation;

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4. Competency: Assessor shall

- ✓ strive to be complete in their evaluations and avoid any omissions;
- ✓ separate fact from opinion clearly and concisely in their evaluations. Support for assessor opinions must be derived from quantitative, measurable data;
- ✓ commit to honest, thorough and straightforward communication in the performance of assessment activities.

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5. Professionalism: Assessor shall

- ✓ act honestly, in good faith and in the best interests of NABH, not engaging in conduct likely to bring discredit upon NABH;
- ✓ abide by the dress code laid down by NABH while carrying out assessments;
- ✓ ensure patient care activities are not disrupted or delayed during the assessment. Any patient care requirement will supersede assessment of that area, which should be rescheduled to a later time;

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5. Professionalism: Assessor shall

- ✓ come to assessment visits well prepared, having read the documentation pre-visit;
- ✓ conduct themselves professionally, with truth, accuracy, fairness and responsibility;
- ✓ remain in communication with the team and secretariat;
- ✓ route any and all queries regarding the assessment directed at the assessee hospital through the Principal Assessor. The secretariat shall also be kept in the loop;

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5. Professionalism: Assessor shall

- ✓ follow the instructions with regard to arrival and meeting prior to the start of assessment;
- ✓ be professional, courteous and honest in all their dealings with members of the team;
- ✓ communicate cordially with all members of the team and should always be directed towards team approach;

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5. Professionalism: Assessor shall

- ✓ not criticize a fellow assessor or colleagues to third parties;
- ✓ respect the hierarchy laid down for the assessment team;
- ✓ promptly inform the Principal Assessor with regard to difficulties encountered during the assessment;
- ✓ co-operate fully with any enquiry in the event of any complaint about their performance as an assessor or any alleged breach of this code.

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Threats to assessor impartiality

- Self-interest threats
- Self-review threats
- Familiarity (or trust) threats
- Intimidation threats
- Advocacy threats
- Competition threats

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PREPARING THE HOSPITAL

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Steps

- Time frames
- Identify Core team at participating hospital (department wise)
- Sensitization workshop of core team
- Make a master list of policies to be developed and by whom

– Map the standards to the respective departments and what is required

Organization structures

– List of departments

– Identify HOD/Coordinator & Quality Manager for each department

– List of Committees that need to be formed

– Identify roles and responsibilities of each

Committees

- Emergency Preparedness Committee
- Pharmacy and Therapeutics Committee
- Infection Control Committee
- Ethics Committee
- Safety Committee
- Medical Audit Committee

SOPs

- Read each standard
- Think: why is this being asked, and how can you implement it.

Emphasis on efficiency, with minimal paper work: Policies on Intranet etc

SOPs

– Identify list of

- Policies & procedures (hospital wide & department specific)
- Formulary
- Clinical Guidelines
- Forms and formats
- Other document needs (patient education)

Emphasis on efficiency, with minimal paper work: Policies on Intranet etc

Essential Documentation

- Apex manual
- Infection Control Manual
- Quality Improvement Manual which also incorporates the quality assurance activities of
  - lab,
  - imaging,
  - intensive care and
  - surgical services
- Safety manual which also incorporates
  - lab safety and
  - radiation safety

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Implementation

Organizational Standards

(These cut across Clinical departments)

- Patient Rights
- Vulnerable patients
- Hand washing
- Safe Injection practices
- Detecting Nosocomial infections
- Universal Precautions
- Isolation practices
- Patient safety
- Reducing Errors
- Code Blue
- Fire Safety

Physician Nurse Paramedic

Patient Care Standards

(These are Department specific)

- Assessments
- Treatment Plans
- Clinical Protocols
- Documentation
- Patient Education
- Disease Outcome Measures

New Systems

- Identify new processes
- Identify new clinical programs required (pain mgmt etc)
- Allocate responsibility for design and roll out
- Resource allocation

New Systems

- Measurements / indicators for each department
- Staffing
- Audits/reviews
- Antibiotic policy

Training

- Training needs analysis for according to the various standards
- Identify Faculty
- Plan training calendar, roll out training
- Audit, audit, audit

Implement

Implement the standards in day to day practice

Measurement

- Measurable Indicators for various departments

Audit

- Make an Internal audit checklist and schedules
- Gap analysis department wise
- Close gaps
- Identify Clinical Audit topics

Time Frames

» Pert Chart for project

Communication

- Periodic Reviews with Core Team and Departments
  - Progress updates

Sample Time Frames

Activity	Days	Jul - Aug	Sep - Oct	Nov – Dec	Jan - Mar
Mapping of Standards & Gap Analysis	30	⇔			
Policies/procedures/ Forms/new programs	60	⇔	⇔		
Train, Train, Train	60		⇔	⇔	
Implement in Practice	30			⇔	
Audit	15			⇔	
Close Gaps	30				⇔

Your Role

- Be familiar with policies in your department: Pl read them.
- Follow the policies
- Please close all the NON Compliances
- Attend ALL Training Programs
- In particular, please be familiar with:
  - CPR
  - Safety codes
  - Fire Safety
  - Disaster drills
  - Radiation Safety
  - Occupational Safety
  - Infection Control practices: BMW, Sharps etc
  - Patient Rights
  - Patient Education and Communication
  - Safe Medication Practices

Your Role

- Documentation
- Pl conduct and participate in Audits with RCA and Improvements
- Adverse events in your department
- Radiation Safety: TLD badges, radiation surveillance
- Clinical records

Ownershsip

- We can only win ...if

<u>you</u>

participate....through cooperation, ownership and accountability...that should lead to changing the way we work .....

We Need Your Commitment…..To make a New Beginning ….

"Never doubt that a small group of thoughtful, committed persons can change the world. Indeed, it's the only thing that ever has."

Annexure - 1

Catheter-Associated Urinary Tract Infection (CAUTI) Event

Introduction: Urinary tract infections (UTIs) are tied with pneumonia as the second most common type of healthcare-associated infection, second only to SSIs. UTIs account for more than 15% of infections reported by acute care hospitals[1]. Virtually all healthcare-associated UTIs are caused by instrumentation of the urinary tract.

CAUTI can lead to such complications as cystitis, pyelonephritis, gram-negative bacteremia, prostatitis, epididymitis, and orchitis in males and, less commonly, endocarditis, vertebral osteomyelitis, septic arthritis, endophthalmitis, and meningitis in all patients. Complications associated with CAUTI cause discomfort to the patient, prolonged hospital stay, and increased cost and mortality[2]. Each year, more than 13,000 deaths are associated with UTIs.[3]

Prevention of CAUTIs is discussed in the CDC/HICPAC document, *Guideline for Prevention of Catheter-associated Urinary Tract Infection*[4].

Settings: Surveillance will occur in any inpatient locations where denominator data can be collected, which may include critical intensive care units (ICU), specialty care areas (SCA), step down units, and long term care wards. Neonatal ICUs may participate, but only off plan (not as a part of their monthly reporting plan). A complete listing of inpatient locations and instructions for mapping can be found in CDC Locations and Descriptions chapter.

NOTE: It is not required to monitor for CAUTIs after the patient is discharged from the facility. However, if discovered, any CAUTI occurring on the day of discharge or the next day should be reported to NHSN; day of discharge is considered Day 1. No additional indwelling catheter days are reported.

Requirements: Surveillance for HAI CAUTI is performed in at least one inpatient location in the healthcare institution for at least one calendar month as indicated in the *Patient Safety Monthly Reporting Plan* (CDC 57.106).

Definitions:

Healthcare-associated infections (HAI): An infection is considered an HAI if all elements of a CDC/NHSN site-specific infection criterion were first present together on or after the 3rd hospital day (day of hospital admission is day 1). For an HAI, an element of the infection criterion may be present during the first 2 hospital days as long as it is also present on or after day 3. All elements used to meet the infection criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between elements.

Urinary tract infections (UTI) are defined using symptomatic urinary tract infection (SUTI) criteria or Asymptomatic Bacteremic UTI (ABUTI) criteria (Table 1 and Figures 1-5).

Date of event: For a UTI the date of event is the date when the last element used to meet the UTI infection criterion occurred. Synonyms: infection date, date of infection.

Indwelling catheter: A drainage tube that is inserted into the urinary bladder through the urethra is left in place, and is connected to a drainage bag (including leg bags), also called a Foley catheter. This does not include suprapubic, condom, or straight in-and-out catheters. This definition includes indwelling urethral catheters that are used for intermittent or continuous irrigation.

Catheter-associated UTI (CAUTI): A UTI where an indwelling urinary catheter was in place for >2 calendar days when all elements of the UTI infection criterion were first present together, with day of device placement being Day 1,
and
an indwelling urinary catheter was in place on the date of event or the day before.

EXAMPLE: A patient has a Foley catheter inserted on an inpatient unit and the following morning the patient meets criteria for a UTI. Because the catheter has not been in place >2 calendar days when all elements of the infection criterion were first present together, this is not a CAUTI.

NOTE:

1. SUTI 1b and 2b and other UTI (OUTI), as defined in the HAI Definitions chapter cannot be catheter-associated.

Location of attribution: The inpatient location where the patient was assigned on the date of the UTI event, which is further defined as the date when the last element used to meet the UTI criterion occurred (see exception below).

EXCEPTION TO LOCATION OF ATTRIBUTION:
Transfer Rule: If all elements of a CAUTI are present within 2 calendar days of transfer from one inpatient location to another in the same facility or a new facility (i.e., on the day of transfer or the next day), the infection is attributed to the transferring location or facility. Receiving facilities should share information about such HAIs with the transferring facility to enable reporting. This is called the Transfer Rule and examples are shown below:

- Patient with a Foley catheter in place in the SICU is transferred to the surgical ward. On the next day, all elements for UTI are first present together. This is reported to NHSN as a CAUTI for the SICU.
- Patient is transferred in the morning to the medical ward from the MSICU after having the Foley catheter removed. Later that night, all elements for a UTI are first present together. This is reported to NHSN as a CAUTI for the MSICU.

- On Monday, patient with a Foley catheter in place is transferred from the medical ward to the coronary care ICU (CCU). Wednesday in the CCU, all elements for UTI are first present together. This is reported to NHSN as a CAUTI for the CCU, as the UTI event date is on the 3rd calendar day after transfer.
- Patient on the urology ward of Hospital A had the Foley catheter removed after it had been in place for 5 days and is discharged home a few hours later. The IP from Hospital B calls the next day to report that this patient has been admitted to Hospital B with a UTI. This CAUTI should be reported to NHSN for Hospital A and attributed to the urology ward.

EXCEPTION TO TRANSFER RULE:
Locations which do not house patients overnight (e.g., Emergency Department or Operating Room) will have no denominator data, i.e., patient days or catheter days. Therefore, CAUTIs cannot be attributed to these locations. Instead, the CAUTI must be attributed to the next inpatient location in which the patient stays.

Table 1. ***Urinary Tract Infection Criteria***

Criterion	Urinary Tract Infection (UTI)
	Symptomatic UTI (SUTI) Must meet at least 1 of the following criteria:
1a	Patient had an indwelling urinary catheter in place for >2 calendar days, with day of device placement being Day 1, and catheter was in place when all elements of this criterion were first present together. *and* at least 1 of the following signs or symptoms: fever (>38°C); suprapubic tenderness*****; costovertebral angle pain or tenderness***** *and* a positive urine culture of $\geq 10^5$ colony-forming units (CFU)/ml with no more than 2 species of microorganisms. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day (see Comments section below). ----------OR---------- Patient had an indwelling urinary catheter in place for >2 calendar days and had it removed the day of or the day before all elements of this criterion were first present together *and* at least 1 of the following signs or symptoms: fever (>38°C); urgency*****; frequency*****; dysuria*****; suprapubic tenderness*****; costovertebral angle pain or tenderness***** *and* a positive urine culture of $\geq 10^5$ colony-forming units (CFU)/ml with no more than 2 species of microorganisms. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day (see Comments section below). *****With no other recognized cause
1b	Patient did <u>not</u> have an indwelling urinary catheter in place at the time of or the day before all elements of this criterion were first present together *and* has at least 1 of the following signs or symptoms: fever (>38°C) in a patient that is ≤65 years of age; urgency*****; frequency*****; dysuria*****; suprapubic tenderness*****; costovertebral angle pain or tenderness***** *and* a positive urine culture of $\geq 10^5$ CFU/ml with no more than 2 species of microorganisms. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day (see Comments section below). *****With no other recognized cause

Criterion	Urinary Tract Infection (UTI)
2a	Patient had an indwelling urinary catheter in place for >2 calendar days, with day of device placement being Day 1, and catheter was in place when all elements of this criterion were first present together *and* at least 1 of the following signs or symptoms: fever (>38°C); suprapubic tenderness*****; costovertebral angle pain or tenderness***** *and* at least 1 of the following findings: a. positive dipstick for leukocyte esterase and/or nitrite b. pyuria (urine specimen with ≥10 white blood cells [WBC]/mm^3 of unspun urine or >5 WBC/high power field of spun urine) c. microorganisms seen on Gram's stain of unspun urine *and* a positive urine culture of ≥10^3 and <10^5 CFU/ml with no more than 2 species of microorganisms. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day (see Comments section below). ----------OR---------- Patient with an indwelling urinary catheter in place for > 2 calendar days and had it removed the day of or the day before all elements of this criterion were first present together *and* at least 1 of the following signs or symptoms: fever (>38°C); urgency*****; frequency*****; dysuria*****; suprapubic tenderness*****; costovertebral angle pain or tenderness***** *and* at least 1 of the following findings: a. positive dipstick for leukocyte esterase and/or nitrite b. pyuria (urine specimen with ≥10 WBC/mm^3 of unspun urine or >5 WBC/high power field of spun urine c. microorganisms seen on Gram's stain of unspun urine *and* a positive urine culture of ≥10^3 and <10^5 CFU/ml with no more than 2 species of microorganisms. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day (see Comments section below). *****With no other recognized cause

Criterion	Urinary Tract Infection (UTI)
2b	Patient did not have an indwelling urinary catheter in place at the time of, or the day before all elements of this criterion were first present together *and* has at least 1 of the following signs or symptoms: fever (>38°C) in a patient that is ≤65 years of age; urgency*****; frequency*****; dysuria*****; suprapubic tenderness*****; costovertebral angle pain or tenderness* *and* at least 1 of the following findings: a. positive dipstick for leukocyte esterase and/or nitrite b. pyuria (urine specimen with ≥10 WBC/mm^3 of unspun urine or >5 WBC/high power field of spun urine c. microorganisms seen on Gram's stain of unspun urine *and* a positive urine culture of ≥10^3 and <10^5 CFU/ml with no more than 2 species of microorganisms. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day (see Comments section below). *****With no other recognized cause
3	Patient ≤1 year of age with****** or without an indwelling urinary catheter has at least 1 of the following signs or symptoms: fever (>38°C core); hypothermia (<36°C core); apnea*****; bradycardia*****; dysuria*****; lethargy*****; vomiting* *and* a positive urine culture of ≥10^5 CFU/ml with no more than 2 species of microorganisms. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day (see Comments section below). *****With no other recognized cause ****** Patient had an indwelling urinary catheter in place for >2 calendar days, with day of device placement being Day 1, and catheter was in place when all elements of this criterion were first present together.
4	Patient ≤1 year of age with****** or without an indwelling urinary catheter has at least 1 of the following signs or symptoms: fever (>38°C core); hypothermia (<36°C core); apnea*****; bradycardia*****; dysuria*****; lethargy*****; vomiting***** *and* at least 1 of the following findings: a. positive dipstick for leukocyte esterase and/or nitrite b. pyuria (urine specimen with ≥10 WBC/mm^3 of unspun urine or >5 WBC/high power field of spun urine c. microorganisms seen on Gram's stain of unspun urine *and* a positive urine culture of between ≥10^3 and <10^5 CFU/ml with no more than two species of microorganisms. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day (see Comments section

Criterion	Urinary Tract Infection (UTI)
	below). *****With no other recognized cause ****** Patient had an indwelling urinary catheter in place for >2 calendar days, with day of device placement being Day 1, and catheter was in place when all elements of this criterion were first present together.

Criterion	Asymptomatic Bacteremic Urinary Tract Infection (ABUTI)
	Patient with* or without an indwelling urinary catheter has no signs or symptoms (i.e., for any age patient, no fever (>38°C); urgency; frequency; dysuria; suprapubic tenderness; costovertebral angle pain or tenderness OR for a patient ≤1 year of age; no fever (>38°C core); hypothermia (<36°C core); apnea; bradycardia; dysuria; lethargy; or vomiting) *and* a positive urine culture of ≥10^5 CFU/ml with no more than 2 species of uropathogen microorganisms** (see Comments section below) *and* a positive blood culture with at least 1 matching uropathogen microorganism to the urine culture, or at least 2 matching blood cultures drawn on separate occasions if the matching pathogen is a common skin commensal. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day (see Comments section below). *Patient had an indwelling urinary catheter in place for >2 calendar days, with day of device placement being Day 1, and catheter was in place when all elements of this criterion were first present together. **Uropathogen microorganisms are: Gram-negative bacilli, *Staphylococcus spp.*, yeasts, beta-hemolytic *Streptococcus spp*., *Enterococcus spp*., *G. vaginalis*, *Aerococcus urinae*, and *Corynebacterium* (urease positive)[+]. [+]Report *Corynebacterium* (urease positive) as either *Corynebacterium species unspecified (COS*) or as *C. urealyticum* (CORUR) if so speciated. (See complete list of uropathogen microorganisms at http://www.cdc.gov/nhsn/XLS/master-organism-Com-Commensals-Lists.xlsx.)
Comments	• Laboratory cultures reported as "mixed flora" represent at least 2 species of organisms. Therefore an additional organism recovered from the same culture, would represent >2 species of microorganisms. Such a specimen cannot be used to meet the UTI criteria. • Urinary catheter tips should not be cultured and are not acceptable for the diagnosis of a urinary tract infection. • Urine cultures must be obtained using appropriate technique, such as clean catch collection or catheterization. Specimens from indwelling catheters should be aspirated through the disinfected sampling ports. • In infants, urine cultures should be obtained by bladder catheterization or suprapubic aspiration; positive urine cultures from bag specimens are unreliable and should be confirmed by specimens aseptically obtained by catheterization or suprapubic aspiration. • Urine specimens for culture should be processed as soon as possible, preferably within 1 to 2 hours. If urine specimens cannot be processed within 30 minutes of collection, they should be refrigerated, or inoculated into primary isolation medium before transport, or transported in an appropriate

	urine preservative. Refrigerated specimens should be cultured within 24 hours. • Urine specimen labels should indicate whether or not the patient is symptomatic. • Report secondary bloodstream infection = "Yes" for all cases of Asymptomatic Bacteremic Urinary Tract Infection (ABUTI). • Report only pathogens in both blood and urine specimens for ABUTI. • Report *Corynebacterium* (urease positive) as either *Corynebacterium species* unspecified (COS) or as *C. urealyticum* (CORUR) if speciated.

Figure 1: Identification and Categorization of SUTI with Indwelling Catheter (see comments section page 7-7 thru 7-8 for important details)

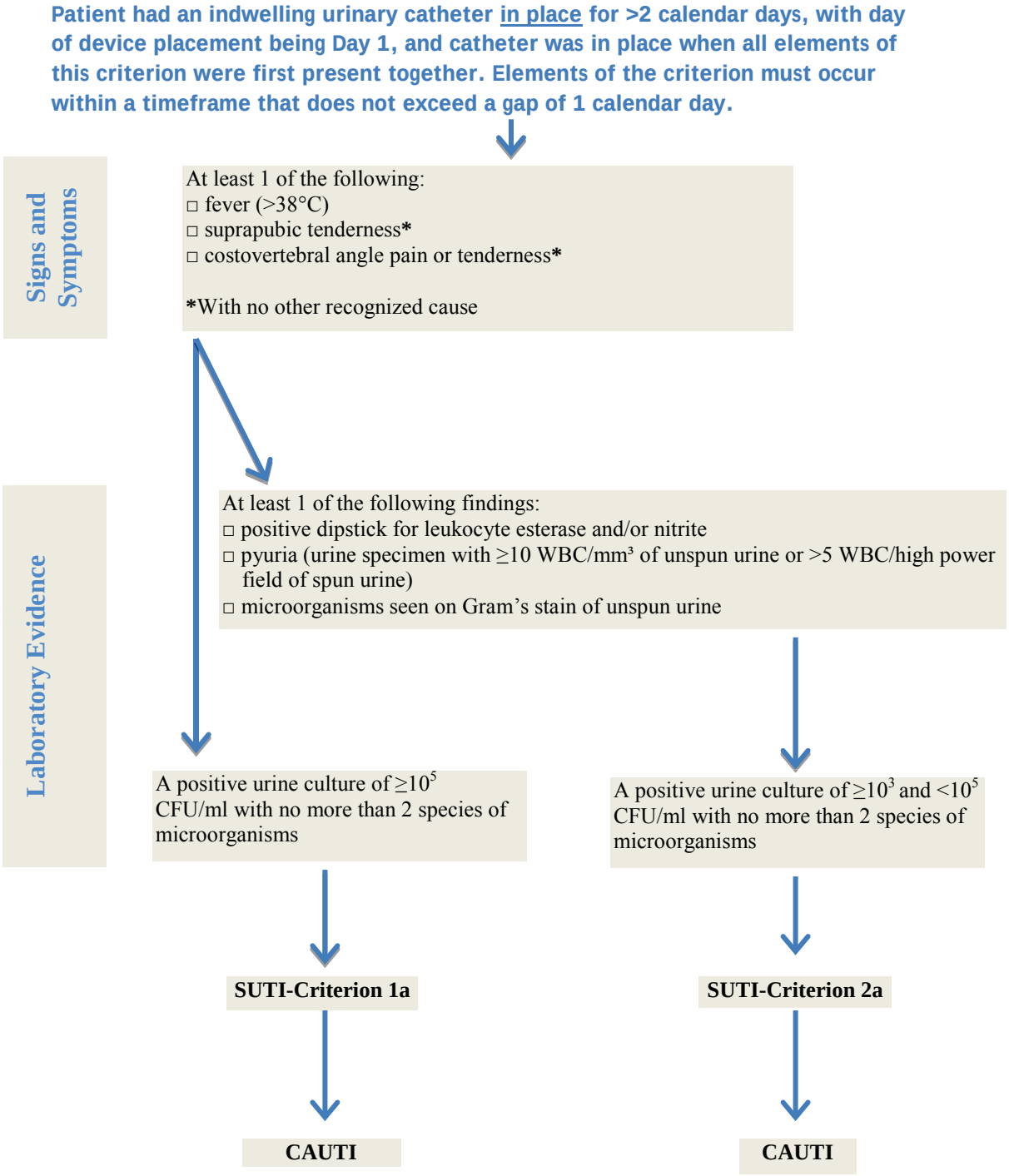


Figure 2: Identification and Categorization of SUTI When Indwelling Catheter has been removed (see comments section page 7-7 thru 7-8 for important details)

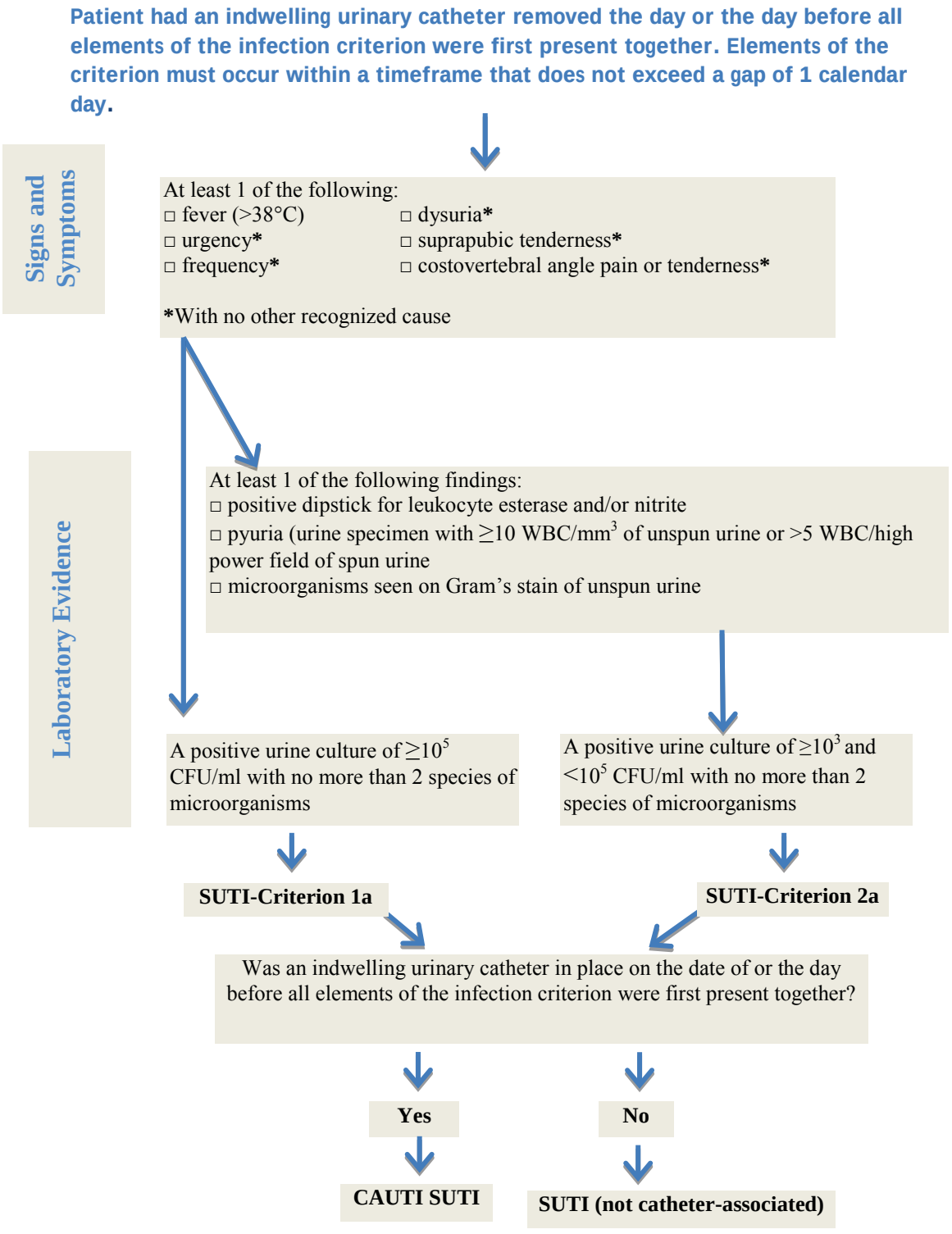


Figure 3: Identification and Categorization of SUTI without Indwelling Catheter (see comments section page 7-7 thru 7-8 for important details)

Patient did not have an indwelling urinary catheter in place at the time of, or the day before all elements of this criterion were first present together. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day.

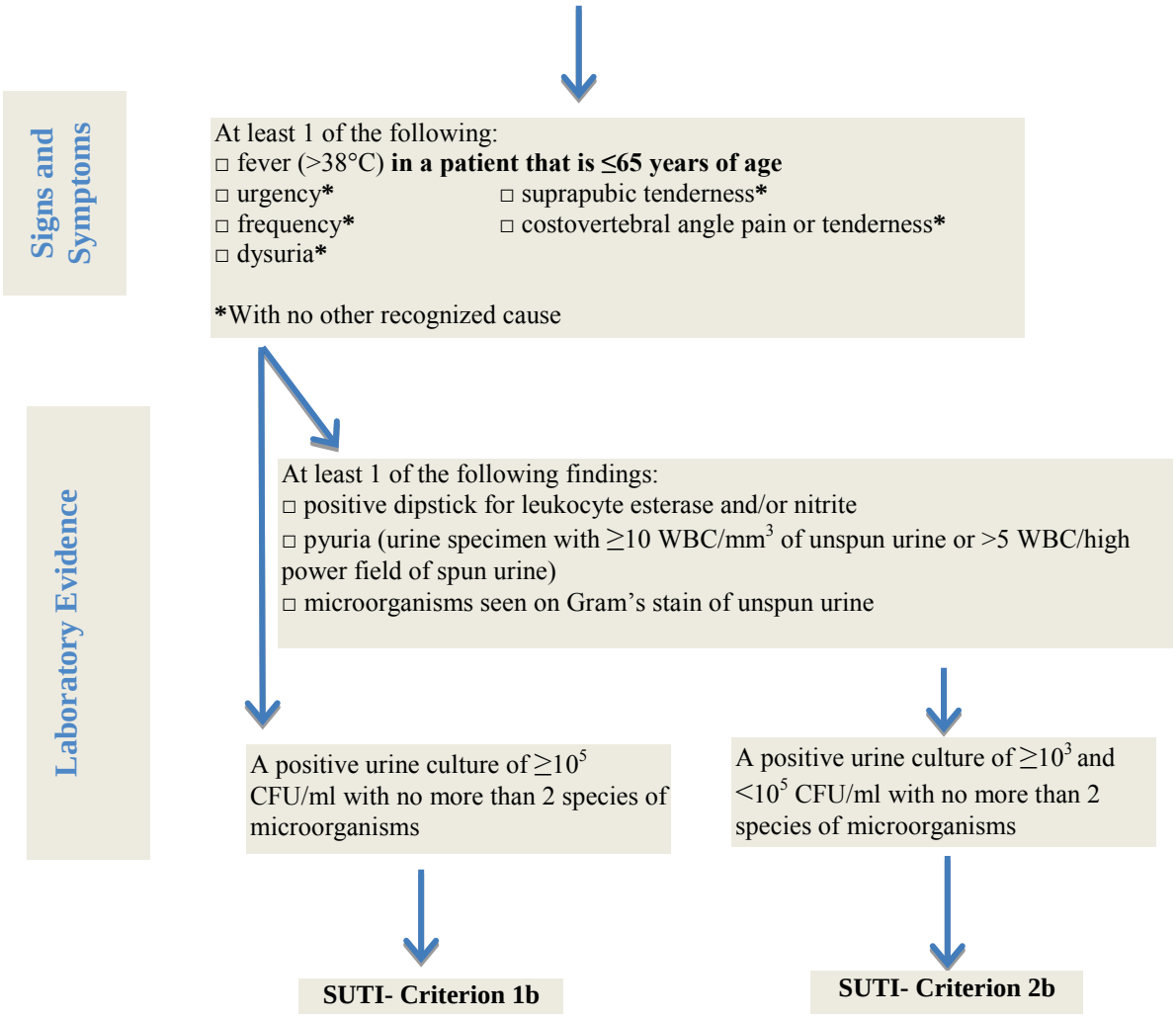
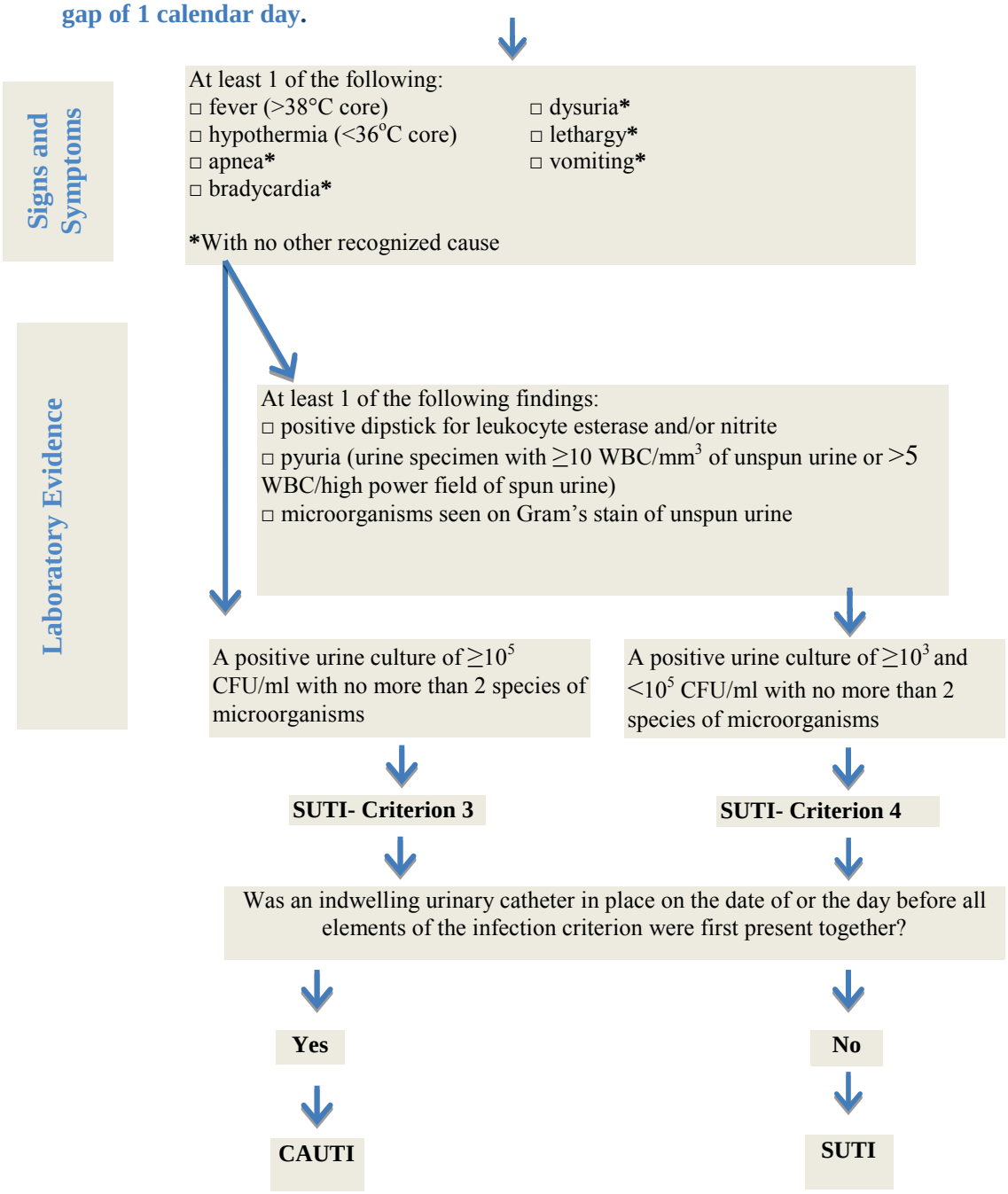
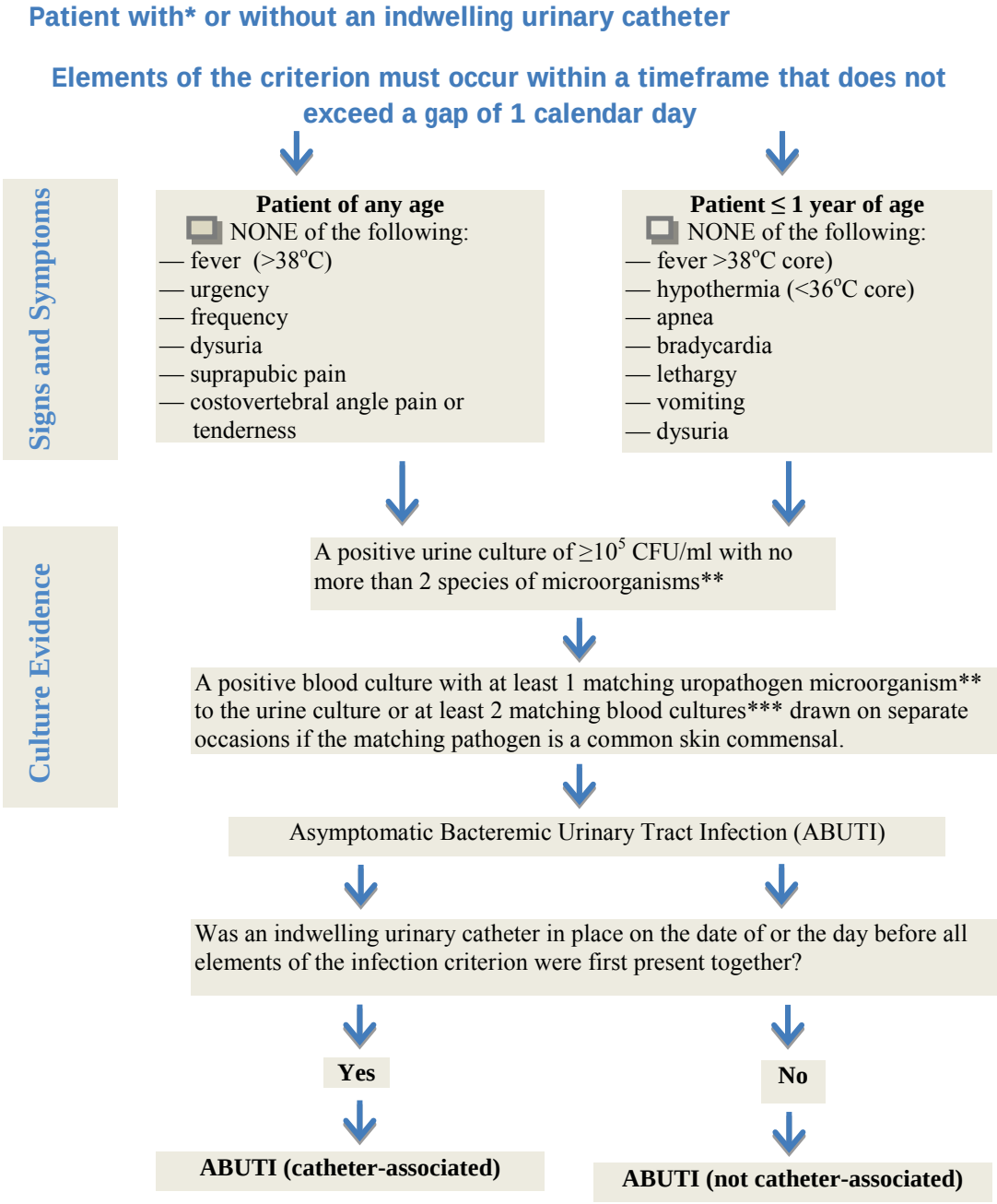


Figure 4: Identification and Categorization of SUTI in Patient ≤1 Year of Age (see comments section page 7-7 thru 7-8 for important details)



** Patient had an indwelling urinary catheter in place for >2 calendar days, with day of device placement being Day 1, and catheter was in place when all elements of this criterion were first present together.

Figure 5: Identification of Asymptomatic Bacteremic Urinary Tract Infection (ABUTI)
(see comments section page 7-7 thru 7-8 for important details)



* Patient had an indwelling urinary catheter in place for >2 calendar days, with day of device placement being Day 1, and catheter was in place when all elements of this criterion were first present together.

**Uropathogen microorganisms are: Gram-negative bacilli, *Staphylococcus* spp., yeasts, beta-hemolytic *Streptococcus* spp., *Enterococcus* spp., *G. vaginalis*, *Aerococcus urinae*, *Corynebacterium* (urease positive)[†].

Only genus and species identification should be utilized to determine the sameness of organisms (i.e. matching organisms). No additional comparative methods should be used (e.g., morphology or antibiograms) because laboratory testing capabilities and protocols may vary between facilities.

Numerator Data: The *Urinary Tract Infection (UTI)* form is used to collect and report each CAUTI that is identified during the month selected for surveillance. The Instructions for Completion of Urinary Tract Infection form include brief instructions for collection and entry of each data element on the form. The UTI form includes patient demographic information and information on whether or not an indwelling urinary catheter was present. Additional data include the specific criteria met for identifying the UTI, whether the patient developed a secondary bloodstream infection, whether the patient died, and the organisms isolated from cultures and their antimicrobial susceptibilities.

REPORTING INSTRUCTIONS:

- If no CAUTIs are identified during the month of surveillance, the Report No Events box must be checked on the appropriate denominator summary screen, e.g., *Denominators for Intensive Care Unit (ICU)/Other Locations (Not NICU or SCA/ONC).*

Denominator Data: Device days and patient days are used for denominators (See Key Terms chapter). Indwelling urinary catheter days, which are the number of patients with an indwelling urinary catheter device, are collected daily, at the same time each day, according to the chosen location using the appropriate form (CDC 57.117 and 57.118). These daily counts are summed and only the total for the month is entered into NHSN. Indwelling urinary catheter days and patient days are collected separately for each of the locations monitored. When denominator data are available from electronic databases, these sources may be used as long as the counts are not substantially different (+/- 5%) from manually collected counts, validated for a minimum of 3 months.

Data Analyses: The Standardized Infection Ratio (SIR) is calculated by dividing the number of observed infections by the number of expected infections. The number of expected infections, in the context of statistical prediction, is calculated using CAUTI rates from a standard population during a baseline time period, which represents a standard population's CAUTI experience.[5]

NOTE: The SIR will be calculated only if the number of expected HAIs (numExp) is ≥1.

$$\text{SIR} = \frac{\text{Observed (O) HAIs}}{\text{Expected (E) HAIs}}$$

While the CAUTI SIR can be calculated for single locations, the measure also allows you to summarize your data by multiple locations, adjusting for differences in the incidence of infection among the location types. For example, you will be able to obtain one CAUTI SIR adjusting for all locations reported. Similarly, you can obtain one CAUTI SIR for all specialty care areas in your facility.

The CAUTI rate per 1000 urinary catheter days is calculated by dividing the number of CAUTIs by the number of catheter days and multiplying the result by 1000. The Urinary Catheter Utilization Ratio is calculated by dividing the number of urinary catheter days by the number of patient days. These calculations will be performed separately for the different types of ICUs, specialty care areas, and other locations in the institution, except for neonatal locations.

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[1]Magill SS, Hellinger W, et al. Prevalence of healthcare-associated infections in acute care facilities. Infect Control Hosp Epidemiol. 2012;33:283-91.

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Annexure - 2

Central Line-Associated Bloodstream Infection (CLABSI) Event

Introduction: An estimated 41,000 central line-associated bloodstream infections (CLABSI) occur in U.S. hospitals each year.[1] These infections are usually serious infections typically causing a prolongation of hospital stay and increased cost and risk of mortality.

CLABSI can be prevented through proper insertion techniques and management of the central line. These techniques are addressed in the CDC's Healthcare Infection Control Practices Advisory Committee (CDC/HIPAC) *Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011*.[2]

Settings: Surveillance will occur in any inpatient location where denominator data can be collected, which may include critical/intensive care units (ICU), specialty care areas (SCA), neonatal units including neonatal intensive care units (NICUs), step down units, wards, and long term care units. A complete listing of inpatient locations and instructions for mapping can be found in the CDC Locations and Descriptions chapter.

NOTE: Surveillance for CLABSIs after the patient is discharged from the facility is not required. However, if discovered, any CLABSIs occurring on the day of discharge or the next day, should be reported to NHSN (see Transfer Rule). No additional central line days are reported.

Requirements: Surveillance for HAI CLABSI is performed in at least one inpatient location in the healthcare institution for at least one calendar month as indicated in the *Patient Safety Monthly Reporting Plan* (CDC 57.106).

Definitions:

Healthcare-associated infections (HAI): An infection is considered an HAI if all elements of a CDC/NHSN site-specific infection criterion were first present together on or after the 3rd hospital day (day of hospital admission is Day 1). For an HAI, an element of the infection criterion may be present during the first 2 hospital days as long as it is also present on or after Day 3. All elements used to meet the infection criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between elements.

Primary bloodstream infections (BSI) are laboratory-confirmed bloodstream infections (LCBI) that are not secondary to an infection at another body site (see Appendix 1. Secondary Bloodstream Infection (BSI) Guide and HAI Definitions chapter).

Date of event: For a BSI the date of event is the date when the last element used to meet the laboratory-confirmed bloodstream infection (LCBI) criterion occurred. Synonyms: infection date, date of infection.

Central line: An intravascular catheter that terminates at or close to the heart or in one of the great vessels which is used for infusion, withdrawal of blood, or hemodynamic monitoring. The following are considered great vessels for the purpose of reporting central-line BSI and counting central-line days in the NHSN system:

- Aorta
- Pulmonary artery
- Superior vena cava
- Inferior vena cava
- Brachiocephalic veins
- Internal jugular veins
- Subclavian veins
- External iliac veins
- Common iliac veins
- Femoral veins
- In neonates, the umbilical artery/vein.

NOTES:

1. Neither the insertion site nor the type of device may be used to determine if a line qualifies as a central line. The device must terminate in one of the great vessels or in or near the heart and be used for one of the purposes outlined above, to qualify as a central line.
2. An introducer is considered an intravascular catheter, and depending on the location of its tip and use, may be a central line.
3. Pacemaker wires and other nonlumened devices inserted into central blood vessels or the heart are not considered central lines, because fluids are not infused, pushed, nor withdrawn through such devices.
4. The following devices are not considered central lines:
    - Extracorporeal membrane oxygenation (ECMO)
    - Femoral arterial catheters
    - Intraaortic balloon pump (IABP) devices.

Infusion: The introduction of a solution through a blood vessel via a catheter lumen. This may include continuous infusions such as nutritional fluids or medications, or it may include intermittent infusions such as flushes, IV antimicrobial administration, or blood transfusion or hemodialysis.

Umbilical catheter: A central vascular device inserted through the umbilical artery or vein in a neonate.

Temporary central line: A non-tunneled or implanted catheter.
Permanent central line: Includes

- Tunneled catheters, including certain dialysis catheters
- Implanted catheters (including ports)

Central line-associated BSI (CLABSI): A laboratory-confirmed bloodstream infection (LCBI) where central line (CL) or umbilical catheter (UC) was in place for >2 calendar days when all elements of the LCBI infection criterion were first present together, with day of device placement being Day 1,
and
a CL or UC was in place on the date of event or the day before. If the patient is admitted or transferred into a facility with a central line in place (e.g., tunneled or implanted central line), day of first access is considered Day1.

EXAMPLES:

- Patient in MICU has central line inserted/accessed on June 1. On June 3, the central line is still in place and the patient has positive blood culture with *S. aureus*. This is a CLABSI because the central line was in place for >2 calendar days when all elements of LCBI Criterion 1 were first present together.
- Patient has a central line inserted on June 1. On June 3, the central line is discontinued and on June 4 the patient has a positive blood culture with *S. aureus*. This is a CLABSI because the central line was in place for >2 calendar days (June 1, 2, and 3) and was in place the day before all elements of LCBI Criterion 1 were first present together.
- On June 3, central line is discontinued and on June 4 patient spikes a fever of 38.3°C. Two blood culture sets collected on June 5 are positive for *S. epidermidis*. This is may be a healthcare-associated bloodstream infection but it is not a CLABSI because the central line was not place the day of or the day before all elements of LCBI Criterion 2 were first present together (June 5).

Location of attribution: The inpatient location where the patient was assigned on the date of the BSI event, which is further defined as the date when the last element used to meet the BSI criterion occurred (see exception below).

NOTE:
When hemodialysis through a central line is provided by contracted staff members who are not employees of the facility, CLABSIs that are identified in these patients are attributed to the inpatient location where the patient was assigned. Facilities are responsible for the care provided within their confines and infection prevention issues related to contracted staff or their agencies should be addressed by the facility.

EXCEPTION TO LOCATION OF ATTRIBUTION:
Transfer Rule: If all elements of a CLABSI are present within 2 calendar days of transfer from one inpatient location to another in the same facility or a new facility (i.e., on the day of transfer or the next day), the infection is attributed to the transferring location or facility. Receiving facilities should share information about such HAIs with the transferring facility to enable reporting. This is called the Transfer Rule and examples are shown below:

- Patient with a central line in place in the SICU is transferred to the surgical ward. On the next day, all elements of LCBI are first present together. This is reported to NHSN as a CLABSI for the SICU.

- Patient without a central line is transferred from the medical ward to MICU. Later that day a central line is inserted. The next day, all elements of LCBI are first present together. This would be considered a BSI and attributed to the medical ward; however, it is not a CLABSI because the central line was not in place >2 days before all elements of LCBI were first present together.
- Patient with a central line in place is transferred from the medical ward to the coronary care ICU (CCU). After 4 days in the CCU and with the central line still in place, all elements of LCBI are first present together. This is reported to NHSN as a CLABSI for the CCU.
- Patient on the urology ward of Hospital A had the central line removed and is discharged home a few hours later. The IP from Hospital B calls the next day to report that this patient has been admitted to Hospital B and meets all elements of LCBI criteria. This CLABSI should be reported to NHSN for, and by, Hospital A and attributed to the urology ward.

EXCEPTION TO TRANSFER RULE:
Locations which do not house patients overnight (e.g., Emergency Department or Operating Room) will have no denominator data, i.e., patient days or central line days. Therefore, CLABSIs cannot be attributed to these locations. Instead, the CLABSI must be attributed to the next inpatient location in which the patient stays.

EXAMPLE:

- Patient, who had no clinical signs or symptoms of sepsis upon arrival to the Emergency Department, has a central line inserted there and then is admitted to the MICU on the same day. All elements of LCBI are first present together on MICU Day 3. This is reported as a CLABSI for the MICU because all elements of LCBI are first present together >2 calendar days after hospital admission and the central line was in place for >2 calendar days.

Table 1. ***Laboratory-Confirmed Bloodstream Infection Criteria***

Criterion	Laboratory-Confirmed Bloodstream Infection (LCBI) *Comments and reporting instructions that follow the site-specific criteria provide further explanation and are integral to the correct application of the criteria.* Must meet one of the following criteria:
LCBI 1	Patient has a recognized pathogen cultured from one or more blood cultures *and* organism cultured from blood is not related to an infection at another site.
LCBI 2	Patient has at least one of the following signs or symptoms: fever (>38°C), chills, or hypotension *and* positive laboratory results are not related to an infection at another site *and* common commensal (i.e., diphtheroids [*Corynebacterium* spp. not *C. diphtheriae*], *Bacillus* spp. [not *B. anthracis*], *Propionibacterium* spp., coagulase-negative staphylococci [including *S. epidermidis*], viridans group streptococci, *Aerococcus* spp., and *Micrococcus* spp.) is cultured from two or more blood cultures drawn on separate occasions. Criterion elements must occur within a timeframe that does not exceed a gap of 1 calendar day. (See complete list of common commensals at http://www.cdc.gov/nhsn/XLS/master-organism-Com-Commensals-Lists.xls)
LCBI 3	Patient ≤ 1 year of age has at least one of the following signs or symptoms: fever (>38°C core) hypothermia (<36°C core), apnea, or bradycardia *and* positive laboratory results are not related to an infection at another site *and* common skin commensal (i.e., diphtheroids [*Corynebacterium* spp. not *C. diphtheriae*], *Bacillus* spp. [not *B. anthracis*], *Propionibacterium* spp., coagulase-negative staphylococci [including *S. epidermidis*], viridans group streptococci, *Aerococcus* spp., *Micrococcus* spp.) is cultured from two or more blood cultures

	drawn on separate occasions. Criterion elements must occur within a timeframe that does not exceed a gap of 1 calendar day. (See complete list of common commensals at http://www.cdc.gov/nhsn/XLS/master-organism-Com-Commensals-Lists.xlsx)
Criterion	**Mucosal Barrier Injury Laboratory-Confirmed Bloodstream Infection (MBI-LCBI)** *In 2013 when reporting an LCBI, it is optional to indicate which of the underlying conditions of the MBI-LCBI criterion was met, if any. However, all CLABSI, whether LCBI or MBI-LCBI, must be reported if CLABSI is part of your Monthly Reporting Plan.* Must meet one of the following criteria:
MBI-LCBI 1	Patient of any age meets criterion 1 for LCBI with at least one blood culture growing any of the following intestinal organisms with no other organisms isolated: *Bacteroides* spp., *Candida* spp., *Clostridium* spp., *Enterococcus* spp., *Fusobacterium* spp., *Peptostreptococcus* spp., *Prevotella* spp., *Veillonella* spp., or Enterobacteriaceae* *and* patient meets at least one of the following: 1. Is an allogeneic hematopoietic stem cell transplant recipient within the past year with one of the following documented during same hospitalization as positive blood culture: a. Grade III or IV gastrointestinal graft versus host disease (GI GVHD) b. ≥1 liter diarrhea in a 24-hour period (or ≥20 mL/kg in a 24-hour period for patients <18 years of age) with onset on or within 7 calendar days before the date the positive blood culture was collected. 2. Is neutropenic, defined as at least 2 separate days with values of absolute neutrophil count (ANC) or total white blood cell count (WBC) <500 cells/mm^3 on or within 3 calendar days before the date the positive blood culture was collected (Day 1). (See Table 4 for example.) *See Table 3 for partial list of eligible Enterobacteriaceae genera.
MBI-LCBI 2	Patient of any age meets criterion 2 for LCBI when the blood cultures are growing only viridans group streptococci with no other organisms isolated *and* patient meets at least one of the following:

	1. Is an allogeneic hematopoietic stem cell transplant recipient within the past year with one of the following documented during same hospitalization as positive blood culture: a. Grade III or IV gastrointestinal graft versus host disease (GI GVHD) b. ≥1 liter diarrhea in a 24-hour period (or ≥20 mL/kg in a 24-hour period for patients <18 years of age) with onset on or within 7 calendar days before the date the first positive blood culture was collected. 2. Is neutropenic, defined as at least 2 separate days with values of absolute neutrophil count (ANC) or total white blood cell count (WBC) <500 cells/mm^3 on or within 3 calendar days before the date the positive blood culture was collected (Day 1). (See Table 4 for example.)
MBI-LCBI 3	Patient ≤1 year of age meets criterion 3 for LCBI when the blood cultures are growing only viridans group streptococci <u>with no other organisms isolated</u> *and* patient meets at least one of the following: 1. Is an allogeneic hematopoietic stem cell transplant recipient within the past year with one of the following documented during same hospitalization as positive blood culture: a. Grade III or IV gastrointestinal graft versus host disease (GI GVHD) b. ≥20 mL/kg in a 24-hour period with onset on or within 7 calendar days before the date the first positive blood culture is collected. 2. Is neutropenic, defined as at least 2 separate days with values of absolute neutrophil count (ANC) or total white blood cell count (WBC) <500 cells/mm^3 on or within 3 calendar days before the date the positive blood culture was collected (Day 1). (See Table 4 for example.)
Comments	1. In LCBI criterion 1, the phrase "one or more blood cultures" means that at least one bottle from a blood draw is reported by the laboratory as having grown at least one organism (i.e., is a positive blood culture). 2. In LCBI criterion 1, the term "recognized pathogen" does not include organisms considered common commensals (see criteria 2 and 3 for the list of common commensals). A few of the recognized pathogens are *S. aureus*, *Enterococcus* spp., *E. coli*, *Pseudomonas* spp., *Klebsiella* spp., *Candida spp*., etc. 3. In LCBI criteria 2 and 3, the phrase "two or more blood cultures drawn on separate occasions" means 1) that blood from at least

two blood draws were collected within two calendar days of each other (e.g., blood draws on Monday and Tuesday would be acceptable for blood cultures drawn on separate occasions, but blood draws on Monday and Wednesday would be too far apart in time to meet this criterion), and 2) that at least one bottle from each blood draw is reported by the laboratory as having grown the same common commensal (i.e., is a positive blood culture). (See Comment 4 for determining sameness of organisms.)

a. For example, an adult patient has blood drawn at 8 a.m. and again at 8:15 a.m. of the same day. Blood from each blood draw is inoculated into two bottles and incubated (four bottles total). If one bottle from each blood draw set is positive for coagulase-negative staphylococci, this part of the criterion is met.
b. For example, a neonate has blood drawn for culture on Tuesday and again on Thursday and both grow the same common commensal. Because the time between these blood cultures exceeds the 2-day period for blood draws stipulated in LCBI and MBI-LCBI criteria 2 and 3, this part of the criterion is not met.
c. "Separate occasions" also means blood draws collected from separate sites or separate accesses of the same site, such as two draws from a single lumen catheter or draws from separate lumens of a catheter. In the latter case, the draws may be just minutes apart (i.e., just the time it takes to disinfect and draw the specimen from each lumen). For example, a patient with a triple lumen central line has blood drawn from each lumen within 15 minutes of each other. Each of these is considered a separate blood draw.
d. A blood culture may consist of a single bottle for a pediatric blood draw due to volume constraints. Therefore, to meet this part of the criterion, each bottle from two or more draws would have to be culture-positive for the same commensal.

4. If the pathogen or common commensal is identified to the species level from one blood culture, and a companion blood culture is identified with only a descriptive name (e.g., to the genus level), then it is assumed that the organisms are the same. The organism identified to the species level should be reported as the infecting organism along with its antibiogram if available (see Table 2 below).
5. Only genus and species identification should be utilized to determine the sameness of organisms (i.e., matching organisms). No additional comparative methods should be used

	(e.g., morphology or antibiograms) because laboratory testing capabilities and protocols may vary between facilities. This will reduce reporting variability, solely due to laboratory practice, between facilities reporting LCBIs meeting criterion 2. Report the organism to the genus/species level only once, and if antibiogram data are available, report the results from the most resistant panel. 6. LCBI criteria 1 and 2 and MCI-LCBI criteria 1 and 2 may be used for patients of any age, including these patients ≤1 year of age. 7. Specimen Collection Considerations: Ideally, blood specimens for culture should be obtained from two to four blood draws from separate venipuncture sites (e.g., right and left antecubital veins), not through a vascular catheter. These blood draws should be performed simultaneously or over a short period of time (i.e., within a few hours).[3,4] If your facility does not currently obtain specimens using this technique, you must still report BSIs using the criteria and comments above, but you should work with appropriate personnel to facilitate better specimen collection practices for blood cultures. 8. "No other organisms isolated" means there is not isolation in a blood culture of another recognized pathogen (e.g., *S. aureus*) or common commensal (e.g., coagulase-negative staphylococci) other than listed in MBI-LCBI criterion 1, 2 or 3 that would otherwise meet LCBI criteria. If this occurs, the infection should not be classified as MBI-LCBI. 9. Grade III/IV GI GVHD is defined as follows: • In adults: ≥1 L diarrhea/day or ileus with abdominal pain • In pediatric patients: ≥20 cc/kg/day of diarrhea
REPORTING INSTRUCTIONS	1. Report organisms cultured from blood as BSI–LCBI when no other site of infection is evident (see Appendix 1. Secondary Bloodstream Infection (BSI) Guide. 2. Catheter tip cultures are not used to determine whether a patient has a primary BSI. 3. When there is a positive blood culture and clinical signs or symptoms of localized infection at a vascular access site, but no other infection can be found, the infection is considered a primary BSI. 4. Purulent phlebitis confirmed with a positive semiquantitative culture of a catheter tip, but with either negative or no blood culture is considered a CVS-VASC, not a BSI nor an SST-SKIN or ST infection. 5. Occasionally a patient with both peripheral and central IV lines develops a primary bloodstream infection (LCBI) that can

	clearly be attributed to the peripheral line (e.g., pus at the insertion site and matching pathogen from pus and blood). In this situation, enter "Central Line = No" in the NHSN application. You should, however, include the patient's central line days in the summary denominator count. 6. If your state or facility requires that you report healthcare-associated BSIs that are not central line-associated, enter "Central Line = No" in the NHSN application when reporting these BSIs. You should, however, include all of the patient's central line days in the summary denominator count.

Table 2. ***Examples of How to Report Speciated and Unspeciated Organisms Isolated from Blood Cultures***

Culture Report	**Companion Culture Report**	**Report as…**
Coagulase-positive staphylococci	*S. aureus*	*S. aureus*
S. epidermidis	Coagulase-negative staphylococci	*S. epidermidis*
Enterococcus spp.	*E. faecium*	*E. faecium*
Bacillus spp. (not *anthracis*)	*B. cereus*	*B. cereus*
S. salivarius	Strep viridans	*S. salivarius*

Table 3. ***Partial List of Criterion 1 MBI-LCBI Eligible Enterobacteriaceae Genera***

(See complete list of MBI Pathogens at http://www.cdc.gov/nhsn/XLS/master-organism-Com-Commensals-Lists.xlsx)

Citrobacter
Enterobacter
Escherichia
Klebsiella
Proteus
Providencia
Salmonella
Serratia
Shigella
Yersina

Table 4. ***Examples Illustrating the MBI-LCBI Criteria for Neutropenia***

		Day -7	Day -6	Day -5	Day -4	Day -3	Day -2	Day -1	Day 1*	Day 2
Pt. A	WBC	100	800	400	300	ND	ND	320	400 + BC* w/ *Candida* spp. x1	230
Pt. B	ANC	ND	410	130	ND	ND	120	110	ND +BC* w/ viridans strep x2 and fever >38°C	110

ND = not done
*Day the blood specimen that was positive was collected

Patient A meets MBI-LCBI criterion 1, sub-criterion 2: Positive blood culture with intestinal organism (*Candida* spp.) and neutropenia (2 separate days of WBC <500 cells/mm^3 occurring on the date the positive blood culture was collected [Day 1, value = 400] or during the 3 days before that date [in this case, the day before or Day -1; value = 320]).

Patient B meets MBI-LCBI criterion 2, sub-criterion 2: At least 2 positive blood cultures with viridans group streptococci (in this case, 2 positive), and fever >38°C and neutropenia (2 separate days of ANC <500 cells/mm^3 occurring on the date the positive blood culture was collected [Day 1] or during the 3 days before that date [in this case, the two days before or Days -1 and -2; values = 110 and 120]).

Numerator Data: The *Primary Bloodstream Infection (BSI)* form (CDC 57.108) is used to collect and report each CLABSI that is identified during the month selected for surveillance. The Instructions for Completion of Primary Bloodstream Infection (BSI) form contains brief instructions for collection and entry of each data element on the form. The *Primary BSI* form includes patient demographic information and whether a central line was present, and, if so, the type of central line the patient had if appropriate to the location; these data will be used to calculate line-specific infection rates. Additional data include the specific criteria met for identifying the primary BSI, whether the patient died, the organisms isolated from blood cultures, and the organisms' antimicrobial susceptibilities.

REPORTING INSTRUCTION:

- If no CLABSIs are identified during the month of surveillance, the Report No Events box must be checked on the appropriate denominator summary screen, e.g., Denominators for Intensive Care Unit (ICU)/Other locations (Not NICU or SCA), etc.

Denominator Data: Device days and patient days are used for denominators (see Key Terms chapter). Device-day denominator data that are collected differ according to the location of the patients being monitored; however, they should be collected at the same time each day. When denominator data are available from electronic databases, these sources may be used as long as the counts are not substantially different (+/- 5%) from manually-collected counts, validated for a minimum of 3 months.

For locations other than specialty care areas/oncology (SCA/ONC) and NICUs, the number of patients with one or more central lines of any type is collected daily, at the same time each day, during the month and recorded on the *Denominators for Intensive Care Unit (ICU)/Other Locations (Not NICU or SCA/ONC)* form (CDC 57.118). Only the totals for the month are entered into NHSN. When denominator data are available from electronic sources (e.g., central line days from electronic charting), these sources may be used as long as the counts are not substantially different (+/- 5%) from manually-collected counts, validated for a minimum of 3 months.

For specialty care areas/oncology, the number of patients with one or more central lines is dichotomized into those with permanent central lines and those with temporary central lines on the *Denominators for Specialty Care Area (SCA)/Oncology (ONC)* form (CDC 57.117). Each is collected daily, at the same time each day. Only the totals for the month are entered into NHSN. This distinction in lines is made because permanent lines are commonly used in patients frequenting these areas and may be associated with lower rates of BSI than central lines inserted for temporary use. If a patient has both a temporary and a permanent central line, count the day only as a temporary line day. The Instructions for Completion of Denominators for Intensive Care Unit (ICU)/Other Locations (Not NICU and SCA/ONC) and Instructions for Completion of Denominators for Specialty Care Areas (SCA)/Oncology (ONC) contain brief instructions for collection and entry of each data element on the forms.

In NICUs, the number of patients with one or more central lines is stratified by birthweight in five categories since risk of BSI varies by birthweight. These data are collected on the *Denominators for Neonatal Intensive Care Unit (NICU)* form (CDC 57.116).

NOTE: The weight of the infant at the time of BSI is not used and should not be reported. For example, if a neonate weighs 1006 grams at birth but remains in the NICU for two months and has a body weight of 1650 grams when a CLABSI develops, record the birthweight of 1006 grams on the BSI form. The Instructions for Completion of Denominators for Neonatal Intensive Care Unit (NICU) form contains brief instructions for collection and entry of each data element on the forms.

Data Analyses: The Standardized Infection Ratio (SIR)[6] is calculated by dividing the number of observed infections by the number of expected infections. The number of expected infections, in the context of statistical prediction, is calculated using CLABSI rates from a standard population during a baseline time period, which represents a standard population's CLABSI experience.[7]

NOTE: The SIR will be calculated only if the number of expected HAIs (numExp) is ≥1.

$$\text{SIR} = \frac{\text{Observed (O) HAIs}}{\text{Expected (E) HAIs}}$$

While the CLABSI SIR can be calculated for single locations, the measure also allows you to summarize your data across multiple locations, adjusting for differences in the incidence of infection among the location types. For example, you will be able to obtain one CLABSI SIR adjusting for all locations reported. Similarly, you can obtain one CLABSI SIR for all specialty care areas in your facility.

The CLABSI rate per 1000 central line days is calculated by dividing the number of CLABSI by the number of central line days and multiplying the result by 1000. The Central Line Utilization Ratio is calculated by dividing the number of central line days by the number of patient days. These calculations will be performed separately for different types of ICUs, specialty care areas, and other locations in the institution. Separate rates and ratios will also be calculated for different types of catheters in specialty care areas/oncology and for birthweight categories in NICUs.

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Appendix 1. Secondary Bloodstream Infection (BSI) Guide (not applicable to Ventilator-associated Events)

What is the meaning of the statement "not related to infection at another site" in relation to a positive blood culture?

The purpose of using the CDC/NHSN infection criteria is to identify and consistently categorize infections that are healthcare-associated into major and specific infection sites or types. Several of the criteria include the caveat that signs, symptoms, and/or laboratory findings cannot be related to infection at another site. When assessing positive blood cultures in particular, one must be sure that there is no other CDC-defined primary site of HAI that may have seeded the bloodstream secondarily; otherwise the bloodstream infection may be misclassified as a primary BSI or erroneously associated with the use of a central line, i.e., called a CLABSI.

Below are listed several scenarios that may occur with guidance on how to distinguish between the primary or secondary nature of a BSI, along with the definition of "matching organisms", and important notes and reporting instructions.

1. **Blood and site-specific specimen cultures match for at least one organism**: In a patient suspected of having an infection, blood and a site-specific specimen are collected for culture and both are positive for at least one matching organism. If the site-specific culture is an element used to meet the infection site criterion, then the BSI is considered secondary to that site-specific infection.
    a. Example: Patient meets HAI criteria for a symptomatic urinary tract infection (suprapubic tenderness and $>10^5$ CFU/ml of *E. coli*) and blood culture from the same date grows *E. coli*. This is an HAI SUTI with a secondary BSI and the reported organism is *E. coli*.
    b. Example: Patient meets HAI criteria for a symptomatic urinary tract infection (suprapubic tenderness and $>10^5$ CFU/ml of *E. coli*) and blood culture from the same date grows *E. coli* and *P. aeruginosa*. This is an HAI SUTI with a secondary BSI and the reported organisms are *E. coli* and *P. aeruginosa*, since *P. aeruginosa* is a logical pathogen for this site of infection.
    c. Example: Patient meets HAI criteria for a symptomatic urinary tract infection (suprapubic tenderness and $>10^5$ CFU/ml of *E. coli*) and blood culture from the same date grows *E. coli* and *S. epidermidis*. This is an HAI SUTI with a secondary BSI and the reported organism is only *E. coli*, since the single common commensal *S. epidermidis* positive blood culture by itself does not meet BSI criteria.

2. **Blood and site-specific specimen cultures do <u>not</u> match**: There are two scenarios that can occur when a patient suspected of having an infection has blood and a site-specific specimen cultured but the organisms do not match.
    a. If the site-specific culture is an element used to meet the infection site criterion and the blood isolate is also an element used to meet another

criterion at the same infection site, then the BSI is considered secondary to that site-specific infection.

i. Example: Postoperative patient becomes febrile and complains of nausea and abdominal pain. Blood and an aseptically-obtained T-tube drainage specimen are collected for culture. A CT scan done that day shows fluid collection suggestive of infection. Culture results show *Escherichia coli* from the drainage specimen but the blood grows *Bacteroides fragilis*. Because the patient meets IAB criteria by positive site-specific culture (IAB criterion 3a) and by positive blood culture as an element of a different criterion of the same infection site (IAB 3c), the blood is considered a secondary BSI to an IAB and both organisms would be listed as the IAB infection pathogens. No primary BSI would be reported.

b. If the site-specific culture is an element used to meet the infection site criterion and the blood isolate is not, then the BSI is considered a primary infection.

i. Example: Postoperative patient has an intraabdominal abscess (IAB) noted during reoperation and purulent material is obtained at that time which grows *Escherichia coli*. The patient spikes a fever two days later and blood culture shows *Bacteroides fragilis.* Because the organisms from the site and blood cultures do not match, and no site-specific criterion that includes positive blood culture as an element is met, both a site-specific infection (IAB criteria 1 and 2) and a primary BSI would be reported.

ii. Example: Unconscious ICU patient with a Foley catheter and central line for past 4 days spikes a fever; blood, urine and sputum specimens are collected for culture. The urine culture grows >100,000 CFU/ml of *Escherichia coli*, blood culture grows *Enterococcus faecium*, and sputum shows oral flora only. Because the organisms from the urine and blood cultures do not match, and a UTI criterion that includes positive blood culture as an element is not met, both a SUTI (criterion 1a) and a primary BSI would be reported. This infection does not meet the ABUTI criterion since that requires at least one matching uropathogen organism in urine and blood in an asymptomatic patient.

3. **No site-specific specimen culture, only a positive blood culture**: In a patient suspected of having an infection, if the only specimen cultured is blood and it grows a logical pathogen for the suspected body site of infection, and a site-specific infection criterion is met, an element of which may or may not include a positive blood culture, the BSI is considered secondary to that site-specific infection.

a. Example: Postoperative patient has an abscess in the small bowel noted during reoperation. The only specimen cultured is blood which grows *B. fragilis*. Because gastrointestinal tract infection (GIT) criterion 1 is met with the surgically-identified abscess alone and because *B. fragilis* is a logical

pathogen for this site of infection, the BSI is considered secondary to a GIT and *B. fragilis* is listed as the GIT infection pathogen.

b. Example: Patient has a positive blood culture with *E. coli* proximal in time with fever, abdominal pain, and CT scan evidence of intraabdominal abscess (IAB). This patient meets IAB criterion 3c, which includes a positive blood culture as one of its elements. The BSI is considered secondary to the IAB and *E. coli* is listed as the IAB infection pathogen.

4. **Negative site-specific specimen culture with positive blood culture**: In a patient suspected of having an infection, if a specimen from the suspected site of infection is cultured and yields no growth, but a blood specimen collected as part of the infection work-up is positive, that BSI is only considered a secondary BSI if another of the site-specific criteria that includes positive blood culture as an element is met. Otherwise, the BSI is considered a primary BSI, even if another criterion for that site is met and the blood isolate is a logical pathogen for the infection.
    a. Example: Patient has purulent material from the IAB space cultured and it yields no growth. The patient also has fever, abdominal pain, a positive blood culture with *Pseudomonas aeruginosa*, and radiographic evidence of IAB infection. This patient does not meet IAB criterion 1 (positive culture from purulent material) but does meet IAB criterion 3c, an element of which is a positive blood culture (signs/symptoms plus positive blood culture plus radiographic evidence). This BSI is considered secondary to the IAB and *P. aeruginosa* is listed as the IAB infection pathogen.
    b. Example: Postoperative knee replacement patient with a central line spikes a fever; blood and knee joint fluid are cultured. Only the blood cultures from at least two separate blood draws are positive for *S. epidermidis*. No other JNT infection criteria are met. This BSI should be reported as a CLABSI.
    c. Example: Patient has a central line in place for 10 days. Patient complains of knee joint tenderness and limited range of motion. CT scan findings suggest joint (JNT) infection but culture of a needle-aspirated joint fluid is negative. However, a blood culture from the same time period grows *S. aureus*. This patient does not meet JNT criterion 1 (positive joint fluid culture) but does meet JNT criterion 3d (signs/symptoms plus imaging test evidence of infection). Even though *S. aureus* is a logical pathogen for this infection site, it is also a likely pathogen for a CLABSI. This BSI should be reported as a CLABSI, not a secondary BSI. So in this example, both a JNT infection and a CLABSI are reported.

A **matching organism** is defined as one of the following:

1. If genus and species are identified in both cultures, they must be the same.
    a. Example: A blood culture reported as *Enterobacter cloacae* and an intraabdominal specimen of *Enterobacter cloacae* are matching organisms.
    b. Example: A blood culture reported as *Enterobacter cloacae* and an intraabdominal specimen of *Enterobacter aerogenes* are NOT matching organisms as the species are different.

2. If the organism is less definitively identified in one culture than the other, the identifications must be complementary.
    a. Example: A surgical wound growing *Pseudomonas* spp. and a blood culture growing *Pseudomonas aeruginosa* are considered a match at the genus level and therefore the BSI is reported as secondary to the SSI.
    b. Example: A blood culture reported as *Candida albicans* and a urine culture reported as yeast are considered to have matching organisms.

Notes:
1. If the blood isolate by itself does not meet BSI criteria (e.g., only one positive blood culture of a common commensal), then that isolate may not be used to indicate the presence of a secondary BSI (see example 1c).
2. Antibiograms of the blood and potential primary site isolates do not have to match.
3. Blood and site-specific specimens do not have to be collected on the same day but their collection dates must be such that they are considered part of the diagnostic work-up for the infection in question.

Reporting Instructions:
1. For reporting secondary BSI for possible and probable VAP, see Chapter 10.
2. Do not report secondary bloodstream infection for vascular (VASC) infections, clinically-defined pneumonia (PNU1), Ventilator-Associated Conditions (VAC), or Infection-related Ventilator-Associated Complications (IVAC).
3. If a site-specific criterion requiring positive culture results is met, be sure to check the positive culture box when specifying the criteria used when adding the event, even if another criterion that does not include culture results is also met. For example, using the scenario in 2.a.i above, the following boxes for criteria used would be checked when entering the SSI into the NHSN application: fever, nausea, pain or tenderness, positive culture, positive blood culture, imaging test evidence of infection.

NOTES

Annexure - 3

Surgical Site Infection (SSI) Event

Introduction: In 2010, an estimated 16 million operative procedures were performed in the United States.[1] A recent prevalence study found that SSIs were the most common healthcare-associated infection, accounting for 31% of all HAIs among hospitalized patients.[2] NHSN data for 2006-2008 (16,147 SSIs following 849,659 operative procedures) showed an overall SSI rate of 1.9%.[3]

While advances have been made in infection control practices, including improved operating room ventilation, sterilization methods, barriers, surgical technique, and availability of antimicrobial prophylaxis, SSIs remain a substantial cause of morbidity and an associated mortality rate of 3% has been attributed to them.[4] Of this, 75% of the mortality rate has been directly related to the SSI.[4]

Surveillance of SSI with feedback of appropriate data to surgeons has been shown to be an important component of strategies to reduce SSI risk.[5,6,7,8] A successful surveillance program includes the use of epidemiologically-sound infection definitions and effective surveillance methods, stratification of SSI rates according to risk factors associated with SSI development, and data feedback.[6,7] Recommendations are outlined in the CDC's *Guideline for Prevention of Surgical Site Infection, 1999*.[8]

Settings: Surveillance of surgical patients will occur in any inpatient and/or outpatient setting where the selected NHSN operative procedure(s) are performed.

Requirements: Perform surveillance for SSI following at least one NHSN operative procedure category (Table 1) as indicated in the *Patient Safety Monthly Reporting Plan* (CDC 57.106). Collect SSI (numerator) and operative procedure category (denominator) data on all procedures included in the selected procedure categories for at least one month. A procedure must meet the NHSN definition of an operative procedure in order to be included in the surveillance.

SSI monitoring requires active, patient-based, prospective surveillance. Post-discharge and ante-discharge surveillance methods should be used to detect SSIs following inpatient and outpatient operative procedures. These methods include 1) direct examination of patients' wounds during follow-up visits to either surgery clinics or physicians' offices, 2) review of medical records or surgery clinic patient records, 3) surgeon surveys by mail or telephone, and 4) patient surveys by mail or telephone (though patients may have a difficult time assessing their infections). Any combination of these methods is acceptable for use; however, CDC criteria for SSI must be used. To minimize Infection Preventionists' (IPs) workload of collecting denominator data, operating room data may be downloaded (see file specifications at: http://www.cdc.gov/nhsn/PDFs/ImportingProcedureData_current.pdf).

An SSI will be associated with a particular NHSN operative procedure and the facility in which that procedure was performed. Refer to the NHSN application's Help system for instruction on linking an SSI to an operative procedure.

The *International Classification of Diseases, 9th Revision Clinical Modifications* (ICD-9-CM) codes, which are defined by the ICD-9 Coordination and Maintenance Committee of the National Center for Health Statistics and the Centers for Medicare and Medicaid Services (CMS), are developed as a tool for classification of morbidity data. The wide use enables the grouping of surgery types for the purpose of determining SSI rates. ICD-9-CM codes are updated annually in October and NHSN operative procedure categories are subsequently updated and changes shared with NHSN users. Table 1 lists NHSN operative procedure category groupings by ICD-9-CM codes. Because ambulatory surgery centers and hospital outpatient surgery departments may not use ICD-9-CM procedure codes, Table 1 provides Current Procedural Terminology (CPT) code mapping for certain NHSN operative procedure categories to assist users in determining the correct NHSN code to report for outpatient surgery cases. However, CPT codes do not take precedence over ICD-9-CM codes when determining the appropriate NHSN operative procedure category for inpatient surgery cases. Table 1 also includes a general description of the types of operations contained in the NHSN operative procedure categories.

Definitions:

An NHSN operative procedure is a procedure

- that is performed on a patient who is an NHSN inpatient or an NHSN outpatient; *and*
- takes place during an operation (defined as a single trip to the operating room [OR] where a surgeon makes at least one incision through the skin or mucous membrane, including laparoscopic approach, and closes the incision primarily***** before the patient leaves the OR); *and*
- that is included in Table 1.

*****Primary closure is defined as closure of all tissue levels, regardless of the presence of wires, wicks, drains, or other devices or objects extruding through the incision. However, regardless of whether anything is extruding from the incision, if the skin edges are not fully reapproximated for the entire length of the incision (e.g., are loosely closed with gaps between suture/staple points), the incision is not considered primarily closed and therefore the procedure would not be considered an operation. In such cases, any subsequent infection would not be considered an SSI, although it may be an HAI if it meets criteria for another specific infection site (e.g., skin or soft tissue infection).

NHSN Inpatient: A patient whose date of admission to the healthcare facility and the date of discharge are different calendar days.

NHSN Outpatient: A patient whose date of admission to the healthcare facility and date of discharge are the same calendar day.

Operating Room (OR): A patient care area that met the Facilities Guidelines Institute's (FGI) or American Institute of Architects' (AIA) criteria for an operating room when it was constructed or renovated.[9] This may include an operating room, C-Section room, interventional radiology room, or a cardiac catheterization lab.

Table 1. ***NHSN Operative Procedure Category Mappings to ICD-9-CM Codes and CPT Codes***
CPT codes are to be used for outpatient surgery cases only.

Legacy Code	Operative Procedure	Description	ICD-9-CM Codes / CPT Codes
AAA	Abdominal aortic aneurysm repair	Resection of abdominal aorta with anastomosis or replacement	38.34, 38.44, 38.64
AMP	Limb amputation	Total or partial amputation or disarticulation of the upper or lower limbs, including digits	84.00-84.19, 84.91
APPY	Appendix surgery	Operation of appendix (not incidental to another procedure)	47.01, 47.09, 47.2, 47.91, 47.92, 47.99
AVSD	Shunt for dialysis	Arteriovenostomy for renal dialysis	39.27, 39.42
BILI	Bile duct, liver or pancreatic surgery	Excision of bile ducts or operative procedures on the biliary tract, liver or pancreas (does not include operations only on gallbladder)	50.0, 50.12, 50.14, 50.21-50.23, 50.25, 50.26, 50.29, 50.3, 50.4, 50.61, 50.69, 51.31-51.37, 51.39, 51.41-51.43, 51.49, 51.51, 51.59, 51.61-51.63, 51.69, 51.71, 51.72, 51.79, 51.81-51.83, 51.89, 51.91-51.95, 51.99, 52.09, 52.12, 52.22, 52.3**,** 52.4, 52.51-52.53, 52.59-52.6, 52.7, 52.92, 52.95, 52.96, 52.99
BRST	Breast surgery	Excision of lesion or tissue of breast including radical, modified, or quadrant resection, lumpectomy, incisional biopsy, or mammoplasty	85.12, 85.20-85.23, 85.31-85.36, 85.41-85.48, 85.50, 85.53-85.55, 85.6, 85.70-85.76, 85.79, 85.93-85.96 19101, 19112, 19120, 19125, 19126, 19300, 19301, 19302, 19303, 19304, 19305, 19306, 19307, 19316, 19318, 19324, 19325, 19328, 19330, 19340, 19342, 19350, 19355, 19357, 19361, 19364, 19366, 19367, 19368, 19369, 19370, 19371, 19380
CARD	Cardiac surgery	Procedures on the heart; includes valves or septum; does not include coronary artery bypass graft, surgery on vessels, heart transplantation, or pacemaker implantation	35.00-35.04, 35.06, 35.08, 35.10-35.14, 35.20-35.28, 35.31-35.35, 35.39, 35.42, 35.50, 35.51, 35.53, 35.54, 35.60-35.63, 35.70-35.73, 35.81-35.84, 35.91-35.95, 35.98-35.99, 37.10-37.12, 37.31-37.33, 37.35-37.37, 37.41, 37.49, 37.60

Legacy Code	Operative Procedure	Description	ICD-9-CM Codes / CPT Codes
CEA	Carotid endarterectomy	Endarterectomy on vessels of head and neck (includes carotid artery and jugular vein)	38.12
CBGB	Coronary artery bypass graft with **both** chest and donor site incisions	Chest procedure to perform direct revascularization of the heart; includes obtaining suitable vein from donor site for grafting	36.10-36.14, 36.19
CBGC	Coronary artery bypass graft with chest incision only	Chest procedure to perform direct vascularization of the heart using, for example the internal mammary (thoracic) artery	36.15-36.17, 36.2
CHOL	Gallbladder surgery	Cholecystectomy and cholecystotomy	51.03, 51.04, 51.13, 51.21-51.24 47480, 47562, 47563, 47564, 47600, 47605, 47610, 47612, 47620
COLO	Colon surgery	Incision, resection, or anastomosis of the large intestine; includes large-to-small and small-to-large bowel anastomosis; does not include rectal operations	17.31-17.36, 17.39, 45.03, 45.26, 45.41, 45.49, 45.52, 45.71-45.76, 45.79, 45.81-45.83, 45.92-45.95, 46.03, 46.04, 46.10, 46.11, 46.13, 46.14, 46.43, 46.52, 46.75, 46.76, 46.94 44140, 44141, 44143, 44144, 44145, 44146, 44147, 44150, 44151, 44160, 44204, 44205, 44206, 44207, 44208, 44210
CRAN	Craniotomy	Excision repair, or exploration of the brain or meninges; does not include taps or punctures	01.12, 01.14, 01.20-01.25, 01.28, 01.29, 01.31, 01.32, 01.39, 01.41, 01.42, 01.51-01.53, 01.59, 02.11-02.14, 02.91-02.93, 07.51-07.54, 07.59, 07.61-07.65, 07.68, 07.69, 07.71, 07.72, 07.79, 38.01, 38.11, 38.31, 38.41, 38.51, 38.61, 38.81, 39.28
CSEC	Cesarean section	Obstetrical delivery by Cesarean section	74.0, 74.1, 74.2, 74.4, 74.91, 74.99
FUSN	Spinal fusion	Immobilization of spinal column	81.00-81.08

Legacy Code	Operative Procedure	Description	ICD-9-CM Codes / CPT Codes
FX	Open reduction of fracture	Open reduction of fracture or dislocation of long bones with or without internal or external fixation; does not include placement of joint prosthesis	79.21, 79.22, 79.25, 79.26, 79.31, 79.32, 79.35, 79.36, 79.51, 79.52, 79.55, 79.56 23615, 23616, 23630, 23670, 23680, 24515, 24516, 24538, 24545, 24546, 24575, 24579, 24586, 24587, 24635, 24665, 24666, 24685, 25337, 25515, 25525, 25526, 25545, 25574, 25575, 25607, 25608, 25609, 25652, 27236, 27244, 27245, 27248, 27254, 27269, 27283, 27506, 27507, 27511, 27513, 27514, 27535, 27536, 27540, 27758, 27759, 27766, 27769, 27784, 27792, 27814, 27822, 27826, 27827, 27828
GAST	Gastric surgery	Incision or excision of stomach; includes subtotal or total gastrectomy; does not include vagotomy and fundoplication	43.0, 43.42, 43.49, 43.5, 43.6, 43.7, 43.81, 43.82, 43.89, 43.91, 43.99, 44.15, 44.21, 44.29, 44.31, 44.38-44.42, 44.49, 44.5, 44.61-44.65, 44.68-44.69, 44.95-44.98
HER	Herniorrhaphy	Repair of inguinal, femoral, umbilical, or anterior abdominal wall hernia; does not include repair of diaphragmatic or hiatal hernia or hernias at other body sites	17.11-17.13, 17.21-17.24, 53.00-53.05, 53.10-53.17, 53.21, 53.29, 53.31, 53.39, 53.41-53.43, 53.49, 53.51, 53.59, 53.61-53.63, 53.69 49491, 49492, 49495, 49496, 49500, 49501, 49505, 49507, 49520, 49521, 49525, 49550, 49553, 49555, 49557, 49560, 49561, 49565, 49566, 49568, 49570, 49572, 49580, 49582, 49585, 49587, 49590, 49650, 49651, 49652, 49653, 49654, 49655, 49656, 49657, 49659, 55540
HPRO	Hip prosthesis	Arthroplasty of hip	00.70-00.73, 00.85-00.87, 81.51-81.53 27125, 27130, 27132, 27134, 27137, 27138, 27236, 27299
HTP	Heart transplant	Transplantation of heart	37.51-37.55

Legacy Code	Operative Procedure	Description	ICD-9-CM Codes / CPT Codes
HYST	Abdominal hysterectomy	Abdominal hysterectomy; includes that by laparoscope	68.31, 68.39, 68.41, 68.49, 68.61, 68.69 58150, 58152, 58180, 58200, 58210, 58541, 58542, 58543, 58544, 58548, 58570, 58571, 58572, 58573, 58951, 58953, 58954, 58956
KPRO	Knee prosthesis	Arthroplasty of knee	00.80-00.84, 81.54, 81.55 27438, 27440, 27441, 27442, 27443, 27445, 27446, 27447, 27486, 27487
KTP	Kidney transplant	Transplantation of kidney	55.61, 55.69
LAM	Laminectomy	Exploration or decompression of spinal cord through excision or incision into vertebral structures	03.01, 03.02, 03.09, 80.50, 80.51, 80.53, 80.54*****, 80.59, 84.60-84.69, 84.80-84.85
LTP	Liver transplant	Transplantation of liver	50.51, 50.59
NECK	Neck surgery	Major excision or incision of the larynx and radical neck dissection; does not include thyroid and parathyroid operations	30.1, 30.21, 30.22, 30.29, 30.3, 30.4, 31.45, 40.40-40.42
NEPH	Kidney surgery	Resection or manipulation of the kidney with or without removal of related structures	55.01, 55.02, 55.11, 55.12, 55.24, 55.31, 55.32, 55.34, 55.35, 55.39, 55.4, 55.51, 55.52, 55.54, 55.91
OVRY	Ovarian surgery	Operations on ovary and related structures	65.01, 65.09, 65.12, 65.13, 65.21-65.25, 65.29, 65.31, 65.39, 65.41, 65.49, 65.51-65.54, 65.61-65.64, 65.71-65.76, 65.79, 65.81, 65.89, 65.92-65.95, 65.99
PACE	Pacemaker surgery	Insertion, manipulation or replacement of pacemaker	00.50-00.54, 17.51, 17.52, 37.70-37.77, 37.79-37.83, 37.85-37.87, 37.89, 37.94-37.99
PRST	Prostate surgery	Suprapubic, retropubic, radical, or perineal excision of the prostate; does not include transurethral resection of the prostate	60.12, 60.3, 60.4, 60.5, 60.61, 60.69
PVBY	Peripheral vascular bypass surgery	Bypass operations on peripheral arteries	39.29

Legacy Code	Operative Procedure	Description	ICD-9-CM Codes / CPT Codes
REC	Rectal surgery	Operations on rectum	48.25, 48.35, 48.40, 48.42, 48.43, 48.49-48.52, 48.59, 48.61-48.65, 48.69, 48.74
RFUSN	Refusion of spine	Refusion of spine	81.30-81.39
SB	Small bowel surgery	Incision or resection of the small intestine; does not include small-to-large bowel anastomosis	45.01, 45.02, 45.15, 45.31-45.34, 45.51, 45.61-45.63, 45.91, 46.01, 46.02, 46.20-46.24, 46.31, 46.39, 46.41, 46.51, 46.71-46.74, 46.93
SPLE	Spleen surgery	Resection or manipulation of spleen	41.2, 41.33, 41.41-41.43, 41.5, 41.93, 41.95, 41.99
THOR	Thoracic surgery	Noncardiac, nonvascular thoracic surgery; includes pneumonectomy and hiatal hernia repair or diaphragmatic hernia repair (except through abdominal approach)	32.09, 32.1, 32.20-32.23, 32.25, 32.26, 32.29, 32.30, 32.39, 32.41, 32.49, 32.50, 32.59, 32.6, 32.9, 33.0, 33.1, 33.20, 33.25, 33.28, 33.31-33.34, 33.39, 33.41-33.43, 33.48, 33.49, 33.98, 33.99, 34.01-34.03, 34.06, 34.1, 34.20, 34.26, 34.3, 34.4, 34.51, 34.52, 34.59, 34.6, 34.81-34.84, 34.89, 34.93, 34.99, 53.80-53.84
THYR	Thyroid and/or parathyroid surgery	Resection or manipulation of thyroid and/or parathyroid	06.02, 06.09, 06.12, 06.2, 06.31, 06.39, 06.4, 06.50-06.52, 06.6, 06.7, 06.81, 06.89, 06.91-06.95, 06.98, 06.99
VHYS	Vaginal hysterectomy	Vaginal hysterectomy; includes that by laparoscope	68.51, 68.59, 68.71, 68.79
VSHN	Ventricular shunt	Ventricular shunt operations, including revision and removal of shunt	02.21, 02.22, 02.31-02.35, 02.39, 02.42, 02.43, 54.95[†]
XLAP	Exploratory laparotomy	Abdominal operations not involving the gastrointestinal tract or biliary system; includes diaphragmatic hernia repair through abdominal approach	53.71, 53.72, 53.75, 54.0, 54.11, 54.12, 54.19, 54.3, 54.4, 54.51, 54.59, 54.61, 54.63, 54.64, 54.71-54.75, 54.92, 54.93

*****If the 80.54 procedure was a percutaneous repair of the anulus fibrosus, it is not considered an NHSN operative procedure and should not be included in LAM denominator data.

[†]Include only if this procedure involves ventricular shunt (i.e., is not a Ladd procedure to repair malrotation of intestines).

For a complete list of all ICD-9-CM codes mapped to their assignment as an NHSN operative procedure category, a surgical procedure other than an NHSN operative procedure (OTH), or a non-operative procedure (NO), see ICD-9-CM Procedure Code Mapping to NHSN Operative Procedure Categories at http://www.cdc.gov/nhsn/XLS/ICD-9-cmCODEScurrent.xlsx.

ASA score: Assessment by the anesthesiologist of the patient's preoperative physical condition using the American Society of Anesthesiologists' (ASA) Classification of Physical Status.[10] Patient is assigned one of the following which may be used as one element of SSI risk adjustment:

1. Normally healthy patient
2. Patient with mild systemic disease
3. Patient with severe systemic disease that is not incapacitating
4. Patient with an incapacitating systemic disease that is a constant threat to life
5. Moribund patient who is not expected to survive for 24 hours with or without the operation. NOTE: If coded as expired or as organ donor, report as ASA = 5.

Duration of operative procedure: The interval in hours and minutes between skin incision and primary skin closure. See also definition of primary closure and the Denominator Data reporting instructions in this chapter.

Emergency operative procedure: A nonelective, unscheduled operative procedure. Emergency operative procedures are those that do not allow for the standard immediate preoperative preparation normally done within the facility for a scheduled operation (e.g., stable vital signs, adequate antiseptic skin preparation, colon decontamination in advance of colon surgery, etc.).

General anesthesia: The administration of drugs or gases that enter the general circulation and affect the central nervous system to render the patient pain free, amnesic, unconscious, and often paralyzed with relaxed muscles.

Scope: An instrument used to visualize the interior of a body cavity or organ. In the context of an NHSN operative procedure, use of a scope involves creation of several small incisions to perform or assist in the performance of an operation rather than use of a traditional larger incision (i.e., open approach). Robotic assistance is considered equivalent to use of a scope for NHSN SSI surveillance. See also Instructions for Completion of *Denominator for Procedure* Form and both Numerator Data and Denominator Data reporting instructions in this chapter.

Trauma: Blunt or penetrating injury.

Wound class: An assessment of the degree of contamination of a surgical wound at the time of the operation. Wound class should be assigned by a person involved in the surgical procedure, e.g., surgeon, circulating nurse, etc. The wound class system used in NHSN is an adaptation of the American College of Surgeons wound classification schema[8]. Wounds are divided into four classes:

Clean: An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tracts are not entered. In addition, clean

wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow nonpenetrating (blunt) trauma should be included in this category if they meet the criteria.
NOTE: The following NHSN operative procedure categories are NEVER considered to have a clean wound classification: APPY, BILI, CHOL, COLO, REC, SB, and VHYS.

Clean-Contaminated: Operative wounds in which the respiratory, alimentary, genital*, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered.*Includes female and male reproductive tracts.

Contaminated: Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered are included in this category.

Dirty or Infected: Includes old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

Table 2. *Surgical Site Infection Criteria*

Criterion	**Surgical Site Infection (SSI)**
	Superficial incisional SSI Must meet the following criterion:
	Infection occurs within 30 days after any NHSN operative procedure, including those coded as 'OTH'***** a*nd* involves only skin and subcutaneous tissue of the incision *and* patient has at least one of the following: a. purulent drainage from the superficial incision. b. organisms isolated from an aseptically-obtained culture of fluid or tissue from the superficial incision. c. superficial incision that is deliberately opened by a surgeon and is culture-positive or not cultured *and* patient has at least one of the following signs or symptoms: pain or tenderness; localized swelling; redness; or heat. A culture negative finding does not meet this criterion. d. diagnosis of a superficial incisional SSI by the surgeon or attending physician. *****http://www.cdc.gov/nhsn/XLS/ICD-9-cmCODEScurrent.xlsx

Comments	There are two specific types of superficial incisional SSIs: 1. Superficial Incisional Primary (SIP) – a superficial incisional SSI that is identified in the primary incision in a patient that has had an operation with one or more incisions (e.g., C-section incision or chest incision for CBGB) 2. Superficial Incisional Secondary (SIS) – a superficial incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (e.g., donor site incision for CBGB)
REPORTING INSTRUCTIONS	• Do not report a stitch abscess (minimal inflammation and discharge confined to the points of suture penetration) as an infection. • Do not report a localized stab wound or pin site infection as SSI. While it would be considered either a skin (SKIN) or soft tissue (ST) infection, depending on its depth, it is not reportable under this module. • Diagnosis of "cellulitis", by itself, does not meet criterion d for superficial incisional SSI. • If the superficial incisional infection extends into the fascial and/or muscle layers, report as a deep incisional SSI only. • An infected circumcision site in newborns is classified as CIRC. Circumcision is not an NHSN operative procedure. CIRC is not reportable under this module. • An infected burn wound is classified as BURN and is not reportable under this module.
	Deep incisional SSI Must meet the following criterion:
	Infection occurs within 30 or 90 days after the NHSN operative procedure according to the list in Table 3 *and* involves deep soft tissues of the incision (e.g., fascial and muscle layers) *and* patient has at least one of the following: a. purulent drainage from the deep incision. b. a deep incision that spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured *and* patient has at least one of the following signs or symptoms: fever (>38°C); localized pain or tenderness. A culture-negative finding does not meet this criterion. c. an abscess or other evidence of infection involving the deep incision that is found on direct examination, during invasive procedure, or by histopathologic examination or imaging test. d. diagnosis of a deep incisional SSI by a surgeon or attending physician.
Comments	There are two specific types of deep incisional SSIs: 1. Deep Incisional Primary (DIP) – a deep incisional SSI that is identified

	in a primary incision in a patient that has had an operation with one or more incisions (e.g., C-section incision or chest incision for CBGB) 2. Deep Incisional Secondary (DIS) – a deep incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (e.g., donor site incision for CBGB)
REPORTING INSTRUCTION	• Classify infection that involves both superficial and deep incisional sites as deep incisional SSI. • Classify infection that involves superficial incisional, deep incisional, and organ/space sites as deep incisional SSI. This is considered a complication of the incision.

	Organ/Space SSI Must meet the following criterion:
	Infection occurs within 30 or 90 days after the NHSN operative procedure according to the list in Table 3 *and* infection involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure *and* patient has at least one of the following: a. purulent drainage from a drain that is placed into the organ/space b. organisms isolated from an aseptically-obtained culture of fluid or tissue in the organ/space c. an abscess or other evidence of infection involving the organ/space that is found on direct examination, during invasive procedure, or by histopathologic examination or imaging test d. diagnosis of an organ/space SSI by a surgeon or attending physician *and* meets at least one criterion for a specific organ/space infection site listed in Table 4.
Comments	Because an organ/space SSI involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure, the criterion for infection at these body sites must be met in addition to the organ/space SSI criteria. For example, an appendectomy with subsequent subdiaphragmatic abscess would be reported as an organ/space SSI at the intraabdominal specific site (SSI-IAB) when both organ/space SSI and IAB criteria are met. Table 4 list the specific sites that must be used to differentiate organ/space SSI. These criteria are in the HAI Definitions chapter.
REPORTING INSTRUCTIONS	• If a patient has an infection in the organ/space being operated on in the first 2-day period of hospitalization and the surgical incision was closed primarily, subsequent continuation of this infection type during the remainder of the surveillance period is considered an organ/space SSI, if

	organ/space SSI and site-specific infection criteria are met. Rationale: Risk of continuing or new infection is considered to be minimal when a surgeon elects to close a wound primarily. • Occasionally an organ/space infection drains through the incision and is considered a complication of the incision. Therefore, classify it as a deep incisional SSI. • Report mediastinitis following cardiac surgery that is accompanied by osteomyelitis as SSI-MED rather than SSI-BONE. • If meningitis (MEN) and a brain abscess (IC) are present together after operation, report as SSI-IC. • Report CSF shunt infection as SSI-MEN if it occurs within 90 days of placement; if later or after manipulation/access, it is considered CNS-MEN and is not reportable under this module. • Report spinal abscess with meningitis as SSI-MEN following spinal surgery.

Table 3. ***Surveillance Period for Deep Incisional or Organ/Space SSI Following Selected NHSN Operative Procedure Categories***

30-day Surveillance			
Code	**Operative Procedure**	**Code**	**Operative Procedure**
AAA	Abdominal aortic aneurysm repair	LAM	Laminectomy
AMP	Limb amputation	LTP	Liver transplant
APPY	Appendix surgery	NECK	Neck surgery
AVSD	Shunt for dialysis	NEPH	Kidney surgery
BILI	Bile duct, liver or pancreatic surgery	OVRY	Ovarian surgery
CEA	Carotid endarterectomy	PRST	Prostate surgery
CHOL	Gallbladder surgery	REC	Rectal surgery
COLO	Colon surgery	SB	Small bowel surgery
CSEC	Cesarean section	SPLE	Spleen surgery
GAST	Gastric surgery	THOR	Thoracic surgery
HTP	Heart transplant	THYR	Thyroid and/or parathyroid surgery
HYST	Abdominal hysterectomy	VHYS	Vaginal hysterectomy
KTP	Kidney transplant	XLAP	Exploratory Laparotomy
		OTH	Other operative procedures not included in the NHSN categories

90-day Surveillance	
Code	**Operative Procedure**
BRST	Breast surgery
CARD	Cardiac surgery
CBGB	Coronary artery bypass graft with both chest and donor site incisions
CBGC	Coronary artery bypass graft with chest incision only
CRAN	Craniotomy
FUSN	Spinal fusion
FX	Open reduction of fracture
HER	Herniorrhaphy
HPRO	Hip prosthesis
KPRO	Knee prosthesis
PACE	Pacemaker surgery
PVBY	Peripheral vascular bypass surgery
RFUSN	Refusion of spine
VSHN	Ventricular shunt

NOTE: Superficial incisional SSIs are only followed for a 30-day period for all procedure types.

Table 4. *Specific Sites of an Organ/Space SSI*. Criteria for these sites can be found in the NHSN Help system (must be logged in to NHSN) or the HAI Definitions chapter.

Code	Site	Code	Site
BONE	Osteomyelitis	JNT	Joint or bursa
BRST	Breast abscess or mastitis	LUNG	Other infections of the respiratory tract
CARD	Myocarditis or pericarditis	MED	Mediastinitis
DISC	Disc space	MEN	Meningitis or ventriculitis
EAR	Ear, mastoid	ORAL	Oral cavity (mouth, tongue, or gums)
EMET	Endometritis	OREP	Other infections of the male or female reproductive tract
ENDO	Endocarditis	OUTI	Other infections of the urinary tract
EYE	Eye, other than conjunctivitis	SA	Spinal abscess without meningitis
GIT	GI tract	SINU	Sinusitis
HEP	Hepatitis	UR	Upper respiratory tract
IAB	Intraabdominal, not specified elsewhere	VASC	Arterial or venous infection
IC	Intracranial, brain abscess or dura	VCUF	Vaginal cuff

Numerator Data: All patients having any of the procedures included in the selected NHSN operative procedure category(s) are monitored for signs of SSI. The *Surgical Site Infection (SSI)* form is completed for each such patient found to have an SSI. If no SSI events are identified during the surveillance month, check the "Report No Events" field in the Missing PA Events tab of the Incomplete/Missing List.

The Instructions for Completion of the Surgical Site Infection form include brief instructions for collection and entry of each data element on the form. The SSI form includes patient demographic information and information about the operative procedure, including the date and type of procedure. Information about the SSI includes the date of SSI, specific criteria met for identifying the SSI, when/how the SSI was detected, whether the patient developed a secondary bloodstream infection, whether the patient died, and the organisms isolated from cultures and the organisms' antimicrobial susceptibilities.

REPORTING INSTRUCTIONS:

1. **Attributing SSI to a Procedure when Several are Performed on Different Dates:** If a patient has several NHSN operative procedures performed on different dates prior to an infection, report the operative procedure code of the operation that was performed most closely in time prior to the infection date, unless there is evidence that the infection was associated with a different operation.

2. **SSI after Laparoscopic Procedures:** Following a laparoscopic surgery, if more than one of the incisions should become infected, only report as a single SSI. If one incision meets criteria for a superficial incisional SSI and another meets criteria for a deep incisional SSI, count as only one deep incisional SSI.

3. **SSI after Breast (BRST) Procedures with More than One Incision**:
    - A single breast operative procedure (BRST) with multiple incisions on a single breast that are not laparoscopic should be reported as only one operative procedure. If more than one of the incisions should become infected, only report as a single SSI.
    - A BRST procedure with a secondary incision for tissue harvest (e.g., Transverse Rectus Abdominis Myocutaneous [TRAM] flap) should be reported as only one operative procedure. If the secondary incision gets infected, report as either SIS or DIS as appropriate.

4. **SSI after Procedures that Allow Secondary Incisions**: For procedures that allow for secondary incisions (i.e., BRST, CBGB, CEA, FUSN, REC, PVBY, RFUSN), the secondary incision site surveillance period will only be 30 days, as long as that site does not have retained implantable materials. For example, a saphenous vein harvest incision in a CBGB procedure is considered the secondary incision and is monitored for only 30 days after surgery for evidence of SSI, but the chest incision is monitored for 90 days.

5. **SSI After Colostomy Reversal:** In a colostomy reversal (take down) procedure, if colostomy stoma site and abdominal operative incision(s) are primarily closed and one or more of the incisions becomes infected, report only as one incisional SSI. If the stoma site is closed at the fascial/muscle layer but not superfically (e.g., left to heal by secondary intention) and the abdominal operative incision(s) is primarily closed, this is still considered an NHSN operative procedure and therefore if an organ/space infection develops, it is considered an SSI. However, if the stoma site becomes infected, it is considered skin or soft tissue infection, not an SSI.

6. **SSI Detected at Another Facility:** If an SSI is detected at a facility other than the one in which the operation was done, notify the IP of the index facility with enough detail so the infection can be reported to NHSN. When reporting the SSI, the index facility should indicate that Detected = RO.

7. **SSI Attribution after Surgical Procedure with More Than One Operative Procedure Category:** If more than one NHSN operative procedure category was performed through a single incision during a single trip to the operating room, attribute the SSI to the procedure that is thought to be associated with the infection. If it is not clear, as is often the case when the infection is a superficial incisional SSI, use the NHSN Principal Operative Procedure Category Selection Lists (Table 5) to select the operative procedure to which the SSI should be attributed.

8. **SSI Following an Implant**: When implanted material is left in place during an NHSN operative procedure with a 90-day surveillance period (e.g., KPRO, VSHN) and the implanted material or the area/structures contiguous with it are later manipulated for diagnostic or therapeutic purposes, organ/space infection can occur. In such a case, if organ/space infection develops during the 90-day surveillance period, the infection is not attributed to the operation in which the implant was inserted; instead it should be attributed to the latter procedure.

9. **Reporting Instructions for Specific Post-operative Infection Scenarios:**
    - Once a patient is discharged from the index hospital, if the incision opens due to fall or other reasons and there was no evidence of incisional infection at the time of its opening (as defined by lack of those symptoms that make up the SSI definition), then subsequent infection of the incision is not considered an SSI or an HAI for the index hospital (if the patient was in a rehab facility when this occurred, it would be an HAI for that facility). This implies a mechanical reason for dehiscence rather than an infectious reason.
    - Post-op patient is still hospitalized following surgery and his asymptomatic incision opens due to fall or other reasons (e.g., picking at it). If subsequent incisional infection develops, it is considered an HAI but not SSI.
    - Post-op patient sustains an injury to the incision area but incision does not open. Later, incisional infection develops; this is considered an SSI.
    - Post-op patient has an intact incision or status of incision is unknown (e.g., dressing never changed so no one has seen the incision), or it is noted that patient showered/bathed "too early" post-op, or it is noted that the patient was incontinent and incision was or may have been contaminated, or patient got intact incision dirty, then subsequent incisional infection is considered an SSI.
    - Post-op patient has skin condition (e.g., dermatitis, blister, impetigo) near intact incision, and then subsequently develops incisional infection within the follow-up surveillance period; this is an SSI.
    - Patient has remote site infection, either prior to or after an operation, or has a manipulation that "seeds" operative site (e.g., dental work), and later develops deep incisional or organ/space infection; this is an SSI if it occurs in the follow up surveillance period.

Table 5. ***NHSN Principal Operative Procedure Category Selection Lists***

The following lists are derived from the operative procedures listed in Table 1. The categories with the highest risk of SSI are listed before those with lower risks.

Priority	Code	Abdominal Operations
1	LTP	Liver transplant
2	COLO	Colon surgery
3	BILI	Bile duct, liver or pancreatic surgery
4	SB	Small bowel surgery
5	REC	Rectal surgery
6	KTP	Kidney transplant
7	GAST	Gastric surgery
8	AAA	Abdominal aortic aneurysm repair
9	HYST	Abdominal hysterectomy
10	CSEC	Cesarean section
11	XLAP	Laparotomy
12	APPY	Appendix surgery
13	HER	Herniorrhaphy
14	NEPH	Kidney surgery
15	VHYS	Vaginal Hysterectomy
16	SPLE	Spleen surgery
17	CHOL	Gall bladder surgery
18	OVRY	Ovarian surgery

Priority	Code	Thoracic Operations
1	HTP	Heart transplant
2	CBGB	Coronary artery bypass graft with donor incision(s)
3	CBGC	Coronary artery bypass graft, chest incision only
4	CARD	Cardiac surgery
5	THOR	Thoracic surgery
Priority	**Code**	**Neurosurgical (Spine) Operations**
1	RFUSN	Refusion of spine
2	CRAN	Crainiotomy
3	FUSN	Spinal fusion
4	LAM	Laminectomy
Priority	**Code**	**Neurosurgical (Brain) Operations**
1	VSHN	Ventricular shunt
2	RFUSN	Refusion of spine
3	CRAN	Craniotomy
4	FUSN	Spinal fusion
5	LAM	Laminectomy
Priority	**Code**	**Neck Operations**
1	NECK	Neck surgery
2	THYR	Thyroid and or parathyroid surgery

Denominator Data: For all patients having any of the procedures included in the NHSN Operative Procedure category(s) selected for surveillance during the month, complete the *Denominator for Procedure* form. The data are collected individually for each operative procedure performed during the month specified on the *Patient Safety Monthly Reporting Plan*. The Instructions for Completion of the Denominator for Procedure Form include brief instructions for collection and entry of each data element on the form.

REPORTING INSTRUCTIONS:

1. **Different Operative Procedure Categories Performed During Same Trip to the OR:** If procedures in more than one NHSN operative procedure category are performed during the same trip to the operating room through the same or different incisions, a *Denominator for Procedure* form is reported for each NHSN operative procedure category being monitored. For example, if a CARD and CBGC are done through the same incision, a *Denominator for Procedure* form is reported for each. In another example, if following a motor vehicle accident, a patient has an open reduction of fracture (FX) and splenectomy (SPLE) performed during the same trip to the operating room and both procedure categories are being monitored, complete a *Denominator for Procedure* form for each.

   EXCEPTION: If a patient has both a CBGC and CBGB during the same trip to the operating room, report only as a CBGB. Only report as a CBGC when there is a chest incision only. CBGB and CBGC are never reported for the same patient for the same trip to the operating room. The time from chest incision to chest primary closure is reported as the duration of the procedure.

2. **Duration of the Procedure when More than One Category of NHSN Operative Procedure is Done Through the Same Incision:** If more than one NHSN operative procedure category is performed through the same incision during the same trip to the operating room, record the combined duration of all procedures, which is the time from skin incision to primary closure. For example, if a CBGC and a CARD are performed on a patient during the same trip to the operating room, the time from skin incision to primary closure is reported for both operative procedures.

3. **Same Operative Procedure Category but Different ICD-9-CM Codes During Same Trip to the OR:** If procedures of different ICD-9-CM codes from the same NHSN operative procedure category are performed through the same incision, record only one procedure for that category. For example, a facility is performing surveillance for CARD procedures. A patient undergoes a replacement of both the mitral and tricuspid valves (35.23 and 35.27, both CARD) during the same trip to the operating room. Complete one CARD *Denominator for Procedure* form because ICD-9-CM codes 35.23 and 35.27 fall in the same operative procedure category [CARD] (see Table 1).

4. **Bilateral Procedures:** For operative procedures that can be performed bilaterally during same trip to operating room (e.g., KPRO), two separate *Denominator for Procedure* forms are

completed. To document the duration of the procedures, indicate the incision time to closure time for each procedure separately or, alternatively, take the total time for both procedures and split it evenly between the two.

5. **More Than One Operative Procedure Through Same Incision Within 24 Hours:** If a patient goes to the operating room more than once during the same admission and another procedure of the same or different NHSN procedure category is performed through the same incision within 24 hours of the end of the original operative incision, report only one *Denominator for Procedure* form for the original procedure, combining the durations for both procedures. For example, a patient has a CBGB lasting 4 hours. He returns to the OR six hours later to correct a bleeding vessel (OTH). The surgeon reopens the initial incision, makes the repairs, and recloses in 1.5 hours. Record the operative procedure as one CBGB and the duration of operation as 5 hour 30 minutes. If the wound class has changed, report the higher wound class. If the ASA class has changed, report the higher ASA class. Do not report an 'OTH' record.

6. **Patient Expires in the OR:** If a patient expires in the operating room, do not complete a *Denominator for Procedure* form. This operative procedure is excluded from the denominator.

7. **Laparoscopic Hernia Repairs.** Laparoscopic hernia repairs are considered one procedure, regardless of the number of hernias that are repaired in that trip to the operating room. In most cases there will be only one incision time documented for this procedure. If more than one time is documented, report the total of the durations.

8. **Open Hernia Repairs:** Open (i.e., non-laparoscopic) hernia repairs are reported as one procedure for each hernia repaired via a separate incision, i.e., if two incisions are made to repair two defects, then two procedures will be reported. It is anticipated that separate incision times will be recorded for these procedures. If not, take the total time for both procedures and split it evenly between the two procedures.

9. **Laparoscopic Hysterectomy – HYST or VHYS:** When assigning the correct ICD-9-CM hysterectomy procedure code, a trained coder must determine what structures were detached and how they were detached based on the medical record documentation. The code assignment is based on the surgical technique or approach used for the detachment of those structures, not on the location of where the structures were physically removed from the patient's body. Therefore, a total laparoscopic HYST procedure will have detachment of the entire uterus and cervix from the surrounding supporting structures via the laparoscopic technique. A laparoscopically-assisted VHYS involves detachment of the uterus and upper supporting structures via laparoscope but the lower supporting structures and cervix are detached via vaginal incision.

10. **A Single NHSN Operative Procedure With Multiple Incisions:** Some operative procedures have more than one incision (e.g., CBGB; CEA; colostomy reversals (COLO); FUSN or RFUSN with anterior and posterior approaches; PVBY; single breast (BRST) procedure with

multiple open or laparoscopic incisions; BRST with Transverse Rectus Abdominis Myocutaneous [TRAM] flap). Complete only one *Denominator for Procedure* form for such procedures as long as any of the incisions is primarily closed. Record the duration as time from skin incision to closure of the primary incision. See Numerator Data Reporting Instructions in this chapter for how to report SSI.

11. **Incidental Appendectomy:** An incidental appendectomy is not reported as a separate appendectomy (APPY) procedure.

12. **XLAP:** For an exploratory laparotomy that results in a procedure from another category being performed, do not report XLAP; instead report only the other procedure. For example, for an exploratory laparotomy that results in a hemicolectomy (COLO), report only a COLO.

Data Analyses: The Standardized Infeciton Ratio (SIR) is calculated by dividing the number of observed infections by the number of expected infections. The number of expected infections, in the context of statistical prediction, is calculated using SSI probabilities estimated from multivariate logistic regression models constructed from NHSN data during a baseline time period, which represents a standard population's SSI experience.[3]

NOTE: The SIR will be calculated only if the number of expected HAIs (numExp) is ≥ 1.

$$\text{SIR} = \frac{\text{Observed (O) HAIs}}{\text{Expected (E) HAIs}}$$

While the SSI SIR can be calculated for single procedure categories and for specific surgeons, the measure also allows you to summarize your data across multiple procedure categories while adjusting for differences in the estimated probability of infection among the patients included across the procedure categories. For example, you will be able to obtain one SSI SIR adjusting for all procedures reported. Alternatively, you can obtain one SSI SIR for all colon surgeries (COLO) only within your facility.

SSI rates per 100 operative procedures are calculated by dividing the number of SSIs by the number of specific operative procedures and multiplying the results by 100. SSI will be included in the numerator of a rate based on the date of procedure, not the date of event. Using the advanced analysis feature of the NHSN application, SSI rate calculations can be performed separately for the different types of operative procedures and stratified by the basic risk index.

The basic SSI risk index assigns surgical patients into categories based on the presence of three major risk factors:

1. Operation lasting more than the duration cut point, where the duration cut point is the approximate 75th percentile of the duration of surgery in minutes for the operative procedure.
2. Contaminated (Class III) or Dirty/infected (Class IV) wound class.
3. ASA score of 3, 4, or 5.

The patient's SSI risk category is simply the sum of the number of these factors present at the time of the operation. Calculating SSI rates with this option provides less risk adjustment than is afforded by the multivariate logistic regression model used in the calculation of the SIR (see above).

Descriptive analysis options of numerator and denominator data are available in the NHSN application, such as line listings, frequency tables, and bar and pie charts. SIRs and SSI rates and control charts are also available. Guides on using NHSN analysis features are available http://www.cdc.gov/nhsn/PS-Analysis-resources/reference-guides.html.

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NOTES

Annexure - 4

Ventilator-Associated Pneumonia (VAP) Event

Introduction: In 2002, an estimated 250,000 healthcare-associated pneumonias developed in U.S. hospitals and 36,000 of these were associated with deaths.[1] Patients with mechanically-assisted ventilation have a high risk of developing healthcare-associated pneumonia. For the year 2011, NHSN facilities reported more than 3,525 VAPs and the incidence for various types of hospital units ranged from 0.0-4.9 per 1,000 ventilator days.[2]

Prevention and control of healthcare-associated pneumonia is discussed in the CDC/HICPAC document, *Guidelines for Prevention of Healthcare-Associated Pneumonia, 2003*[3]. The Guideline strongly recommends that surveillance be conducted for bacterial pneumonia in ICU patients who are mechanically ventilated to facilitate identification of trends and for inter-hospital comparisons.

Settings: Surveillance will occur in any inpatient pediatric or neonatal locations where denominator data can be collected, which may include critical/intensive care units (PICUs/NICUs), specialty care areas (SCA), step-down units, wards and long term care units. In 2013, in-plan surveillance for ventilator-associated pneumonia (PNEU) using the criteria found in this chapter will be restricted to patients <18 years old only. In 2013, in-plan surveillance conducted for mechanically-ventilated patients ≥18 years will use the Ventilator-Associated Event (VAE) criteria and monitored under that protocol (see VAE chapter). The PNEU definitions are still available for those units seeking to conduct off-plan PNEU surveillance for mechanically-ventilated and non-ventilated adults or children. A complete listing of inpatient locations and instructions for mapping can be found in the CDC Locations and Descriptions chapter.

NOTE: It is not required to monitor for VAPs after the patient is discharged from the facility. However, if discovered, any VAPs occurring on the day of discharge or the next day should be reported to NHSN (see Transfer Rule below). No additional ventilator days are reported.

Requirements: Surveillance for VAP will occur in at least one inpatient pediatric or neonatal location in the healthcare institution for at least one calendar month as indicated in the *Patient Safety Monthly Reporting Plan* (CDC 57.106).

Definitions:
Healthcare-associated infections (HAI): An infection is considered an HAI if all elements of a CDC/NHSN site-specific infection criterion were first present together on or after the 3rd hospital day (day of hospital admission is day 1). For an HAI, an element of the infection criterion may be present during the first 2 hospital days as long as it is also present on or after day 3. All elements used to meet the infection criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between elements.

Pneumonia (PNEU) is identified by using a combination of radiologic, clinical and laboratory criteria. The following pages detail the various criteria that may be used for meeting the surveillance definition of healthcare-associated pneumonia (Tables 2-5 and Figures 1 and 2), general comments applicable to all specific site criteria, and reporting instructions. Table 6 shows threshold values for cultured specimens used in the surveillance diagnosis of pneumonia.

Date of event: For VAP the date of event is the date when the last element used to meet the Pneumonia (PNEU) criteria occurred. Synonyms: infection date, date of infection.

Ventilator: A device to assist or control respiration continuously, inclusive of the weaning period, through a tracheostomy or by endotracheal intubation.

NOTE: Lung expansion devices such as intermittent positive-pressure breathing (IPPB); nasal positive end-expiratory pressure (PEEP); and continuous nasal positive airway pressure (CPAP, hypoCPAP) are not considered ventilators unless delivered via tracheostomy or endotracheal intubation (e.g., ET-CPAP).

Ventilator-associated PNEU (VAP): A pneumonia where the patient is on mechanical ventilation for >2 calendar days when all elements of the PNEU infection criterion were first present together, with day of ventilator placement being Day 1,
and
the ventilator was in place on the date of event or the day before. If the patient is admitted or transferred into a facility on a ventilator, the day of admission is considered Day1.

Location of attribution: The inpatient location where the patient was assigned on the date of the VAP event, which is further defined as the date when the last element used to meet the PNEU criterion occurred (see exception below).

EXCEPTION TO LOCATION OF ATTRIBUTION:
Transfer Rule: If all elements of a VAP are present within 2 days of transfer from one inpatient location to another in the same facility or a new facility (i.e., on the day of transfer or the next day), the infection is attributed to the transferring location or facility. Receiving facilities should share information about such HAIs with the transferring facility to enable reporting. This is called the Transfer Rule and examples are shown below:

- Child has been on a ventilator for 7 days in the PICU and is transferred on the ventilator to the pediatric surgical ward. On the next day, the patient meets the criteria for PNEU. This is reported to NHSN as a VAP for the PICU.
- Child has been on a ventilator for 5 days and is transferred in the morning to the pediatric medical ward from the pediatric medical critical care unit after having ventilator discontinued. Later that night, the child meets criteria for a PNEU. This is reported to NHSN as a VAP for the pediatric medical critical care unit.

- Pediatric patient on a ventilator is transferred from the neonatal intensive care unit (NICU) to the pediatric intensive care unit (PICU). After 4 days in the PICU, the patient meets the criteria for a PNEU. This is reported to NHSN as a VAP for the PICU.
- Pediatric patient on the Respiratory ICU (RICU) of Hospital A had the endotracheal tube and ventilator removed after being on the ventilator for 5 days and is discharged home a few hours later. The IP from Hospital B calls the next day to report that this patient has been admitted to Hospital B with a PNEU. This VAP should be reported to NHSN for, and by, Hospital A and attributed to the RICU. No additional ventilator days for the RICU are reported.

EXCEPTION TO TRANSFER RULE: Locations that do not house patients overnight (e.g., Emergency Department or Operating Room) will have no denominator data, i.e., patient days or catheter days. Therefore VAPs cannot be attributed to these locations. Instead, the VAP must be attributed to the next inpatient location in which the patient stays.

General comments applicable to all pneumonia specific site criteria:

1. Physician's diagnosis of pneumonia alone is not an acceptable criterion for healthcare-associated pneumonia.
2. Although specific criteria are included for infants and children, pediatric patients may meet any of the other pneumonia specific site criteria.
3. When assessing a patient for presence of pneumonia, it is important to distinguish between changes in clinical status due to other conditions such as myocardial infarction, pulmonary embolism, respiratory distress syndrome, atelectasis, malignancy, chronic obstructive pulmonary disease, hyaline membrane disease, bronchopulmonary dysplasia, etc. Also, care must be taken when assessing intubated patients to distinguish between tracheal colonization, upper respiratory tract infections (e.g., tracheobronchitis), and early onset pneumonia. Finally, it should be recognized that it may be difficult to determine healthcare-associated pneumonia in the elderly, infants, and immunocompromised patients since such conditions may mask typical signs or symptoms associated with pneumonia. Alternate specific criteria for the elderly, infants and immunocompromised patients have been included in this definition of healthcare-associated pneumonia.
4. Healthcare-associated pneumonia can be characterized by its onset: early or late. Early-onset pneumonia occurs during the first four days of hospitalization and is often caused by *Moraxella catarrhalis, H. influenzae*, and *S. pneumoniae*. Causative agents of late-onset pneumonia are frequently Gram-negative bacilli or *S. aureus*, including methicillin-resistant *S. aureus*. Viruses (e.g., Influenza A and B or Respiratory Syncytial Virus) can cause early- and late-onset healthcare-associated pneumonia, whereas yeasts, fungi, legionellae, and *Pneumocystis carinii* are usually pathogens of late-onset pneumonia.

5. Pneumonia due to gross aspiration (for example, in the setting of intubation in the field, emergency room, or operating room) is considered healthcare-associated if it meets any specific criteria and the infection itself was not clearly present at the time of admission to the hospital.
6. Multiple episodes of healthcare-associated pneumonia may occur in critically ill patients with lengthy hospital stays. When determining whether to report multiple episodes of healthcare-associated pneumonia in a single patient, look for evidence of resolution of the initial infection. The addition of or change in pathogen alone is not indicative of a new episode of pneumonia. The combination of new signs and symptoms and radiographic evidence or other diagnostic testing is required.
7. Positive Gram's stain for bacteria and positive KOH (potassium hydroxide) mount for elastin fibers and/or fungal hyphae from appropriately collected sputum specimens are important clues that point toward the etiology of the infection. However, sputum samples are frequently contaminated with airway colonizers and therefore must be interpreted cautiously. In particular, *Candida* is commonly seen on stain, but infrequently causes healthcare-associated pneumonia, especially in immunocompetent patients.

Table 1: Abbreviations used in PNEU laboratory criteria

BAL – bronchoalveolar lavage	LRT – lower respiratory tract
EIA – enzyme immunoassay	PCR – polymerase chain reaction
FAMA – fluorescent-antibody staining of membrane antigen	PMN – polymorphonuclear leukocyte
IFA – immunofluorescent antibody	RIA − radioimmunoassay

REPORTING INSTRUCTIONS:

- There is a hierarchy of specific categories within the major site pneumonia. Even if a patient meets criteria for more than one specific site, report only one:
    - If a patient meets criteria for both PNU1 and PNU2, report PNU2.
    - If a patient meets criteria for both PNU2 and PNU3, report PNU3.
    - If a patient meets criteria for both PNU1 and PNU3, report PNU3.
- Report concurrent lower respiratory tract infection (e.g., abscess or empyema) and pneumonia with the same organism(s) as PNEU.
- Lung abscess or empyema without pneumonia is classified as LUNG.
- Bronchitis, tracheitis, tracheobronchitis, or bronchiolitis without pneumonia are classified as BRON.

Table 2: Specific Site Algorithms for Clinically Defined Pneumonia (PNU1)

<table>
<tr><th>Radiology</th><th>Signs/Symptoms/Laboratory</th></tr>
<tr><td rowspan="3">Two or more serial chest radiographs with at least <u>one</u> of the following[1,2]:

• New or progressive <u>and</u> persistent infiltrate

• Consolidation

• Cavitation

• Pneumatoceles, in infants ≤1 year old

NOTE: In patients without underlying pulmonary or cardiac disease (e.g., respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema, or chronic obstructive pulmonary disease), <u>one</u> <u>definitive</u> chest radiograph is acceptable.[1]</td><td>For ANY PATIENT, at least <u>one</u> of the following:

• Fever (>38°C or >100.4°F)
• Leukopenia (<4000 WBC/mm^3) or leukocytosis (≥12,000 WBC/mm^3)
• For adults ≥70 years old, altered mental status with no other recognized cause

<u>and</u>
at least <u>two</u> of the following:

• New onset of purulent sputum[3], or change in character of sputum[4], or increased respiratory secretions, or increased suctioning requirements
• New onset or worsening cough, or dyspnea, or tachypnea[5]
• Rales[6] or bronchial breath sounds
• Worsening gas exchange (e.g., O_2 desaturations (e.g., PaO_2/FiO_2 ≤240)[7], increased oxygen requirements, or increased ventilator demand)</td></tr>
<tr><td>ALTERNATE CRITERIA, for infants ≤1 year old:

Worsening gas exchange (e.g., O_2 desaturations [e.g. pulse oximetry <94%], increased oxygen requirements, or increased ventilator demand)

<u>and</u>
at least <u>three</u> of the following:

• Temperature instability
• Leukopenia (<4000 WBC/mm^3) <u>or</u> leukocytosis (≥15,000 WBC/mm^3) and left shift (≥10% band forms)
• New onset of purulent sputum[3] or change in character of sputum[4], or increased respiratory secretions or increased suctioning requirements
• Apnea, tachypnea[5], nasal flaring with retraction of chest wall or grunting
• Wheezing, rales[6], or rhonchi
• Cough
• Bradycardia (<100 beats/min) or tachycardia (>170 beats/min)</td></tr>
<tr><td>ALTERNATE CRITERIA, for child >1 year old or ≤12 years old, at least <u>three</u> of the following:

• Fever (>38.4°C or >101.1°F) or hypothermia (<36.5°C or <97.7°F)
• Leukopenia (<4000 WBC/mm^3) or leukocytosis (≥15,000 WBC/mm^3)
• New onset of purulent sputum[3], or change in character of sputum[4], or increased respiratory secretions, or increased suctioning requirements
• New onset or worsening cough, or dyspnea, apnea, or tachypnea[5].
• Rales[6] or bronchial breath sounds
• Worsening gas exchange (e.g., O_2 desaturations [e.g., pulse oximetry <94%], increased oxygen requirements, or increased ventilator demand)</td></tr>
</table>

Table 3: Specific Site Algorithms for Pneumonia with Common Bacterial or Filamentous Fungal Pathogens and Specific Laboratory Findings (PNU2)

Radiology	Signs/Symptoms	Laboratory
Two or more serial chest radiographs with at least **one** of the following[1,2]: • New or progressive and persistent infiltrate • Consolidation • Cavitation • Pneumatoceles, in infants ≤1 year old NOTE: In patients **without** underlying pulmonary or cardiac disease (e.g., respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema, or chronic obstructive pulmonary disease), one definitive chest radiograph is acceptable.[1]	At least **one** of the following: • Fever (>38°C or >100.4°F) • Leukopenia (<4000 WBC/mm^3) or leukocytosis (≥12,000 WBC/mm^3) • For adults ≥70 years old, altered mental status with no other recognized cause **and** at least **one** of the following: • New onset of purulent sputum[3], or change in character of sputum[4], or increased respiratory secretions, or increased suctioning requirements • New onset or worsening cough, or dyspnea or tachypnea[5] • Rales[6] or bronchial breath sounds • Worsening gas exchange (e.g., O_2 desaturations [e.g., PaO_2/FiO_2 ≤240][7], increased oxygen requirements, or increased ventilator demand)	At least **one** of the following: • Positive growth in blood culture[8] not related to another source of infection • Positive growth in culture of pleural fluid • Positive quantitative culture[9] from minimally-contaminated LRT specimen (e.g., BAL or protected specimen brushing) • ≥5% BAL-obtained cells contain intracellular bacteria on direct microscopic exam (e.g., Gram's stain) • Histopathologic exam shows at least **one** of the following evidences of pneumonia: – Abscess formation or foci of consolidation with intense PMN accumulation in bronchioles and alveoli – Positive quantitative culture[9] of lung parenchyma – Evidence of lung parenchyma invasion by fungal hyphae or pseudohyphae

Table 4: Specific Site Algorithms for Viral, Legionella, and other Bacterial Pneumonias with Definitive Laboratory Findings (PNU2)

Radiology	Signs/Symptoms	Laboratory
Two or more serial chest radiographs with at least **one** of the following[1,2]: • New or progressive and persistent infiltrate • Consolidation • Cavitation • Pneumatoceles, in infants ≤1 year old NOTE: In patients **without** underlying pulmonary or cardiac disease (e.g., respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema, or chronic obstructive pulmonary disease), one definitive chest radiograph is acceptable.[1]	At least **one** of the following: • Fever (>38°C or >100.4°F) • Leukopenia (<4000 WBC/mm^3) or leukocytosis (≥12,000 WBC/mm^3) • For adults ≥70 years old, altered mental status with no other recognized cause **and** at least one of the following: • New onset of purulent sputum[3], or change in character of sputum[4], or increased respiratory secretions, or increased suctioning requirements • New onset or worsening cough or dyspnea, or tachypnea[5] • Rales[6] or bronchial breath sounds • Worsening gas exchange (e.g., O_2 desaturations [e.g., PaO_2/FiO_2 ≤240][7], increased oxygen requirements, or increased ventilator demand)	At least **one** of the following[10-12]: • Positive culture of virus or *Chlamydia* from respiratory secretions • Positive detection of viral antigen or antibody from respiratory secretions (e.g., EIA, FAMA, shell vial assay, PCR) • Fourfold rise in paired sera (IgG) for pathogen (e.g., influenza viruses, *Chlamydia*) • Positive PCR for *Chlamydia* or *Mycoplasma* • Positive micro-IF test for *Chlamydia* • Positive culture or visualization by micro-IF of *Legionella* spp, from respiratory secretions or tissue. • Detection of *Legionella pneumophila* serogroup 1 antigens in urine by RIA or EIA • Fourfold rise in *L. pneumo*phila serogroup 1 antibody titer to ≥1:128 in paired acute and convalescent sera by indirect IFA.

Table 5: Specific Site Algorithm for Pneumonia in Immunocompromised Patients (PNU3)

Radiology	Signs/Symptoms	Laboratory
Two or more serial chest radiographs with at least **one** of the following[1,2]: • New or progressive and persistent infiltrate • Consolidation • Cavitation • Pneumatoceles, in infants ≤1 year old NOTE: In patients **without** underlying pulmonary or cardiac disease (e.g., respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema, or chronic obstructive pulmonary disease), one definitive chest radiograph is acceptable.[1]	Patient who is immunocompromised[13] has at least **one** of the following: • Fever (>38°C or >100.4°F) • For adults ≥70 years old, altered mental status with no other recognized cause • New onset of purulent sputum[3], or change in character of sputum[4], or increased respiratory secretions, or increased suctioning requirements • New onset or worsening cough, or dyspnea, or tachypnea[5] • Rales[6] or bronchial breath sounds • Worsening gas exchange (e.g., O_2 desaturations [e.g., PaO_2/FiO_2 ≤240][7], increased oxygen requirements, or increased ventilator demand) • Hemoptysis • Pleuritic chest pain	At least **one** of the following: • Matching positive blood and sputum cultures with *Candida* spp.[14,15] • Evidence of fungi or *Pneumocystis carinii* from minimally-contaminated LRT specimen (e.g., BAL or protected specimen brushing) from one of the following: – Direct microscopic exam – Positive culture of fungi Any of the following from **LABORATORY CRITERIA DEFINED UNDER PNU2**

Footnotes to Algorithms:

1. Occasionally, in nonventilated patients, the diagnosis of healthcare-associated pneumonia may be quite clear on the basis of symptoms, signs, and a single definitive chest radiograph. However, in patients with pulmonary or cardiac disease (for example, interstitial lung disease or congestive heart failure), the diagnosis of pneumonia may be particularly difficult. Other non-infectious conditions (for example, pulmonary edema from decompensated congestive heart failure) may simulate the presentation of pneumonia. In these more difficult cases, serial chest radiographs must be examined to help separate infectious from non-infectious pulmonary processes. To help confirm difficult cases, it may be useful to review radiographs on the day of diagnosis, 3 days prior to the diagnosis and on days 2 and 7 after the diagnosis. Pneumonia may have rapid onset and progression, but does not resolve quickly. Radiographic changes of pneumonia persist for several weeks. As a result, rapid radiographic resolution suggests that the patient does not have pneumonia, but rather a non-infectious process such as atelectasis or congestive heart failure.

2. Note that there are many ways of describing the radiographic appearance of pneumonia. Examples include, but are not limited to, "air-space disease", "focal opacification", "patchy areas of increased density". Although perhaps not specifically delineated as pneumonia by the radiologist, in the appropriate clinical setting these alternative descriptive wordings should be seriously considered as potentially positive findings.

3. Purulent sputum is defined as secretions from the lungs, bronchi, or trachea that contain $\geq$25 neutrophils and $\leq$10 squamous epithelial cells per low power field (x100). If your laboratory reports these data qualitatively (e.g., "many WBCs" or "few squames"), be sure their descriptors match this definition of purulent sputum. This laboratory confirmation is required since written clinical descriptions of purulence are highly variable.

4. A single notation of either purulent sputum or change in character of the sputum is not meaningful; repeated notations over a 24-hour period would be more indicative of the onset of an infectious process. Change in character of sputum refers to the color, consistency, odor and quantity.

5. In adults, tachypnea is defined as respiration rate >25 breaths per minute. Tachypnea is defined as >75 breaths per minute in premature infants born at <37 weeks gestation and until the 40th week; >60 breaths per minute in patients <2 months old; >50 breaths per minute in patients 2-12 months old; and >30 breaths per minute in children >1 year old.

6. Rales may be described as "crackles".

7. This measure of arterial oxygenation is defined as the ratio of the arterial tension (PaO_2) to the inspiratory fraction of oxygen (FiO_2).

8. Care must be taken to determine the etiology of pneumonia in a patient with positive blood cultures and radiographic evidence of pneumonia, especially if the patient has invasive devices in place such as intravascular lines or an indwelling urinary catheter. In general, in an immunocompetent patient, blood cultures positive for coagulase-negative staphylococci, common skin contaminants, and yeasts will not be the etiologic agent of the pneumonia.

9. Refer to threshold values for cultured specimens (Table 6). An endotracheal aspirate is not a minimally-contaminated specimen. Therefore, an endotracheal aspirate does not meet the laboratory criteria for PNU2 or PNU3.

10. Once laboratory-confirmed cases of pneumonia due to respiratory syncytial virus (RSV), adenovirus, or influenza virus have been identified in a hospital, a clinician's presumptive diagnosis of these pathogens in subsequent cases with similar clinical signs and symptoms is an acceptable criterion for presence of healthcare-associated infection.

11. Scant or watery sputum is commonly seen in adults with pneumonia due to viruses and *Mycoplasma* although sometimes the sputum may be mucopurulent. In infants, pneumonia due to RSV or influenza yields copious sputum. Patients, except premature infants, with viral or mycoplasmal pneumonia may exhibit few signs or symptoms, even when significant infiltrates are present on radiographic exam.

12. Few bacteria may be seen on stains of respiratory secretions from patients with pneumonia due to *Legionella* spp, mycoplasma, or viruses.

13. Immunocompromised patients include those with neutropenia (absolute neutrophil count <500/mm^3), leukemia, lymphoma, HIV with CD4 count <200, or splenectomy; those who are early post-transplant, are on cytotoxic chemotherapy, or are on high dose steroids (e.g., >40mg of prednisone or its equivalent (>160mg hydrocortisone, >32mg methylprednisolone, >6mg dexamethasone, >200mg cortisone) daily for >2weeks).

14. Blood and sputum specimens must be collected within 48 hours of each other.

15. Semiquantitative or nonquantitative cultures of sputum obtained by deep cough, induction, aspiration, or lavage are acceptable. If quantitative culture results are available, refer to algorithms that include such specific laboratory findings.

Figure 1: Pneumonia Flow Diagram

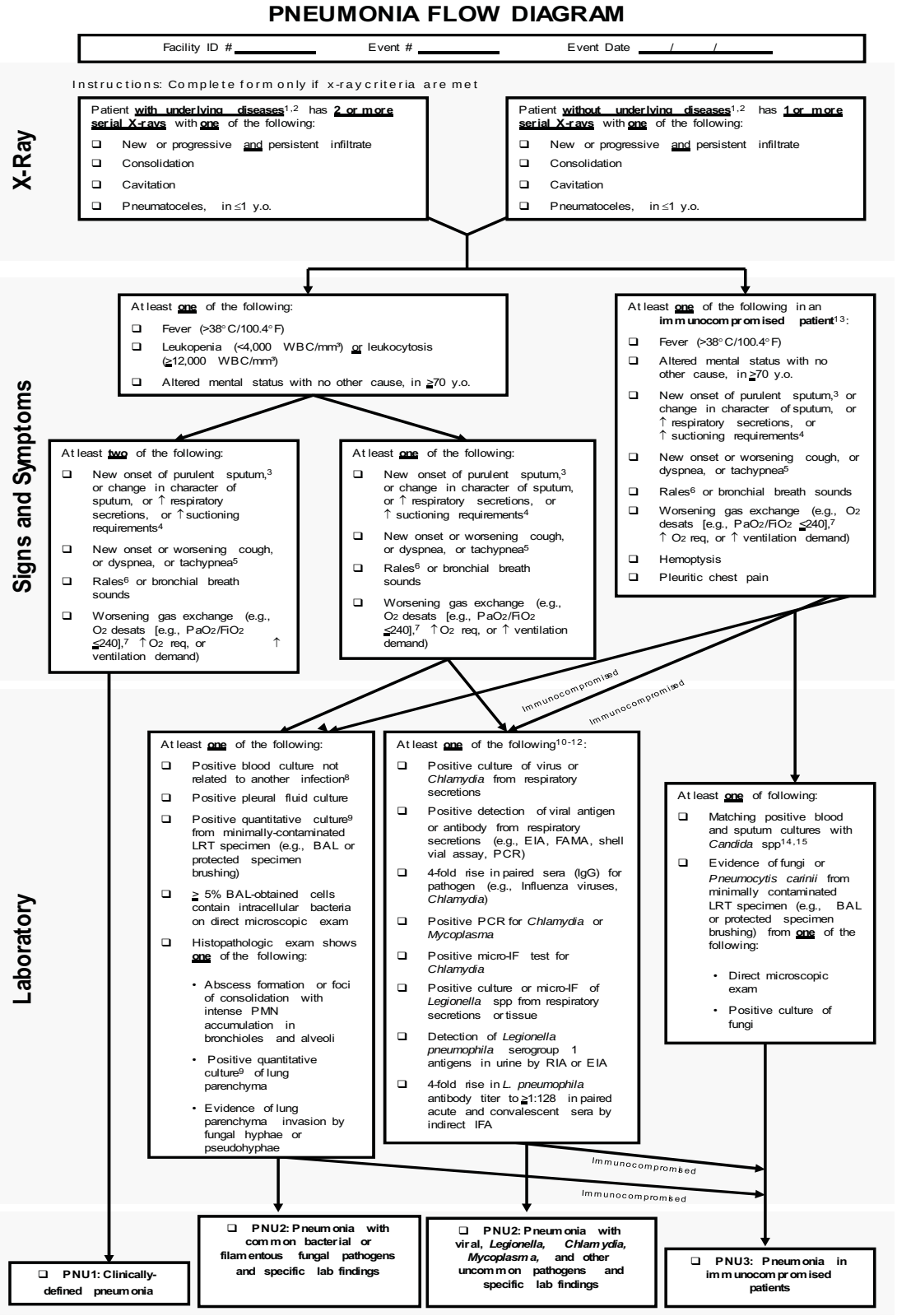


Figure 2: Pneumonia Flow Diagram, Alternative Criteria for Infants and Children

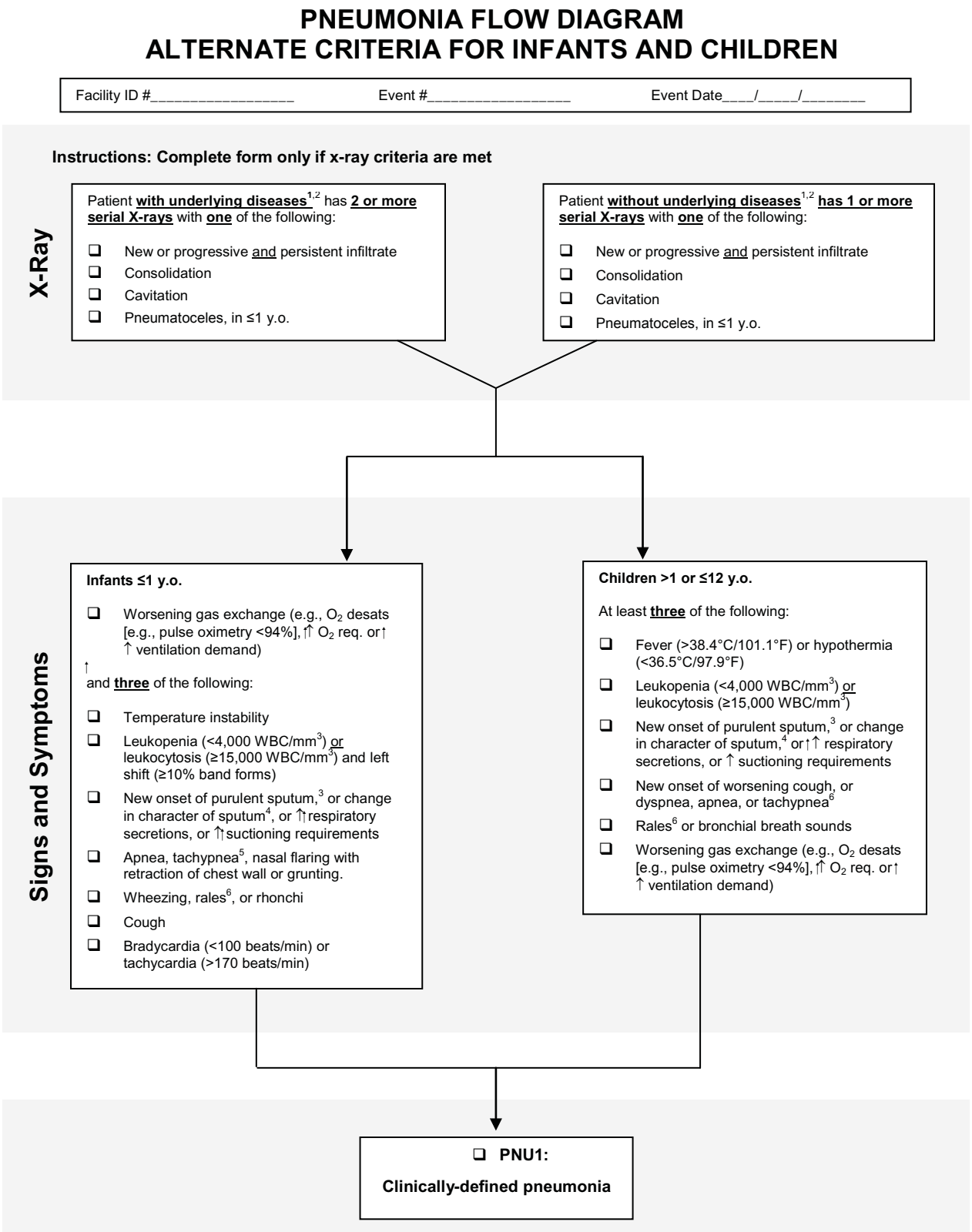


Table 6: Threshold values for cultured specimens used in the diagnosis of pneumonia

Specimen collection/technique	Values
Lung parenchyma*	≥10^4 CFU/g tissue
Bronchoscopically (B) obtained specimens	
Bronchoalveolar lavage (B-BAL)	≥10^4 CFU/ml
Protected BAL (B-PBAL)	≥10^4 CFU/ml
Protected specimen brushing (B-PSB)	≥10^3 CFU/ml
Nonbronchoscopically (NB) obtained (blind) specimens	
NB-BAL	>10^4 CFU/ml
NB-PSB	≥10^3 CFU/ml

CFU = colony forming units
g = gram
ml = milliliter
* Open-lung biopsy specimens and immediate post-mortem specimens obtained by transthoracic or transbronchial biopsy

Numerator Data: The *Pneumonia (PNEU)* form (CDC 57.111) is used to collect and report each VAP that is identified during the month selected for surveillance. The Instructions for Completion of Pneumonia (PNEU) Form contains brief instructions for collection and entry of each data element on the form. The pneumonia form includes patient demographic information and information on whether or not mechanically-assisted ventilation was present. Additional data include the specific criteria met for identifying pneumonia, whether the patient developed a secondary bloodstream infection, whether the patient died, the organisms isolated from cultures, and the organisms' antimicrobial susceptibilities.

REPORTING INSTRUCTION:

- If no VAPs are identified during the month of surveillance, the Report No Events box must be checked on the appropriate denominator summary screen, e.g., Denominators for Intensive Care Unit (ICU)/Other Locations (Not NICU or SCA/ONC), etc.

Denominator Data: Device days and patient days are used for denominators (see Key Terms chapter). Ventilator days, which are the number of patients managed with a ventilatory device, are collected daily, at the same time each day, according to the chosen location using the appropriate form (CDC 57.116, 57.117, and 57.118). These daily counts are summed and only the total for the month is entered into NHSN. Ventilator days and patient days are collected for each of the locations monitored. When denominator data are available from electronic sources (e.g., ventilator days from respiratory therapy), these sources may be used as long as the counts are not substantially different (+/- 5%) from manually-collected counts, validated for a minimum of 3 months.

Data Analyses: The Standardized Infection Ratio (SIR[4]) is calculated by dividing the number of observed infections by the number of expected infections. The number of expected infections, in the context of statistical prediction, is calculated using VAP rates from a standard population during a baseline time period, which represents a standard population's VAP experience.[5]

NOTE: The SIR will be calculated only if the number of expected HAIs (numExp) is ≥1.

$$SIR = \frac{\text{Observed (O) HAIs}}{\text{Expected (E) HAIs}}$$

While the PNEU SIR can be calculated for single locations, the measure also allows you to summarize your data by multiple locations, adjusting for differences in the incidence of infection among the location types. For example, you will be able to obtain one PNEU SIR adjusting for all locations reported. Similarly, you can obtain one PNEU SIR for all specialty care areas in your facility.

The VAP rate per 1000 ventilator days is calculated by dividing the number of VAPs by the number of ventilator days and multiplying the result by 1000. The Ventilator Utilization Ratio is calculated by dividing the number of ventilator days by the number of patient days. These calculations will be performed separately for the different types of ICUs, SCAs, and other locations in the institution, as well as by each birthweight category in NICUs.

---

[1] Klevens RM, Edward JR, Richards CL, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007;122:160-166.

[2] Dudeck MA, Horan TC, Peterson KD, et al. National Healthcare Safety Network (NHSN) Report, Data Summary for 2011, Device-associated Module. Available at http://www.cdc.gov/nhsn/PDFs/dataStat/2012NHSNReport.pdf.

[3] Centers for Disease Control and Prevention. Guidelines for preventing health-care-associated pneumonia, 2003: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. MMWR 2004;53(No. RR-3).

[4] Your guide to the Standardized Infection Ratio (SIR). October 2010. http://www.cdc.gov/nhsn/PDFs/Newsletters/NHSN_NL_OCT_2010SE_final.pdf

[5] Edwards JR, Peterson KD, Mu Y, et al. National Healthcare Safety Network (NHSN) report: Data summary for 2006 through 2008, issued December 2009. Am J Infect Control 2009;37:783-805. Available at: http://www.cdc.gov/nhsn/PDFs/dataStat/2009NHSNReport.PDF.

NOTES

Annexure - 5

INCIDENT REPORT FORM

IP No

To be filled within 12 hours of Incident & submitted to Nursing Supervisor/TL within 24 hours

List of Incidents to be reported (Please tick the desired option)

- ☐ Patient Fall
- ☐ Medication Errors
- ☐ Pressure Sores
- ☐ Hypoglycemia (Less than 70mg/dl)
- ☐ Nosocomial Infection
- ☐ Infection Out break
- ☐ Needle Stick Injury
- ☐ Readmission within 14 days
- ☐ Return to OT within 7 days
- ☐ Return to ICU within 7 days
- ☐ Return to Emergency within 7 days
- ☐ Mortality
- ☐ Adverse Drug Reactions
- ☐ Sentinel Events
- ☐ Blood Transfusion related errors

Other Adverse Events

- ☐ Patient Identification Error
- ☐ Acute Limb ischemia
- ☐ Discrepancy in Sponge/gauge count
- ☐ Cautery Burns
- ☐ Needle left inside Porta Cath
- ☐ Others …….

Near Miss

- ☐ Patient Fall
- ☐ Medication Error
- ☐ Patient Identification Error
- ☐ Any other kind of Near Miss

Please specify……

Incident Details

☐ Inpatient	☐ Out -patient	☐ Relative

Patient's Admission Diagnosis:

Admitting Consultant/Consultant in charge:

Name of witness / first person to attend:

Ward/Dept:	Exact Location:

Date & Time of the Incident:

Describe what happened and the kind of incident

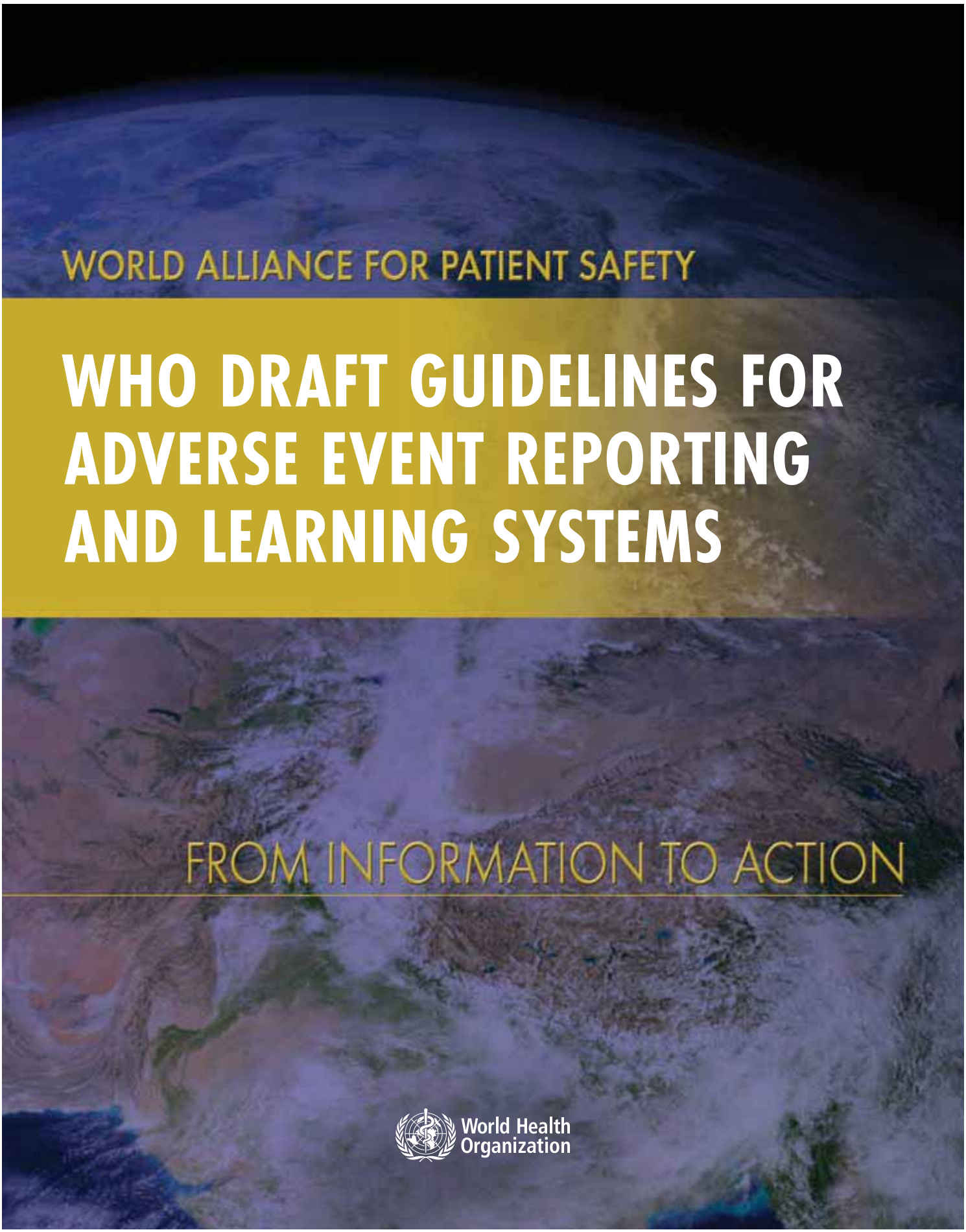
Impact on the Patient (e.g description of any injury/harm sustained to patient)
Mention category : minor, major or near miss

Sign & Name of Admitting Consultant + ICU In charge (If applicable)/ RMO/Floor Doctor

Sign & Name of the Reporting Staff		Emp Code Date & Time
Sign & Name of Nursing Supervisor/TL		Emp Code Date & Time

NOTES

Annexure - 6


WORLD ALLIANCE FOR PATIENT SAFETY
WHO DRAFT GUIDELINES FOR ADVERSE EVENT REPORTING AND LEARNING SYSTEMS
FROM INFORMATION TO ACTION
World Health Organization

WHO/EIP/SPO/QPS/05.3

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FROM INFORMATION TO ACTION

EIP/SPO

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This document reflects collaborative effort across WHO, led by the Evidence and Information for Policy Cluster, with significant input from the staff at WHO regional offices and from partners working in collaboration with WHO worldwide.

FOREWORD

Imagine a jet aircraft which contains an orange coloured wire essential for its safe functioning. An airline engineer in one part of the world doing a pre-flight inspection spots that the wire is frayed in a way that suggests a critical fault rather than routine wear and tear. What would happen next? I think we know the answer. It is likely that – probably within days – most similar jet engines in the world would be inspected and the orange wire, if faulty, would be renewed.

When will health-care pass the orange-wire test?

The belief that one day it may be possible for the bad experience suffered by a patient in one part of the world to be a source of transmitted learning that benefits future patients in many countries is a powerful element of the vision behind the WHO World Alliance for Patient Safety.

The most important knowledge in the field of patient safety is how to prevent harm to patients during treatment and care. The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the health care system. We know that most problems are not just a series of random, unconnected one-off events. We know that health-care errors are provoked by weak systems and often have common root causes which can be generalized and corrected. Although each event is unique, there are likely to be similarities and patterns in sources of risk which may otherwise go unnoticed if incidents are not reported and analysed.

These draft guidelines are a contribution to the Forward Programme 2005 of the World Alliance for Patient Safety. The guidelines introduce patient safety reporting with a view to helping countries develop or improve reporting and learning systems in order to improve the safety of patient care. Ultimately, it is the action we take in response to reporting – not reporting itself – that leads to change.

Reporting is fundamental to detecting patient safety problems. However, on its own it can never give a complete picture of all sources of risk and patient harm. The guidelines also suggest other sources of patient safety information that can be used both by health services and nationally.

The currency of patient safety can only be measured in terms of harm prevented and lives saved. It is the vision of the World Alliance that effective patient safety reporting systems will help to make this a reality for future patients worldwide.

Sir Liam Donaldson

Chair
World Alliance for Patient Safety

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1. INTRODUCTION

Reducing medical errors has become an international concern. Population-based studies from a number of nations around the world have consistently demonstrated unacceptably high rates of medical injury and preventable deaths. In response, a global effort, the World Alliance for Patient Safety, has been launched by WHO to galvanize and facilitate efforts by all Member States to make health care safer.

These draft guidelines are a contribution to the Forward Programme 2005 of the World Alliance for Patient Safety (1). The guidelines introduce adverse event reporting and focus on reporting and learning to improve the safety of patient care.

Purposes of reporting

In seeking to improve safety, one of the most frustrating aspects for patients and professionals alike is the apparent failure of health-care systems to learn from their mistakes. Too often neither health-care providers nor health-care organizations advise others when a mishap occurs, nor do they share what they have learned when an investigation has been carried out. As a consequence, the same mistakes occur repeatedly in many settings and patients continue to be harmed by preventable errors.

One solution to this problem is reporting: by the doctor, nurse, or other provider within the hospital or health-care organization, and by the organization to a broader audience through a system-wide, regional, or national reporting system. Some believe that an effective reporting system is the cornerstone of safe practice and, within a hospital or other health-care organization, a measure of progress towards achieving a safety culture. At a minimum, reporting can help identify hazards and risks, and provide information as to where the system is breaking down. This can help target improvement efforts and systems changes to reduce the likelihood of injury to future patients.

Objectives

The objective of these draft guidelines is to facilitate the improvement or development of reporting systems that receive information that can be used to improve patient safety. The target audience is countries, which may select, adapt or otherwise modify the recommendations to enhance reporting in their specific environments and for their specific purposes. The guidelines are not meant to be an international regulation and will undergo modification over time as experience accumulates.

The guidelines draw on a review of the literature about reporting systems, a survey of countries about existing national reporting systems, and the experience of the authors.

Reporting may capture errors, injuries, non-harmful errors, equipment malfunctions, process failures or other hazards (see definitions below). While an individual report may contain important information about a specific incident or event, the notion of a reporting system refers to the processes and technology involved in the standardization, formatting, communication, feedback, analysis, learning, response, and dissemination of lessons learned from reported events.

Reports are generally initiated by health-care workers such as care providers or administrators from hospitals, ambulatory sites, or communities. Reporting systems may also be designed to receive reports from patients, families, or consumer advocates.

Definitions

Safety: Freedom from accidental injuries (2).

Error: The failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning) (3). Errors may be errors of commission or omission, and usually reflect deficiencies in the systems of care.

Adverse event: An injury related to medical management, in contrast to complications of disease (4). Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable.

Preventable adverse event: An adverse event caused by an error or other type of systems or equipment failure (5).

"Near-miss" or "close call": Serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted. Also called potential adverse event.

Adverse drug event: A medication-related adverse event.

Hazard: Any threat to safety, e.g. unsafe practices, conduct, equipment, labels, names.

System: A set of interdependent elements (people, processes, equipment) that interact to achieve a common aim.

Other commonly used terms:

Event: Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events, and hazards (see also incident).

Incident (or adverse incident): Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events, and hazards.

Potential adverse event: A serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted (also called "near miss" or "close call") (6).

Latent error (or latent failure): A defect in the design, organization, training or maintenance in a system that leads to operator errors and whose effects are typically delayed (3).

Many other terms have been used: adverse outcomes, mishaps, untoward or unanticipated events, etc. WHO has commissioned the development of an international taxonomy for patient safety in order to promote greater standardization of terminology and classification. Meanwhile, for these guidelines we will use the simpler terms: errors, hazards, adverse events and incidents.

Why should individuals or health-care organizations report adverse events and errors?

Health-care organizations or individuals benefit from reporting incidents if they receive back useful information gained by generalizing and analysing similar cases from other institutions. Consider the following case: In an intensive care unit at a hospital, the oxygen tubing is inadvertently connected to an intravenous line and causes an air embolism. Investigation reveals that the tubing connectors are similar, the oxygen tubing had been left disconnected from a prior respiratory treatment, and the lights in the unit were dim. The hospital's response might include implementing a new policy requiring that all tubing be labelled, a weak and cumbersome solution.

If the event and the results of the analysis are not reported to an external authority, the lessons learned are trapped within the walls of that hospital. The opportunity to generalize the problem is lost and the opportunity to develop more powerful and generalizable solutions is missed.

In contrast, if the event is reported and the findings from the investigation are entered into a database, the event can be aggregated with similar incidents to elucidate common underlying causes. A variety of solutions could emerge, ranging from

nursing practice standards to label and trace all tubing, to a requirement for medical device manufacturers to develop incompatible connectors for all medical tubing.

Appendix 1 contains an excerpt from the landmark Institute of Medicine report To Err is Human, which provides an overview of the systems approach to human error within health-care and other industries.

Core concepts

The four core principles underlying the guidelines are:

- The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the health-care system.
- Reporting must be safe. Individuals who report incidents must not be punished or suffer other ill-effects from reporting.
- Reporting is only of value if it leads to a constructive response. At a minimum, this entails feedback of findings from data analysis. Ideally, it also includes recommendations for changes in processes and systems of health care.
- Meaningful analysis, learning, and dissemination of lessons learned requires expertise and other human and financial resources. The agency that receives reports must be capable of disseminating information, making recommendations for changes, and informing the development of solutions.

Organization of the Guidelines

Section 2 describes the role of reporting in enhancing patient safety, its purposes and the ways in which reporting can enhance safety.

Section 3 discusses the essential components of a patient safety reporting system, considering the types of systems, the process of reporting (what is reported, by whom, and how), analysis of reports, response and dissemination, and application of results.

Section 4 examines alternative sources of information for safety. Reporting is but one method of obtaining such information, not necessarily the best. Other sources of useful data are briefly described.

Section 5 provides information about several existing national reporting systems, both governmentally sponsored and those implemented by non-governmental agencies or groups. This illustrates the broad variation in how Member States have dealt with these issues.

Section 6 describes the characteristics of successful reporting systems. While experience is limited in health care, successful existing systems have common features in purpose, design and operation, that have general applicability.

Section 7 outlines the requirements for a national adverse event reporting system, including the mechanism for collecting reports, the capacity to perform investigations, the expertise required, the technical infrastructure, and the capacity to disseminate findings.

Section 8 concludes with recommendations to WHO Member States.

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2. THE ROLE OF REPORTING IN ENHANCING PATIENT SAFETY

Key messages

- **The primary purpose of patient safety reporting systems is to learn from experience.**
- **A reporting system must produce a visible, useful response to justify the resources expended and to stimulate reporting.**
- **The most important function of a reporting system is to use the results of data analysis and investigation to formulate and disseminate recommendations for systems change.**

The purpose of reporting adverse events and errors

The primary purpose of patient safety reporting systems is to learn from experience. It is important to note that reporting in itself does not improve safety. It is the response to reports that leads to change. Within a health-care institution, reporting of a serious event or serious "near-miss" should trigger an in-depth investigation to identify underlying systems failures and lead to efforts to redesign the systems to prevent recurrence.

In a state or national system, expert analyses of reports and dissemination of lessons learned are required if reports are to influence safety. Merely collecting data contributes little to patient safety advancement. Even monitoring for trends requires considerable expert analysis and oversight of the reported data.

The important point is that a reporting system must produce a visible, useful response by the receiver to justify the resources expended in reporting, or, for that matter, to stimulate individuals or institutions to report. The response system is more important than the reporting system.

Methods of learning from reporting

There are several ways in which reporting can lead to learning and improved safety. First, it can generate alerts regarding significant new hazards, for example, complications of a new drug. Second, lessons learned by health-care organizations from

investigating a serious event can be disseminated. Third, analysis of many reports by the receiving agency or others can reveal unrecognized trends and hazards requiring attention. Finally, analysis of multiple reports can lead to insights into underlying systems failures and generate recommendations for "best practices" for all to follow.

Alerts

Even a small number of reports can provide sufficient data to enable expert analysts to recognize a significant new hazard and generate an alert. An excellent example of this function is the series of warnings issued every two weeks by the Institute for Safe Medication Practices entitled "Medication Alert". This system was one of the first to call attention to the high risk of death following accidental injection of concentrated potassium chloride and recommend that this substance be removed from patient care units.

Investigation of serious events

In a health-care organization committed to safety, a serious (especially disabling or life-threatening) event will trigger an investigation to search for underlying causes and contributing factors. Ideally, every institution will respond to a serious event with an investigation. Alternatively, an external authority (such as the health ministry) can conduct an independent investigation. If the investigation is done well, systems analysis of a serious adverse event can yield significant insights into the vari-

ous contributing factors that lead to a mishap, and often suggest potential remedies. This information can then be disseminated to other organizations. Solutions to some common hazards, such as wrong site surgery, have been developed in response to lessons learned from investigations of serious incidents.

Analysis of large datasets

Detailed analysis of thousands of reports also makes it possible to identify hazards (1). In the Australian Incident Monitoring System (AIMS) classification system, information about an incident is entered into the database using the generic classification scheme of clinically relevant categories. Natural questions guide analysts through details of context and contributing causes to probe interrelationships among event types, risk factors, and contributing causes. Statistical correlations identify meaningful relationships and provide analyses that can generate insights into the overall systems of care.

In the United States, USP's MedMARx[SM] system receives thousands of reports of medication errors and adverse drug events confidentially from participating health-care organizations. These data are classified and fed back to health-care organizations with benchmarking from the entire database and with their own prior experience, to identify targets for improvement as well as providing monitoring of progress.

Systems analysis and development of recommendations

The most important function that a large reporting system can perform is to use the results of investigations and data analyses to formulate and disseminate recommendations for systems changes. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has performed this function using a relatively small number of thoroughly investigated incidents reported to its sentinel events monitoring programme. Similarly, in the United States, some of the state reporting systems have developed safety recommendations from their data.

An example of a system aimed at translating learning into safety improvements is the relatively new National Reporting and Learning System (NRLS) developed by the National Patient Safety Agency (NPSA) in England and Wales. Reports are aggregated and analysed with expert clinical input to understand the frequency of types of incidents, patterns, trends, and underlying contributory factors. The NPSA has a "solutions" programme, involving all stakeholders. Recent initiatives include reducing errors associated with infusion devices, changes in doses of methotrexate, and a hand hygiene campaign.

Accountability

Some reporting systems, such as those of state health departments in the United States have been developed primarily to hold health-care organizations accountable for ensuring safe practice. Accountability systems are based on the notion that the government has a fiduciary responsibility to ensure that health-care organizations take necessary precautions to ensure that care is safe (2). A serious and presumably preventable injury, such as amputation of the wrong leg, suggests that the hospital's error prevention mechanisms are defective (3). Knowing that there is oversight by a government agency helps maintain the public's trust.

Accountability reporting systems hold health-care organizations responsible by requiring that serious mishaps be reported and by providing disincentives (citations, penalties, sanctions) to continue unsafe practices (4). Reporting in these systems can also lead to learning, if lessons are widely shared (2). However, if the government agency does not have sufficient resources to investigate or to analyse reports and disseminate results, the opportunity for learning is lost. In addition, the risk of sanctions may make health-care organizations reluctant to report events that can be concealed.

Since most reports elicit no response, and lessons from investigations are seldom shared, health-care organizations often perceive reporting in these systems as all risk and no gain (5). The result is that typical accountability systems receive relatively few reports. This is unlikely to change unless more resources are provided for analysis and reporting, and the consequences of reporting are made less punitive.

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3. COMPONENTS OF A REPORTING SYSTEM

Key messages

- **Current reporting systems span a spectrum of objectives incorporating both learning and accountability considerations.**
- **The primary objectives of a reporting system will determine the design, for example, whether reporting is voluntary and confidential.**
- **Reporting systems need to be clear on who reports, the scope of what is reported and how reports are made.**
- **Reporting of incidents is of little value unless the data collected are analysed and recommendations are disseminated.**
- **Experts who understand statistical methods, the practice concerns, clinical significance, systems issues, and potential preventive measures are essential to analyse reported incidents.**
- **Classification and simple analytic schemes start the process of categorizing the data and developing solutions that can be generalized.**

Types of systems

Current reporting systems span a spectrum of specific aims. At one end of the spectrum are reporting systems that focus on learning and contributing to system redesign. At the other end are systems developed by external regulatory or legal agencies primarily to ensure public accountability. These latter systems typically seek to identify health-care organizations where the level of care is unacceptable, for corrective action or discipline.

In practice, reporting systems may seek to address multiple objectives. Striking a balance within a single system between the aims of public accountability and learning for improvement is possible, but most reporting systems focus on one or the other. Although these aims are not necessarily incompatible, the primary objectives of the system will determine several design features, including whether the reports

are mandatory or voluntary, and whether they are held in complete confidence, or reported to the public or to regulatory agencies.

Learning systems

Reporting to learning systems is usually voluntary, and typically spans a wider scope of reportable events than the defined set of events typically required by a mandatory system. Rather than assure a minimum standard of care, learning systems are designed to foster continuous improvements in care delivery by identifying themes, reducing variation, facilitating the sharing of best practices, and stimulating system-wide improvements. Following careful expert analysis of underlying causes, recommendations are made for system redesign to improve performance and reduce errors and injuries.

In Australia, for example, over 200 health-care organizations or health services voluntarily send incident reports to the Australian Incident Monitoring System (AIMS) sponsored by the Australia Patient Safety Foundation (APSF). AIMS uses the Healthcare Incident Types (HIT) classification system, which elicits very detailed information from the reporter regarding generic incident types, contributing factors, outcomes, actions, and consequences.

The Japan Council for Quality Health Care collects voluntarily reported adverse events from health-care organizations in Japan, particularly sentinel cases with root cause analysis. A research team led by Tokai University asks health-care organizations to voluntarily pool their events, which are then aggregated and results disseminated. In 2003, the Ministry of Health, Labour and Welfare patient safety committee recommended a national reporting system.

The National Reporting and Learning System (NRLS) in England and Wales is another example of a learning system. NRLS receives reports of patient safety incidents from local health-care organizations.

For more details about the above systems, see Section 5.

Accountability systems

Reporting in accountability systems is usually mandatory and restricted to a list of defined serious events (also called "sentinel" events) such as unexpected death, transfusion reaction, and surgery on the wrong body part. Accountability systems typically prompt improvements by requiring an investigation and systems analysis ("root cause analysis") of the event. Few regulatory agencies have the resources to perform external investigations of more than a small fraction of reported events, however, which limits their capacity to learn. In Slovenia, a brief description of a sentinel event must be sent to the Ministry of Health within 48 hours, and 45 days later a satisfactory analysis with corrective actions must be submitted or else a follow-up consultation with the Ministry occurs. The Czech Republic has reporting requirements that follow from their accreditation standards.

The Netherlands has a two-tiered process. The Health Care Inspectorate, the agency accountable for taking actions against substandard performance, mandates hospitals to report adverse events that have led to death or permanent impairment. Other adverse events are reported voluntarily. There is interest in moving towards a more uniform blame-free reporting system to aggregate events nationally.

A number of states in the United States have reporting systems that require hospitals or other providers to report certain types of serious, usually preventable events (see Section 6).

Most accountability systems not only hold health-care organizations accountable by requiring that serious mishaps be reported, they provide disincentives to unsafe care through citations, penalties or sanctions. The effectiveness of these systems depends on the ability of the agency to induce health-care organizations to report serious events and to conduct thorough investigations.

Accountability systems can (and should) be learning systems if investigations are carried out and if the lessons learned are disseminated to all other providers by the agency. For example, the Danish Health Care System recently passed an Act on Patient Safety that requires health-care providers to report adverse events so information can be shared and aggregated for quality improvement.

Confidentiality and public access to data

Experience has shown that learning systems are most successful when reports are confidential and reporters do not feel at risk in sharing information about errors. Indeed, some feel it is only with such safe reporting systems that subtle system issues and the multitude of contributing factors will be uncovered. From a pragmatic standpoint, many believe that protecting the confidentiality of health-care organizations significantly enhances participation in reporting (1, 2).

However, some citizen advocacy groups have called for public disclosure of information uncovered during investigations of serious adverse events, asserting the public's right to know about these events. Surveys in the United States show that 62–73% of Americans believe that health-care providers should be required to make this information publicly available (3, 4). Nonetheless, all but three states in the United States have statutes that provide legal protection of confidentiality (5).

Internal reporting

Reports to an agency or other national body from a hospital or other health-care organization usually originate from a report within the institution. While such reports may merely reflect statutory requirements, an institution that values patient safety will have an internal reporting system that captures much more than that.

The objectives of an internal reporting system for learning are first, to identify errors and hazards, and then through investigation to uncover the underlying sys-

tems failures, with the goal of redesigning systems to reduce the likelihood of patient injury. The key conceptual point here, and the heart of a non-punitive approach to error reporting, is the recognition that adverse events and errors are symptoms of defective systems, not defects themselves. Reporting, whether retrospective (adverse events and errors) or prospective ("hazards", or "errors waiting to happen") provides the entry point into investigation and analysis of systems' defects, which, if skillfully done, can lead to substantial system improvements. Reporting is one way to get this type of information, but not the only way (see Section 4).

Ideally, internal reporting systems should go hand in hand with external reporting systems, by identifying and analysing events that warrant forwarding to external reporting agencies. Conversely, external reporting systems are most effective when they are an extension of internal systems.

Process

What is reported

Types of reports

Reporting systems may be open-ended and attempt to capture adverse events and close-calls along the entire spectrum of care delivery, or may focus on particular types of events, such as medication errors or pre-defined serious injuries. In general, focused reporting systems are more valuable for deepening the understanding of a particular domain of care than for discovering new areas of vulnerability. While these guidelines focus on reporting systems related to adverse events and medical errors, other types of health-related reporting systems focus on medical devices, epidemiological outcomes such as emergence of antimicrobial resistance, post-marketing medication surveillance, and specific areas such as blood transfusions.

Formats and processes vary from prescribed forms and defined data elements to free-text reporting. The system may allow for reports to be submitted via mail, telephone, electronically, or on the World Wide Web.

Types of events

Adverse events. An adverse events is an injury related to medical management, in contrast to a complication of disease (6).Other terms that are sometimes used are "mishaps", "unanticipated events" or "incidents", and "accidents". Most authorities caution against use of the term accident since it implies that the event was unpreventable.

Adverse events are not always caused by an error. For example, one form of adverse drug event, "adverse drug reaction" is, according to the WHO definition, a complication that occurs when the medication is used as directed and in the usual

dosage (7). Adverse drug reactions are, therefore, adverse drug events that are not caused by errors.

Many adverse events are caused by errors, either of commission or omission, and do, in fact, reflect deficiencies in the systems of care (8). Some reporting systems require that only preventable adverse events be reported, while others solicit reports whether or not a medical error occurred. One advantage of focusing reporting on adverse events rather than on errors is that it is usually obvious when a mishap has occurred; actual events focus attention.

Error. Error has been defined as "the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning)" (9). Although reporting of errors, whether or not there is an injury, is sometimes done within institutions, if reporting of all errors is requested, the number may be overwhelming. Therefore, some sort of threshold is usually established – such as "serious" errors, or those with the potential for causing harm (also called "near misses" or "close calls"). Establishing such a threshold for a reporting system can be difficult. Hence, most "error reporting systems" are actually "adverse events caused by errors" systems.

"Near miss" or "close call". " A near miss" or "close call" is a serious error or mishap that has the potential to cause an adverse event, but fails to do so by chance or because it was intercepted. It is assumed (though not proven) that the underlying systems failures for near misses are the same as for actual adverse events. Therefore, understanding their causes should lead to systems design changes that will improve safety.

A key advantage of a near miss reporting system is that because there has been no harm the reporter is not at risk of blame or litigation. On the contrary, he or she may be deserving of praise for having intercepted an error and prevented an injury. This positive aspect of reporting of near misses, has led some to recommend near miss systems for internal reporting systems within health-care organizations or other health-care facilities where a blaming culture persists. However, any hospital that is serious about learning will also invite reports of near misses.

Hazards and unsafe conditions. Reporting of hazards, or "accidents waiting to happen" is another way to achieve prevention without the need to learn from an injury. If health care were as safe as some other industries, reports of hazards – potential causes of adverse events (as opposed to near misses, which are actual errors) – would outnumber those of actual events. Of all major systems, the Institute for Safe Medication Practices system for medication-related events has been most successful at capturing hazards (e.g. "look alike" packaging and "sound alike" names.) and calling for their remedy before a predictable error occurs.

Within a health-care organization, hazard reports raise alerts about unsafe conditions. Providers can imagine accidents waiting to happen based on their observations of weakness in the system and their experience as users. With appropriate analysis, these reports can provide valuable information for changes to systems design.

Who reports

Reporting systems must specify who files reports. In accountability systems, such as state health department systems and the JCAHO in the United States, reporting is done by the organization. Many also solicit and receive reports from caregivers (doctors and nurses). Some jurisdictions require caregivers to file reports. Some reporting systems allow patients, families and consumer advocates to report events. The latter are typically merely a notice that an event has occurred. In general, learning systems solicit reports from caregivers or organizations. Focused systems targeting specific areas such as medication errors or intensive care errors solicit reports from specialists such as pharmacists or intensive care specialists, while broad-based systems look to organizations and caregivers, but usually accept reports from anyone.

A potential source of reports that has not been significantly used is patients and families who have experienced medical error. Patients often report a high desire to see remedial action taken to prevent future harm to others. Reporting can initiate that process. Patients may report otherwise unidentified issues that help health-care organizations understand where the holes in their safety nets are, identify root causes, and mitigate harm. A patient may experience an injury that does not manifest until after discharge from a hospital and therefore is not otherwise captured. Patients may be better positioned than their care providers to identify failures in hand-overs and gaps between providers across the continuum of care.

How do they report

Method: e-mail, fax, Internet, mail, phone calls

Methods for submitting reports vary according to local infrastructure and technology. They can range from mailing written reports to a central address, to web-based systems that centralize and aggregate multiple reports into a highly structured database. Mail, fax, and phone calls are most widely used, since these mechanisms are widely available. A streamlined process can be set up to receive reports by e-mail or over the Internet; for users who have access to these technologies, this can be very quick and easy (although it may be costly to establish the technical infrastructure). Systems that use e-mail or the Internet must be able to provide technical support for users.

Structured forms or narrative text

Reports may be highly structured, requiring specific types of information, or provide for a narrative description of events for analysis. The extent to which datasets can be developed for analysis depends in part on the degree of standardization inherent in the data reported. Events based on commonly accepted data elements, such as the classification of medication errors into wrong medication, wrong dose, wrong frequency and so on, can be readily configured into a standardized reporting format.

A higher level of structured reporting asks reporters to select options from defined fields as part of the reporting process. This can greatly facilitate input into datasets developed for analysis. The Australian Patient Safety Foundation's Advanced Incident Management System (AIMS), offers a highly sophisticated customizable data entry form that guides users through a cascade of natural questions and response choices that are structured and consistent.

However, much of what promotes learning in patient safety lacks crisply defined data elements, so most authorities believe it is important for reports to include narrative to convey meaning. Narrative reports provide the opportunity to capture the rich context and storyline that allow the conditions that contributed to the error to be explored and understood. Indeed, some believe that only narrative reports are capable of providing information that provides meaningful insight into the nature of the underlying systems defects that caused the incident (Richard Cook, personal communication).

The vast majority of reporting forms have at least some room for a narrative description, and some, such as the United States Food and Drug Administration (FDA) MedWatch programme include open narrative for other relevant medical information such as laboratory data or patient condition.

Because of the nature of analysis that is required, systems that elicit open-ended, narrative texts require additional resources for data analysis and interpretation. In contrast, reports to systems with a standardized format, fixed fields, and predefined choices are swiftly entered and readily classified, making possible aggregated analysis at lower cost.

Another consideration is the effect of reporting on the reporter. Providing reporters with the chance to tell their stories implicitly values their observations. When the reporter can trust in a considered and non-punitive response, the process raises the individual's awareness of patient safety and sense of responsibility for reporting.

Classification

Reporting of events is of little value unless the data are analysed. Regardless of the objective of the system – whether to identify new and previously unsuspected hazards, discover trends, prioritize areas for remedial efforts, uncover common contributing factors, or develop strategies to decrease adverse events and patient harm – neither the act of reporting nor the collection of data will accomplish that objective unless the data are analysed and recommendations are made for change. Classification of the event is the first step in the analysis.

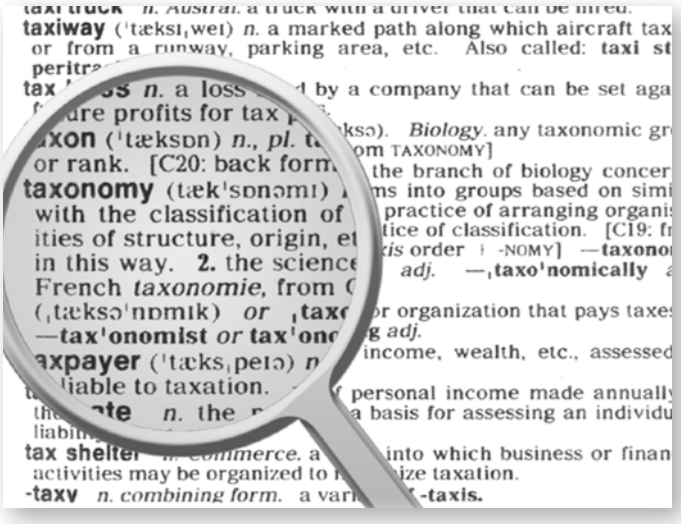
Why classify?

Recall the case presented in Section 1 of the inadvertent connection of oxygen tubing to an intravenous line the result being an air embolism. After the incident is reported, classification by the reporting system turns a specific event into an example that could happen anywhere; this particular incident becomes an example of "tubing mix-up". When aggregated with similar incidents, depending on the availability of contextual information, a variety of solutions can emerge, ranging from changes in nursing practice standards to a requirement for medical device manufacturers to develop incompatible connectors for all medical tubing. Classification starts the process of developing solutions that can be generalized.

Classification systems (taxonomies)

A number of quite different systems have been used for classifying patient safety incidents. These systems are also called "taxonomies". Because of differences between taxonomies, data can often not be shared among systems. Further, none have been validated, in the sense of studies that demonstrate that the classification and analysis method used leads to significant improvements in patient safety. As a result, the WHO World Alliance for Patient Safety has included in its Forward Programme 2005 an action area focusing on the development of an internationally agreed taxonomy of events.

Some of the factors that have been used to classify events include: error type (wrong dose, wrong diagnosis, etc.), patient outcome (level of harm, from none to death), setting, personnel involved, product or equipment failures, proximal (obvious) causes (misidentification of a patient), underlying causes (lack of knowledge, information, skills, etc.), contributing factors (organizational factors, environmental factors, etc.), stage in process of care (ordering, implementation, responding to laboratory results), and mechanism of error (knowledge-based, rule-based, skill-based). These taxonomies tend to fall into three major categories: classification by event, by risk, or by causation.


taxiway (ˈtæksɪˌweɪ) *n.* a marked path along which aircraft tax
or from a runway, parking area, etc. Also called: taxi st
taxon (ˈtæksɒn) *n., pl.* t
or rank. [C20: back form
taxonomy (tækˈsɒnəmɪ)
with the classification of
ities of structure, origin, et
in this way. **2.** the science
French *taxonomie*, from
—**taxˈonomist** *or* **taxˈonc**
axpayer (ˈtæksˌpeɪə) *n*
liable to taxation.
ate *n.* the
tax shelter
activities may be organized to
-taxy *n. combining form.* a var
Biology. any taxonomic gr
the branch of biology concer
practice of arranging organi
tice of classification. [C19: f
is order + -NOMY] —**taxono**
adj. —**ˌtaxoˈnomically**
or organization that pays taxes
adj.
income, wealth, etc., assessed
personal income made annually
a basis for assessing an individu
into which business or finan
ize taxation.
-taxis.

A taxonomy of adverse events classifies by event type, such as how many medication errors are attributable to "wrong dose" or "wrong patient". Event classification schemes work best when describing a specialized medical domain, such as medication errors, dialysis events or transfusion mismatches.

Several systems use taxonomies to assess risk, in order to prioritize events for action or to determine if further investigation is warranted. The United States Pharmacopoeia (USP) uses a nine-tier approach to rank medication risk. The Veterans Health Administration (VHA) uses a scoring system to prioritize both the potential severity, and the likelihood of occurrence of events, based on specific

scales and definitions; these are organized into a "safety assessment code" matrix (10). See Figure below.

The Australian Patient Safety Foundation uses explicit criteria for assessing the degree of risk expressed as a risk matrix that plots the severity of the outcome against the likelihood of its recurrence (11). The United States Agency for Healthcare Research and Quality (AHRQ) has indicated that a risk assessment scale should be included in its Patient Safety Network reporting system currently being developed in collaboration with the Institute of Medicine's Committee on Data Standards for Patient Safety

Figure: Safety Assessment Code (SAC) Matrix

		SEVERITY			
		Catastrophic	Major	Moderate	Minor
PROBABILITY	Frequent	16	12	8	4
	Occasional	12	9	6	3
	Uncommon	8	6	4	2
	Remote	4	3	2	1

Source: Veterans Health Administration National Center for Patient Safety, United States of America

The earliest classification system that focused on causation was the Eindhoven Classification Model, developed at Eindhoven University of Technology in the Netherlands. It is used in high-risk industries such as chemical manufacturing. It has recently been adapted for use in the VHA root cause analysis to identify factors based on the principles of human, organizational, and technical factors.

Another causation-oriented system is the Australian Incident Monitoring System developed by the Australian Patient Safety Foundation. This classification system comprises more than a million permutations of terms to describe an incident or adverse event. The system allows the end user to deconstruct an incident into a very detailed data set that defines the relationships between the component factors of the classification system.

A related system is classification by contributing factors, used at the Clinical Risk Unit at University College in London, England to identify patient, provider, team, task, work environment, organizational and other factors, through comprehensive systems analysis (12).

Design of a classification system

At least three key factors should be considered in the design of a classification system:

- The purpose of the reporting system. What is the expected product? How will the classification scheme facilitate analysis that will produce the desired outcome?
- The types of data that are available. Are reporters expected to have carried out an investigation and analysis of the event? If not, it is

unlikely that they will be able to provide useful information concerning underlying systems causes, and events will not be able to be classified at that level.

- Resources. The more detailed and elaborate the classification system is, the more expertise will be required, and the costlier the system will be to maintain.

A report commissioned by WHO and prepared by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) notes that the following attributes are desirable in an ideal classification scheme (13):

- It should address a broad and diverse range of patient safety issues and concerns across multiple health-care settings.
- It should identify high-priority patient safety data elements that are important to health-care systems.
- It should classify information related to what, where and how medical management goes wrong, the reasons why medical incidents occur, and what preventive and corrective strategies can be developed to keep them from occurring or to ameliorate their effects in health care.
- It must provide a meaningful and comprehensive linkage between the contributory factors and the errors and systems failures that lead to adverse events.
- It should facilitate the monitoring, reporting, and investigation of adverse events and near misses at the public health level – allowing aggregated data to be combined and tracked.

Because the resources required for taxonomy and analytical development tools are substantial, development of classification schemes is probably better left to national or international agencies rather than individual health-care systems.

The role of classification

Classification can be the cornerstone of what the system does. If the main goal is to produce data on the frequency of different types of events, as in the USP MedMARx[SM] system, then performing the classification, determining frequencies, and feeding back that information may be all that is needed to meet the objective of the reporting system.

More commonly, classification is the beginning of more complex analysis, the first step. A direct link exists between the type and complexity of the classification scheme, and the level of analysis that is possible. That is, the analytic plan should determine the classification scheme, not the reverse.

Analysis

Hazard identification

At a minimum, a reporting system should permit identification of new and unsuspected hazards, such as previously unrecognized complications associated with use of a medication or a new device. A simple way this can be done is by direct human review of incoming reports. For example, if even a few people report that free flow protection on a particular pump model can fail, that may be sufficient for the receivers of the reports to recognize the problem, alert the providers and communicate directly with the pump manufacturer.

This type of analysis requires that knowledgeable experts review reports, but the reports do not need to be based on extensive investigation by the reporting organization. A good example of a hazard identification model is the Institute for Safe Medication Practice (ISMP) Medical Error Reporting Program, where a small group of pharmacists reviews all reports, identifies new hazards, and prioritizes them for action. Recommendations are then disseminated to the participants (most hospitals) every two weeks via a newsletter, Medication Safety Alert.

Both JCAHO, through its sentinel events alert warning and ISMP have legitimately taken credit for the success in removing concentrated potassium chloride from nursing units in the United States (14). ISMP alerts have also led to drug name and label changes, as well as the removal or restriction of the use of many drugs (15). MedMARx[SM] analysis revealed reports of three drugs with a high frequency of medication errors: insulin, heparin, and warfarin (16).

Summaries and descriptions

At the next level, a simple classification scheme can provide summaries and descriptions that permit determination of frequencies or ranking by order of frequency. An example of this would be a reporting system that records medication errors classified by dose, route, patient, etc. Calculating frequencies permits prioritization that can be used by focused systems to allocate further resources.

Trend and cluster analysis

Trend analysis, obtained by calculating and observing rates of events over time, can identify significant changes that suggest new problems (or, if improving, that safety measures are working). Trends can also be detected using statistical control methodologies. These assist a particular organization in discerning whether its own trends, when compared with benchmarks, are attributable to what is known as “special cause” variation, rather than stemming from normal process fluctuations.

A cluster of events that suddenly arises suggests a need for inquiry. It is important to note that trends or clusters identified by reporting systems are those of reported events, not those of the events themselves. For example, the JCAHO recently released a sentinel event alert concerning wrong site surgery when the rate of reports it received increased substantially over a two-year period. However, it acknowledged that only a small fraction of events are reported, so the data may not be representative. The United States Pharmacopeia (USP) MedMARxSM system analyses events to identify trends. Such trends may influence standard-setting practices. Large-scale reporting systems such as the National Reporting and Learning System, of the National Health Service in England, also provide pattern analysis and recognition of trends or clusters (17).

Correlations

While trends over time or control charts are ways of using the factor of time, other analytical methods are available for additional cofactors. To take the example of 'medication error – wrong patient', other factors captured may include, for example, the health-care setting (whether clinic or hospital), the patient diagnosis, or the age of the patient. These can be subjected to an analysis of correlations to evaluate the strength of the relationship between two variables, such as whether dosing errors occur more frequently among chemotherapy patients than among patients undergoing other treatments, or whether wrong patient medication errors are more highly correlated with elderly patients than with younger (and perhaps more alert) patients.

Risk analysis

With adequate data, a reporting system can develop valuable information about risk. With a large number of reports, estimations of the probability of recurrence of a specific type of adverse event or error can be calculated. Analysis of reported outcomes can also produce an estimate of the average severity of harm caused by the incident. The Safety Assessment Code of the United States Veterans Health Administration uses these two factors, probability of recurrence and severity, to calculate a score for prioritizing incidents for safety initiatives.

Causal analysis

When many factors are classified and coded along with the event, a more complex set of correlations and relationships among the factors can be considered and tested in the database. If causal factors such as workloads, communication, teamwork, equipment, environment, staffing and the like are included, then correlations among many cause and effect relationships can yield important insights into a health-care system's vulnerabilities.

Another analytical tool that can be applied to datasets with a rich set of cofactors is regression analysis, which assesses the predictive value of multiple factors upon

the outcome. For example, regression analysis can be used to investigate whether patient diagnosis is a predictive factor for dosing error. The major use for this analytical approach is to go beyond identifying relationships to hypothesis testing.

The sentinel event alerts issued by JCAHO include risk reduction strategies based on causal analyses submitted with reports, such as finding that medication errors attributable to illegible handwriting or poor communication are more common when abbreviations are used. Eliminating abbreviations has thus become one of the JCAHO patient safety goals for hospital accreditation.

Systems analysis

The ultimate aim of reporting is to lead to systems improvements by understanding the systems failures that caused the error or injury. At the organizational level, this requires investigation and interviews with involved parties to elicit the contributing factors and underlying design failures. A national reporting system must receive this level of information in order to identify common and recurring systems failures. For example, if analysts repeatedly find similar underlying systems defects in reports of a specific type of error, then remedial actions should focus on correction of that failure.

The Australian Patient Safety Foundation identified problems with valve-controlled flow and pressure occurring with anaesthetic machines. Query of the database provided a deconstruction of the malfunction types and suggested, among other things, that frequent maintenance and audible alarms on pressure relief valves could prevent these mishaps (18).

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4. ALTERNATIVE SOURCES OF INFORMATION FOR PATIENT SAFETY

Key messages

- **Reporting systems are clearly of value for learning from others' experience.**
- **Reporting systems do not provide a complete picture of risks, hazards and system vulnerabilities.**
- **There are other valuable sources of information that can be used within a health service and nationally to complement reporting.**
- **These options may present less expensive options than establishing national reporting systems.**

National or system-wide reporting systems are clearly of great value for learning from others' experience. Many adverse events occur rarely, and thus to observers in the institution may seem to be isolated (outlier) cases. Commonality and common causation only emerge with analysis of aggregated data. Similarly, demonstrating occurrence of serious events in respectable peer institutions helps counteract a typical response of "that could never happen here", which providers may genuinely feel when asked about a serious adverse event, such as amputation of the wrong leg.

However, there are other valuable sources of patient safety information that can be used at both the internal health-care organizational level and nationally. Many are much less expensive, and therefore constitute important options for states and health-care organizations that are unable to finance a large reporting system. They are worthy of consideration even for those with highly developed reporting systems. We look at internal options first.

Internal alternative sources of safety information

An effective internal reporting system is an essential component of a hospital patient safety programme. However, even a simple reporting system can be a significant expense. For many institutions, providing the financial resources and expertise required to establish a reporting system may be a burden, and may not be the wisest use of scarce funds. Another problem is compliance. Studies have repeatedly shown that many events are not captured by typical reporting systems. Personnel often fail

to make reports for a host of reasons: because they forget, are too busy, or think it is unimportant, or because the reporting does not lead to significant change. Too often, failure to report reflects a punitive environment in which it can be harmful to the reporter or colleagues to report.

Fortunately, reporting is not the only way to obtain information about hazards and systems defects. Hospital personnel – nurses, pharmacists, doctors, risk managers, and others – are a rich source of information that even well run reporting systems do not fully exploit. Medical records, laboratory reports, and other routinely collected data can also be used to find evidence of safety problems. Several methods that have been found useful for utilizing these resources are described in this section. In addition, several alternative methods for collecting data on quality and safety of care are described that do require more extensive resources but offer the promise of more complete and less intrusive data collection. These alternatives are presented in order of increasing resource intensity.

Safety WalkRounds

A "Safety WalkRound" is a process whereby a group of senior leaders visit areas of a health-care organization and ask front-line staff about specific events, contributing factors, near misses, potential problems, and possible solutions. The leaders then prioritize the events and the patient safety team develops solutions with the clinicians. The results are fed back to the staff (1).

The information gleaned in this process often has the solution embedded in the event description. Thus, this process can often result in prompt changes that improve care and safety. It also can lead to culture change, as the concerns of front-line staff are addressed and as front-line staff are engaged in continuous observation of hazards and solutions for discussion with senior leadership. Leadership walkrounds are a low-cost way to identify hazards of concern to front-line staff and make needed changes. They require no additional staff, equipment, or infrastructure.

Focus groups

Focus groups are facilitated discussions with staff or with patients and families to elicit insights, concerns, and perceptions in an open, learning environment. Most nurses, for example, are aware of hazards in their daily work, accidents "waiting to happen", and are willing to discuss them if given the opportunity. A few hours with front-line people can generate a safety improvement agenda that will keep a hospital busy for months.

Focus groups offer an opportunity for a very rich learning environment as members within the group discuss and develop ideas. While this method of information gathering cannot provide trends or benchmarks like a reporting system, it can identify both hazards and potential solutions that otherwise remain hidden.

Medical record review

Medical record review has historically been the major method for oversight of quality. While labour intensive, record review often provides the reviewer with the story and context in which to understand events. In addition, medical record review allows for evaluation of processes as well as outcomes, and can yield information about whether important processes occurred, such as communication, documentation, use of a checklist, or administration of an evidence-based therapy.

Record reviews may be explicit, in which the reviewer searches for specific types of data that define events (such as "failure to rescue") or implicit, in which a clinical expert makes a judgment as to whether an adverse event and/or error has occurred (such as failure to follow up a positive laboratory test). Record reviews have been the cornerstone of the major population-based studies that defined the extent of medical injury (2-6). They are also widely used to monitor progress in preventing adverse events when new safe practices are implemented.

The major limitations of record review are its cost, and variability of content. Aside from laboratory reports and orders, much of the content is determined by the subjective judgments of those who write notes. While serious adverse events are almost always mentioned, errors and underlying conditions almost never are. "Near misses" are rarely noted. Thus, records can be valuable for case finding, but provide only limited contextual information.

Focused review

Medical record reviews that focus on a specific type of event can identify critical points of care that represent widespread vulnerabilities. Focused reviews of adverse drug events, for example, might show that ordering medications for patients with renal impairment, managing anticoagulation, and tracking allergies are areas that warrant widespread, systematic improvements. A focused record review might reveal not only the incidence of wrong-site surgery, but also whether a site checklist was executed and a time-out took place during each operation. Other focused analyses might include identifying high complexity processes.

Failure modes and effects analysis

Adverse events can be viewed as the outcomes of vulnerable systems. In addition to acquiring information about the outcomes, or events, it is very helpful to learn about the vulnerabilities in the system and about possible solutions to buffer and strengthen the systems of care.

Failure modes and effects analysis (FMEA) is a widely used tool for proactively identifying process vulnerabilities. It begins by systematically identifying each step in the process and then searches out "failure modes", that is, noticing what could go wrong. The next step is to evaluate how the failure mode could occur, and what are the "effects" of this failure. If a failure mode could result in catastrophic effects, the

process must be corrected or buffered. The FMEA is a proactive tool, used to evaluate a new process, or an existing process for proposed design changes.

Screening

Screening is the use of routine data to identify a possible adverse event. It can be performed retrospectively, or in "real" time, either by analysis of traditional paper records or automatically by computer programs if patient clinical and laboratory data are available in electronic form. "Occurrence" screening identifies when a predefined event occurs, such as a return to the operating room within an admission or a readmission for the same problem.

Screening criteria are sometimes referred to as "triggers". When a screening criterion is met, further investigation, usually in person by an expert, is needed to determine whether an event has, in fact, occurred.

For example, laboratory data can be screened for out of range International Normalized Ratio (INR) results in patients taking warfarin. Records of patients with a positive screen – defined as values above or below a defined range – are then reviewed to determine if an episode of haemorrhage or thrombosis has occurred.

The Institute for Healthcare Improvement (IHI) has pioneered in the use of a "trigger tool" to retrospectively discover adverse drug events (ADE) (7). Records are searched for the presence of any of a list of highly sensitive indicators (such as prescribing a narcotic antidote or out of range INR). If the trigger is found, further investigations are carried out to determine if the ADE did in fact occur. This tool can be used both to assess the rate of selected ADEs and to measure progress when new safe practices are implemented.

Observation

The observation method for discovering errors consists first of a knowledgeable expert (such as a nurse or pharmacist) observing a process and writing down precisely the steps that are taken by the provider. This log is then compared with the written orders to identify deviations. Observational studies of nurse administration of medications in a large number of hospitals have shown high error rates (average 11% of doses) (8). The nurses were not aware of the errors which would, thus, not be captured in a reporting system.

The observation method is very labour-intensive, and therefore costly. However, it yields very rich data that facilitate understanding, not only about what events occur, but also about the processes and dynamics that affect the outcome. It is a tool that can be used intermittently, as resources permit, both to identify and understand systems breakdowns and to monitor improvement after changes are implemented.

Observing the hand-over during a transition between caregivers, for example, will yield not only whether there is an error, but also meaningful clues as to the barriers

and solutions. Observation can also identify areas where process designs such as standardization, simplification, and forcing functions may be useful to avoid harm.

External alternative sources of safety information

At the national or systems level, alternatives to reporting have not been widely employed. Medical record reviews have been occasionally used in random audits to identify adverse events and estimate frequency. Specific one-off studies, such as the Confidential Enquiries in the United Kingdom have served this function for several decades (9,10). This type of sampling can identify system weaknesses that require attention with much fewer resources than required by a reporting system. Several other methods of gathering safety data are available, as described below.

Malpractice claims analysis

Where frequent, as in the United States, malpractice claims can provide a rich source of data concerning a small number of serious events. When a serious incident occurs, risk managers typically start a patient file (called a claim, even if no litigation ever ensues) and promptly conduct an investigation, interviewing all personnel involved to understand and correctly document exactly what happened. This type of analysis, while much less sophisticated than a root cause or systems analysis carried out by experts, produces far more information than the usual hospital reporting systems.

Analysis of claims, for example, has identified the factors that increase the probability of a foreign body being retained following surgery and demonstrated the need for fail-safe follow-up systems to ensure that positive mammograms lead to biopsy (11).

The limitation of malpractice claims is their non-representativeness. However, they do provide data on events that are significant – serious injuries – as well as data that are typically much more comprehensive than provided to most reporting systems.

Surveillance

Surveillance systems collect specific case data, checking for predefined factors and outcomes on all patients in a defined category (such as those with infection). These systems can identify the prevalence of risk and risk factors for key events, as well as provide benchmarks for organizations and assist in monitoring progress.

One of the best examples of a surveillance system is the National Nosocomial Infections Surveillance System, a voluntary, confidential cooperative effort between the United States Centers for Disease Control and Prevention (CDC) and participating hospitals to identify hospital-acquired infections and create a national database that is used to understand the epidemiology of nosocomial infections and antibiotic

resistance trends, and to provide robust benchmarks for organizations to track their own performance (12,13).

Another form of surveillance focuses on review of hospital discharge diagnostic codes. A list has been developed in the United States by the Agency for Healthcare Research and Quality (AHRQ) of specific discharge codes, called Patient Safety Indicators (PSI), that are highly correlated with "problems that patients experience as a result of exposure to the healthcare system and that are likely amenable to prevention"(14). Examples include retention of foreign bodies, complications of anaesthesia, obstetric trauma, decubitus ulcers, and postoperative hip fracture. Hospitals can use the PSI to identify potential systems failures and to monitor improvement in safety. As the indicators are refined, it seems likely that they will be used in a national monitoring programme.

Routine data collection

A variant of surveillance on a much larger scale is exemplified by the United States Veterans Health Administration National Surgical Quality Improvement Program (NSQIP) (15). Trained surgical clinical nurse reviewers collect data on 129 clinical and outcome variables (including 30-day postoperative outcomes) for all major operations performed at each Veterans Health hospital. These data are electronically transmitted to a coordinating centre that uses predictive models to generate risk-adjusted predicted probability of death or complications for each patient.

Observed and expected ratios of complication rates and mortality are then calculated for each hospital and service for all major surgical procedures and for each of the subspecialties and fed back to each hospital, together with de-identified benchmark data from all institutions for comparison. A central committee annually reviews the data, commends low outliers, and issues warnings to high outliers. Recurrent high outlier status leads to review by regional authorities and, when indicated, site visits to assist hospitals in identifying and remedying deficiencies. Since inception of NSQIP, data for more than 1 million cases have been entered into the national database.

Over a ten-year period, 1991-2000, after implementation of NSQIP, surgical mortality decreased by 27% and complications by 45% (16). Programme leaders attribute most of these reductions to changes made by the hospitals in response to data feedback. The total cost of the program is US$ 4 million annually, approximately US$ 12 per case. The savings from reduced mortality and complications are several multiples of this expense; thus there is a net saving with this method.

The success of NSQIP in reducing adverse events and mortality can be attributed to five factors: (i) data collection is automatic part of the daily routine for all patients, not just those with complications; (ii) designated trained individuals are responsible for data collection; (iii) results are risk-adjusted; (iv) results are fed back to hospitals as site-specific data with peer hospital comparisons; (v) outcomes are monitored

by a central oversight authority with the power to conduct site visits and require changes. After initial resistance, these systems have been well-accepted by physicians and hospitals.

Routine data collection bodes well for ultimately replacing reporting as the primary source of safety information in the future. For highly developed health-care systems that have fully electronic medical records, automated data collection and analysis can provide continuous monitoring of quality and safety at a fraction of the cost of a reporting system. Similarly, automatic feed of data to a central authority (as in the Veterans Health system) can occur rapidly and inexpensively. In such a system "reporting" would be much less important, and full attention could be given to analysis and focused investigation of key events uncovered by the data analysis.

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5. NATIONAL REPORTING SYSTEMS

Key messages

- **Existing national reporting systems exhibit great variation in sponsorship, support, participation, and function.**
- **All of these reporting systems aim to improve patient safety.**
- **Reporting to most national systems is voluntary.**
- **A major issue for all reporting systems, public or private, mandatory or voluntary, is confidentiality.**

Existing national reporting systems exhibit great variation in sponsorship, support, participation, and function. Some, such as the National Reporting and Learning System (NRLS) in England and Wales, and those of Denmark, the Czech Republic, and Sweden were developed by governmental agencies to provide information to improve patient safety. Others, such as the Australian Incident Monitoring System (AIMS) sponsored by the Australia Patient Safety Foundation and the JCAHO Sentinel Events Reporting System, have been developed within the private or non-government sector.

All of these reporting systems aim to improve patient safety. However, their ability to do that varies considerably according to the sophistication of the analyses and the vigour with which efforts are pursued to turn insights into changes in practice. Patient safety is a relatively new concern for most governments. Not surprisingly, many still do not have a large cadre devoted to advancing safety or resources to carry out the plans they do make. A number of Member States have no current governmental initiatives in safety and no reporting system.

Reporting to most national systems is voluntary. However, systems in the Czech Republic and Slovenia require hospitals to report, and reporting of some especially serious events is required in the Netherlands, Japan, and other systems as well (see below for details).

Voluntary systems invite a professional ethic of participation in continuous learning and prevention, encouraged by acknowledgement and the reward of visible change. Experience from industries outside of health care, particularly aviation, as well as from some long-standing health-care reporting systems, for example, the Institute for Safe Medication Practice, shows that reporting systems are more likely to be successful if those reporting do not need to worry about adverse consequences to themselves or others.

A major issue for all reporting systems, public or private, mandatory or voluntary, is confidentiality. There is broad agreement across many systems that patients' and caregivers' names should not be disclosed, and these are protected by almost all systems. However there is much less agreement on whether the public should have access to hospital-level information.

Governmental health-care systems have a fiduciary responsibility to the public to ensure reasonable levels of safe care in health-care organizations, and reporting systems are one mechanism for discharging that responsibility.

Although accountability does not require release of all information, some form of public disclosure of adverse incidents seems indicated. Some systems make the events themselves available to the public; others disclose results of investigations or summary reports. Another option is to provide public notice of the occurrence of a serious event and of the actions taken in response by the institution and the government. Some agencies issue annual reports that summarize events and actions taken.

Types of patient safety reporting systems

The following information has been provided by representatives of reporting systems from across the world as a result of a survey undertaken for these guidelines.

Czech Republic

Type of reporting system: The Czech Republic has a mandatory reporting system. Voluntary reporting has also been in place for two years in 50 hospitals, and a national pilot project has been launched for voluntary reporting.

What is reported: Reportable events include nosocomial infections, adverse drug reactions, transfusion reactions, and medical equipment failures.

Who reports: Health care professionals.

How they report: Reports yield simple statistics of adverse events.

Analysis: Information is aggregated at different levels, including by hospital, medical specialization, region, and the republic. Analysis of sentinel event reporting in the field of acute hospital care launched in 2004; a similar project has been launched in long term care.

Response, dissemination and application of results: Reports are not accessible to the public.

Denmark

Type of reporting system: The Act on Patient Safety in the Danish Health Care System came into force January 1, 2004. The objective of the Act is to improve patient safety within the Danish health care system. The law obligates health care professionals to report specified adverse events to a national database. To support learning, this national mandatory system is sharply separated from the system of sanctions.

What is reported: Reportable adverse events are "events resulting from treatment by or stay in a hospital and not from the illness of a patient, if such event is at the same time either harmful, or could have been harmful had it not been avoided beforehand, or if the event did not occur for other reasons. Adverse events shall comprise events and errors known and unknown" Surgical events and medication errors, including close calls, must be reported.

Who reports: Healthcare professionals who become aware of an adverse event in connection with a patient's treatment or hospital stay are required to report the event.

How they report: Health care professionals report to the national database. Reports are automatically forwarded to the county where the event occurred and county councils record, analyse, and de-identify the reports. Lastly, reports are forwarded to the National Board of Health, which maintains a national register of adverse events.

Analysis: Although there are no national requirements for analysis, there is general use of the Safety Assessment Code (SAC) score. Adverse events with less serious SAC scores are acted upon locally, whereas serious adverse events (SAC score of three) prompt a root cause analysis.

Response, dissemination and application of results: Hospital owners are obligated by the Act on Patient Safety to act on reports, while the National Board of Health is charged with dissemination of lessons learnt. The National Board of Health issues alerts in the form of regular newsletters, in addition to an annual report.

Further information: www.patientsikkerhed.dk

England and Wales

Type of reporting system: The National Reporting and Learning System (NRLS) has been developed by the National Patient Safety Agency (NPSA) to promote an open reporting culture and a process for learning from adverse events. The purpose of the NRLS is to elicit reports of patient safety incidents, identify themes and patterns in the types of incidents being reported including major systems failures, and to develop and promote implementation of solutions.

The NRLS was launched in February 2004. As of July 2005, 548 NHS organizations have successfully connected to NRLS (90% of the total number).

What is reported: Patient safety incidents to be reported are defined as "any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare". Reports are anonymous, although a NHS Trust identifier is maintained; if staff or patient names are provided, they are removed before data are entered in the database.

Who reports: Any health care staff member can report a patient safety incident to the NRLS. The NPSA receives reports from NHS Trusts who in turn encourage reporting of patient safety incidents from each organization. The Trusts can be Acute, Primary Care, Mental Health or Ambulance Service oriented. Participation by health care services is voluntary.

How they report: Health care organizations with electronic risk management systems can use a technical link to submit reports directly from this local system into the NRLS. The NPSA has worked with local risk management software vendors to establish compatibility and interfaces. The objective is to have reports that are already collected for local use forwarded seamlessly to the national repository, therefore avoiding any duplication of data entry. Data are submitted to the NRLS at a rate of around 10,000 reports a week. The NSPA has worked with every Trust to 'map' its dataset to that of the NRLS (1).

The NPSA has also developed an electronic reporting form, the 'eForm', for use by organizations without compatible commercial risk management system software or for reports submitted independently of an organization's risk management system. The NRLS provides a detailed report form that guides the user through multiple question categories with coded options defining categories of where, when how, and what occurred. Brief sections for narratives are embedded throughout the form.

Patients and carers can telephone reports to the relevant Trusts' NHS Patient Advice and Liaison Service. Staff can also send in reports directly and plans exist to enable patients and from 2006 carers to report via an eForm.

Analysis: After data cleansing (the removal of identifying information), the NPSA database supports the identification of trends based on the specific data elements defined in the reporting formats. Standardized data are extracted that include the 'when and where', level of patient harm, patient characteristics, and contributing factors.

Adverse events are categorized into classes such as a medication event; these are further broken down into descriptors such as wrong quantity, wrong route, etc. The report form allows for narrative throughout, but the data provided in the structured, standardized format, can be automatically entered in the database and correlated to identify trends and relationships among the events and causes.

Reports are aggregated and analysed with expert clinical input to help understand the frequency of types of patient safety incidents, patterns and trends and underlying contributory factors. Investigation of reports submitted locally remains the responsibility of the local organizations. The NPSA does not investigate individual incidents or become involved in discipline or performance management.

Response, dissemination and application of results: Lessons learnt from NRLS are disseminated through the publication of NPSA Patient Safety Observatory reports and through feedback to reporting organizations on incident trends and solutions. Lessons learned from the NRLS feeds into the NPSA work on safety solutions.

Incident reports are not accessible to the public, but NHS Trusts may (and do) make information available at their discretion. The NPSA also provides root cause analysis training.

Further information: www.npsa.nhs.uk

The Netherlands

Type of reporting system: Non-punitive, voluntary reporting systems for adverse events are in place within most hospitals and other health care organizations. A mandatory system also exists for reporting serious adverse events (with permanent injury or death as result) which is monitored by the Health Care Inspectorate. There is considerable under-reporting.

What is reported: There is a legal requirement that serious adverse events are reported to the Health Care Inspectorate; adverse events resulting in persistent patient injury or death are reported, as well as suicides and acts of sexual harassment. Medical equipment failures are reported by manufacturers in accordance with legal European obligations.

Who reports: Voluntary reporting is conducted by anonymous sources, hospital or health care organizations, other health care organizations, patients, health care professionals and members of the public. Mandatory reporting is conducted by hospital or healthcare organizations, other health care organizations or by licensing or disciplinary actions.

How they report: Reports can be submitted by mail, fax, or phone.

Analysis: Data classification among the hospital systems is not standardized, meaning no national aggregation of data. The national mandatory system collates data.

As part of a regulatory response all hospitals are required to investigate serious events and redesign systems.

Response, dissemination and application of results: Following receipt of reports by the agency, most reports are investigated; receive analysis of incident causation and feedback to the reporter. The classification and collation of data is not solid and, therefore, may be unreliable. The Health Care Inspectorate received 2716 reports in 2003; average annual number of reports 3000. Committees for the investigation of adverse events in individual health care institutions are required to make an annual report. The Health Care Inspectorate produces an annual report of summary data which is made publicly available.

Further information: www.minvws.nl

Ireland

Type of reporting system: The Republic of Ireland established enterprise liability under a Clinical Indemnity Scheme (CIS) in 2002 to promote safe patient care, to reduce the number of claims and to manage claims in a timely fashion. A secure web based Clinical Incident Reporting System is being rolled out nationally.

What is reported: Reportable adverse incidents include "events arising as consequence of provision of, or failure to provide clinical care that results in injury, disease, disability, death or prolonged hospital stay for the patient" and "near misses".

Who reports: All enterprises covered by the CIS are required to report on a mandatory basis, all adverse clinical events and "near misses".

How they report: Paper reports are submitted to local risk management personnel. These data are then transmitted electronically to the Clinical Indemnity Scheme central database via a secure web based system (STARSweb).

Analysis: STARSweb enables aggregated statistical analysis and supports detection of trends both at the enterprise and national level.

Response, dissemination and application of results: Lessons learnt will be disseminated through quarterly newsletters, topic-based seminars, and via a regularly updated website.

Further information: www.dohc.ie

Slovenia

Type of reporting system: A voluntary national reporting system for sentinel events was established in 2002, similar to that developed by the Joint Commission on Accreditation of Healthcare Organizations in the United States.

What is reported: Sentinel events reported include: unexpected death; major permanent loss of function; suicide of a patient while in the hospital; discharge of a newborn infant to a wrong family; hemolytic transfusion reaction following administration of blood or blood products because of the incompatibility of major blood groups; surgery on a wrong patient or body part; and neglect which has a possible characteristic of a criminal offence.

Who reports: Hospitals

How they report: Reported information is analyzed at the Ministry of Health, who also provide an initial feedback to the health care organization where the error occurred.

Response, dissemination and application of results: Reports are accessible to the public as anonymous summaries disseminated via the internet.

Sweden

Type of reporting system: The Swedish healthcare law of 1997 requires every medical institution to have a quality system; most medical institutions have implemented different forms of quality systems, which are regulated by Statutes issued by the National Board of Health and Welfare (NBHW). The reporting and learning system is part of a regulatory response that requires hospitals to investigate serious events and redesign systems.

What is reported: Events resulting in unanticipated serious injury or disease or risk thereof are reported; this covers adverse events, near misses, equipment failures, suicide and other hazardous events.

Who reports: Reports are received from hospital and health care organizations and health care professionals.

Hospitals, heath care organization, licensing and disciplinary bodies are required to report adverse events to their nearest superior offices. Patients, health care professionals and members of the public voluntarily report events.

How they report: Reporting is done in paper format via mail or fax. The National Board of Health and Welfare receives reports; approximately 1100 mandatory and 2400 voluntary reports are received annually. The board investigates most reports and provides an analysis of incident causation; in all cases feedback is provided to the reporter.

Analysis: Regional supervisory units of the NBHW receive reports and carry out inspections. In a limited number of cases reports are sent to the Medical responsibility board (HSAN), where certified health care personnel may be subject to disciplinary actions.

Response, dissemination and application of results: The Board issues recommendations to influence statutes in order to promote patient safety.

All reports to the NBHW are accessible to the public, but all personal data about any patients involved are confidential.

United States of America

Type of reporting system: The United States does not have a national governmental reporting system, but 21 of the 50 state governments operate mandatory reporting systems. Many of these have been in place for decades. All 21 mandate reporting of unexpected deaths, and several mandate reporting of wrong-site surgery. Beyond this, definitions of reportable events vary widely. Reports of serious events may trigger on-site investigations by state health departments. Less serious reports usually do not elicit a visible response. States cite insufficient staff as a barrier to follow-up, education, consultation, and oversight. Some degree of public disclosure occurs in all states, but the degrees of protection and methods of public release of information vary considerably.

Private and non-government initiated systems

Australia - the Australian Incident Monitoring System (AIMS)

Type of reporting system: The Australian Incident Monitoring System (AIMS) was founded in 1993, as an extension of the Anesthesia AIMS, formed in 1987. The objectives of AIMS is to promote learning of new hazards, trends, risk factors and contributing factors.

What is reported: AIMS is designed to receive a wide range of events, including predefined "Sentinel" events, all adverse events, near misses, equipment failures, new hazards, and specific events such as suicide and abduction. AIMS can accept and classify incident information from any source including incident reports, sentinel events, root cause analysis, coroner's findings, consumer reports, and morbidity and mortality reviews.

Deliberately unsafe, abusive or criminal acts are not reported to AIMS but to mandatory reporting agencies.

Who reports: Reports are accepted from all sources, including hospitals, outpatient facilities, emergency departments, aged care (long term care), community care, professionals, patients and families, and anonymous sources.

The system is voluntary and confidential. By law, AIMS databases have been designated a formal quality assurance activity. This status confers protection from legal disclosure; revealing or disseminating individually-identifying information that becomes known solely as a result of safety and quality activities is a criminal offense.

Databases reside in a fully secure location with strictly limited access.

How they report: A single system (incorporating different forms) is used for all incidents. Reports are submitted by paper, electronically, or by phone.

Analysis: The classification system in AIMS is perhaps the most highly developed of any known reporting system, comprising more than a million permutations of terms to describe an incident or adverse event. The purpose of the classification process is to translate information about an incident into a common language and create an electronic record that can be compared with other records and can be analysed as part of a larger set of data. The latest classification is based on the Professor Runciman's Generic Reference Model (GRM). The GRM is based on the Reason model of complex system failure (2).

The GRM has the components contributing factors (environmental, organizational, human, subject of incident, agents), details of the incident (type, component, person involved, timing of the incident, timing of detection, method of detection, preventability), factors minimizing or aggravating outcomes or consequences, and outcomes for the patient and organization.

The GRM is implemented via Healthcare Incident Types (HITs). HITs are a series of cascading, hierarchically based questions and answers designed to "de-construct" the information in a way that facilitates subsequent analysis and learning.

AIMS allows the reporter to deconstruct an incident into a very detailed data set that can be used for analysis, aggregation, and trending. Owing to the rich "natural categories" in the classification scheme, interrelationships among event types, risk factors, and contributing causes can be probed.

A specific data module allows the user to develop a risk matrix to determine the severity of risk. Statistical correlations among the many elements in each category are explored to identify meaningful relationships and provide analysis that can generate insights into the overall systems of care.

AIMS has a hierarchically-based, completely customizable organization tree. All wards, departments, divisions, hospitals, health services, states or territories and nations can be represented. The organization tree has the potential for 13 levels.

Incidents can be analysed at the organization level and below at which the analyst has security rights (security constraints prevent analysts querying incidents above the organization node where they security privileges).The organization tree structure allows the whole spectrum of analysis from local management of problems to aggregated analysis at a national level. The AIMS system is well equipped to provide reports and queries on any term in the database, which makes it possible for institutions or departments to compare data.

Response, dissemination and application of results: The Australian Patient Safety Foundation provides newsletters, publications, and advice at a system level. The Health Departments who use AIMS also distribute information in the form of newsletters and publications.

Putting the information, trends, and recommendations into action is the responsibility of reporting facilities. Health care facilities and organizations are able to access AIMS findings from problem-specific task forces to lead patient safety initiatives.

Further information: www.apsf.net.au

Japan

Type of reporting system: In Japan, hospitals are mandated by the Ministry of Health, Labour and Welfare to have internal reporting systems. The Japan Council for Quality Health Care collects voluntary incident reports and implemented a national reporting system in 2004. Reporting to the new system is mandatory for teaching hospitals, voluntary for others

Reporting systems exist on three levels; hospital or health facility; voluntary system in several different forms such as accreditation body for hospitals and a research group, and at national level which is mandatory.

What is reported: Patient injuries, sometimes referred to as adverse events are reported along with near-misses and equipment failures.

Who reports: Reports are received from hospitals or health care organizations.

How they report: Any hospital or healthcare organization can voluntarily report to accrediting bodies. There is a mandatory requirement to report to the Japan Council for Quality Health Care. Information is reported electronically.

Analysis: The Agency will provide analysis of incident causation and feedback of analysis to the reporter. The data are classified and summary results are disseminated to healthcare providers and to the public.

Response, dissemination and application of results: Cases deemed particularly important are evaluated individually. Otherwise, reports are aggregated for statistical analysis (further details not available). The Japan Council for Quality Health Care produces summary reports of events and disseminates them to healthcare providers and to the public.

U.S.A. - Institute for Safe Medication Practices (ISMP)

Type of reporting system: ISMP is a national, confidential medication error reporting system. that distributes hazard alerts and other medication safety information to 600,000 providers every other week.

What is reported: ISMP is a focused reporting system for adverse drug events and hazards in medication delivery and management.

Who reports: Reports are accepted from health care professionals, organizations, or patients.

How they report: Reports from organizations or professionals can be submitted online, electronically, by telephone, mail, or fax.

Analysis: Over half of reporters are called back to elicit details about hazardous medication packaging or devices information of brand name, model number, or a photograph illustrating the problem This detailed information is extracted to enable specific, direct and immediate influence on hazard reduction. Medication information is classified according to 10 key elements. Hazard identification is done by human expertise; a group of experts observes recurrent reports, works closely together, and applies their knowledge to appreciate the urgency of a problem. Rapid turnaround permits numerous hazard alerts, so that an overall analysis for prioritization is unwarranted.

Response, dissemination and application of results: ISMP is engaged in numerous actions to support hazard reduction, such as promoting maximum dose statements on chemotherapy vial caps, elimination of pre-filled syringes for hazardous cardiac medications, identification and reduction of hazardous medical abbreviations among providers and pharmaceutical advertisements, and several other collaborations with pharmaceutical companies, device manufacturers, and the United States FDA.

Further information: www.ismp.org

U.S.A - Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Type of reporting system: The Joint Commission on Accreditation of Healthcare Organizations implemented a Sentinel Event Reporting System in 1996. The system is designed to facilitate identification and learning among healthcare organizations of sentinel events and their prevention strategies. The system is voluntary and confidential. Accreditation status is not penalized for any organization that reports an error and applies due process to its future prevention.

What is reported: Reported sentinel events include: event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition, or the event is one of the following (even if the outcome was not death or major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition): suicide of any individual receiving care, treatment or services in staffed around-the-clock care setting or within 72 hours of discharge; unanticipated death of a full-term infant; abduction of any individual receiving care, treatment or services; discharge of an infant to the wrong family; rape; hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities; surgery on the wrong individual or wrong body part; unintended retention of a foreign object in an individual after surgery or other procedure.

Who reports:Reports are received from health care organizations and other sources such as media, complaints and the State Health Department.

How they report:Any accredited healthcare organization may submit reports.

Analysis: JCAHO require organizations to conduct a root cause analysis accompanied by an action plan. JCAHO also require access to review the organization's response to the sentinel event (which may or may not include actually reviewing the RCA). Guidance on conducting root cause analysis is offered by JCAHO on their website or upon request. Although reporting is voluntary, providing a root cause analysis is required.

Before the data describing the event, its root causes, and risk reduction strategies can be accepted into the database, the organization's response must meet certain defined criteria for acceptability.

Response, dissemination and application of results: Using their database and collaborating with experts, JCAHO periodically chooses a reported event type and develops a Sentinel Event Alert describing the events, causes, and strategies gathered from organizations for prevention. Publications began in 1998; to date 34 issues of Sentinel Event Alert have been published.

The individual organization's action plan is monitored by the JCAHO in a manner similar to the monitoring of corrective actions of other quality concerns. On a broader scale, hospitals' responses to the "Sentinel Event Alerts" are considered

during accreditation survey. The JCAHO have instituted National Patient Safety Goals as an influential derivative of the Sentinel Event reporting process.

Further information: www.jcaho.org

U.S.A - United States Pharmacopoeia MedMARx℠

Type of reporting system: MedMARx℠ is a voluntary system designed to identify hazards and systems vulnerabilities, identify best practices, and gather information that will support the standard-setting activities of USP.

What is reported: Adverse drug events, near misses, and errors can all be submitted to MedMARx℠.

Who reports: MedMARx℠ accepts reports from healthcare professionals,organizati ons, and patients. Since its introduction in 1998, over 900 healthcare facilities have contributed over 630,000 medication error reports (Personal communication with J.Silverstone National Patient Safety Foundation email listserve, editor. 4-20-2004). Currently, they receive approximately 20,000 reports each month (Personal communication with D. Cousins 5-19-2004) or about 20 per month for each of their 900 healthcare facilities.

How they report: Reports can be submitted directly through a web-based portal, submitted electronically, or by telephone, mail, and fax.

Analysis: Reports are entered into a database that can be searched and used to count, sort, and correlate events.

Response, dissemination and application of results: USP analyzes the errors in MedMARx℠ and provides an annual summary report. The database gathered by the USP is provided to the US Food and Drug Administration. A research partnership is underway with the Agency for Healthcare Research and Quality (AHRQ) to study the data for further improvement opportunities.

Further information: www.medmarx.com

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6. CHARACTERISTICS OF SUCCESSFUL REPORTING SYSTEMS

Key messages

A successful reporting and learning system to enhance patient safety should have the following characteristics:

- **reporting is safe for the individuals who report;**
- **reporting leads to a constructive response;**
- **expertise and adequate financial resources are available to allow for meaningful analysis of reports;**
- **the reporting system must be capable of disseminating information on hazards and recommendations for changes.**

The ultimate measure of the success of a reporting system is whether the information it yields is used appropriately to improve patient safety. How that is done varies greatly according to the aims of its sponsor. While both learning and accountability systems seek to improve learning from mistakes, the fiduciary objectives of the latter impose an additional constraint: satisfying the public's interest in making sure that known mechanisms for injury prevention are being used (rules and safe practices) and that new hazards are promptly addressed when they are uncovered. This may require some departure from the following concepts, particularly regarding confidentiality and independence.

Successful patient safety reporting systems have the following characteristics:

- reporting must be safe for the individuals who report;
- reporting is only of value if it leads to a constructive response, and meaningful analysis;
- learning requires expertise and adequate financial resources. The agency that receives reports must be capable of disseminating information and making recommendations for changes, and informing the development of solutions.

Table One lists the characteristics that have been identified by various authors as essential to the success of any reporting systems concerned with patient safety (1-4). Many of these characteristics are derived from long experience both in health care (for example, the Institute for Safe Medication Practice) and in other industries, particularly aviation. These essential characteristics are discussed below.

Non-punitive. The most important characteristic for success of a patient safety reporting system is that it must be non-punitive. Neither reporters nor others involved in the incidents can be punished as a result of reporting. For public systems, this requirement is the most difficult to achieve, since the public often assumes an individual is to blame, and there can be strong pressure to punish the "culprit". While perhaps temporarily emotionally satisfying, this approach is doomed to fail. People will not report any errors they can hide. It is important for national systems to protect reporters from blame. The best way to do this is by keeping the reports confidential.

Confidential. The identities of the patient and reporter must never be revealed to any third party. At the institutional level, confidentiality also refers to not making public specific information that can be used in litigation. Although, historically, breach of confidentiality has not been a problem in public or private systems, concern about disclosure is a major factor inhibiting reporting for many voluntary reporting programmes (5).

Independent. The reporting system must be independent of any authority with the power to punish the reporter or organization with a stake in the outcome. Maintaining a "firewall" between the reporting agency and the disciplinary agency in a governmental system can be difficult, but it is essential if trust in reporting is to be maintained.

Expert analysis. Reports must be evaluated by experts who understand the clinical circumstances under which the incidents occur and who are trained to recognize underlying systems causes. While it seems obvious that collecting data and not analysing it is of little value, the most common failure of governmentally run reporting systems is to require reporting but not to provide the resources needed to analyse the reports. Huge numbers of reports are collected only to sit in boxes or on computers. Expertise is a major, and essential, resource requirement for any reporting system.

Credible. The combination of independence and the use of content experts for analysis is necessary if recommendations are to be accepted and acted upon.

Timely. Reports must be analysed without delay, and recommendations must be promptly disseminated to those who need to know. When serious hazards are identified, notification should take place rapidly. For example, the Institute for Safe Medication Practice issues prompt alerts through its regular publication when new hazards in drugs are discovered.

Systems-oriented. Recommendations should focus on changes in systems, processes or products, rather than being targeted at individual performance. This is a cardinal principle of safety that must be reinforced by the nature of recommendations that come from any reporting system. It is based on the concept that even an apparently egregious individual error results from systems defects, and will recur with another person at another time if those systems defects are not remedied.

Responsive. For recommendations to result in widespread systems changes, the organization receiving reports must be capable of making and disseminating effective recommendations, and target organizations must make a commitment to implement recommendations. A good example is the National Reporting and Learning System in England and Wales which allows the National Patient Safety Agency to develop new solutions that are disseminated throughout the system.

Table 1 Characteristics of Successful Reporting Systems (7)

Non-punitive	Reporters are free from fear of retaliation against themselves or punishment of others as a result of reporting.
Confidential	The identities of the patient, reporter, and institution are never revealed.
Independent	The reporting system is independent of any authority with power to punish the reporter or the organization.
Expert analysis	Reports are evaluated by experts who understand the clinical circumstances and are trained to recognize underlying systems causes.
Timely	Reports are analysed promptly and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified.
Systems-oriented	Recommendations focus on changes in systems, processes, or products, rather than being targeted at individual performance.
Responsive	The agency that receives reports is capable of disseminating recommendations. Participating organizations commit to implementing recommendations whenever possible.

Several of these characteristics are included among the attributes that Runciman has proposed for national reporting and learning systems (6):

- an independent organization to coordinate patient safety surveillance;
- agreed frameworks for patient safety and surveillance systems;
- common, agreed standards and terminology;
- a single, clinically useful classification for things that go wrong in health care;
- a national repository for information covering all of health care from all available sources;
- mechanisms for setting priorities at local, national and international levels;
- a just system which caters for the rights of patients, society, and health-care practitioners and facilities;
- separate processes for accountability and "systems learnings";
- the right to anonymity and legal privilege for reporters;
- systems for rapid feedback and evidence of action;
- mechanisms for involving and informing all stakeholders.

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7. REQUIREMENTS FOR A NATIONAL ADVERSE EVENT REPORTING AND LEARNING SYSTEM

Key messages

Certain capacities are needed for all reporting systems, whether simple or complex. These are:

- **clear objectives;**
- **clarity about who should report;**
- **clarity about what gets reported;**
- **mechanisms for receiving reports and managing the data;**
- **expertise for analysis;**
- **capacity to respond to reports;**
- **a method for classifying and making sense of reported events;**
- **the capacity to disseminate findings;**
- **technical infrastructure and data security.**

Before deciding whether to establish a national adverse event reporting and learning system, states should carefully consider (i) what the objectives of the system are (ii) whether they can develop the capacity to respond to reports; and (iii) the resources that will be required. It is also important to decide the scope of what is to be reported and the data to be collected.

Appendix 2 provides a quick reference checklist of issues to consider in developing a reporting system.

Objectives

Ideally, the objectives of a reporting system emerge from the perceived needs of a patient safety programme. Reporting is a tool for obtaining safety information. A national reporting system, therefore, can usefully be regarded as a tool to advance public policy concerning patient safety. It should be an extension of a programme

of quality improvement and error prevention. To be effective, learnings from the analysis of reports must feed into a mechanism for developing and disseminating changes in policy and practice that improve safety.

If the commitment to improvement is weak, or if there is no infrastructure to carry out implementation of changes, such as an agency charged with improving safety, a reporting system will be of little value. Stating it simply, it is more important to develop a response system than a reporting system. If there is a commitment to improvement of patient safety and some infrastructure, but resources are scant, alternative methods of identifying problem areas may be preferable (See Section 4).

Capacity to respond

Certain capacities are needed for all reporting systems, whether simple or complex. These are a mechanism for receiving the reports and managing the data, some capacity to get additional information, a technical infrastructure, a method for classifying events, expertise for analysis, and the capacity to disseminate findings.

Mechanism for collecting reports and database management

The optimal process for receiving, inputting, analysing, and disseminating reports will vary according to the specific objectives and focus of an individual reporting system. For example, a structured input can help with analysis, whereas story telling captures rich detail and context. Personal contact from phone calls or reading written reports engages the receiver with each report, whereas direct electronic transmission facilitates ease of use and direct database entry. Keeping in mind the essential objectives of the reporting system and considering available types of technical support and overall resources will help developers determine which methods are most suitable.

When reports are received by mail, phone, or fax, front-line staff must have a process for the initial sorting and triage of reports. Staff may be called upon to judge whether a report can be entered directly into the database, or requires forwarding to an internal expert for further understanding.

One advantage of reports being received by individuals (as opposed to automatic data transfer) is that staff may recognize that reports of certain types of events have recurred and then query the database to confirm a trend. Reporting systems that receive reports in this fashion require resources to perform data entry and manage the integrity of the database for organizing identifying information about each report.

Capacity to investigate

Even with simple systems that focus primarily on recognizing hazards, resources should be available to support follow-up on reports, provide feedback to the reporter, and conduct at least a limited investigation when indicated. More sophisticated systems will have the capacity to find out more about the context in which the event occurred and conduct a systems analysis or other process for understanding the clinical issues and systems flaws underlying the event. This may also require further discussions with the reporter or an on-site investigation. Experts who perform this function must be sufficiently familiar both with the clinical context and with systems principles to identify potential themes and extract the essential learnings from the event.

Technical infrastructure

The technical infrastructure required to support reporting systems may be very simple or quite sophisticated. Reporting systems that use phone, mail or fax require as a minimum an efficient method for communicating with internal or external experts, tracking the database and generating reports. Web-based systems offer ease of use to reporters and also eliminate the need for staff to do data entry. The technical infrastructure to enable entered reports to be downloaded into a database is most readily achieved with standardized data fields.

Finally, all systems must provide technical support to users who may require assistance, whether with paper forms or on-line reporting functions.

Method for classifying events

There are three key factors in determining what classification system should be used:

- the purpose of the reporting system, and thus the type of information desired and how the classification scheme will facilitate the purpose for which data are being collected;
- the nature of the data available since underlying systems causes cannot be included in a classification scheme if those data are not reported;
- Resources, bearing in mind that elaborate classification systems that require substantial expertise can be expensive.

Reporting systems with predefined events may have a minimal classification scheme that sorts events into simple categories. Such a scheme yields a count and possibly trends but provides little opportunity for further analysis.

A more sophisticated classification scheme will include categories such as causal factors, severity, probability of recurrence, and type of recovery. An ideal system will also obtain, and classify, information about contributing factors (see Section 3 for a detailed discussion of classification systems).

Expert analysis

Whether analysing relatively simple reports to identify and understand new hazards, or searching for common underlying contributing factors in serious adverse events, all reporting systems need experts who understand the content and context of reported events. Experts determine whether reports are for identifying trends only, require follow-up with the reporter for further information, should trigger an on-site investigation, or herald an emerging hazard that warrants alerting the health-care organizations.

To provide meaningful recommendations, it is necessary to have experts who understand the practice concerns, clinical significance, systems issues, and potential preventive measures for the problems raised by the reports. Ultimately, it is human experts who must translate the knowledge gleaned from aggregated reports into meaningful recommendations for action to improve care.

Capacity to disseminate findings and recommendations

To fulfill their mission, reporting systems must communicate back to the community from which the reports are received. Reports, newsletters, communications, or alerts distill the meaning of aggregated reports into meaningful themes, identify proposed actions to prevent harm, inform policy-makers of issues, broadcast solutions and best practices, or alert pharmaceutical companies, device manufacturers, or health-care providers to new hazards. This requires staff to write reports and a mechanism to disseminate reports, such as large-scale mailings, press releases, newsletters, or electronic bulletins.

At a higher level, findings from the reporting system inform new safety initiatives that are generated and implemented by the appropriate authority. The National Reporting and Learning System of England and Wales, for example, feeds information and recommendations to the National Patient Safety Agency, which develops initiatives and campaigns to implement solutions.

While ultimately the effectiveness of a reporting system is measured by improvements in clinical outcomes, an intermediary measure is the number of recommendations generated from analyses of reports.

Security issues

Whereas reports within a health-care organization often have rich detail and usually contain information that makes it possible to identify the people concerned, it is important that such information is removed from external reports and de-identified to protect patients, providers and reporters. Confidentiality protection against unauthorized access must be implemented with a data security system. This may include a process for de-identifying reports upon their receipt or after a follow-up

investigation has occurred. A lock box or "firewall" may be indicated to protect against inadvertent data sharing with other parties or agencies. Data encryption methods are essential for web-based reporting systems. Data security systems also should have a mechanism for identifying breaches of security.

8. RECOMMENDATIONS TO WHO MEMBER STATES

1. Adverse event reporting and learning systems should have as their main objective the improvement of patient safety through the identification of errors and hazards which may warrant further analysis and investigation in order to identify underlying systems factors.

2. When designing adverse event reporting and learning systems, the responsible parties should clearly set out:

- the objectives of the system
- who should report
- what gets reported
- mechanisms for receiving reports and managing the data
- sources of expertise for analysis
- the response to reports
- methods for classifying and making sense of reported events
- ways to disseminate findings
- technical infrastructure and data security.

3. Health-care workers and organizations should be encouraged to report a wide range of safety information and events.

4. Health-care workers who report adverse events, near misses and other safety concerns should not be punished as a result of reporting.

5. Reporting systems should be independent of any authority with power to punish the reporter.

6. The identities of reporters should not normally be disclosed to third parties.

7. Reported events should be analysed in a timely way.

8. Reported events should be analysed by experts who understand the clinical circumstances and care processes involved and who are trained to recognize underlying systems causes.

9. The entity that receives reports should be capable of making and disseminating recommendations. Participating organizations should agree to implement recommendations wherever possible.

10. Recommendations for preventative strategies should be rapidly disseminated, especially when serious hazards are identified.

APPENDIX 1
EXCERPT FROM INSTITUTE OF MEDICINE REPORT TO ERR IS HUMAN

Why Do Errors Happen?

The common initial reaction when an error occurs is to find and blame someone. However, even apparently single events or errors are due most often to the convergence of multiple contributing factors. Blaming an individual does not change these factors and the same error is likely to recur. Preventing errors and improving safety for patients require a systems approach in order to modify the conditions that contribute to errors. People working in health care are among the most educated and dedicated workforce in any industry. The problem is not bad people; the problem is that the system needs to be made safer.

This chapter covers two key areas. First, definitions of several key terms are offered. This is important because there is no agreed-upon terminology for talking about this issue.[1] Second, the emphasis in this chapter (and in this report generally) is about how to make systems safer; its primary focus is not on "getting rid of bad apples," or individuals with patterns of poor per-formance. The underlying assumption is that lasting and broad-based safety improvements in an industry can be brought about through a systems approach.

Finally, it should be noted that although the examples may draw more from inpatient or institutional settings, errors occur in all settings. The concepts presented in this chapter are just as applicable to ambulatory care, home care, community pharmacies, or any other setting in which health care is delivered.

This chapter uses a case study to illustrate a series of definitions and concepts in patient safety. After presentation of the case study, the chapter will define what comprises a system, how accidents occur, how human error contributes to accidents and how these elements fit into a broader concept of safety. The case study

will be referenced to illustrate several of the concepts. The next section will examine whether certain types of systems are more prone to accidents than others. Finally, after a short discussion of the study of human factors, the chapter summarizes what health care can learn from other industries about safety.

WHY DO ACCIDENTS HAPPEN?

Major accidents, such as Three Mile Island or the Challenger accident, grab people's attention and make the front page of newspapers. Because they usually affect only one individual at a time, accidents in health care delivery are less visible and dramatic than those in other industries. Except for celebrated cases, such as Betsy Lehman (the Boston Globe reporter who died from an overdose during chemotherapy) or Willie King (who had the wrong leg amputated),[2] they are rarely noticed. However, accidents are a form of information about a system.[3] They represent places in which the system failed and the breakdown resulted in harm.

The ideas in this section rely heavily upon the work of Charles Perrow and James Reason, among others. Charles Perrow's analysis of the accidentat Three Mile Island identified how systems can cause or prevent accidents.[4] James Reason extended the thinking by analyzing multiple accidents to examine the role of systems and the human contribution to accidents.[5] *"A system is a set of interdependent elements interacting to achieve a common aim. The elements may be both human and non-human (equipment, technologies, etc.)."*

Systems can be very large and far-reaching, or they can be more localized. In health care, a system can be an integrated delivery system, a centrally owned multihospital system, or a virtual system comprised of many different partners over a wide geographic area. However, an operating room or an obstetrical unit is also a type of system. Furthermore, any element in a system probably belongs to multiple systems. For example, one operating

An Illustrative Case in Patient Safety

Infusion devices are mechanical devices that administer intravenous solutions containing drugs to patients. A patient was undergoing a cardiac procedure. This patient had a tendency toward being hypertensive and this was known to the staff.

As part of the routine set-up for surgery, a nurse assembled three different infusion devices. The nurse was a new member of the team in the operating room; she had just started working at the hospital a few weeks before. The other members of the team had been working together for at least six months. The nurse was being very careful when setting up the devices because one of them was a slightly different model than she had used before.

Each infusion device administered a different medication that would be used during surgery. For each medication, the infusion device had to be programmed according to how much medication would flow into the patient (calculated as "cc's/hour"). The medications had different concentrations and each required calculation of the correct dose for that specific patient. The correct cc's/hour were programmed into the infusion devices.

The anesthesiologist, who monitors and uses the infusion devices during surgery, usually arrived for surgery while the nurse was completing her set-up of the infusion devices and was able to check them over. This particular morning, the anesthesiologist was running behind from a previous surgery. When he arrived in the operating room, the rest of the team was ready to start. The anesthesiologist quickly glanced at the set-up and accepted the report as given to him by the nurse.

One of the infusion devices was started at the beginning of surgery. About halfway through the surgery, the patient's blood pressure began to rise. The anesthesiologist

room is part of a surgical department, which is part of a hospital, which is part of a larger health care delivery system. The variable size, scope, and membership of systems make them difficult to analyze and understand.

In the case study, one of the systems used during surgery is the automated, medication adminstration system, which includes the equipment, the people, their interactions with each other and with the equipment, the procedures in place, and the physical design of the surgical suite in which the equipment and people function.

When large systems fail, it is due to multiple faults that occur together in an unanticipated interaction,[6] creating a chain of events in which the faults grow and evolve.[7] Their accumulation results in an accident. "An accident is an event that involves damage to a defined system that disrupts the ongoing or future output of that system." [8]

The *Challenger* failed because of a combination of brittle O-ring seals, unexpected cold weather, reliance on the seals in the design of the boosters, and change in the roles of the contractor and NASA. Individually, no one factor caused the event, but when they came together, disaster struck. Perrow uses a DEPOSE (Design, Equipment Procedures, Operators, Supplies and materials, and Environment) framework to identify the potential sources of failures. In evaluating the environment, some researchers explicitly include organizational design and characteristics.[9]

tried to counteract this by starting one of the other infusion devices that had been set up earlier. He checked the drip chamber in the intravenous (IV) tubing and did not see any drips. He checked the IV tubing and found a closed clamp, which he opened. At this point, the second device signaled an occlusion, or blockage, in the tubing by sounding an alarm and flashing an error message. The anesthesiologist found a closed clamp in this tubing as well, opened it, pressed the re-start button and the device resumed pumping without further difficulty. He returned to the first device that he had started and found that there had been a free flow of fluid and medication to the patient, resulting in an overdose. The team responded appropriately and the patient recovered without further incident.

The case was reviewed two weeks later at the hospital's "morbidity and mortality" committee meeting, where the hospital staff reviews cases that encountered a problem to identify what happened and how to avoid a recurrence.

The IV tubing had been removed from the device and discarded. The bioengineering service had checked the pump and found it to be functioning accurately. It was not possible to determine whether the tubing had been inserted incorrectly into the device, whether the infusion rate had been set incorrectly or changed while the device was in use, or whether the device had malfunctioned unexpectedly. The anesthesiologist was convinced that the tubing had been inserted incorrectly, so that when the clamp was open the fluid was able to flow freely rather than being controlled by the infusion device. The nurse felt the anesthesiologist had failed to check the infusion system adequately before turning on the devices. Neither knew whether it was possible for an infusion device to have a safety mechansim built into it that would prevent free flows from happening.

In the case study, the accident was a breakdown in the delivery of IV medicationsduring surgery.

The complex coincidences that cause systems to fail could rarely have been foreseen by the people involved. As a result, they are reviewed only in hindsight; however, knowing the outcome of an event influences how we assess past events.[10] Hindsight bias means that things that were not seen or understood at the time of the accident seem obvious in retrospect. Hindsight bias also misleads a reviewer into simplifying the causes of an accident,

highlighting a single element as the cause and overlooking multiple contributing factors. Given that the information about an accident is spread over many participants, none of whom may have complete information,[11] hindsight bias makes it easy to arrive at a simple solution or to blame an individual, but difficult to determine what really went wrong.

Although many features of systems and accidents in other industries are also found in health care, there are important differences. In most other industries, when an accident occurs the worker and the company are directly affected. There is a saying that the pilot is always the first at the scene of an airline accident. In health care, the damage happens to a third party; the patient is harmed; the health professional or the organization, only rarely. Furthermore, harm occurs to only one patient at a time; not whole groups of patients, making the accident less visible.*

In any industry, one of the greatest contributors to accidents is human error. Perrow has estimated that, on average, 60–80 percent of accidents involve human error. There is reason to believe that this is equally true in health. An analysis of anesthesia found that human error was involved in 82 percent of preventable incidents; the remainder involved mainly equipment failure.[12] Even when equipment failure occurs, it can be exacerbated by human error.[13] However, saying that an accident is due to human error is not the same as assigning blame. Humans commit errors for a variety of expected and unexpected reasons, which are discussed in more detail in the next two sections.

Understanding Errors

The work of Reason provides a good understanding of errors. He defines an error as the failure of a planned sequence of mental or physical activities to achieve its intended outcome when these failures cannot be attributed to chance.[14] It is important to note the inclusion of "intention." According to Reason, error is not meaningful without the consideration of intention. That is, it has no meaning when applied to unintentional behaviors because errors depend on two kinds of failure, either actions do not go as intended or the intended action is not the correct one. In the first case, the desired outcome may or may not be achieved; in the second case, the desired outcome cannot be achieved.

Reason differentiates between slips or lapses and mistakes. A slip or lapse occurs when the action conducted is not what was intended. It is an error of execution. The difference between a slip and a lapse is that a slip is observable and a lapse is not.

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* *Public health has made an effort to eliminate the term, "accident," replacing it with unintentional injuries, consistent with the nomenclature of the International Classification of Diseases. However, this report is not focused specifically on injury since an accident may or may not result in injury. See Institute of Medicine, Reducing the Burden of Injury, eds. Richard J. Bonnie, Carolyn Fulco and Catharyn Liverman. Washington, D.C., National Academy Press, 1999).*

For example, turning the wrong knob on a piece of equipment would be a slip; not being able to recall something from memory is a lapse.

In a mistake, the action proceeds as planned but fails to achieve its intended outcome because the planned action was wrong. The situation might have been assessed incorrectly, and/or there could have been a lack of knowl- edge of the situation. In a mistake, the original intention is inadequate; a failure of planning is involved.

In medicine, slips, lapses, and mistakes are all serious and can potentially harm patients. For example, in medicine, a slip might be involved if the physician chooses an appropriate medication, writes 10 mg when the intention was to write 1 mg. The original intention is correct (the correct medication was chosen given the patient's condition), but the action did not proceed as planned. On the other hand, a mistake in medicine might involve selecting the wrong drug because the diagnosis is wrong. In this case, the situation was misassessed and the action planned is wrong. If the terms "slip" and "mistake" are used, it is important not to equate slip with "minor." Patients can die from slips as well as mistakes. For this report, *error is defined as the failure of a planned action to be completed as intended (e.g., error of execution) or the use of a wrong plan to achieve an aim (e.g., error of planning)*. From the patient's perspective, not only should a medical intervention proceed properly and safely, it should be the correct intervention for the particular condition. This report addresses primarily the first concern, errors of execution, since they have their own epidemiology, causes, and remedies that are different from errors in planning. Subsequent reports from the Quality of Health Care in America project will consider the full range of quality-related issues, sometimes classified as overuse, underuse and misuse.[15]

Latent and Active Errors

In considering how humans contribute to error, it is important to distinguish between active and latent errors.[16] *Active errors occur at the level of the frontline operator, and their effects are felt almost immediately. This is sometimes called the sharp end.*[17] *Latent errors tend to be removed from the direct control of the operator and include things such as poor design, incorrect installation, faulty maintenance, bad management decisions, and poorly structured organizations*. These are called the blunt end. The active error is that the pilot crashed the plane. The latent error is that a previously undiscovered design malfunction caused the plane to roll unexpectedly in a way the pilot could not control and the plane crashed

In the case study, the active error was the free flow of the medication from the infusion device.

Latent errors pose the greatest threat to safety in a complex system because they are often unrecognized and have the capacity to result in multiple types of active errors. Analysis of the Challenger accident traced contributing events back nine years. In the Three Mile Island accident, latent errors were traced back two years.[18] Latent errors can be difficult for the people working in the system to notice since the errors may be hidden in the design of routine processes in computer programs or in the structure or management of the organization. People also become accustomed to design defects and learn to work around them, so they are often not recognized.

In her book about the *Challenger* explosion, Vaughan describes the "normalization of deviance" in which small changes in behavior became the norm and expanded the boundaries so that additional deviations became acceptable.[19] When deviant events become acceptable, the potential for errors is created because signals are overlooked or misinterpreted and accumulate without being noticed.

Current responses to errors tend to focus on the active errors by punishing individuals (e.g., firing or suing them), retraining or other responses aimed at preventing recurrence of the active error. Although a punitive response may be appropriate in some cases (e.g., deliberate malfeasance), it is not an effective way to prevent recurrence. Because large system failures represent latent failures coming together in unexpected ways, they appear to be unique in retrospect. Since the same mix of factors is unlikely to occur again, efforts to prevent specific active errors are not likely to make the system any safer.[20]

In our case study, a number of latent failures were present:

- *Multiple infusion devices were used in parallel during this cardiac surgery. Three devices were set up, each requiring many steps. each step in the assembly presents a possibility for failure that could disrupt the entire system.*
- *Each of the three different medications had to be programmed into the infusion device with the correct dose for that patient.*
- *Possible scheduling problems in the operating suites may have contributed to the anesthesiologist having insufficient time to check the devices before surgery.*
- *A new nurse on the team may have interrupted the "normal" flow between the team members, especially communication between the anesthesiologist and the nurse setting up the devices. There was no standardized list of checks between the nurse and anesthesiologist before starting the procedure.*
- *Training of new team members may be insufficient since the nurse found herself assembling a device that was a slightly different model. As a new employee, she may have been hesitant to ask for help or may not have known who to ask.*

Focusing on active errors lets the latent failures remain in the system, and their accumulation actually makes the system more prone to future failure. [21] Discovering and fixing latent failures, and decreasing their duration, are likely to have a greater

effect on building safer systems than efforts to minimize active errors at the point at which they occur.

In the case study, a typical response would have been to retrain the nurse on how to assemble the equipment properly. However, this would have had no effect on weaknesses in equipment design, team management and communications, scheduling problems, or orienting new staff. Thus, free flow errors would likely recur.

Understanding Safety

Most of this chapter thus far has drawn on Perrow's normal accident theory, which believes that accident are inevitable in certain systems. Al- though they may be rare, accidents are "normal" in complex, high technology industries. In contrast to studying the causes of accident and errors, other researchers have focused on the characteristics that make certain industries, such as military aircraft carriers or chemical processing, highly reliable.[22] High reliability theory believes that accidents can be prevented through good organizational design and management.[23] Characteristics of highly reliable industries include an organizational commitment to safety, high levels of redundancy in personnel and safety measures, and a strong organizational culture for continuous learning and willingness to change.[24] Correct performance and error can be viewed as "two sides of the same coin."[25] Although accidents may occur, systems can be designed to be safer so that accidents are very rare.

The National Patient Safety Foundation has defined patient safety as the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the processes of health care.[26] Safety does not reside in a person, device or department, but emerges from the interactions of components of a system. Others have specifically examined pharmaceutical safety and defined it to include maximizing therapeutic benefit, reducing risk, and eliminating harm.[27] That is, benefit relates to risk. Other experts have also defined safety as a relative concept. Brewer and Colditz suggest that the acceptability of an adverse event depends on the seriousness of the underlying illness and the availability of alternative treatments.[28] The committee's focus, however, was not on the patient's response to a treatment, but rather on the ability of a system to deliver care safely. From this perspective, the committee believes that there is a level of safety that can and should be ensured. Safety is relative only in that it continues to evolve over time and, when risks do become known, they become part of the safety requirements.

Safety is more than just the absence of errors. Safety has multiple dimensions, including the following:

- an outlook that recognizes that health care is complex and risky and that solutions are found in the broader systems context;

- a set of processes that identify, evaluate, and minimize hazards and are continuously improving, and
- an outcome that is manifested by fewer medical errors and minimized risk or hazard.[29]

For this report, safety is defined as freedom from accidental injury. This simple definition recognizes that from the patient's perspective, the primary safety goal is to prevent accidental injuries. If an environment is safe, the risk of accidents is lower. Making environments safer means looking at processes of care to reduce defects in the process or departures from the way things should have been done. Ensuring patient safety, therefore, involves the establishment of operational systems and processes that increase the reliability of patient care.

ARE SOME TYPES OF SYSTEMS MORE PRONE TO ACCIDENTS?

Accidents are more likely to happen in certain types of systems. When they do occur, they represent failures in the way systems are designed. The primary objective of systems design ought to be to make it difficult for accidents and errors to occur and to minimize damage if they do occur.[30]

Perrow characterizes systems according to two important dimensions: complexity and tight or loose coupling.[31] Systems that are more complex and tightly coupled are more prone to accidents and have to be made more reliable.[32] In Reason's words, complex and tightly coupled systems can "spring nasty surprises."[33]

In complex systems, one component of the system can interact with multiple other components, sometimes in unexpected or invisible ways. Although all systems have many parts that interact, the problem arises when one part serves multiple functions because if this part fails, all of the dependent functions fail as well. Complex systems are characterized by specialization and interdependency. Complex systems also tend to have multiple feedback loops, and to receive information indirectly, and because of specialization, there is little chance of substituting or reassigning personnel or other resources.

In contrast to complex systems, linear systems contain interactions that are expected in the usual and familiar production sequence. One component of the system interacts with the component immediately preceding it in the production process and the component following it. Linear systems tend to have segregated subsystems, few feedback loops, and easy substitutions (less specialization).

An example of complexity is the concern with year 2000 (Y2K) computer problems. A failure in one part of the system can unexpectedly interrupt other parts, and all of the interrelated processes that can be affected are not yet visible. Complexity is also the reason that changes in long-standing production processes must be made cautiously.[34] When tasks are distributed across a team, for example, many interac-

tions that are critical to the process may not be noticed until they are changed or removed.

Coupling is a mechanical term meaning that there is no slack or buffer between two items. Large systems that are tightly coupled have more timedependent processes and sequences that are more fixed (e.g., y depends on x having been done). There is often only one way to reach a goal. Compared to tightly coupled systems, loosely coupled systems can tolerate processing delays, can reorder the sequence of production, and can employ alternative methods or resources.

All systems have linear interactions; however, some systems additionally experience greater complexity. Complex interactions contribute to accidents because they can confuse operators. Tight coupling contributes to accidents because things unravel too quickly and prevent errors from being intercepted or prevent speedy recovery from an event.[35] Because of complexity and coupling, small failures can grow into large accidents.

In the case study, the medication adminstration system was both complex and tightly coupled. The complexity arises from three devices functioning simultaneously, in close proximity, and two having problems at the same time. The tight coupling arises from the steps involved in making the system work properly, from the steps required to assemble three devices, to the calculation of correct medication dosage levels, to the operation of multiple devices during surgery, to the responses when alarms start going off.

Although there are not firm assignments, Perrow considered nuclear power plants, nuclear weapons handling, and aircraft to be complex, tightly coupled systems.[36] Multiple processes are happening simultaneously, and failure in one area can interrupt another. Dams and rail transportation are considered tightly coupled because the steps in production are closely linked, but linear because there are few unexpected interactions. Universities are considered complex, but loosely coupled, since the impact of a decision in one area can likely be limited to that area.

Perrow did not classify health care as a system, but others have suggested that health care is complex and tightly coupled.[37] The activities in the typical emergency room, surgical suite, or intensive care unit exemplify complex and tightly coupled systems. Therefore, the delivery of health care services may be classified as an industry prone to accidents.[38]

Complex, tightly coupled systems have to be made more reliable.[39] One of the advantages of having systems is that it is possible to build in more defenses against failure. Systems that are more complex, tightly coupled, and are more prone to accidents can reduce the likelihood of accidents by simplifying and standardizing processes, building in redundancy, developing backup systems, and so forth.

Another aspect of making systems more reliable has to do with organizational design and team performance. Since these are part of activities within organizations, they are discussed in Chapter 8.

Conditions That Create Errors

Factors can intervene between the design of a system and the production process that creates conditions in which errors are more likely to happen. James Reason refers to these factors as psychological precursors or preconditions.[40] Although good managerial decisions are required for safe and efficient production, they are not sufficient. There is also a need to have the right equipment, well-maintained and reliable; a skilled and knowledgeable workforce; reasonable work schedules, well-designed jobs; clear guidance on desired and undesired performance, et cetera. Factors such as these are the precursors or preconditions for safe production processes.

Any given precondition can contribute to a large number of unsafe acts. For example, training deficiencies can show up as high workload, undue time pressure, inappropriate perception of hazards, or motivational difficulties.[41] Preconditions are latent failures embedded in the system. Designing safe systems means taking into account people's psychological limits and either seeking ways to eliminate the preconditions or intervening to minimize their consequences. Job design, equipment selection and use, operational procedures, work schedules, and so forth, are all factors in the production process that can be designed for safety.

One specific type of precondition that receives a lot of attention is technology. The occurrence of human error creates the perception that humans are unreliable and inefficient. One response to this has been to find the unreliable person who committed the error and focus on preventing him or her from doing it again. Another response has been to increase the use of technology to automate processes so as to remove opportunities for humans to make errors. The growth of technology over the past several decades has contributed to system complexity so this particular issue is highlighted here.

Technology changes the tasks that people do by shifting the workload and eliminating human decision making.[42] Where a worker previously may have overseen an entire production process, he or she may intervene now only in the last few steps if the previous steps are automated. For example, flying an aircraft has become more automated, which has helped reduce workload during nonpeak periods. During peak times, such as take-off and landing, there may be more processes to monitor and information to interpret.

Furthermore, the operator must still do things that cannot be automated. This usually involves having to monitor automated systems for rare, abnormal events[43] because machines cannot deal with infrequent events in a constantly changing environment.[44] Fortunately, automated systems rarely fail. Unfortunately, this means that

operators do not practice basic skills, so workers lose skills in exactly the activities they need in order to take over when something goes wrong.

Automation makes systems more "opaque" to people who manage, maintain, and operate them.[45] Processes that are automated are less visible because machines intervene between the person and the task. For example, automation means that people have less hands-on contact with processes and are elevated to more supervisory and planning tasks. Direct information is filtered through a machine (e.g., a computer), and operators run the risk of having too much information to interpret or of not getting the right information.

In the case study, the infusion device administered the medication and the professional monitored the process, intervening when problems arose. The medication administration process was "opaque" in that the device provided no feedback to the user when the medication flowed freely and minimal feedback when the medication flow was blocked.

One of the advantages of technology is that it can enhance human performance to the extent that the human plus technology is more powerful than either is alone.[46] Good machines can question the actions of operators, offer advice, and examine a range of alternative possibilities that humans cannot possibly remember. In medicine, automated order entry systems or decision support systems have this aim. However, technology can also create new demands on operators. For example, a new piece of equipment may provide more precise measurements, but also demand better precision from the operator for the equipment to work properly.[47] Devices that have not been standardized, or that work and look differently, increase the likelihood of operator errors. Equipment may not be designed using human factors principles to account for the human–machine interface.[48]

In the case study, safer systems could have been designed by taking into consideration characteristics of how people use machines and interact with each other in teams. For example:

- *Redesign the devices to default to a safe mode*
- *Reduce the difficulties of using multiple devices simultaneously*
- *Minimize the variety of equipment models purchased*
- *Implement clear procedures for checking equipment, supplies, etc., prior to beginning surgery*
- *Orient and train new staff with the team(s) with which they will work*
- *Provide a supportive environment for identifying and communicating about errors for organizational learning and change to prevent errors.*

Technology also has to be recognized as a "member" of the work team. When technology shifts workloads, it also shifts the interactions between team members.

Where processes may have been monitored by several people, technology can permit the task to be accomplished by fewer people. This affects the distributed nature of the job in which tasks are shared among several people and may influence the ability to discover and recover from errors.[49]

In this context, technology does not involve just computers and information technology. It includes "techniques, drugs, equipment and procedures used by health care professionals in delivering medical care to individuals and the systems within which such care is delivered."[50] Additionally, the use of the term technology is not restricted to the technology employed by health care professionals. It can also include people at home of differentages, visual abilities, languages, and so forth, who must use different kinds of medical equipment and devices. As more care shifts to ambulatory and home settings, the use of medical technology by non-health professionals can be expected to take on increasing importance.

RESEARCH ON HUMAN FACTORS

Research in the area of human factors is just beginning to be applied to health care. It borrows from the disciplines of industrial engineering and psychology. *Human factors is defined as the study of the interrelationships between humans, the tools they use, and the environment in which they live and work.*[51]

In the context of this report, a human factors approach is used to under- stand where and why systems or processes break down. This approach examines the process of error, looking at the causes, circumstances, conditions, associated procedures and devices and other factors connected with the event. Studying human performance can result in the creation of safer systems and the reduction of conditions that lead to errors. However, not all errors are related to human factors. Although equipment and materials should take into account the design of the way people use them, human factors may not resolve instances of equipment breakdown or material failure.

Much of the work in human factors is on improving the human–system interface by designing better systems and processes.[52] This might include, for example, simplifying and standardizing procedures, building in redundancy to provide backup and opportunities for recovery, improving communications and coordination within teams, or redesigning equipment to improve the human–machine interface.

Two approaches have typically been used in human factors analysis. The first is critical incident analysis. Critical incident analysis examines a significant or pivotal occurrence to understand where the system broke down, why the incident occurred, and the circumstances surrounding the incident.[53] Analyzing critical incidents, whether or not the event actually leads to a bad outcome, provides an

understanding of the conditions that produced an actual error or the risk of error and contributing factors.

In the case study, researchers with expertise in human factors could have helped the team investigate the problem. They could examine how the device performed under different circumstances (e.g., what the alarms and displays did when the medication flow changed), varying the setup and operation of the infusion device to observe how it performed under normal and abnormal conditions. They could observe how the staff used the particular infusion device during surgery and how they interacted with the use of multiple infusion devices.

A critical incident analysis in anesthesia found that human error was involved in 82 percent of preventable incidents. The study identified the most frequent categories of error and the riskiest steps in the process of administering anesthesia. Recommended corrective actions included such things as labeling and packaging strategies to highlight differences among anesthesiologists in the way they prepared their workspace, training issues for residents, work–rest cycles, how relief and replacement processes could be improved, and equipment improvements (e.g., standardizing equipment in terms of the shape of knobs and the direction in which they turn).

Another analytic approach is referred to as "naturalistic decision making."[54] This approach examines the way people make decisions in their natural work settings. It considers all of the factors that are typically controlled for in a laboratory-type evaluation, such as time pressure, noise and other distractions, insufficient information, and competing goals. In this method, the researcher goes out with workers in various fields, such as firefighters or nurses, observes them in practice, and then walks them through to reconstruct various incidents. The analysis uncovers the factors weighed and the processes used in making decisions when faced with ambiguous information under time pressure.

In terms of applying human factors research, David Woods of Ohio State University describes a process of reporting, investigation, innovation, and dissemination (David Woods, personal communication, December 17, 1998). Reporting or other means of identifying errors tells people where errors are occurring and where improvements can be made. The investigation stage uses human factors and other analyses to determine the contributing factors and circumstances that created the conditions in which errors could occur. The design of safer systems provides opportunities for innovation and working with early adopters to test out new approaches. Finally, dissemination of innovation throughout the industry shifts the baseline for performance. The experience of the early adopters redefines what is possible and provides models for implementation. Aviation has long analyzed the role of human factors in performance. The Ames Research Center (part of the National Aeronautics and Space Administration) has examined areas related to information technology, automation,

and the use of simulators for training in basic and crisis skills, for example. Other recent projects include detecting and correcting errors in flight; interruptions, distractions and lapses of attention in the cockpit; and designing information displays to assist pilots in maintaining awareness of their situation during flight.[55]

SUMMARY

The following key points can be summarized from this chapter.

1. Some systems are more prone to accidents than others because of the way the components are tied together. Health care services is a complex and technological industry prone to accidents.
2. Much can be done to make systems more reliable and safe. When large systems fail, it is due to multiple faults that occur together.
3. One of the greatest contributors to accidents in any industry including health care, is human error. However, saying that an accident is due to human error is not the same as assigning blame because most human errors are induced by system failures. Humans commit errors for a variety of known and complicated reasons.
4. Latent errors or system failures pose the greatest threat to safety in a complex system because they lead to operator errors. They are failures built into the system and present long before the active error. Latent errors are difficult for the people working in the system to see since they may be hidden in computers or layers of management and people become accustomed to working around the problem.
5. Current responses to errors tend to focus on the active errors. Although this may sometimes be appropriate, in many cases it is not an effective way to make systems safer. If latent failures remain unaddressed, their accumulation actually makes the system more prone to future failure. Discovering and fixing latent failures and decreasing their duration are likely to have a greater effect on building safer systems than efforts to minimize active errors at the point at which they occur.
6. The application of human factors in other industries has successfully reduced errors. Health care has to look at medical error not as a special case of medicine, but as a special case of error, and to apply the theory and approaches already used in other fields to reduce errors and improve reliability.[56]

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APPENDIX 2
CHECKLIST FOR DEVELOPING A REPORTING SYSTEM

1. Clarify objectives

- Learning
- Accountability
- Both

2. What types of learning are the priorities?

- Alerts regarding significant new hazards
- Lessons learned by hospitals
- Analysis of trends
- Analysis of systems failures
- Recommendations for best practices

3. Voluntary or mandatory?

- Voluntary
- Mandatory

4. Confidential or public disclosure?

- Confidential
- Public disclosure of individual reports
- Public disclosure of analysis or trends

5. What is the process for the reporting system?

- What is reported?
- Who can report?
- How does one report?

6. Is confidential information held secure?

- Patient confidentiality
- Reporter confidentiality
- Organization confidentiality

7. What is the data infrastructure?

- Human receiver recognizing hazard reports
- Simple spreadsheet
- Relational database

8. What is the approach to classification?

- By event type
- By risk
- By causation

9. What is the approach to analysis?

- Hazard identification
- Summaries and descriptions
- Trend and cluster analysis
- Correlations
- Risk analysis
- Causal analysis
- Systems analysis

10. How will responses be generated and disseminated?

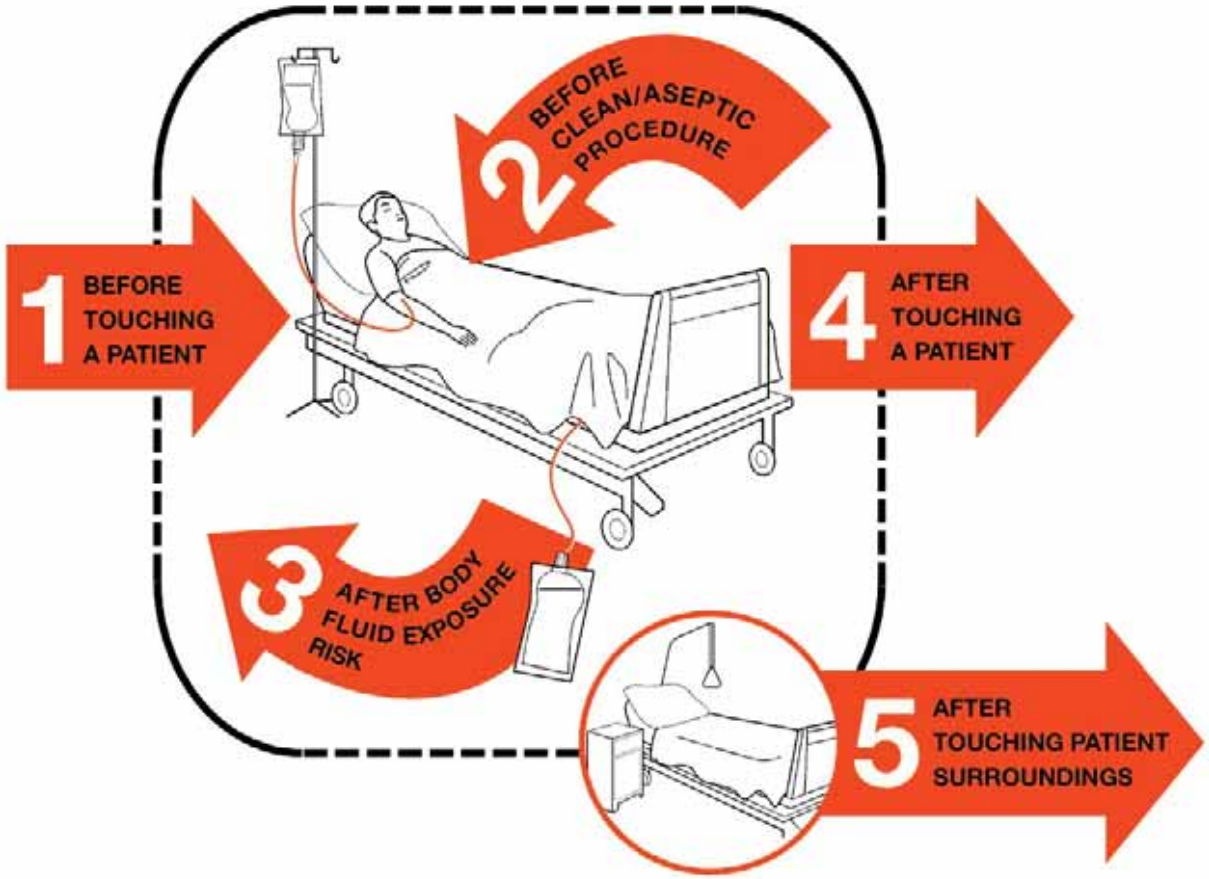
- Acknowledgement to reporter
- Alerts generated to organizations
- Trends, themes, or best practices in periodic newsletters

11. Are there sufficient resources?

- Mechanism for collecting reports
- Database management
- Capacity to investigate
- Technical infrastructure
- Method for classifying events
- Expert analysis
- Capacity to disseminate findings and recommendations

Annexure - 7

Your 5 Moments for Hand Hygiene



1	BEFORE TOUCHING A PATIENT	WHEN?	Clean your hands before touching a patient when approaching him/her.
		WHY?	To protect the patient against harmful germs carried on your hands.
2	BEFORE CLEAN/ ASEPTIC PROCEDURE	WHEN?	Clean your hands immediately before performing a clean/aseptic procedure.
		WHY?	To protect the patient against harmful germs, including the patient's own, from entering his/her body.
3	AFTER BODY FLUID EXPOSURE RISK	WHEN?	Clean your hands immediately after an exposure risk to body fluids (and after glove removal).
		WHY?	To protect yourself and the health-care environment from harmful patient germs.
4	AFTER TOUCHING A PATIENT	WHEN?	Clean your hands after touching a patient and her/his immediate surroundings, when leaving the patient's side.
		WHY?	To protect yourself and the health-care environment from harmful patient germs.
5	AFTER TOUCHING PATIENT SURROUNDINGS	WHEN?	Clean your hands after touching any object or furniture in the patient's immediate surroundings, when leaving – even if the patient has not been touched.
		WHY?	To protect yourself and the health-care environment from harmful patient germs.

World Health Organization | Patient Safety
A World Alliance for Safer Health Care | SAVE LIVES Clean Your Hands

WHO acknowledges the Hôpitaux Universitaires de Genève (HUG), in particular the members of the Infection Control Programme, for their active participation in developing this material.

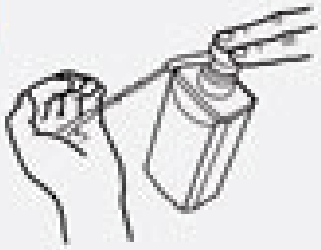
May 2009

How to Handrub?

RUB HANDS FOR HAND HYGIENE! WASH HANDS WHEN VISIBLY SOILED

Duration of the entire procedure: 20-30 seconds

1a



1b

Apply a palmful of the product in a cupped hand, covering all surfaces;

2

Rub hands palm to palm;

3

Right palm over left dorsum with interlaced fingers and vice versa;

4

Palm to palm with fingers interlaced;

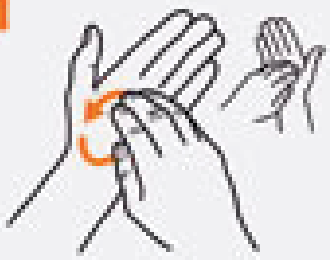
5

Backs of fingers to opposing palms with fingers interlocked;

6

Rotational rubbing of left thumb clasped in right palm and vice versa;

7



Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;

8

Once dry, your hands are safe.

World Health Organization | Patient Safety | SAVE LIVES Clean Your Hands

How to Handwash?

WASH HANDS WHEN VISIBLY SOILED! OTHERWISE, USE HANDRUB

Duration of the handwash (steps 2-7): 15-20 seconds

Duration of the entire procedure: 40-60 seconds

0

Wet hands with water;

1

Apply enough soap to cover all hand surfaces;

2

Rub hands palm to palm;

3

Right palm over left dorsum with interlaced fingers and vice versa;

4

Palm to palm with fingers interlaced;

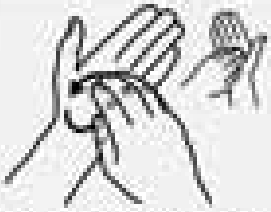
5

Backs of fingers to opposing palms with fingers interlocked;

6

Rotational rubbing of left thumb clasped in right palm and vice versa;

7



Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;

8

Rinse hands with water;

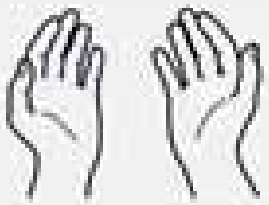
9

Dry hands thoroughly with a single use towel;

10

Use towel to turn off faucet;

11



Your hands are now safe.

World Health Organization | Patient Safety | SAVE LIVES Clean Your Hands

NOTES

Annexure - 8

ANAESTHESIA RECORD

Name :	Age :	Sex : M / F	MRN No :
Surgical Procedure :	Height :		Weight :
Previous Anaesthesia/Surgery :	Current Medication : Off Asprin / Antiplatelet Drugs ..... days.		

Pre Anaesthesia Evaluation

Airway Assessment

Mouth Opening:

Teeth:

Neck Movements:

Mallampatti Score: I ☐ II ☐ III ☐ IV ☐

Difficult Intubation :

Allergies :

Blood Group :

ASA Grading

I II III IV V

☐ ☐ ☐ ☐ ☐

Emergency : Yes ☐ No ☐

Systems	Clinical Evaluation	Investigations
Respiratory System ☐ Asthma ☐ Dyspnoea ☐ COPD ☐ Orthopnoea ☐ Pneumonia ☐ Cough ☐ Expectoration ☐ Recent URI ☐ SpO_2 ☐ Smoke	**PULSE :** **BP :**	☐ Chest X-Ray ☐ Pulmonary Function Tests ☐ ABG
Cardio Vascular System ☐ Hypertension ☐ Congestive Heart Failure ☐ CAD/MI ☐ RHD / Valvular ☐ Angina ☐ Thrombolysed ☐ Pace Maker ☐ Dysrhythmias ☐ Cyanosis ☐ Clubbing ☐ Oedema NYHA: I II III IV		☐ ECG ☐ ECHO ☐ TMT
CNS / Musculoskeletal ☐ CVA / Stroke ☐ Head injury ☐ Seizures ☐ Spinal injury ☐ Paraplegia ☐ Others ☐ Neuromuscular Disorder		
Hepatic/GI/Renal ☐ Jaundice ☐ Oliguria ☐ Hepatic Failure ☐ Acid peptic disease ☐ Splenomegaly ☐ Hepatomegaly ☐ Chronic renal failure ☐ Hepatitis		☐ SGOT ☐ SGPT ☐ ALP ☐ Albumin ☐ Blood urea ☐ Creatinine ☐ Na ☐ K ☐ Urine ☐ Cl ☐ HCO3
Endocrine ☐ Diabetes ☐ Ketosis ☐ Thyroid ☐ Hypoglycemia ☐ Pituitary ☐ Hyperglycemia ☐ Adrenals		☐ FBS ☐ RBS ☐ GTT ☐ T_4 ☐ T_3 ☐ TSH ☐ HBSAg ☐ HIV ☐ HCV
Others ☐ Anaemia ☐ Psychiatry ☐ Bleeding disorders ☐ Build ☐ Cancer / Chemotherapy ☐ Nutrition ☐ Pregnancy ☐ Temperature		☐ Hb ☐ PCV ☐ ESR ☐ TLC ☐ BT ☐ ACT ☐ PT ☐ APTT ☐ Platelets ☐ INR

SPECIFIC PROBLEMS OF ANAESTHESIA	PLAN OF ANAESTHESIA

Name: **Signature:**

Pre-Operation Instruction

☐ Patient identified
☐ Anaesthesia consent taken
☐ Artificial denture/Contact lens/Hearing aids/Ornaments removed
☐ Recent investigation Checked

NPO Since :
Surgery consent taken ☐ Yes ☐ No
Blood / FFP (Standby Cross Method)
Any significant history :

Name Signature

Immediate Pre-operative Re-evaluation

☐ Immediate Prec Evaluation done
☐ Salient Features
☐ Plan

SURGEON ANAESTHETIST

Pre - Anaesthetic State

☐ Awake ☐ Apprehensive ☐ Un-cooperative ☐ Calm ☐ Asleep ☐ Confused ☐ Un-responsive ☐ GCS

Patient Safety

☐ Anaes Machine Checked ☐ Pressure Points Checked ☐ Eye Care ☐ Ointment ☐ Eye Pad

GENERAL ANAESTHETIC TECHNIQUE

General : ☐ Pre-Oxygenatio
Induction: ☐ Intravenous ☐ Inhalational ☐ Rapid Sequence ☐ Cricoid Pressure

Airway Management

Laryngoscopy : ☐ Direct ☐ Fibre Optic Scope ☐ Blind ☐ Difficult ☐ Cormack & Lehane
Endo Tracheal Tube : ☐ Oral ☐ Nasal ☐ Cuff ☐ Uncuff Size Fixed at:_____
ETT Type : ☐ Regular ☐ Reinforced ☐ RAE
Airway : ☐ Oral ☐ LMA ☐ Nasal
Mask Anaesthesia : ☐ Nasal Cannula ☐ Oxygen Mask ☐ Via Tracheostomy ☐ DLT Others:_____

MAINTENANCE

Inhalational: ☐ TIVA ☐ IPPV ☐ Regional

Position

☐ Supine ☐ R/L Lateral ☐ Prone ☐ Lithotomy ☐ Trendelenberg ☐ Sitting ☐ Park Bench

IV Access

(1) Site _____ Size G _____

(2) Site _____ Size G _____

REGIONAL ANAESTHESIA / ANALGESIA

Position: ☐ Sitting ☐ Lateral

Central Blocks

☐ Spinal ☐ Needle G ☐ Catheter ☐ Level
☐ Epidural ☐ Needle G ☐ Catheter ☐ Level
☐ Drug ☐ Bolus ☐ Infusion

Regional Block

☐ Brachial Plexus ☐ Sciatic ☐ Femoral ☐ Ankle ☐ Caudal ☐ Others
☐ Effect

Monitoring

☐ ECG ☐ NIBP ☐ Pulse Oximetry ☐ $EtCO_2$ ☐ ABG ☐ ST Segments
☐ ABP Site _____ Size G _____ ☐ Temperature site
☐ CVP Site _____ Size G _____ ☐ FiO_2

Total Fluids Transfused

Crystalloids _____ Colloids _____ Total Urine Output _____ Total Blood loss _____

POST ANAESTHESIA CARE

Transfer To: _____ ☐ O_2 MASK ☐ ETT ☐ Spont ☐ Ventilation

Time:

Vitals at Shifting: BP HR / Pulse RR SPO_2

POST OPERATIVE INSTRUCTION

Routinely check the following every 5 to 10 minutes :

Pulse Rate

Blood Pressure

Respiration

MONITORS

☐ ECG ☐ ABP ☐ NIBP

☐ CVP ☐ Urine Output

☐ SaO_2 ☐ Temp

☐ ABG

RECOVERY SCORE: Ideally the patient should be discharged when total score is 10

Score	Respiration	BP	Consciousness	Colour	Activity on command
2	Can breath deeply & cough	SBP-+20% of base line	Awake,alert and oriented	Pink	Moves all extremities
1	Shallow but adequate echange	SBP-+20-50% of base line	Arousable but drifts back to sleep	Pale or dusky	Moves limbs to pain
0	Apnea or obstruction	SBP+->50% of base line	No response to verbal commands	Cyanotic	Dose not move to pain

Patient's Score on Admission to Recovery	Patient's Score on Before Transfer

Patient's receving regional anaesthesia should also show signs of resolution of both sensory and motor blackade

Time	Conciousness	Respiration	Pulse Rate	BP	SaO_2	Remarks

Post Operative Complications

☐ Pain
☐ Nausea/Vomiting
☐ Hyo/Hyper Ventilation
☐ Hypoxia
☐ Laryngospasm/Bronchospasm
☐ Hypo/Hypertension
☐ Arrhythmia
☐ Eye injury
☐ Dental injury
☐ Awareness during anaesthesia
☐ Pressure sore.
☐ Neurological complications
☐ Complications due to invasive lines.
☐ Others

Post Operative Medications

1) I.V.fluids
2)
3)
4)
5)

Drugs	Total

	200	
V	Systolic	
Λ	Diastolic	
O	Pulse 150	
X	CVP	
*	Respitration 100	
○	Operation	
ϕ	Temperature 50	

N_2O / O_2 / Air																					
Oxygen Fi/Fe																					
Vapour Fi / Fe																					
End Tidal CO_2																					
O2 Saturation %																					
ECG Rhythm																					
Temperature																					
IV Fluids, Blood																					
Blood Loss																					
Urine Output																					
Tourniquet																					

Fluids	Volume

Total Fluid Balance

Comments

Critical Incidents/Complications

Anesthesia Start Time:

Incision at:

End of Surgery at:

Anesthesia End Time:

Pain Management Flow Sheet

☐ PCA	☐ EPIDURAL	☐ PNB	**Patient Name :**		
Physician:			**Age :**	**Sex : M / F**	**MRN No :**

	Date									
	Time									
MONITORING	Pain at REST									
	Pain on MOVEMENT									
	Sedation Level (0-3)									
	Resp. Rate/min									
	Blood Pressure mmHg									
	SpO2%									
	Sensory Level									
	Motor Level									
	Side Effects									
	RN Intials									
EPIDURAL	EPIDURIAL/PNB									
	Medication									
	Bolus (ml)									
	Infusion (ml/hr)									
	Shift Total (ml)									
	RN Intials									
IV PCA	IV PCA									
	Medication (conc.)									
	Dose									
	Interval									
	1Hr Lockout									
	Basal									
	Shift Total (mg)									
	Attempt/injections									
	RN Intials									

GUIDELINES

SEDATION LEVEL

0-Alert
1-Easily Arousable
2-Dificult to Arouse
3-Unarousable / Unresponsive

SIDE EFFECTS

Nausea / Vomiting
Pruritis
Urinary Retention
Others - hallucination etc.

PAIN SCALE

0 - No Pain
10 - Worse Pain
1 - 3 Mild Pain
4 - 6 Moderate Pain
7 - 10 Severe Pain

CONTACT Acute Pain Service for:

1. Uncontrolled pain
2. "0" of pain at rest and "0" pain with movement
3. A sedation level =3
4. Total absence of sensory blockade
5. Weakness or motor blockade
6. Respiratory Rate of less than 9 breaths per minute
7. Elevated temperature (>101),
8. Syncope, tinnitus or perioral numbness
9. Hypotension or postural hypotension,
10. Urinary retention (not voided in 6 hrs)
11. Loss of epidural catheter integrity
12. If IV Heparin, Coumadin, LMWH, Plavix, or any other anticoagulant therapy needed to be initiated
13. Erythema, edema, drainage, pain or tenderness at the catheter insertion site

NOTES

Annexure - 9

APACHE score

Acute Physiology and Chronic Health Evaluation

The Acute Physiology and Chronic Health Evaluation (APACHE) score is probably the best-known and most widely used score. The original APACHE score was first used in 1981 and scores for three patient factors that influence acute illness outcome (pre-existing disease, patient reserve, and severity of acute illness). These included 34 individual variables, a chronic health evaluation, and the two combined to produce the severity score.

The APACHE II scoring system was released in 1985 and incorporated a number of changes from the original APACHE. These included a reduction in the number of variables to 12 by eliminating infrequently measured variables such as lactate and osmolality. The weighting of other variables were altered; most notably, the weightings for Glasgow Coma Score and acute renal failure were increased. In addition, weightings were added for end-organ dysfunction and points given for emergency or non-operative admissions. Each variable is weighted from 0 to 4, with higher scores denoting an increasing deviation from normal. The APACHE II is measured during the first 24 h of ICU admission; the maximum score is 71. A score of 25 represents a predicted mortality of 50% and a score of over 35 represents a predicted mortality of 80%. The APACHE II severity score has shown a good calibration and discriminatory value across a range of disease processes, and remains the most commonly used international severity scoring system worldwide.

APACHE III, released in 1991, was developed with the objectives of improved statistical power, ability to predict individual patient outcome, and identify the factors in ICU care that influence outcome variations. The weightings are far more complex than the two previous scoring systems, but notably are the addition of HIV and hematological malignancy (as well as disseminated malignancy and liver disease) to the chronic health points. The performance of the APACHE III severity score is slightly better than that of APACHE II, but the former has not achieved widespread acceptance perhaps because the statistical analysis used to score it is under copyright control.

Simplified Acute Physiology Score

The SAPS was first released in 1984 as an alternative to APACHE scoring. The original score is obtained in the first 24 h of ICU admission by assessment of 14 physiological variables and their degree of deviation from normal, but no input of pre-existing disease was included. It has been superseded by the SAPS II and SAPS III, both of which assess the 12 physiological variables in the first 24 h of ICU admission and include weightings for pre-admission health status and age.

Mortality Prediction Model

The MPM is based on two models and allows a probability of in-hospital death to be calculated, rather than a severity score that needs to be converted. Assessment of chronic health status, acute diagnosis, and weightings for physiological variables allows a prediction of death to be made. Data at admission and 24 h after ICU admission are included. The newer MPM II is based on multiple regression analysis from a large population and includes weightings for physiology, acute and chronic illness, age, and therapeutic interventions. Sequential calculations can be made at 0, 24, 48, and 72 h from ICU admission.

Sepsis-related Organ Failure Assessment

The SOFA was produced by a group from the European Society of Intensive Care Medicine to describe the degree of organ dysfunction associated with sepsis. However, it has since been validated to describe the degree of organ dysfunction in patient groups with organ dysfunctions not due to sepsis. Six organ systems—respiratory, cardiovascular, central nervous systems, renal, coagulation, and liver—are weighted (each 1–4) to give a final score [6–24 (maximum)].

Multiple Organ Dysfunction Score

The MODS scores six organ systems: respiratory (Po_2: FI_{O_2} ratio in arterial blood); renal (measurement of serum creatinine); hepatic (serum bilirubin concentration); cardiovascular (pressure-adjusted heart rate); hematological (platelet count); and central nervous system (Glasgow Coma Score) with weighted scores (0–4) awarded for increasing abnormality of each organ systems. Scoring is performed on a daily basis and so allows a day-by-day prediction for patients.

Classification of Scoring Systems

There is no agreed classification of the scoring systems that are used in critically ill patients. Scores can be applied either to a single set of data or repeated over time. The available methods include:

1. *Anatomical scoring*. These depend on the anatomical area involved. Anatomical scoring systems are mainly used for trauma patients [e.g. abbreviated injury score (AIS) and injury severity score (ISS)].

2. *Therapeutic weighted scores*. These are based on the assumption that very ill patients require a greater number of interventions and procedures that are more complex than patients who are less ill. Examples include the therapeutic intervention scoring system (TISS).

3. *Organ-specific scoring*. This is similar to therapeutic scoring; the underlying premise is the sicker a patient the more organ systems will be involved, ranging from organ dysfunction to failure [e.g. sepsis-related organ failure assessment (SOFA)].

4. ***Physiological assessment*. It is based on the degree of derangement of routinely measured physiological variables [e.g. acute physiology and chronic health evaluation (APACHE) and simplified acute physiology score (SAPS)].**

5. *Simple scales.* It is based on clinical judgement (e.g. survive or die).

6. *Disease specific* [e.g. Ranson's criteria for acute pancreatitis, subarachnoid haemorrhage assessment using the World Federation of Neurosurgeons score, and liver failure assessment using Child-Pugh or model for end-stage liver disease (MELD) scoring].

Example to show them is following calculator (internet required)

Link for Apache score calculator
http://reference.medscape.com/calculator/apache-ii-scoring-system

Other example

APACHE II Calculator

Acute Physiology and Chronic Health Evaluation (APACHE) II score to predict hospital mortality

Use the *worst* value for each physiological variable within the past 24 hours.

Age	☐ years
Glasgow coma score	☐
Vitals	
Temp	☐ C or F
MAP	☐ mmHg
Heart rate	☐ bpm
Resp rate	☐ bpm
Oxygenation	
FiO_2	☐ %
PaO_2	☐
Arterial pH	☐
Chemistry	
Sodium	☐ mEq/L
Potassium	☐ mEq/L
Creatinine	☐
Acute renal failure	◉ No ○ Yes
Hematology	
Hematocrit	☐ %

WBC [ ] x 10^9/L

Severe organ system insufficiency or is immunocompromised (?) ◉ No ○ Yes

Reset Calculate

US units

Press 'Calculate' to view calculation results.

Load an Example

NOTES