PATIENT SAFETY
ATTENTION TO DEVICES & EQUIPMENT

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PATIENT SAFETY

PRIMUM NON NOCERE
Organizational Vision And Commitment To Medical Excellence

- **Medical Excellence Experienced Patients at All Points of Patient Care**

- **Patient Focussed**
- **Efficiency and Timeliness**
- **Ethics**
- **Clinical Audits/Measures**
- **Standards**
- **Patient Safety**
- **Education and Training**
- **Infection Control**
- **Management and Leadership**
- **Systems and Processes**

Medical Excellence Experienced Patients at All Points of Patient Care
Why Worry About Patient Safety?
## Deaths Per 100 Million Hours

- Being pregnant: 1
- Traveling by train: 5
- Working at home: 8
- Working in agriculture: 10
- Being in traffic: 50
- Working in construction: 67
- Flying on a commercial airplane: 100
- Being hospitalized: 2000
Product or Device Events

Patient death or serious disability associated with use of contaminated drugs, devices or biologics provided by the facility

Patient death or serious disability from patient care device in which the device is used or functions other than as intended

Patient death or serious disability from intravascular air embolism

Environmental Events

Patient death or serious disability associated with an electric shock
Environmental Challenges

• Rapidly changing environment
  – Affordability
  – Accountability
  – Challenges of Cost control
  – ‘Tight’ business models
  – Changing demands of patients
Env. Changes ..contd..

• Accreditation of healthcare systems (NABH, JCI)
• Fire safety norms (NFPA: USA)
• Rapidly changing technology
• Easy availability and affordability of expensive technology
• Evolving knowledge wrt HFE
• Pressure: latest and the best: short learning curves
Why Patient Safety?

Patient satisfaction
Reduced ALOS
Reduced wastes... lean organisation
Better ARPOB
Higher profits
Higher ability for further investment
Improvement of facilities
Better patient care...
Patient Delight...
Patient Life Cycle & Patient safety

Patient Safety
- Information Safety
- Communication Safety
- Medication Safety
- Diagnostic Safety
- Treatment Safety
- Environmental Safety

Patient Treatment
- Diagnosis
- Investigation
- Treatment
  - Medical
  - Surgical
- Outcome

Patient Comfort
- Admission
- Discharge
- Housekeeping
- F & B
- Others
**Patient safety is the sustained, proactive process of identifying, avoiding and rapidly resolving errors, omissions, mishaps and miscommunications that could affect a patient’s healing, health or well-being at any point, at any time, in any care setting.**

<table>
<thead>
<tr>
<th>Domains</th>
<th>Objective: Six International patient safety goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information Safety</td>
<td><strong>Identify patients correctly</strong> – Ensure availability of secure, up-to-date, complete and <strong>accurate medical records</strong> for every patient.</td>
</tr>
<tr>
<td>Communication Safety</td>
<td><strong>Improve effective communication</strong> - Sharing of relevant, real-time information to all authorized, interested parties with particular focus on the need to improve hand-off communications.</td>
</tr>
<tr>
<td>Medication Safety</td>
<td><strong>Improve safety of high alert medications</strong> - Dockside-to-bedside medication administration strategy, designed to ensure the “five-Rights”- Right patient, Right medication, <strong>Right dose</strong>, Right route and Right time.</td>
</tr>
<tr>
<td>Diagnostic Safety</td>
<td><strong>Eliminate wrong site, wrong patient, wrong procedure surgery</strong> - Gathering and interpretation of data that supports optimal patient care planning and treatment.</td>
</tr>
<tr>
<td>Treatment Safety</td>
<td><strong>Reduce the risk of Healthcare acquired infections</strong> - Accurate capture, recording, executing &amp; sharing of data to support patient safety.</td>
</tr>
<tr>
<td>Environmental Safety</td>
<td><strong>Reduce the risk of patient harm resulting from fall or any other injuries</strong> - Safety of patient’s environment, from staff management and <strong>equipment tracking</strong>.</td>
</tr>
</tbody>
</table>
HOW?

- Correct Patient Identification
- Effective Communications
- Eliminate Medication Errors
- Eliminate wrong site, wrong patient & wrong procedure
- Control over Hospital-Associated Infections (HAIs)
- Prevent Falls
- Prevent Adverse Events
Limited address in IPSG

• Quality of manpower
• Device safety
• Accountability of clinical care
• Documentation
• Culture of medical quality
Health care system:

Infrastructure: equipments 40: 60
Man: Tool 50:50
Challenges:

- Cost over quality
- Skilled Manpower to **operate, repair/maintain** these equipments is not available in all settings
- Medical device safety: norms and knowledge application in practice HFE
Evolution....
The list is adding up like never before..
EQUIPMENT SAFETY

Operator training
Electrical safety
Mechanical safety
Other safety parameters
Performance assurance
Using correct disposables
Cleaning/disinfection/ sterilisation prior to reuse
Acquiring suitable equipment
Initial inspection on delivery for manufacturing defects
Maintenance
Handling & operation of equipment
SOPs to follow when an accident has occurred

CE: conformite europeenne
   single/ double use
   concomitant use
Concerns…

• Electrical safety:
  – Gross shock
  – Micro shock

• Excessive temperature, fire /others
Electrical safety

international guidelines/standards IEC 60601..
maintenance in hospitals .. IEC 62353/ IS 8607

Mandatory reporting of accidents related to devices (must in UK)
Concerns...

- Mechanical hazards
- Radiation hazards
- Explosion
Concerns…

- Infection
Concerns: Accuracy & Patient Safety

- Data and Lab Management
- Safety
- Customer Service

- Patient/Client Prep
- Sample Collection
- Sample Receipt and Accessioning
- Record Keeping
- Reporting
- Personnel Competency Test Evaluations
- Testing
- Sample Transport

Concerns: Accuracy & Patient Safety
Concerns: Accuracy & Patient Safety
Documentation & Reporting

- standard formats
- Mandatory reporting
- Knowledge sharing limited
Clinical care: accountability

• Determination of standards of care
• Clinical protocols and care pathways
• Lack of Outcome based approach: generic specific
Culture of medical quality

• Improved patient safety and outcomes
• Clinical governance: framework to assure & improve quality of clinical outcomes (cornerstone of clinical excellence)
The 7 pillars of Clinical Governance

- Clinical audit
- Clinical effectiveness
- Risk management
- Use of information
- Education and training
- Staff/staff management
- Patient/public involvement

Based on NHS
Proactive Risk Management
1. Establish the Context of Risks
2. Identify Risks
3. Analyze Risks
4. Evaluate Risks
5. Treat Risks
6. Monitoring and Review
7. Communication & Consultation
Device safety, Infection Hazard & Patient Safety
Components of Risk

Risk is measured in terms of likelihood and consequence or impact (e.g. financial loss, fatality, reputation).
<table>
<thead>
<tr>
<th>No</th>
<th>Risk Identified</th>
<th>Likelihood</th>
<th>Consequence</th>
<th>Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Risk of unplanned prolonged breakdown of critical medical equipment</td>
<td>Moderate</td>
<td>High</td>
<td>Major</td>
</tr>
<tr>
<td>2</td>
<td>Risk of malpractice and litigation</td>
<td>Unlikely</td>
<td>Extreme</td>
<td>Major</td>
</tr>
<tr>
<td>3</td>
<td>Risk of patient safety incident (e.g. miscommunication during patient transfer/handover, misidentification of patient, wrong dispensing of medicine, wrong site surgery, slips and trips, etc.)</td>
<td>Rare</td>
<td>Extreme</td>
<td>Major</td>
</tr>
<tr>
<td>4</td>
<td>Risk of hospital acquired infection (HAI)</td>
<td>Rare</td>
<td>Extreme</td>
<td>Major</td>
</tr>
<tr>
<td>5</td>
<td>Risk of wrong babies given to parents</td>
<td>Rare</td>
<td>Extreme</td>
<td>Major</td>
</tr>
<tr>
<td>6</td>
<td>Risk of non-compliance with regulatory requirements</td>
<td>Rare</td>
<td>Extreme</td>
<td>Major</td>
</tr>
<tr>
<td>7</td>
<td>Risk of fire</td>
<td>Rare</td>
<td>Extreme</td>
<td>Major</td>
</tr>
</tbody>
</table>
What needs to be done...

- Active involvement of BME/ Clinical Engg.
  - Reporting relationships/ Job Descriptions
  - Eliminate space constraints
  - Role in planning and purchase- CAPEX ownership
  - Resource optimisation
  - Role in local improvisation/ repair
  - Preventive maintenance, safety checks
  - Statutory compliances
• More stringent compliance criteria by the accreditation body
  – Structure
  – Scope of work
  – Job content
• Trained Manpower
• Development of criteria and recommendations for device and equipment safety

– Workshop: ACEW 2010 (Nov 28th), Pune
1 PATIENT SAFETY FIRST
Thank You!