

National Healthcare Priorities 2021 Draft_1

1. Effective Leadership (LD).....	4
2. Person-Centered Care (PCC).....	12
3. Clinical Privileging (CP).....	19
4. Safe Staffing Level (SSL).....	26
5. Emergency Department (ED).....	57
6. Stroke-Readiness (SR).....	67
7. Trauma-Readiness (TR).....	77
8. ACS-Readiness (ACS).....	83
9. Venous Thromboembolism (VTE).....	89
10. Peri-operative Safety (POS).....	93
11. Safe Labor and Birth (SL).....	106
12. Rapid Response System (RRS).....	115
13. Patient Transfer (PT).....	123
14. Critical Care Services (ICC).....	134
15. Neonatal Care Safety (NIC).....	141
16. End-of-life Patient care (EOL).....	150
17. Blood Transfusion Safety (BTS).....	158
18. Medication Safety (MM).....	172
19. Radiation Safety (RS).....	192
20. Central Sterile Service Department (CSS).....	199
21. Healthcare Associated Infection (HAI).....	206
22. Fire Safety (FS).....	219
23. Physical Environment (PE).....	
24. Housing (HOU).....	224

ID	Chapter Code	Chapter Name	Number of Standards	Number of Sub-Standards
1	LD	Effective Leadership	7	50
2	PCC	Person-Centered Care	9	45
3	CP	Clinical Privileging	8	37
4	SSL	Safe Staffing Levels	7	108
5	ED	Emergency Department	11	50
6	SR	Stroke-Readiness	7	33
7	TR	Trauma-Readiness	5	32
8	ACS	ACS-Readiness	5	24
9	VTE	Venous Thromboembolism	2	8
10	POR	Perioperative Safety	7	39
11	SLB	Safe labor and birth	10	47
12	RRS	Rapid Response System	4	26
13	PT	Patient Transfer	7	35
14	ICC	Adult Critical Care Services	9	40
15	NIC	Neonatal Care Safety	7	56
16	EOL	End-of-Life Care	7	26
17	BTS	Blood Transfusion Safety	11	43
18	MM	Medication Safety	10	64
19	RS	Radiation Safety	7	32
20	CSS	Central Sterile Service Department	10	57
21	HAI	Healthcare Associated Infection	6	43
22	FS	Fire Safety	11	54
23	PHE	Physical Environment	9	51
24	HOU	Housing	4	19
		Total:	180	1019

Effective Leadership (LD)

Healthcare transformation is one of the key pillars of the 2030 vision with the primary objectives focused creating coordinated healthcare services to assure accessibility, quality and safety, efficiency and preventive care. The 2030 vision aims to create sustainable transformation that is effective, transparent, accountable to enable and achieve high performing governments. Due to the national healthcare reform and to ensure adaptability and illustrate accountability, these Leadership and Governance standards were developed. Healthcare leaders are stewardship of protecting and serving the public interest and therefore have the ultimate responsibility of assuring conditions allow people to be the healthiest they can be.

Leadership and governance are core component of a resilient healthcare system, that plays an intrinsic role within every layer of a healthcare organization. Leadership sets direction and oversight at each level within an organization while governance ensures that accountability and organization outcomes are achieved. The standards were designed to reflect the international shift to healthcare models such as, integrated care models, accountable Care Organizations, value-based healthcare and Bundled Payments.

Leadership and governance can directly and indirectly play a role in healthcare outcomes and challenges the delivery of quality healthcare services in an equitable manner. Inadequate healthcare leadership and/or governance can affect patient safety, patient and employee satisfaction, efficiency and effectiveness, and healthcare costs.

These standards aim to ensure the effective implementation of a governance framework that achieves clear responsibilities and accountabilities from all levels of management. They intend to support the best management practices by ensuring strategic goal and outcome-oriented approach across the organization to achieve the highest delivery of population and patient care.

LD.1 The governing body carries out its roles and responsibilities towards achieving AHRQ's Quadruple Aim.

LD.1.1. The governing body approves the hospital's scope of services in accordance with the health needs of its target population, inclusive of the Voice of the Customer (VoC).

LD.1.2. The governing body appoints a qualified hospital Chief Executive Officer (CEO) or equivalent role/title and establishes transparent processes for hiring hospital leaders.

LD.1.3 The hospital has three clinical branches represented as physicians, allied health, and nursing, each with c-suite representation (CMO, CAHO, & CNO) reporting directly to the CEO.

LD.1.4 The governing body includes the Chief Nursing Officer (CNO) or equivalent roles/titles with relevant clinical and operational experience as a permanent member.

LD.1.5. All clinical nurses and all education staff for nurses report under nursing, under the CNO.

LD.1.6. All clinical allied health staff report under allied health, under the CAHO.

LD.1.7. The governing body sets the strategic priorities, as well as the mission, vision, and goals of the hospital.

LD.1.8. The governing body approves the hospital's budget and ensures its alignment with its scope of service and strategic priorities.

LD.1.9. The governing body outlines the authority delegation for the CEO and the hospital's leaders.

LD.1.10. The governing body has mechanisms for performance appraisal, inclusive of Key Performance Indicators (KPIs), for both the organization and the hospital's leaders.

LD.1.11. The governing body ensures accountability at every level of the organization (from the board to the ward) via a regularly updated organization structure inclusive of an accountability matrix.

Explanations:

The needs of the target population are addressed in designing the hospital scope of services and in accordance with the AHRQ's Quadruple Aim. The Quadruple Aim has four components: (1) to enhance the patient experience, (2) improve population health, (3) reduce costs, and (4) improve the work-life of health care providers.

LD.2 The hospital has effective and efficient resources management processes.

LD.2.1. The hospital has a multidisciplinary Human Resources (HR) committee with Executive chairmanship and membership.

LD.2.2. The hospital has a Revenue Cycle Management (RCM) process.

LD.2.3. The hospital has processes for asset management.

LD.2.4. The hospital has processes for the selection, contracting, and ongoing management of all vendors.

LD.2.5. The hospital has processes for Supply Chain Management (SCM) that ensures quality and safety inclusive of each clinical area/unit identifying minimum and maximum par levels and maintaining identified safe minimum par levels at all times.

LD.2.6. Material resources are managed by an effective Planned Preventive Maintenance (PPM) process.

Explanations:

To ensure a sustainable management process to effectively plan and utilize the hospital budget for support strategy and scope of service.

LD.3 The hospital leadership establishes a clinical and evidence-based governance framework.

LD.3.1. Clinical leaders are appointed utilizing a standardized competency-based system in order to achieve the hospital's strategic goals.

LD.3.2. The hospital leadership ensures all staff practices are within the approved scope of services with regular review of alignment, as well as departmental and staff compliance.

LD.3.3. The hospital establishes a culture of patient and family rights inclusive of the right to receive evidence-based, best practices clinical care with a system of regular feedback to clinicians regarding their compliance and clinical practice.

LD.3.4. Clinical services outcomes are regularly reviewed and benchmarked with action plans for improvement initiated and completed.

LD.3.5. Hospital departments ensure the achievement of integrated health care delivery with continuous monitoring of multidisciplinary clinical activities.

LD.3.6. High-risk situations, procedures, clinical activities, and high-risk, vulnerable patient populations are identified, and the hospital ensures systematic communication to relevant staff and mitigation strategies.

LD.3.7. Credentialing and privileging of clinical staff are done systematically, and competencies are aligned with the hospital's scope of services.

Explanations:

Define accountability and responsibilities of clinical leadership to meet stakeholders' expectations of safe and effective care.

LD.4 The hospital leaders continuously improve the quality and safety of healthcare services.

LD.4.1. Hospital leaders develop, implement, and monitor a comprehensive and integrated quality and safety program.

LD.4.2. Hospital leaders identify and communicate at all levels of the organization (ward to board) never events.

LD.4.2. Hospital leaders establish and monitor clinical and non-clinical measures that are effectively linked to the integrated quality and safety program, and work collaboratively to identify and address opportunities for improvements.

LD.4.3. Hospital leaders benchmark the measures with national and international best practices.

LD.4.4. Hospital leaders work collaboratively to meet measurable and benchmarked patient and family experience expectations of its target population and continually identify and address opportunities for improvements.

LD.4.5. Hospital leaders develop, implement, and monitor an integrated enterprise risk management program.

LD.4.6. The hospital has a change management program to reduce operational disruptions.

Explanations:

Hospital leaders need to showcase their drive to improve the quality of services provided and safe practices. This needs to be promoted throughout the hospital with the ability to articulate examples and show evidence of systematic improvement to quality and safety.

LD.5 Health Information management (HIM) systems meet national and cited international standards and regulations and enables the hospital to meet its strategic and operational goals.

LD.5.1. Health, corporate and managerial records management systems support the collection of information and meet patient and hospital needs.

LD.5.2. Data and information are collected, stored, and used for strategic, operational, and improvement purposes.

LD.5.3. The organization has an integrated approach to the planning, use, and management of information and communication technology (ICT).

LD.5.4. Medical records are secured and the information is accurate, comprehensive, clear and gathered collaboratively in order to support decision making and meet the organizational and patient needs.

Explanations:

Effective record management will be maintained via a consistent, organization-wide data collection and storage system that complies with requirements of legislation, organizational policies and all relevant regulatory standards and guidelines. The system also ensures that access to records is restricted, and records are created, monitored, retrieved, transferred and stored in a secure, accurate and timely manner. Related staff receive training in record management appropriate to their positions and responsibilities.

LD.6 Clinical documentation improvement (CDI) meets national and cited international standards and regulations and enables the hospital to meet its strategic and operational goals as per the principles of value-based health care.

LD.6.1. The hospital implements minimum data sets reflective of administrative reported outcomes, clinical reported outcomes and patient reported outcomes for all identified medical conditions, as applicable.

LD.6.2. The hospital implements a CCI billing system, inclusive of ALOS that is linked to the unified national medical code platform and has information integrity safeguards.

LD.6.3. The hospital's clinical documentation accurate, transparent, and available to all relevant stakeholders at all times.

LD.6.4. The hospital has a policy and processes for DRG with measurement of healthcare provider compliance, with continuous communication feedback loops, and performance improvement and action plans.

LD.6.5. CDI staff and medical coders code to accurately represent patient care, resources consumed, severity of illness, and risk of mortality as well as identify and communicate opportunities and risks related to documentation inefficiencies in the medical record.

LD.7 The hospital has an effective communication process throughout the care continuum.

LD.7.1. The hospital has an effective communication plan with systemic dissemination to all staff.

LD.7.2. The governing body and hospital leadership communicates the values, vision, mission, hospital strategy, and scope of services to all levels of staff (to the board to the ward) and its target population.

LD.7.3. The governing body and hospital leadership promptly communicate strategic and operational decisions as well as the performance of the hospital to the workforce and community.

LD.7.4. The governing body and hospital leadership communicate and model expectations of hospital workforce code of conduct as well as ethical behavior and performance to ensure a culture of safe staff and person-centered community-based care.

LD.7.5. The governing body and hospital leadership communicate clear and comprehensive accountability matrixes and delegation based on the hospital's organizational structure for both clinical and nonclinical responsibilities.

LD.7.6. The governing body and leadership openly communicate hospital strategic, clinical and non-clinical performance-based outcomes against national and international benchmarks to the workforce and community.

LD.7.7. The governing body and hospital leadership communicate safeguarded reporting processes to ensure a just culture and culture of anti-retaliation for the hospital staff, patients and families.

Explanations:

To ensure a timely process for comprehensive and integrated communication by the hospital governing body and leadership to drive effective behavior to enhance quality care coordination, patient safety and staff engagement.

LD.8. The hospital leadership establishes an effective clinical governance framework.

LD.8.1. Clinical leaders are appointed utilizing a standardized competency-based system in order to achieve the hospitals strategic goals.

LD.8.2. The hospital leadership ensures all staff practices are within the approved scope of services with regular review of alignment as well as departmental and staff compliance.

LD.8.3. The hospital establishes a culture of patient and family rights inclusive of the right to receive evidence based best practices clinical care with a system of regular feedback to clinicians regarding their compliance and clinical practice.

LD.8.4. Clinical services outcomes are regularly reviewed and benchmarked with action plans for improvement initiated and completed.

LD.8.5. Hospital departments ensure the achievement of integrated health care delivery with continuous monitoring of multidisciplinary clinical activities.

LD.8.6. High-risk situations procedures clinical activities and high-risk vulnerable patient populations are identified with effective mechanisms of systematic communication to relevant staff and mitigation strategies in place.

LD.8.7. Credentialing and privileging of clinical staff are done systematically and validated competencies are aligned with the hospitals scope of services.

Explanations:

XXX

Person-Centered Care (PCC)

Patient Surveyors are key contributors to the assessment process. The main responsibility of a patient surveyor is to assess the people-centered care related criteria from the standards. Patient surveyors are peers to other patients. They are ideally placed to generate meaningful discussions with other patients and families to deepen understanding of patient experiences within the organization and of services that are being assessed. Having them be part of the survey team brings a unique patient perspective to the organization and is consistent with a person-centered care approach and acknowledges the important role that patients play as co-producers of health at the direct care, organizational and system levels. (Source: Accreditation Canada with modification).

PCC.1. Person-centered care is integrated and reflected in all aspects of the delivery and provision of patient care.

PCC.1.1 Person-centered care is supported by the hospital's mission, vision, values, scope of service and strategic plan's objectives.

PCC.1.2. Hospital leaders, along with patient experience advocates, patients, and families, co-produce the hospital's person-centered care.

PCC.1.3. The hospital has policies, processes, governance, and structures to deliver person-centered care.

PCC.1.4. The hospital has structures and processes to measure, monitor, and continuously improve person-centered care performance based on feedback from patients, families, and staff.

Explanations:

A common set of core values among all parties, as part of a strategic vision is essential in the provision and receiving of care with standardized and common understanding of person-centered care among key stakeholders.

PCC.2. The hospital has processes to provide person-centered care that represents the culture and values of compassion, responsiveness, diversity, inclusiveness, civility, and respect.

PCC.2.1 The governing body and hospital leaders regularly interact with staff in their department or service area. Staff are involved in decision-making processes affecting their scope of service, practice, well-being, and person-centered care.

PCC.2.2. Staff well-being is included as one of the driving principles of person-centered care and is reflected in hospital plans, policies, and procedures.

PCC.2.3 Staff attitudes and behaviors are positively reflected and demonstrated in person-centered care.

PCC.2.4. The hospital incorporates the principles of person-centered care into the Human Resource management processes.

PCC.2.6 The hospital incorporates the principles of person-centered care into its performance measurement, KPIs, and improvement processes.

Explanations:

The hospital facilitates a culture that values a person-centered approach to care delivery. This approach is reflected in attitudes, behaviors and service delivery. The hospital identifies how it will address and respond to the person-centered care needs of its people. This includes how knowledge, skills, and behaviors will enable staff to work effectively demonstrating compassion, responsiveness, and respect for patient and family preferences.

PCC.3. The hospital has structures and processes to support access to care, access to patient information, and patient-healthcare provider communication.

PCC.3.1. Hospital systems support person-centered care through easy access to care and services by patients and families.

PCC.3.2. Hospital systems support timely and accurate access to patient information between health care providers.

PCC.3.3. The hospital has multiple, communicated mechanisms for patients and families to access their information.

Explanations:

The hospital should encourage the use of solutions that exchange information across providers and patients with the capacity to link all healthcare data across the continuum of care through the implementation of person-centered care enhancement initiatives, training, solutions, or technologies.

PCC.4. The hospital is responsive to patient and family feedback (including concerns, queries, and complaints) received from multiple channels.

PCC.4.1. Patients and families have access to numerous and various channels to communicate their feedback.

PCC.4.2. Information is readily available regarding the channels available to patients and families to communicate their feedback.

PCC.4.3. Feedback is provided to patients and families, within a reasonable time frame, in response to concerns, queries, and complaints.

PCC.4.4. Responding to patient and family concerns, queries and complaints is established as a key responsibility for all staff.

PCC.4.5. The hospital evaluates patients' and families' satisfaction and experience with the responses and resolutions they have received.

PCC.4.6. Hospital leadership is involved, when appropriate, to ensure effective handling of patient and family feedback.

Explanations:

To ensure that patients and families can provide feedback and that health hospitals adopt effective approaches, tools and processes for managing patient and family concerns, queries and complaints.

PCC.5. The hospital evaluates and acts on the voice of the customer (VoC) data to guide improvements in its person-centered care approach.

PCC.5.1. Voice of the customer (VoC) data is collected, analyzed, and utilized to continually identify and action opportunities for improvements.

PCC.5.2. The hospital regularly reviews VoC data to measure performance against appropriate benchmarks.

PCC.5.3. The insights, patterns, and lessons obtained from the analysis of VoC data are disseminated throughout the hospital, among staff at all levels.

PCC.5.4. The impact of the improvements to person-centered care is evaluated through analysis of the VoC data.

Explanations:

To ensure that hospitals utilize various channels to elicit voice of the customer, and the data collected is utilized to guide service improvement.

PCC.6. The hospital practices effective co-production of services to promote person-centered care.

PCC.6.1. Hospital leaders, including non-clinical leaders, regularly interact with patients, families, and staff.

PCC.6.2. Hospital leaders establish formal groups that meet regularly to ensure active collaboration between healthcare providers, staff, patients, and family members.

PCC.6.3. Patients, families, and staff are involved in setting the hospital's strategic plan and objectives.

PCC.6.4. Specific recommendations for improvements by patients, families, and staff have been acted upon to improve care and services.

PCC.6.5. Patients and families serve as integral team members on implemented performance improvement initiatives.

PCC.6.6. The hospital offers education and training to staff to build competency in patient, family, and staff engagement.

Explanations:

To ensure that the patient and family are involved in the design, delivery and evaluation of care.

PCC.7. The hospital has effective processes to facilitate integrated, access across the care continuum taking into consideration and incorporating the patient and family preferences.

PCC.7.1. Multidisciplinary Clinical Team (MDCT) members are educated about the involvement of the patient and family in care decisions, treatment goals, and care planning.

PCC.7.2. The hospital has a process to orient the patient and family as a member of the care team, with documentation of the most responsible decision-maker in the medical record,

PCC.7.3. The hospital establishes a process to incorporate the personal preferences and goals of the patient and family into care planning.

PCC.7.4. The hospital educates the patient and family in differentiating between the available care options and clarifies how different options align with their personal priorities and goals.

PCC.7.5. The hospital establishes mechanisms to accommodate personal preferences related to healing modalities, the personal environment, diversional therapy, and life enrichment activities.

PCC.7.6. The hospital establishes partnerships with external organizations at different points across the care continuum to improve care transitions and care coordination.

Explanations:

The hospital demonstrates commitment to facilitate patient access to care and addresses barriers to full and active patient and family participation in care decisions and delivery. The hospital implements an integrated and shared partnership approach to care delivery. This approach will be demonstrated by active communication and collaboration among staff involving the patient and family. The hospital applies the concepts of person-centered care along the entire care continuum from pre-access through to post service delivery needs including follow up care. The hospital measures its ability to facilitate access to care, integrate care, and apply the concepts of person-centered care along the entire care continuum and take the necessary actions to improve.

PCC.8. The hospital has systems to support the active involvement of patients and families in communication with their Multidisciplinary Clinical Team (MDCT) members across all settings.

PCC.8.1. The hospital has processes to ensure health care providers introduce themselves to patients and family members.

PCC.8.2. The hospital has processes to guide the structure of person-centered care encounters.

PCC.8.3. The hospital has processes to promote compassionate, empathic communication and caring attitudes.

PCC.8.4. The hospital has policies and processes for capturing, reporting, disclosing, and monitoring unanticipated incidents and medical errors during the provision of care.

PCC.8.5. Employees are trained in attitude and technique to disclose unanticipated incidents and medical errors to patients and families.

PCC.8.6. The hospital has processes to measure compliance to unanticipated incidents and medical error disclosure with feedback to clinicians.

PCC.8.7. Patient and families are actively involved in care planning activities, case conferences, change of shift, and transfer of care communication.

Explanations:

Patients and family members are integral members of their own care team. This should be demonstrated by active participation of patients, and family members when appropriate, in the decisions about their care. To achieve this, the hospital should establish a transparent, open, and direct communication within the organization.

PCC.9. The hospital provides care in a safe, user-friendly, and supportive environment and culture.

PCC.9.1. The hospital has a physical environment and culture that supports patient and family engagement in their care.

PCC.9.2. The hospital has a physical environment and culture designed to preserve users' privacy and dignity.

PCC.9.3. The hospital has a physical environment and culture that provides for the needs of chaperones and visitors.

PCC.9.4. The hospital has a physical environment and culture that provides education, interactions, and experience based on the patient's age and abilities.

Explanations:

The built environment is designed in a friendly style to all users, with multiple elements introduced to reduce the stress and anxiety often associated with healthcare environments, as well as to encourage patients and families to participate in care. In planning and design efforts, the hospital balances the need for patient/resident safety with the importance of patient comfort, privacy, and modesty.

Glossary and Resources

Term	Definition	Resource
Access	Barriers or lack thereof for persons in obtaining services. May apply at the level of the individual patient (timeliness or other barriers) or the target population for the hospital.	CARF2021
Accessibility	Services are directly and permanently accessible with no undue barriers of cost, language, culture, or geography. Health services are close to the people, with a routine point of entry to the service network at primary care level (not at the specialist or hospital level). Services may be provided in the home, the community, the workplace, or health facilities as appropriate.	WHO Health Service Delivery who.int/healthinfo/systems/WHO_MBHS_S_2010_section1_web.pdf
Access to Care	Having the timely use of personal health services to achieve the best health outcomes (IOM, 1993). Access to health care consists of four components <u>coverage</u> (facilitates entry into the health care system), <u>services</u> (having a usual source of care) <u>timeliness</u> (ability to provide health care when the need is recognized) and <u>workforce</u> (capable, qualified, culturally competent providers).	AHRQ, Department of Health and Human Services, USA. Elements of Access to Healthcare.
Accountability and Efficiency	Health services are well managed so as to achieve the core elements described above with a minimum wastage of resources. Managers are allocated the necessary authority to achieve planned objectives and held accountable for overall performance and results. Assessment includes appropriate mechanisms for the participation of the target population and civil society.	WHO Health Service Delivery who.int/healthinfo/systems/WHO_MBHS_S_2010_section1_web.pdf
Care Continuum	A patient-oriented system of care that spans an entire lifetime, is composed of both services and integrating mechanisms, and guides and tracks patients over time through a comprehensive array of health, mental health, and social services across all levels of intensity of care (acute care, ambulatory care, home care, extended care, wellness programs, etc.)	Post University, American Sentinel College of Nursing and Health Sciences. Americansentinel.edu
Care Coordination	Care coordination involves deliberately organizing patient care activities and sharing information among all of the participants concerned with a patient's care to achieve safer and more effective care. This means that the patient's needs and preferences are known ahead of time and communicated at the right time to the right people, and that this information is used to provide safe, appropriate, and effective care to the patient.	AHRQ, Care Coordination. ahrq.gov/ncepcr/care/coordination.html
Care Continuity	Continuity of care is concerned with quality of care over time. It is the process by which the patient and his/her physician-led care team are cooperatively involved in ongoing health care management toward the shared goal of high quality, cost-effective medical care. It reduces fragmentation of care and thus improves patient safety and quality of care.	AAFP Foundation. Continuity of Care Definition. Aafp.org/about/policies/all/continuity-of-care-definition.html
Care Transitions	The transfer of an individual between settings of care, internally within the same setting, or to a different setting, and/or to a different team of caregivers	Planetree 2017

Community Resources	Services that are available to members of a community. They commonly offer people help to become more self-reliant, increase their social connectedness, and maintain their human rights and wellbeing.	CARF2021
Competency	The criteria established for the adequate skills, knowledge, and capacity required to perform a specific set of job functions.	CARF2021
Competency-based Training	An approach to education that focuses on the ability to demonstrate adequate skills, knowledge, and capacity to perform a specific set of job functions.	CARF2021
Compassion	The ability to understand another person's suffering, combined with a willingness to help and promote the well-being of that person	Kalra, Sanjay, Priya et. al., (2018). Lessons for the Health-care Practitioner from Buddhism. Indian Journal of Endocrinology and Metabolism. 22. 812. 10.4103/ijem.IJEM_286_17.
Comprehensiveness	Comprehensiveness: A comprehensive range of health services is provided, appropriate to the needs of the target population, including preventative, curative, palliative and rehabilitative services and health promotion activities.	WHO Health Service Delivery who.int/healthinfo/systems/WHO_MBHS_S_2010_section1_web.pdf
Continuum of Care / Services	A system of services addressing the ongoing and / or intermittent needs of people at risk or with ongoing medical needs resulting from disease, trauma, aging, and/or congenital and/or developmental conditions. Such a system of services may be achieved by accessing a single provider, multiple providers, and / or a network of providers. This intensity and diversity of services may vary depending on the ongoing medical and psychological needs of the patient.	CARF2021
Continuity	Service delivery is organized to provide an individual with continuity of care across the network of services, health conditions, levels of care, and over the life-cycle.	WHO Health Service Delivery who.int/healthinfo/systems/WHO_MBHS_S_2010_section1_web.pdf
Cultural Competence	The ability of health providers and organizations to deliver health care services that meet the cultural, social, and religious needs of patients and their families. Culturally competent care can improve patient quality and care outcomes.	Swihart DL, Yarrarapu SNS, Martin RL. Cultural Religious Competence In Clinical Practice. [Updated 2021 Feb 18]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan-. Available from:

		https://www.ncbi.nlm.nih.gov/books/NBK493216/
Cultural Norms.	The provision of culturally appropriate care requires an understanding of the social life and customs of the population served. The health care provider's cultural awareness is their understanding of the differences between themselves and people from other backgrounds, especially relating to differences in values and attitudes.	Latif A. S. (2020). The Importance of Understanding Social and Cultural Norms in Delivering Quality Health Care-A Personal Experience Commentary. <i>Tropical medicine and infectious disease</i> , 5(1), 22. https://doi.org/10.3390/tropicalmed5010022
Cultural Values	The values of a person or group are the moral principles and beliefs that they think are important.	collinsdictionary.com
Coverage	Service delivery is designed so that all people in a defined target population are covered, i.e. the sick and the healthy, all income groups and all social groups.	WHO Health Service Delivery who.int/healthinfo/systems/WHO_MBHS_S_2010_section1_web.pdf
Diversional Therapy	Diversional therapy is a client centered practice and recognizes that leisure and recreational experiences are the right of all individuals. Diversional therapy practitioners work with people of all ages and abilities to design and facilitate leisure and recreation programs. Activities are designed to support, challenge and enhance the psychological, spiritual, social, emotional and physical wellbeing of individuals.	Diversional and Recreation Therapy Australia, www.diversionaltherapy.org.au
Governance	The body vested with the legal authority by applicable law to direct the business and affairs of the hospital.	CARF2021
Governing Body	The highest authority with governance responsibilities.	Planetree 2017
Healing Environment	Healing environments in which the influence of the immediate surroundings helps people to get better. Such healing environments shorten people's post-operative recovery period and help to return them to a good state of mind and physical health. the built environment of a hospital influences the healing process and has a direct effect on patient health outcomes. A healing environment can help to reduce the stress that patients encounter during a period of hospitalization and thereby help them in their personal recovery and recuperation.	Douglas, C. H., & Douglas, M. R. (2004). Patient-friendly hospital environments: exploring the patients' perspective. <i>Health expectations : an international journal of public participation in health care and health policy</i> , 7(1),

		61–73. https://doi.org/10.1046/j.1369-6513.2003.00251.x
Healing Modalities	Complementary and alternative medicine (CAM) is a broad term that encompasses diverse healthcare modalities that emanate from a variety of healing cultures. One of the basic principles of CAM is the promotion of cultural pluralism and openness to diverse cultural aspects of health and illness. The most common CAM modalities are: reflexology, Chinese Medicine and acupuncture, massage, shiatsu, twina, homeopathy and naturopathy.	Keshet Y, Ben-Arye E. [Which complementary and alternative medicine modalities are integrated within Israeli healthcare organizations and do they match the public's preferences?]. Harefuah. 2011 Aug;150(8):635-8, 690, 689. Hebrew. PMID: 21939112.
Healthcare /Patient Experience	Patient experience encompasses the range of interactions that patients have with the health care system, including their care from health plans, and from doctors, nurses, and staff in hospitals, physician practices, and other health care facilities. As an integral component of health care quality, patient experience includes several aspects of health care delivery that patients value highly when they seek and receive care, such as getting timely appointments, easy access to information, and good communication with health care providers. Understanding patient experience is a key step in moving toward patient-centered care. By looking at various aspects of patient experience, one can assess the extent to which patients are receiving care that is respectful of and responsive to individual patient preferences, needs and values. Evaluating patient experience along with other components such as effectiveness and safety of care is essential to providing a complete picture of health care quality	.AHRQ, Department of Health and Human Services, USA. What is patient experience? ahrq.gov/cahps/about-chaps/patient-experience/index.html
Informed Choice	A decision made by the patient or family that is based on sufficient experience and knowledge, including exposure, awareness, interactions, or instructional opportunities, to ensure that the choice is made with adequate awareness of the alternatives to and consequences of the options available.	CARF2021
Informed Decisions	A well-informed patient can actively participate in the decision-making process about their care, and better understand the likely or potential outcomes of their treatment. Informed decision-making also provides an additional layer of vigilance and protection against errors which may result in adverse events. Informed decision-making is the two-way communication process between a patient and one or more health practitioners that is central to patient-centered health care. It reflects the ethical principle that a patient has the right to decide what is appropriate for them, taking into account their personal circumstances, beliefs and priorities. This includes the right to accept or to decline the offer of certain	Queensland Health Clinical Excellence Division, Guide to Informed Decision Making in Health Care.

	health care and to change that decision. In order for a patient to exercise this right to decide, they require the information that is relevant to them.	
Integrated	Integrated health care, often referred to as interprofessional health care, is an approach characterized by a high degree of collaboration and communication among health professionals. What makes integrated health care unique is the sharing of information among team members related to patient care and the establishment of a comprehensive treatment plan to address the biological, psychological and social needs of the patient. The interprofessional health care team includes a diverse group of members (e.g., physicians, nurses, psychologists and other health professionals), depending on the needs of the patient.	American Psychological Association apa.org/health/integrated-health-care
Interventions	A health intervention is an act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote, or modify health, functioning or health conditions.	International classification of Health Interventions (ICHI) https://www.who.int
Leadership	Leadership creates and sustains a focus on the patients, the organization's core values and mission, and the pursuit of organizational and performance excellence. It is responsible for the integration of the organization's core values and performance expectations into its management system. Leadership promotes and advocates for the organizations and community's commitment to the patients.	CARF2021
Life Enrichment Activities	Life enrichment activities cover the dimensions of wellness—emotional, social, spiritual, physical, educational, and occupational support.	Leadingage.org
Multidimensional	Having many different features	dictionary.cambridge.org
Mission	An organization's reason for being. An effective mission statement reflects people's idealistic motivations for doing the organization's work	CARF2021
Open Communication	Open Communication is characterized by a mutual exchange of information and ideas, transparency, and access to people and information	CARF2021
Organizational Culture	An <i>organization's culture</i> defines the proper way to behave within the <i>organization</i> . This <i>culture</i> consists of shared beliefs and values established by leaders and then communicated and reinforced through various methods, ultimately shaping employee perceptions, behaviors and understanding.	SHRM, Better Workplaces Better World shrm.org/ResourcesAndTools/tools-and-samples/toolkits/Pages/understanding and developing organizationalculture.aspx
Patient Centered	The Institute of Medicine defines patient-centered care as “Providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions.” This approach requires a true partnership between individuals and their healthcare providers, one where the individual's needs and aspirations drive both healthcare decisions and how outcomes are measured. Under a patient-centered model, care teams work to know and treat the <i>full patient</i> — developing individualized, comprehensive care plans in which mental health and social needs receive equal attention to traditional medical treatment. Patient- or family-centered care plans	www.healthleadsusa.org/resources/patient-centered-care-elements-benefits-and-examples

	prompt health systems to rethink their approach to healthcare delivery — bringing new attention to active collaboration and shared decision-making with patients.	
Patient Preferences	Patient preferences refer to the individual's evaluation of dimensions of health outcomes and are but one of a large number of preferences that may influence health care choices. These judgments are expressed as statements or actions.	Brennan, P. F., & Strombom, I. (1998). Improving health care by understanding patient preferences: the role of computer technology. <i>Journal of the American Medical Informatics Association: JAMIA</i> , 5(3), 257–262. https://doi.org/10.1136/jamia.1998.0050257
Performance Indicator	A quantitative expression that can be used to evaluate key performance in relation to objectives. It is often expressed as a percent, rate, or ratio (CARF2021).	CARF2021
Person-Centeredness (Partners in Healthcare)	Services are organized around the person, not the disease or the financing. Users perceive health services to be responsive and acceptable to them. There is participation from the target population in service delivery design and assessment. People are partners in their own health care.	WHO Health Service Delivery who.int/healthinfo/systems/WHO_MBHSS_2010_section1_web.pdf
Personal Preferences	Patient preferences result from deliberation about specific elements, such as anticipated treatments or health outcomes. Patient preferences refer to the individual's evaluation of dimensions of health outcomes and are but one of a large number of preferences that may influence health care choices. These judgments are expressed as statements or actions. Patient preferences result from cognition, experience, and reflection and exist as the relatively enduring consequences of values.	Brennan, P. F., & Strombom, I. (1998). Improving health care by understanding patient preferences: the role of computer technology. <i>Journal of the American Medical Informatics Association : JAMIA</i> , 5(3), 257–262. https://doi.org/10.1136/jamia.1998.0050257
Performance Target	Measurable level of achievement identified to show progress toward an overall objective. The target can be expressed as a percentage, ratio, or number to be reached.	CARF2021

Plan	Written direction that is action oriented and related to a specific project or defined goal, either present and/or future oriented. A plan may include the steps to be taken to achieve stated goals, a timeline, priorities, the resources needed and/or available for achieving the plan, and the positions or persons responsible for implementing the identified steps	CARF2021
Plan of Care	The document that contains the requirements designed to meet the needs of the patient. This document is prepared with input from the team, including the patient. The plan is modified and revised, as needed, depending on the needs of the patient	CARF2021
Policy	Written course of action or guidelines adopted by leadership and reflected in actual practice	CARF2021
Responsiveness	How well the health system meets the legitimate expectations of the population for the non-health enhancing aspects of the health system. It includes seven elements: dignity, confidentiality, autonomy, prompt attention, social support, basic amenities, and choice of provider.	WORLD HEALTH ORGANIZATION (WHO): STRATEGY ON MEASURING RESPONSIVENESS Charles Darby Nicole Valentine Christopher JL Murray Amala de Silva GPE Discussion Paper Series: No. 23 EIP/GPE/FAR World Health Organization. who.int/healthinfo/paper23.pdf
Quality	Health services are of high quality, i.e., they are effective, safe, centred on the patient's needs and given in a timely fashion.	WHO Health Service Delivery who.int/healthinfo/systems/WHO_MBHS_S_2010_section1_web.pdf
Safety Culture	The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.	Study Group on Human Factors. Organizing for safety: third report of the ACSNI (Advisory Committee on the Safety of Nuclear Installations). Sudbury, England: HSE Books; 1993. Accessed from ahrq.gov
Service Delivery	Service delivery is a fundamental input to population health status, along with other factors, including social determinants of health. The precise organization and content of health services will differ from one country to another, but in any well-functioning health system, the network of service	WHO Health Service Delivery who.int/healthinfo/systems/WHO_MBHS

	delivery should have the following key characteristics. 1. Comprehensiveness; 2. Accessibility; 3. Coverage; 4. Continuity; 5. Quality; 6. Person-centeredness; 7. Coordination; 8. Accountability and Efficiency:	S_2010_section1_w_e b.pdf
Spiritual Beliefs	The diversity of religions around the world creates challenges for health care providers and systems to provide culturally competent medical care. Cultural competence is the ability of health providers and organizations to deliver health care services that meet the cultural, social, and religious needs of patients and their families. Culturally competent care can improve patient quality and care outcomes. Strategies to move health professionals and systems towards these goals include providing cultural competence training and developing policies and procedures that decrease barriers to providing culturally competent patient care.	Swihart DL, Yarrarapu SNS, Martin RL. Cultural Religious Competence In Clinical Practice. [Updated 2021 Feb 18]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK493216/
Shared Decision Making:	The process of interacting with patients who wish to be involved in arriving at an informed, values-based choice among two or more medically reasonable alternatives	Planetree 2017 →Health Affairs 2004
Staff Engagement	Staff are engaged when they feel valued, are emotionally connected, fully involved, enthusiastic and committed to providing a good service...when each person knows that what they do and say matters and makes a difference.	National Quality Improvement Team, Ireland, 2016. Hse.ie/eng/about/wh_o/qid/aboutqid
Team	At a minimum, the patient and the primary personnel directly involved in the participatory process of defining, refining, and meeting the patient's goals. The team may also include other significant persons such as family members at the option of the patient and the organization.	CARF2021
Transition	The process of moving from one level of care or service to another.	CARF2021
Treatment Goals	During an admission to hospital or a planned outpatient appointment, important Goals of Patient Care decisions are made in light of the patients current health, individual health care needs, and patient preferences regarding future care. The patient may also want to describe treatments that they would prefer not have. It also involves the ability of the patient to be able to ask questions and hear the opinion of the treating clinician. Having an open discussion about Goals of Patient Care will enable the patient's preferences for care to be discussed and their views heard.	Department of Health, Government of Western Australia, Goals of Patient Care
Treatment Goals Documentation	Goals of Patient Care process uses a clinical document (medical record) to record information about the shared decisions that have been made. This document is written by the healthcare team following the goals of care discussions between the patient, the doctor or health care team and the family or carer (s). these goals can change over time.	Department of Health, Government of Western Australia, Goals of Patient Care
Wellbeing	Well-being includes the presence of positive emotions and moods (e.g., contentment, happiness), the absence of negative emotions (e.g., depression, anxiety), satisfaction with life, fulfillment and positive functioning. ^{4, 33-35} In simple terms, well-being can be described as judging life positively and feeling good. ^{36, 37} For public health purposes, physical well-being (e.g., feeling very healthy and full of energy) is also viewed as critical to overall well-being.	cdc.gov/hrqol/wellbeing.htm#three

Wellness Education	Learning activities that are intended to improve the patient's or employee's health status. There include but are not limited to healthcare education, self-management of medications, nutritional instructions, exercise programs, stress management.	CARF2021
Workforce Engagement	Refers to the level of an individual's commitment and connection to an organization.	CARF2021

DRAFT

Clinical Privileging (CP)

Clinical Privileging considered the cornerstone of patient safety and is an essential element to promote quality of care. Privileging is an internal process implemented within a healthcare facility for the purpose of verifying and integrating the training and experience of the healthcare practitioner with the organization's scope of service and to confirm that all granted privileges may be practiced within the amenities of the facility. Delineation of privileges must be an ongoing process that should be flexible enough to add new procedures or conditions to treat and be firm, fair, and consistent. Obtaining privileges is the right of all health care providers through an appropriate scheme.

Privileging process must start with a list of competencies, associated with evidence, checked by the practitioner, approved, or modified by the department head and finally discussed for approval by the credentialing and privileging committee of the facility or at times by a centralized credentialing and privileging committee approval. On other occasions, especially when advanced skills must be assessed, credentialing and privileging may be conducted in a referral hospital or center approved by the authority that rules the facility the practitioner is looking to practice in. Some of the difficulties encountered in the privilege delineation process involve granting privileges for new procedures, monitoring compliance with privileges, and granting privileges that may be performed by members of several departments.

The key to effective privilege delineation is that specific written criteria be applied uniformly to all healthcare providers. Once privileges are granted, they should be disseminated into the different areas of the healthcare facility where the practitioner will practice. Granted privileges are to be monitored through performance evaluation, morbidity and mortality committees, infection rates, adverse events related to the practitioner, etc. In some cases, privileges may be revisited, suspended, or entirely revoked.

Privileging is an internal or institutional issue, varies largely from sector to sector and from provider to provider. Different examples of privileging processes exist in the Kingdom of Saudi Arabia. Some healthcare provider sectors use a centralized privileging practice covering its hospitals while others, privileging is left to the hospital itself. Another example is that most hospitals use some form of 'laundry list' for privileging, whereby the healthcare worker is offered a checklist of privileges to choose from that can be initially verified by the Department Head followed by the Credentialing and Privileging Committee (CPC) within this hospital. 1

Alternatively, other hospitals and health providers sectors may conduct competence-based privileging. In this process, the training and experience per each privilege, especially for carrying out advanced or high-risk medical procedures is thoroughly evaluated in terms of training quality, actual experience, and mentoring. Continuous monitoring of privileges also varies.

Credentialing practices vary despite a centralized body, namely the SCFHS. In KSA, issues in credentialing directly lead to flaws in the privileging process. Healthcare facilities are required to ensure that all practitioners are credentialed and carry valid licenses. The credentialing of healthcare practitioners in KSA is centralized in the Saudi Commission for Health Specialties (SCFHS) involving two main courses for credentialing namely, credentialing of Saudi healthcare practitioners with local qualifications and credentialing of expatriates and Saudi healthcare practitioners with overseas qualifications.

There is a major process gap and cause for concern with applicants arriving to KSA and practicing in advance of completing the entire Primary Source Verification (PSV) process. This poses a substantial risk, not only to patients, but also to the facility.

CP.1. The hospital has hospital-level privileging processes as part of its clinical privileging.

CP.1.1. The hospital defines and details all available clinical services which it provides in line with its scope of service.

CP.1.2. The hospital ensures any new clinical service introduced or expanded is in alignment with the hospital's scope of service with the required resources secured (staff, medications medical equipment and devices) for the provision of safe care, and, if applicable, participation of external subject matter experts for clinical privileging.

Explanations:

XXX

CP.2. The hospital has credentialing and privileging committees.

CP.2.1. The chief medical officer or qualified senior consultant physician designee, chairs the physician credentialing and privileging committee, inclusive of human resources representation, with the committee determining the final privileging and re-privileging status.

CP.2.2. The chief allied health officer, or qualified designee, chairs the allied health credentialing and privileging committee, inclusive of human resources representation, with the committee determining the final privileging and re-privileging status.

CP.2.3. The chief nursing officer, or qualified designee, and CMO co-chair the advanced practice nurse credentialing and privileging committee, inclusive of human resources representation with the committee determining the final privileging and re-privileging status.

CP.2.4. The chief nursing/midwifery officer, or qualified designee, chairs the nurse and midwife credentialing and privileging committee, inclusive of human resources representation with the committee determining the final privileging and re-privileging status.

CP.2.5. Credentialing and privileging committees set the criteria for clinicians' clinical privileges, per the committees' charges and in accordance with the standards of care within the clinicians' specialties. The committee also determines clinical assignment/job title, required competencies, and periodic reviews.

CP.2.6. Credentialing and privileging committees meet regularly, and as needed, to facilitate efficient and timely on-boarding and re-credentialing of staff to meet the hospital's staffing requirements and the provision of care.

Explanations:

XXX

CP.3. The hospital has credentialing processes.

PC.3.1. Credentialing is inclusive of Primary Source Verification (PSV), with confirmatory documentation via the original source, completed by the hospital's human resources staff, the credentialing committees or by a recognized third party, such as DATAFLOW.

PC.3.2. The hospital has processes to verify education, licensure, and experience through PSV for all candidates and staff clinicians within established time frames. Training, references, and certifications are verified, as applicable.

PC.3.3. The hospital retains confirmatory credentialing documentation for all clinicians for education, licensure, and, when applicable, experience (if most recent experience is outside the Kingdom). Valid certificate of experience (COE) is acceptable for recent experience from within the Kingdom.

PC.3.4. The hospital documents the reasons and outcome of instances when the PSV cannot be completed within established time frames.

Explanations:

XXX

CP.4. The hospital has processes for granting clinical privilege.

CP.4.1. Clinical privileges are granted and re-granted only to fully credentialed clinicians and per the credentialing and privileging committees' decision.

CP.4.2. The hospital grants preliminary clinical privileges for a 90-day probationary period for newly hired clinicians.

CP.4.3. The hospital has processes for proctoring (observing) or precepting clinicians during the probationary period.

CP.4.4. Physician surgical or procedural privileging is based on training, surgical certification, and on-going practice experience.

CP.4.5. Advanced practice nurse privileges are based on credentialing and clinical/specialty area competency, as determined by the designated physician clinical supervisor and the signed collaborative stakeholder agreement in accordance with the hospital or national scope of advanced practice.

CP.4.6. Midwives are privileged by education, competency and per the national scope of midwifery practice to independently conduct low-risk births with an immediate back-up obstetrician available at all times and register births conducted under their names on the birth register/notification.

PC.4.7. Non-physician/non-advanced practice privileges are based on credentialing and competencies for the relevant clinical area/specialties with required training, certifications/equivalencies, and unit-based/clinical area-based/patient population-based competencies identified and maintained with established periodic reviews and time frames.

Explanations:

XXX

CP.5. The hospital has processes for maintaining clinical privileges.

CP.5.1. The hospital monitors the clinical and ethical performance of all clinicians with regular intervals for re-privileging.

CP.5.2. The corresponding privileging committees utilize morbidity and mortality committee discussions and decisions, clinician productivity, outcomes, and feedback from other channels to maintain, suspend or revoke clinical privileges.

CP.5.3. Non-physician/non-advanced practice clinicians maintain clinical privileging based on competency re-assessment as outlined per policy by clinical area/specialties (unit based competency).

Explanations:

XXX

CP.6. The hospital processes in place for granting special clinical privileging.

CP.6.1. The hospital has a process for granting telemedicine credentialing and privileges.

CP.6.2. The hospital has a process for granting robotic surgery privileging

CP.6.3. The hospital has a process for granting high-risk procedure privileges.

CP.6.4. The hospital has a process for granting emergency privileging.

CP.6.5. The hospital ensures moderate (conscious) sedation privileges are granted only to clinicians who have a valid certificate of moderate sedation education/training and advanced life support appropriate to the age of the patients served.

CP.6.6. The hospital ensures the availability and accessibility of valid privileging documentation for all physicians, advanced practice nurses and midwives, as well as moderate sedation privileges for all relevant clinicians.

Explanations:

XXX

CP.7. The hospital grants order and prescriber privileges, including medications.

CP.7.1. The hospital has policies and processes for granting ordering and prescribing medications privileges for independent healthcare providers and advanced practice nurses.

CP.7.2. The hospital has a policy granting antibiotic prescribing privileges to independent healthcare providers and advanced practice nurses, in alignment with the antibiotic stewardship program (ASP).

CP.7.3. The hospital has a policy granting prescribing privileges of controlled and narcotic substances, chemotherapy agents, high-alert, radioactive, investigational, and other specialty medications to independent healthcare providers and advanced practice nurses.

Explanations:

XXX

CP.8. The hospital incorporates or extends its privileging, on-duty status, and clinical assignment to include basic and advanced life support.

CP.8.1. All health care providers hold a valid BLS to be on duty and to provide direct patient care.

CP.8.2. In the critical care areas (all ages), Cath Lab, and recovery areas/PACU, all clinicians on duty providing direct patient care hold valid advanced life support, per the ages served.

CP.8.3. In the ED, all clinicians on duty, with direct patient care hold at least one valid advanced life support, with the on-duty staff providing adequate neonatal, pediatric and adult advanced life support coverage per the ages served, per the scope of service.

CP.8.4. Specialty areas, including OR, endoscopy, radiology, and non-invasive cardiology, determine a percentage of staff per the roster who hold advanced life support per ages served and scope of service with on-duty staff providing sufficient coverage per shift, per the provision of patient care.

CP.8.5. All other clinical areas determine a percentage of staff with advanced life support per ages served and scope of service and determine on-duty coverage, as applicable.

CP.8.6. All health providers providing direct patient care to the newborns or neonates, regardless of the clinical area, hold a valid NRP.

References:

- Salem Al Wahabi, Fayssal Farahat and Ahmed Y. Bahloul (2017) - Prevalence and preventability of sentinel events in Saudi Arabia: Analysis of reports from 2012 to 2015, Eastern Mediterranean Health Journal (EMHJ), EMRO, WHO, Vol. 23 No. 7.
- ESR1-HR5 CBAHI 2015: <http://cbahi.securehostsite.biz/Library/Assets/ESR%20cover%20final.pdf>
- ESR2-MS7 CBAHI 2015: <http://cbahi.securehostsite.biz/Library/Assets/ESR%20cover%20final.pdf>
- Salem Alwahabi, et al. [Credentialing and Privileging in the Kingdom of Saudi Arabia A Whitepaper by the Saudi Central Board for Accreditation of Healthcare Institutions \(CBAHI\) September 2017](#)

DRAFT

Glossary

Board-certified

Saudi board certification or equivalent as per SCFHS classification.

Clinical staff

Pharmacists, nurses, midwives, medical technicians, respiratory therapists, physiotherapists, health educators, dietitians.

Competency

Knowledge, skills, and attitudes required to perform the job. Knowledge is the understanding of facts and procedures. Skill is the ability to perform specific actions.

Committee

A multidisciplinary body of persons officially delegated to consider, investigate, act on, or report on some matter or perform a specified function.

Credentialing

The process of obtaining, verifying, and assessing the qualifications of a healthcare professional to determine if that individual can provide patient care services in or for a healthcare organization.

Criteria

Expected level(s) of achievement or specifications against which performance can be assessed. Data Raw facts and figures from which information can be generated.

Evidence Based

The practice of medicine or the use of healthcare interventions guided by or based on supportive scientific evidence.

Healthcare Facility

A generic term used to describe many types of organizations that provide healthcare services.

Healthcare Professional

Any person who has completed a course of study and is skilled in a field of health. This includes physicians, dentists, nurses, or other healthcare professionals. Healthcare professionals are often licensed by a government agency or certified by a professional organization.

Medical Record

A record that contains patient health information generated by one or more encounters. Included in this information are patient demographics, assessment findings, problems, medications, immunizations, diagnostic reports, provided education, and any other relevant patient-specific information.

Medical Staff

Physicians and dentists.

High Risk

High probability that severe injury will occur. Incidents Events that are unusual, unexpected, may have an element of risk, or that may have a negative effect on patients, staff, or the hospital.

Leaders

The identified and designated individuals who have the responsibility to oversee effective functioning of processes within a defined scope of services.

Mission

The reason or purpose for the existence of an organization or one of its components.

Monitoring

A planned, systemic, ongoing process to gather, organize, and review data/information on a regular basis with the purpose of identifying changes in a situation.

Objectives

Concrete measurable steps taken to achieve goals.

Patient

A person for whom a hospital accepts responsibility for treatment, care and/or service.

Patient Safety

Freedom from accidental injuries during the course of medical care; activities to avoid, prevent, or correct adverse outcomes which may result from the delivery of health care.

Personnel File

Collection of information about a staff member covering personnel issues such as licensure, certifications, leaves, appraisal reviews, and job description.

Policy

A written document which outlines the rules and expected performance of staff within the organization. Policies are dynamic and reflect current knowledge and practice and need to be reviewed on a regular basis.

Privileging

The process of reviewing an individual's credentials through credentials body to determine the authority and responsibility to be granted to a practitioner for making independent decisions to diagnose, initiate, alter, or terminate a regimen of medical or dental care. Privileging determines the physician's scope of practice in the organization determined by his/her competencies.

Procedure

A written set of instructions that describe the approved and recommended steps for a particular act or sequence of acts.

Process

A set of interrelated steps directed at one particular outcome. Process Improvement Mechanisms utilized to make improvements to a process through the use of continuous quality improvement methods.

Quality

The degree to which health services for individuals and population increases the likelihood of desired outcome and are consistent with current professional knowledge.

Risk

The combination of the assessment of magnitude of injury, or potential injury, with the probability that certain actions/events will occur.

Scope of Services

The range of activities provided to the patients and/or other customers by the leadership, clinical, and support personnel. This describes the full range of services, the demographics (age groups, types of patients), diagnostics provided, therapeutic interventions provided, and the number of patients who are provided each service annually. All of the resource and competency requirements flow from the organization's scope of services. Screening A system for examining and separating into different groups.

Standard

Statement of structure, process, or outcome expectations necessary to enhance quality care.

Supervising body (Governing Body)

In healthcare, it represents the individual(s), group, or agency that has ultimate authority, responsibility, and accountability for the overall strategic direction, methods of operations (management and planning), establishment of policies, maintenance of safety and quality of care provided by the hospital. Guidelines Principles guiding or directing actions.

Vision

Description of what the organization would like to be or to reach in the future.

Safe Staffing Levels (SSL)

Projections for Saudi Arabia's population growth predict it will reach 39.8 million by 2025, followed by 54.7 million by 2050 (Al-Hanawi, Khan & Al-Borie, 2019). In 2014, within the Kingdom, every 1000 population was served by 11 healthcare professionals; this is half the average rate of 22 healthcare professionals per 1000 population in G20 countries (Al-Hanawi, Khan & Al-Borie, 2019). The establishment of minimum safe staffing requirements has the potential to stabilize the health workforce to meet society's evolving healthcare demands and support the provision of safe patient care.

The assurance of minimum safe staffing requirements is a major strategic intervention to improve the safety of patients and the well-being of health workers. It is the only mechanism to safeguard adequate staffing levels, in all settings, at all times.

Currently, there is a vast variation in staffing levels at healthcare facilities throughout the Kingdom. Such variation in staffing levels negatively impacts the provision of care, resulting in missed care, medical errors, and adverse events leading to avoidable patient harm, including patient death. Variation in staffing levels also negatively impacts health workers at large, with increased levels of work-related injuries, job dissatisfaction, burnout, and turnover. Minimum safe staffing requirements that ensure adequate staffing across the private and public sectors is a required first step to guarantee both staff and patient safety.

Safe staffing is achieved when an appropriate number of health workers are always available across the continuum of care with the correct education, skills/competence, and experience to deliver safe patient care. The evidence is definitive. Healthcare facilities with adequate staffing standards have lower costs through decreased length of stay, prevention of hospital-acquired infections, reduced pressure injuries, fewer medication errors, lower staff turnover, and increased patient and staff satisfaction. Therefore, safe staffing standards are the most cost-effective approach to bringing about improvements in patient safety and the quality of care.

Countries with understaffed healthcare systems endanger their own citizens' health, becoming thereby more vulnerable to crises and their corresponding negative economic and social impact (UN High-Level Commission on Health Employment and Economic Growth, 2016).

Safe staffing levels ensures that the Saudi healthcare system achieves universal health coverage as well as the Kingdom's population health goals for Vision 2030 and national security goals. The implementation of minimum safe staffing requirements across the continuum of care leads to the highest standards of health service coverage and care to the Saudi population, whose rights to the attainment of the most optimal level of personal health is dependent on the availability, accessibility, acceptability, and quality of skilled healthcare professionals (Aba-Namay, 1993 & KSA MoH VRO, n.d.). Minimum safe staffing requirements enhance the safety of care provided to Saudi citizens and ensure the Saudi healthcare workers' protection and growth, thereby promoting the Kingdom's prosperity.

Objectives:

- To guarantee the minimum number of health workers to patient or bed ratio [Health Workers – Patient/Bed Ratios], assuring that the care provided within any given hospital meets patient safety, health worker safety, and quality of care standards.
- To have competent, adequate, motivated, and empowered health workers to carry out their roles and responsibilities at the highest level according to both the scope of practice and scope of service (IOM, 2010).
- To highlight the importance and impact of multidisciplinary health workers teams in improving the safety, efficiency, and effectiveness of the care provided.
- To emphasize the impact of health worker–patient ratios on health workers' well-being.
- To promote the application of best research-based evidence onto the health Worker–patient/bed ratios decision-making process.
- To align the health workers–patient/bed ratios with the overall goals of the Saudi Healthcare System Transformation and National Workforce Planning.

SSL.1. The hospital has a Multidisciplinary Clinical Team (MDCT) inclusive of care process and communication.

SSL.1.1. The hospital has a policy for the Multidisciplinary Clinical Team (MDCT).

SSL.1.2. Multidisciplinary Clinical Care Teams (MDCT) are comprised of the Most Responsible Physician (MRP), other physicians, in the critical care setting, the consultant of the primary service under which the patient was first admitted, pharmacists, clinical pharmacists, nurses, and allied healthcare providers.

SSL.1.3. Hospital leaders conduct multidisciplinary leadership safety walkrounds with MDCT members, engaging direct-care clinical, patients and families.

SSL.1.4. The MDCT practices effective communication amongst the MDCT members and with patients and families.

SSL.1.5. The hospital adopts team-based training to improve the performance of the MDCT.

SSL.1.6. The hospital has standardized patient handover and endorsement process of patients during change of shift, transition of care (to higher or lower levels of care), and for the transfer of patient responsibility.

Explanation:

The hospital has a policy and procedures with clear terms of references that highlight the overall details of the MDCT approach, including team members, frequency, communication, and documentation in the Medical Record. It is essential that for each patient, an MDCT is identified. Each team is led by the MRP (Consultant or Board-Certified Physician), in addition to the unit nurses, specialized nurses, other physicians from the team, pharmacists, and allied healthcare professionals (as needed).

To show their accountability to safety, the hospital leadership conducts regular Safety WalkRounds. Such practice helps bring safety concerns to leadership by staff from all levels during leadership safety rounds.

For the MDCT to be effective and safe, it must practice effective communication (in the preferred language of the patient/family). The communication is patient-centered and engages patients and families in the decision-making and treatment plan. The hospital strives to have team-based, simulated training especially in high-risk departments (Critical Care, OR, OB/L&D, and Emergency Department).

To guarantee the quality and safety of patients, there is an effective Patients' Handover process that assures all of the patients' pertinent information is shared between the outgoing and incoming clinical

teams (physicians, nurses and allied health), as well as whenever there is a transition of care of patients from one unit to another.

SSL.2. The hospital supports staff well-being.

SSL.2.1. The hospital has an employee wellbeing program, inclusive of the management of a work-life balance and healthy lifestyle programs.

SSL.2.2. The hospital has policies and processes for the resolution of workplace issues, with measures to reduce workplace incivility, harassment and violence.

SSL.2.3. The hospital has clear policies and processes for performance management, corrective disciplinary action, including the management of underperformance and staff a grievance process.

SSL.2.4. The hospital has a policy and processes for Anti-retaliation protecting individuals who raise or report ethical violations, legal wrongdoings, and/or safety concerns within an organization from retaliation or mistreatment, loss of pay, demotion, slander, non-contracting, or termination.

Explanation:

The hospital has a Staff Wellbeing Policy/Program (WHO, 2020). The policy includes the following areas:

- Promoting civility and addressing incivility/abuse.
- Incentives to promote reporting staff safety-related adverse events, near misses, or other concerns
- Prevent/address burnout
- Counseling
- Dedicated coordinator/team
- Work/life balance programs and facilities including breakrooms

SSL.3. The hospital has qualified staff in clinical and non-clinical areas.

SSL.3.1. The multidisciplinary Human Resources (HR) committee addresses all strategic human resources decisions, inclusive of manpower needs assessments, staff ratios, and succession planning.

SSL.3.2. All clinical services are led by an accountable qualified consultant physician head of department (HOD) who provides direct leadership, overseeing all departmental aspects, including scope of services, policies, processes, morbidity and mortality review, and clinical and operational KPIs.

SSL.3.3. The chief nursing officer holds a baccalaureate degree in nursing and a SCFHS as a specialist or higher.

SSL.3.4. The deputy chief nursing officer holds a baccalaureate degree in nursing and SCFHS as a specialist or higher.

SSL.3.5. All clinical areas/units have an accountable qualified, manager/supervisor providing direct leadership, overseeing assigned non-physician staff and department aspects per their scope, and adherence to scope of service, policies, processes, and clinical and operational KPIs.

SSL.3.6. All senior nurse leaders/director level accountable for the ED, critical care (ICU, PICU & NICU), CCU, OR, PACU, oncology and hemodialysis hold a baccalaureate degree in nursing and SCFHS as a specialist or higher.

SSL.3.7. The nurse manager of the CCU holds a baccalaureate degree in nursing and SCFHS as a specialist or higher.

SSL.3.8. The nurse manager of hemodialysis holds a baccalaureate degree in nursing and SCFHS as a specialist or higher.

SSL.3.9. The nurse manager of oncology units or outpatient settings holds a baccalaureate degree in nursing and SCFHS as a specialist or higher.

SSL.3.10. There is a staffing plan which supports sufficient and agile staffing for all clinical and non-clinical areas.

SSL.3.11. Each defined area or service has staffing plan customized for its scope of service, staff skill-mix, staff competency, physical characteristics, volumes, and for clinical areas, specialties and patient acuity, as well as quality and safety requirements.

SSL.3.12. The hospital has policies and programs to float and cross-train employees between clinical areas.

Explanation:

The effective policy for staffing (WHO, 2020; SPSC, 2019) highlights the following:

- Linked to the budget and budget cycles.
- Agility- linked to professions' supply and demand.
- Adaptability /Adjustable to changing conditions (internal and external).
- Linked to the hospital scope of service (current and future)

The health workers' staffing plan reflects the following influencing factors:

- Clinical Specialty, Scope of Service, Scope of Practice.
- Acuity of Care.
- Skill Mix – Experience, Qualification and Competencies the hospital workforce.
- Maximum allowed working hours per staff (day, week, and month).
- Volume.
- The clinical unit physical layout.

SSL.4. The hospital complies with the minimum nurse staffing standards in all clinical areas at all times.

SSL.4.1. Nurse staffing in the Emergency Department meets the minimum staffing requirements at all times.

SSL.4.2. Nurse staffing in the Adult Intensive Care Unit meets the minimum staffing requirements at all times.

SSL.4.3. Nurse staffing in the Adult and Pediatric Cardiovascular Intensive Care Unit(s) meets the minimum staffing requirements at all times.

SSL.4.4. Nurse staffing in the Cardiac Care Unit meets the minimum staffing requirements at all times.

SSL.4.5. Nurse staffing in the Pediatric Intensive Care Unit meets the minimum staffing requirements at all times.

SSL.4.6. Nurse staffing in the Neonatal Intensive Care Unit(s) meets the minimum staffing requirements at all times.

SSL.4.7. Nurse staffing in the Antenatal Ward (latent phase/induction area) meets the minimum staffing requirements at all times.

SSL.4.8. Midwives and nurse staffing in the Labor Room – Not in Active Labor and Active Labor meets the minimum staffing requirements at all times.

SSL.4.9. Nurse staffing in the Post-partum- “MOTHER-BABY SET” model of care meets the minimum staffing requirements at all times

SSL.4.10. Nurse staffing in the Post-partum- “MOTHER ONLY” model of care meets the minimum staffing requirements at all times.

SSL.4.11. Nurse staffing in the Well Baby Nursery meet the minimum staffing requirements at all times.

SSL.4.12. Nurse staffing in the Burn Unit meets the minimum staffing requirements at all times.

SSL.4.13. Nurse staffing in the Step-Down Unit/High-Dependency Unit/ Intermediate Care/ Chronic Ventilation Unit meets the minimum staffing requirements at all times.

SSL.4.14. Nurse staffing in the Operating Room (moderate and major cases) meets the minimum staffing requirements at all times.

SSL.4.15. Nurse staffing in the Recovery Room/PACU meets the minimum staffing requirements at all times.

SSL.4.16. Nurse staffing in the Cath. Lab meet the minimum staffing requirements at all times.

SSL.4.17. Nurse staffing in Endoscopy meet the minimum staffing requirements at all times.

SSL.4.18. Nurse staffing in the Radiology Department: Diagnostic/Interventional meets the minimum staffing requirements at all times.

SSL.4.19. Nurse staffing in Hemodialysis meets the minimum staffing requirements at all times.

SSL.4.20. Nurse staffing in the Telemetry Unit meets the minimum staffing requirements at all times.

SSL.4.21. Nurse staffing in the Oncology Unit and Clinics meets the minimum staffing requirements at all times.

SSL.4.22. Nurse staffing in the Adult and Pediatric Bone Marrow Transplant meets the minimum staffing requirements at all times.

SSL.4.23. Nurse staffing in the Medical Adult Unit meets the minimum staffing requirements at all times.

SSL.4.24. Nurse staffing in the Surgical Adult Unit meets the minimum staffing requirements at all times.

SSL.4.25. Nurse staffing in the Medical Pediatric Unit meets the minimum staffing requirements at all times.

SSL.4.26. Nurse staffing in the Surgical Pediatric Unit meets the minimum staffing requirements at all times.

SSL.4.27. Nurse staffing in Adult Psychiatric Unit meets the minimum staffing requirements at all times.

SSL.4.28. Nurse staffing in the Adolescent Psychiatric Unit meets the minimum staffing requirements at all times.

SSL.4.29. Nurse staffing in the Pediatric Psychiatric Unit meets the minimum staffing requirements at all times.

SSL.4.30. Nurse staffing in the Rehabilitation Unit meets the minimum staffing requirements at all times.

SSL.4.31. Nurse in Ambulatory Care/Out-Patient Department meets the minimum staffing requirements at all times.

Explanation:

To assure staffing processes and allocations promote safety and well-being for both employees and patients.

Table 1.: Safe Staffing Minimum Requirements.

SSL.5. The hospital complies with the minimum staffing standards for all physician and allied health staff in all clinical areas at all times.

SSL.5.1. Physician and allied health staffing in the Emergency Department meets the minimum staffing requirements at all times.

SSL.5.2. Physician and allied health staffing in the Adult Intensive Care Unit meets the minimum staffing requirements at all times.

SSL.5.3. Physician and allied health staffing in the Adult and Pediatric Cardiovascular Intensive Care Unit(s) meets the minimum staffing requirements at all times.

SSL.5.4. Physician and allied health staffing in the Cardiac Care Unit meets the minimum staffing requirements at all times.

SSL.5.5. Physician and allied health staffing in the Pediatric Intensive Care Unit meets the minimum staffing requirements at all times.

SSL.5.6. Physician and allied health staffing in the Neonatal Intensive Care Unit(s) meets the minimum staffing requirements at all times.

SSL.5.7. Physician and allied health staffing in the Antenatal Ward (latent phase/induction area) meets the minimum staffing requirements at all times.

SSL.5.8. Physician and allied health staffing in the Labor Room – Not in Active Labor and Active Labor meets the minimum staffing requirements at all times.

SSL.5.9. Physician and allied health staffing in the Post-partum- “MOTHER-BABY SET” model of care meets the minimum staffing requirements at all times

SSL.5.10. Physician and allied health staffing in the Post-partum- “MOTHER ONLY” model of care meets the minimum staffing requirements at all times.

SSL.5.11. Physician and allied health staffing in the Well Baby Nursery meet the minimum staffing requirements at all times.

SSL.5.12. Physician and allied health staffing in the Burn Unit meets the minimum staffing requirements at all times.

SSL.5.13. Physician and allied health staffing in the Step-Down Unit/High-Dependency Unit/ Intermediate Care/ Chronic Ventilation Unit meets the minimum staffing requirements at all times.

SSL.5.14. Physician and allied health staffing in the Operating Room (moderate and major cases) meets the minimum staffing requirements at all times.

SSL.5.15. Physician and allied health staffing in the Recovery Room/PACU meets the minimum staffing requirements at all times.

SSL.5.16. Physician and allied health staffing in the Cath. Lab meet the minimum staffing requirements at all times.

SSL.5.17. Physician and allied health staffing in Endoscopy meet the minimum staffing requirements at all times.

SSL.5.18. Physician and allied health staffing in the Radiology Department:
Diagnostic/Interventional meets the minimum staffing requirements at all times.

SSL.5.19. Physician and allied health staffing in Hemodialysis meets the minimum staffing requirements at all times.

SSL.5.20. Physician and allied health staffing in the Telemetry Unit meets the minimum staffing requirements at all times.

SSL.5.21. Physician and allied health staffing in the Oncology Unit and Clinics meets the minimum staffing requirements at all times.

SSL.5.22. Physician and allied health staffing in the Adult and Pediatric Bone Marrow Transplant meets the minimum staffing requirements at all times.

SSL.5.23. Physician and allied health staffing in the Medical Adult Unit meets the minimum staffing requirements at all times.

SSL.5.24. Physician and allied health staffing in the Surgical Adult Unit meets the minimum staffing requirements at all times.

SSL.5.25. Physician and allied health staffing in the Medical Pediatric Unit meets the minimum staffing requirements at all times.

SSL.5.26. Physician and allied health staffing in the Surgical Pediatric Unit meets the minimum staffing requirements at all times.

SSL.5.27. Physician and allied health staffing in Adult Psychiatric Unit meets the minimum staffing requirements at all times.

SSL.5.28. Physician and allied health staffing in the Adolescent Psychiatric Unit meets the minimum staffing requirements at all times.

SSL.5.29. Physician and allied health staffing in the Pediatric Psychiatric Unit meets the minimum staffing requirements at all times.

SSL.5.30. Physician and allied health staffing in the Rehabilitation Unit meets the minimum staffing requirements at all times.

SSL.5.31. Physician and allied health staffing in Ambulatory Care/Out-Patient Department meets the minimum staffing requirements at all times.

Explanation:

To assure staffing processes and allocations promote safety and well-being for both employees and patients.

Table 1.: Safe Staffing Minimum Requirements.

SSL.6. The hospital complies with the minimum standards for service-based hospital staffing.

SSL.6.1. Pharmacist staffing meets the minimum staffing requirements at all times.

SSL.6.2. Pharmacy Technician staffing meets the minimum staffing requirements at all times.

SSL.6.3. Medical Laboratory Technician staffing meets the minimum staffing requirements at all times.

SSL.6.4. Radiology Technician staffing meets the minimum staffing requirements at all times.

SSL.6.5. Physiotherapy staffing meets the minimum staffing requirements at all times.

SSL.6.6. Occupational Therapy meets the minimum staffing requirements at all times.

SSL.6.7. Social Services staffing meets the minimum staffing requirements at all times.

SSL.6.8. Palliative Care staffing meets the minimum staffing requirements at all times.

SSL.6.9. Dietary Services staffing meets the minimum staffing requirements at all times.

SSL.6.10. Quality & Patient Safety Specialists staffing meets the minimum staffing requirements at all times.

SSL.6.11. Infection Prevention & Control Specialist staffing meets the minimum staffing requirements at all times.

SSL.6.12. CSSD staffing in hospitals with bed capacity 100 beds meets the minimum staffing requirements at all times.

SSL.6.13. CSSD staffing in hospitals with bed capacity > 100 meets the minimum staffing requirements at all times.

SSL.6.14. Diabetic Educator staffing meets the minimum staffing requirements at all times.

SSL.6.15. Environmental Services staffing meets the minimum staffing requirements at all times.

SSL.6.16. Unit Clerks /Ward Clerks staffing meets the minimum staffing requirements at all times.

SSL.6.17. Porter staffing meets the minimum staffing requirements at all times.

SSL.6.18. Clinical Coder staffing meets the minimum staffing requirements at all times.

SSL.6.19. Emergency Medical Services staffing meets the minimum staffing requirements at all times.

SSL.6.20. Dental Services staffing meets the minimum staffing requirements at all times.

Explanation:

To assure staffing processes and allocations promote safety and well-being for both employees and patients.

Table 1.: Safe Staffing Minimum Requirements.

SSL.7. There is an effective Business Continuity Plan (BCP) for dealing with disasters and emergencies.

SSL.7.1. The Business Continuity Plan (BCP) is activated by clear criteria during disasters and emergencies.

SSL.7.2. The hospital establishes a multidisciplinary team led by the CEO (or senior executive) to ensure effective implementation of the BCP.

SSL.7.3. The BCP focuses on the continuity of critical processes, functions, and mission-essential services of the hospital.

SSL.7.4. The BCP has a robust staffing component to plan and re-assign hospital staff according to the need to maintain patient safety, staff safety, and continuity of essential services.

Explanation:

To develop a BCP for the hospital to continue delivering healthcare services at an acceptable predefined threshold following any disruptive incidence/disaster or crisis (man-made and/or natural).

BCP is activated using a pre-defined criterion. The hospital establishes a multidisciplinary BCP team (taskforce), to ensure that the BCP is implemented effectively. The multidisciplinary BCP team (taskforce) is empowered and accountable to provide prompt action. The CEO (or a senior executive) chairs the BCP task force to assure its effectiveness.

The objective of the BCP is to minimize the impact of disasters/emergencies on the safety of patients and healthcare workers while maintaining essential operations during the response and recovery period. Disasters/emergencies can negatively disrupt daily operations and clinical services.

The hospital's BCP has a core component that addresses the healthcare staffing of clinical units/services to guarantee the agility of the response and the safety of patients and healthcare workers.

Table 1. Safe Staffing Minimum Requirements

The following are the minimum safe staffing requirements for health workers ratio per patient, per bed or as listed.

Safe staffing requirements can be influenced by the following factors (when applicable), which include but are not limited to the following:

- Designated hospital level, as per MOH definition.
- Status of open or closed Intensive Care Unit (ICU).
- Patient acuity or dependency, regardless of patient location.
- Occupancy rates (average daily census).
- Health workers' experience and competence (i.e., skill-mix).
- Patient volume/turnover: it includes planned and unplanned admissions, discharges, and transfers per 24-hour period.
- Unit physical layout: consider the safety of patients who may need closer observation, the distance that staff must travel to access resources within the unit.
- Availability of or proximity to technological support, automation and/ or other resources including, but not limited to electronic medical record (EMR), Pyxis systems, pneumatic tubes systems and pharmacy staff to prepare medications.
- Other patient/family-specific factors.

NOTE¹: These numbers and ratios do not allow for replacement or substitution: [i.e., Pharmacy Technicians do not replace Pharmacists or non-nurse licensed ancillary staff do not replace licensed nurses].

NOTE²: All professional categories are defined and licensed as per the Saudi Commission for Health Specialties (SCFHS).

	Clinical units	Physicians	Nurses/Midwives (when applicable)	Respiratory Therapists & Ancillary Staff (when applicable)
	Emergency Room	1:2.5 patients or fewer per hour [Augustine, 2016]	1:3 patients or fewer [SPSC 2019 & NNEP, 2020] 1 supernumerary charge nurse at all times	Per hospital inpatient bed coverage.
	Adult Intensive Care Unit/Cardiovascular Intensive Care Unit	ICU Consultant 1:20 patients or fewer ICU Specialist 1:10 patients or fewer ICU Resident 1:5 patients or fewer [MOH, 2018]	1:2 patients or fewer (Ratios can be either 1:2, 1:1 or 2:1 or more if needed) [SPSC 2019 & NNEP, 2020] 1 supernumerary charge nurse at all times	RTs 1:5 patients or fewer [MOH, 2018] Clinical Pharmacist 1:20patients Clinical Dietician 1:20patients 1 Physiotherapist
	Cardiac Coronary Unit	ICU Consultant 1:20 patients or fewer ICU Specialist 1:10 patients or fewer ICU Resident 1:5 patients or fewer [MOH, 2018]	1:3 patients or fewer [SPSC 2019 & NNEP 2020] 1 supernumerary charge nurse at all times	RTs 1:5 patients or fewer [MOH, 2018]

	<p>Pediatric Intensive Care Unit</p>	<p>ICU Consultant 1:20 patients or fewer ICU Specialist 1:10 patients or fewer ICU Resident 1:5 patients or fewer [MOH, 2018]</p>	<p>1:2 patients or fewer (Ratios can be either 1:2, 1:1 or 2:1 or more if needed) [SPSC 2019 & NEEP,2020] 1 supernumery charge nurse at all times</p>	<p>RTs 1:5 patients or fewer [MOH, 2018]</p>
	<p>Neonatal Intensive Care Unit</p>	<p>ICU Consultant 1:20 patients or fewer ICU Specialist 1:10 patients or fewer ICU Resident 1:5 patients or fewer [MOH, 2018]</p>	<p>LEVEL 3 - 1:1 patient (Ratios can be either 1:1 or 2:1 or more if needed) LEVEL 2 - 1:3 patients or fewer [SPSC 2019, NNEP, 2020] 1 supernumery charge nurse at all times, per unit level of neonatal care/unit</p>	<p>RTs 1:5 patients or fewer [MOH, 2018]</p>
	<p>Antenatal Ward: latent phase/induction area)</p>	<p>Consultant: 1:140 patients or fewer Specialist: 1:70 patients or fewer Resident 1:21 patients or fewer [MOH, 2018]</p>	<p>1:6 patients or fewer [Stones et al, 2019] 1 supernumery charge nurse at all times</p>	<p>RTs Per hospital inpatient bed coverage.</p>

Labor Room				
<u>Not In active labor</u>	Enough OB/Gyn specialists or midwives to meet the active labor requirements (3.1.7.2.) and as per CBAHI Safe Labor and Birth Standards.	1:2 patients or fewer. Staff is either a licensed and privileged midwife or a competent/experienced Labor & Delivery (L&D) nurse as per the International Confederation of Midwives, with NRP. [CBAHI Safe Labor & Birth, 2021, SPSC, 2019, NNEP, 2020, & Stones et al. 2019] 1 supernumery charge nurse at all times	RTs Per hospital inpatient bed coverage.	
<u>Active labor</u>	2 or more:1 – of which at a minimum 1 of the clinicians (physician or midwife) is privileged to deliver and the others are "skilled" (i.e., competent per the International Confederation of Midwives, with NRP and experienced in L&D) [CBAHI Safe Labor & Birth, 2021, SPSC, 2019 & SPSC, 2020, Stones et al. 2019]		RTs Per hospital inpatient bed coverage.	

		1 supernumerary charge nurse at all times	
	Post-partum		
	<u>"MOTHER-BABY SET" model of care</u>	Consultant: 1:140 patients or fewer Specialist: 1:70 patients or fewer Resident 1:21 patients or fewer [MOH, 2018]	1:4 patients or fewer [SPSC, 2019 & NEEP, 2020] 1 supernumerary charge nurse at all times
	<u>"MOTHER ONLY" model of care</u>	Consultant: 1:140 patients or fewer Specialist: 1:70 patients or fewer Resident 1:21 patients or fewer [MOH, 2018]	1:6 patients or fewer [SPSC, 2019 & NEEP, 2020] 1 supernumerary charge nurse at all times
	Well Baby Nursery	Covered by NICU medical staff.	1:8 patients or fewer [SPSC, 2019 & NEEP, 2020] 1 supernumerary charge nurse at all times

	Burn Unit	Consultant 1:20 patients or fewer Specialist 1:10 patients or fewer Resident 1:5 patients or fewer [MOH, 2018]	1:2 patients or fewer (Ratios can be either 1:2, 1:1 or 2:1 or more if needed) [SPSC 2019 & NEEP,2020] 1 supernumery charge nurse at all times	RTs 1:5 patients or fewer [MOH, 2018]
	Step-Down Unit/High-Dependency Unit/Intermediate Care/Chronic Ventilation Unit or Patient	Consultant: 1:140 patients or fewer Specialist: 1:70 patients or fewer Resident 1:21 patients or fewer [MOH, 2018]	1:3 patients or fewer [NNEP, 2020, MOH 2018] 1 supernumery charge nurse at all times	RTs 1:5 patients or fewer [MOH, 2018]
	Operating Room (moderate and major cases)	1 Primary Surgeon and 1 Assistant (scrub-in):1 case , as per case classification (Expert Opinion, 2021).	3 or more:1 For moderate or major cases. Fewer nurses for minor cases. [NEEP, 2020] 1 supernumery charge nurse at all times	RTs Per hospital inpatient bed coverage.

		<p>1 Anesthesiologist assigned to each operating room/ongoing case. May increase to 2:1 based on case classification. (CBAHI Standards Peri-Op 4th edition, 2021 & Expert Opinion, 2021).</p>		
	Recovery Room	<p>1 Anesthesiologist assigned per Recovery Room. (CBAHI Standards Peri-Op 4th edition, 2021 & Expert Opinion, 2021).</p>	<p>1:2 patients or fewer (Ratios can be either 1:2, 1:1 or 2:1 or more if needed) [SPSC 2019 & NEEP, 2020] 1 supernumery charge nurse at all times</p>	RTs Per hospital inpatient bed coverage.
	Cath Lab	<p>1 Attending Consultant and an additional board- certified physician as needed per case</p>	<p>2 or more:1 patient [NEEP, 2020] & 1 Radiology/Cath Lab Technician.</p>	RTs Per hospital inpatient bed coverage.

		definition (diagnostics vs. interventional (Expert Opinion, 2021).	1 supernumerary charge nurse at all times	
	Endoscopy Unit	1 Attending Consultant and an additional board- certified physician as needed per case definition (diagnostics vs. interventional (Expert Opinion, 2021).	2 or more:1 patient [NEEP, 2020] & 1 Radiology/Endoscopy Technician (as required). 1 supernumerary charge nurse at all times	RTs Per hospital inpatient bed coverage.
	Radiology Department: Diagnostic/Interven- tional	1 Radiologist per hospital or 1:100 beds or fewer (MOH, 2018] and 1 Medical Physicist per hospital	2 or more:1 patient [NEEP, 2020] 1 supernumerary charge nurse at all times	RTs Per hospital inpatient bed coverage.
	Oncology	Consultant: 1:140 patients or fewer Specialist: 1:70 patients or fewer	1:3 patients or fewer [SPSC, 2019 & NEEP, 2020]	RTs Per hospital inpatient bed coverage. Clinical Pharmacist 1:20

		Resident 1:21 patients or fewer	1 supernumerary charge nurse at all times	
Bone Marrow Transplant (Adult and Pediatric)	BMT Consultant 1:20 patients or fewer BMT Specialist 1:10 patients or fewer BMT Resident 1:5 patients or fewer	1:2 patients or fewer [SPSC, 2019 & NEEP, 2020] 1 supernumerary charge nurse at all times	RTs Per hospital inpatient bed coverage. Clinical Pharmacist 1:20	
Hemodialysis Unit	1 Nephrologist per hospital then 1: 200 patients or fewer at any given time (Harley et al, 2013). 1 Consultant Nephrologist:15 or fewer HD stations 1 specialist:10 or fewer HD stations 1 Resident 1:15 or fewer HD stations (MOH, n.d.)	1:3 HD stations or fewer [NEEP, 2020] 1 Dialysis Technicians:3 machines 1 supernumerary charge nurse at all times	RTs Per hospital inpatient bed coverage.	

	Telemetry	Consultant: 1:140 patients or fewer Specialist: 1:70 patients or fewer Resident 1:21 patients or fewer [MOH, 2018]	1:4 patients or fewer [SPSC, 2019 & NEEP, 2020] 1 supernumerary charge nurse at all times	RTs Per hospital inpatient bed coverage.
	Medical Adult	Consultant: 1:140 patients or fewer Specialist: 1:70 patients or fewer Resident 1:21 patients or fewer [MOH, 2018]	1:5 patients or fewer [SPSC 2019 & NNEP,2020] 1 supernumerary charge nurse at all times	RTs 1:15 beds or fewer [MOH, 2018]
	Medical Pediatrics	Consultant: 1:140 patients or fewer Specialist: 1:70 patients or fewer Resident 1:21 patients or fewer [MOH, 2018]	1:4 patients or fewer [SPSC 2019 & NNEP,2020] 1 supernumerary charge nurse at all times	RTs 1:15 beds or fewer [MOH, 2018]

	Surgical Adult	Consultant: 1:140 patients or fewer Specialist: 1:70 patients or fewer Resident 1:21 patients or fewer [MOH, 2018]	1:4 patients or fewer [SPSC 2019 & NNEP,2020] 1 supernumerary charge nurse at all times	RTs 1:15 beds or fewer [MOH, 2018]
	Surgical Pediatrics	Consultant: 1:140 patients or fewer Specialist: 1:70 patients or fewer Resident 1:21 patients or fewer [MOH, 2018]	1:4 patients or fewer [SPSC 2019 & NNEP,2020] 1 supernumerary charge nurse at all times	RTs 1:15 beds or fewer [MOH, 2018]
	Adult Psychiatric	Consultant: 1:140 patients or fewer Specialist: 1:70 patients or fewer Resident 1:21 patients or fewer [MOH, 2018]	1:3 patients or fewer & Suicidal patients 1:1 [NEEP, 2020] 1 supernumerary charge nurse at all times	RTs Per hospital inpatient bed coverage.

	<p>Adolescent Psychiatric</p>	<p>Consultant: 1:140 patients or fewer Specialist: 1:70 patients or fewer Resident 1:21 patients or fewer [MOH, 2018]</p>	<p>1:2 or fewer & Suicidal patients 1:1 [NEEP, 2020] 1 supernumerary charge nurse at all times</p>	<p>RTs Per hospital inpatient bed coverage.</p>
	<p>Pediatrics Psychiatric</p>	<p>Consultant: 1:140 patients or fewer Specialist: 1:70 patients or fewer Resident 1:21 patients or fewer [MOH, 2018]</p>	<p>1:1 patient & Suicidal patients 1:1 [NEEP, 2020] 1 supernumerary charge nurse at all times</p>	<p>RTs Per hospital inpatient bed coverage.</p>
	<p>Rehabilitation</p>	<p>Consultant and Specialist 1:140 patients or fewer Psychiatric Consultant and Specialists: 1:30 patients or fewer Resident 1:50 or fewer [MOH, 2018]</p>	<p>1:7 patients or fewer [MOH,2018; SPSC 2019] 1 supernumerary charge nurse at all times</p>	<p>RTs 1:30 patients or fewer [MOH, 2018]</p>

	Ambulatory Care/Out-Patient Department	1 Board Certified physician per designated clinic. [Expert Opinion, 2021].	<p>A licensed nurse is required only for procedural areas or highly specialized/expert nursing care, as per the scope of nurse practice.</p> <p>Non-nurse licensed ancillary staff to cover activities and assist the physician, as per documented competency (i.e., vital signs, glucose monitoring, etc.).</p> <p>The non-licensed ancillary staff as patient chaperone duties and administrative assistance to the physician. [Expert Opinion, 2021] [NEEP, 2020].</p>	RTs Per hospital inpatient bed coverage.

Pharmacists	<p>1:5 inpatient beds [Schneider et al, 2019].</p> <p>In the outpatient setting 1:80-120 prescribed items per 8-hour shift [Expert Opinion, 2021]</p>
Pharmacy Technicians	<p>1:10 inpatients beds [Schneider et al, 2019]</p> <p>In the outpatient setting 1:80-120 prescribed items per 8-hour shift [Expert Opinion, 2021]</p>
Medical Laboratory Technicians	<p>1:70 beds or fewer [MOH, 2018]</p> <p>Note: 1:50 or fewer for ICU and Chronic Ventilator Beds/patients (MOH, 2018)</p>
Radiology Technicians	<p>1:50 beds or fewer [MOH, 2018]</p> <p>Note: 1:30 or fewer for ICU and Chronic Ventilator Beds/patients [MOH, 2018].</p> <p>Each Radiology Department to have at a minimum 1 technician per shift per department</p>
Physiotherapy	<p>1:50 beds or fewer [MOH, 2018]</p>
Occupational Therapy	<p>1:30 beds or fewer [MOH, 2018]</p>

Social Services	1:70 beds or fewer [MOH, 2018]
Palliative Care	Nurse 1:4 patients or fewer [NNEP, 2020]
Dietary Services	1:25 to 50 beds [MOH, 2018; Cartmill et al, 2013]
Quality & Patient Safety Specialists	1:100 beds [MOH, 2018]
Infection Prevention & Control Specialist	1:50 beds [CBAHI, 3rd version]
CSSD [hospitals with bed capacity 100 beds or less]	<p>1 CSSD worker:20 beds or fewer & 1 additional CSSD worker per 100 surgical procedures done per month but with a minimum of 3 CSSD workers.</p> <p>Note: Facilities without OR and no surgical procedures done on-site a minimum of 3 CSSD workers is required [MOH, 2021]</p>
CSSD [hospitals with bed capacity > 100 beds]	<p>1 CSSD worker:50 beds or fewer & 1 additional CSSD worker per 100 surgical procedures done per month but with a minimum of 5 CSSD workers.</p> <p>Note: Facilities without OR and no surgical procedures done on-site a minimum of 3 CSSD workers is required [MOH, 2021]</p>

Diabetic Education	1:50 beds or fewer (Expert Opinion, 2021)
Environmental Services	1:2 hospital beds [Ministry Of Health and Family Welfare Government of India, 2015]
Unit Clerks /Ward Clerks	<p>1 clerk per inpatient unit 24/7.</p> <p>On nights and weekends, 1 clerk may cover 2 units based on occupancy rates, training/competency, and geographic proximity.</p>
Porters	<p>Enough porters are, available based on occupancy/volume, to ensure nurses do not leave the unit for routine, stable patient transport (i.e., not requiring primary assigned nurse, RT or physician to accompany the patient).</p> <p>ED, ICU and OR require porters designated/assigned to their unit/area.</p> <p>Other units may either have a porter pool/assigned porter to their unit.</p>
Clinical Coders	<p>Inpatients - 1 Clinical Coder:20 episodes' reviews per/day</p> <p>Day Medical and Surgical - 1 Clinical Coder:40 patient files' reviews per/day [Case mix Center of Excellence, Saudi Arabia, 2021; AHIMA, McKenzie K., et al., 2004]</p>

Emergency Medical Services	Three (3) EMS (Paramedic and EMTs) staff per ambulance transport (inclusive that one of the three professionals is performing the driving skills). EMS transport includes 1 paramedic or higher HW. [Expert Opinion, 2021]
Dental Services	1 Dentist:1 patient Licensed dental technician or equivalent required only for procedural areas or highly specialized/expert dental care, as per the scope of practice. Non-technician licensed ancillary staff to cover activities and assist the dentist, as per documented competency. The non-licensed ancillary staff as patient chaperone duties and administrative assistance to the dentist. [Expert Opinion, 2021].

References:

- Aba-Namay, R. (1993). The Recent Constitutional Reforms in Saudi Arabia. The International and Comparative Law Quarterly, 42(2), 295-331. www.jstor.org/stable/761101*
- Aiken, L. H., Clarke, S.P., Sloane, D.M., Sochalski, J., & Silber, J.H. (2002). Hospital nurse staffing and patient mortality, nurse burnout, and job dissatisfaction. JAMA, 288(16), 1987-1993.*
- Aiken, L.H. (2007). U.S. nurse labor market dynamics are key to global nurse sufficiency. Health Services 42(3),1299-1320.*
- Al-Hanawi, M.K., Khan, S.A., & Al-Borie, H.M. (2019). Health care human resource development in Saudi Arabia: Emerging challenges and opportunities – a critical review. Public Health Reviews, 1-6.*
- Augustine, J.J. (2016). Emergency Department Benchmarking Alliance Releases 2014 Data on Staffing, Physician Productivity. American College of Emergency Physicians (ACEP) Now. <https://www.acepnow.com/article/emergency-department-benchmarking-alliance-releases-2014-data-on-staffing-physician-productivity/>*
- ANA's Principles for Nurse Staffing. (2019). American Nurses Association. Silver Springs, MD.*
- Cartmill, L., Coman, T.A., Clark, M.J., Ash, S., & Sheppard, L. (2012). Using staffing ratios for workforce planning: Evidence on nine allied health professions. Human Resources for Health,10(2).*
- Expert Opinion. (2021). Expert Opinion is defined as consensus of three (3) or more health care clinicians or leaders.*
- Goddard, A. F., Hodgson, H., & Newbery, N. (2010). Impact of EWTD on patient: doctor ratios and working practices for junior doctors in England and Wales 2009. Clinical Medicine, 10(4), 330–335. <https://doi.org/10.7861/clinmedicine>.*
- Harley, K.T. & et al. (2013). Nephrologist Caseload and Hemodialysis Patient Survival in an Urban Cohort. Journal of the American Society of Nephrology, 24(10): 1678–1687*
- Institution of Medicine (IOM). (2010). The Future of Nursing. Washington (DC): National Academies Press. U.S. <https://pubmed.ncbi.nlm.nih.gov/24983041/>*
- Institute of Medicine. (2021). Patient Safety Leadership Walk Rounds. <http://www.ihl.org/resources/Pages/Tools/PatientSafetyLeadershipWalkRounds.aspx#:~:text=WalkRounds%E2%84%A2%20are%20conducted%20in,support%20for%20staff%%20errors>.*
- Murray, M., Davies, M., Boushon, B. (2007). Panel size: How many patients can one doctor manage? Family Practice Management, 14(4): 44-51.*

Miller, T., Canfield, C., Buckingham, T., Johnston, G., Hammerman, S., Skinner, G., & Tote, J. (2016). "Long-term acute care: Where does it fit in the health care continuum?" *American Journal of Critical Care*, 25(4), 362-367.

Ministry Of Health and Family Welfare Government of India (2015). *National Guidelines for Clean Hospitals. Hospitals.*
https://main.mohfw.gov.in/sites/default/files/7660257301436254417_0.pdf

Ministry of Health (MOH). (n.d.). *Standards Guideline for Establishing, Equipping and Renal Dialysis Centers.*

Ministry of Health. (2018). *Extended Care Hospitals.* <https://www.moh.gov.sa/en/ministry/vro/private-sector-participation/work-streams/hospitals/Pages/default.aspx>

Ministry of Health. (2020). *Guidelines for Central Sterile Service Department Version 1.*

National Nurse Expert Panel (NNEP). 2020. *The Kingdom of Saudi Arabia Mandated Safe Staffing/Midwife-to-Patient Ratios.* Copyrights by Saudi Patient Safety Center.

National Institute for Health & Care Excellence (NICE). (2017). *Multi-disciplinary team meetings. Chapter 29.*
<https://www.nice.org.uk/guidance/ng94/documents/draft-guideline-29>

Saudi Patient Safety Center. (2019). *White paper on nurse staffing levels for patient safety and workforce safety.*

Saudi Patient Safety Center. (2020). *Healthcare Business Continuity Planning Guide.*

<https://spsc.gov.sa/English/PublishingImages/Pages/BCP/Healthcare%20Business%20Continuity%20Planning%20Guide%20Updated%2012-4-2020.pdf>

Schneider, P.J., Pedersen, C.A., Gonio, M.C., & Scheckelhoff, D.J. (2019). *ASHP national survey of pharmacy practice in hospital settings: Workforce-2018.* *American Journal of Health-System Pharmacy*, 76(15):1127-1141.

Stones, W., Visser, G.H.A., & Theron, G. (2019). *FIGO Statement: Staffing requirements for delivery care, with special reference to low- and middle-income countries.* *International Journal of Gynecology & Obstetrics.*
<https://obgyn.onlinelibrary.wiley.com/doi/full/10.1002/ijgo.12815>

World Health Organization (WHO). (2020). *Keep health workers safe to keep patients safe.*

<https://www.who.int/news/item/17-09-2020-keep-health-workers-safe-to-keep-patients-safe-who>

Emergency Department (ED)

Emergency departments (EDs) are considered the hub for patient entry. Patients with varying injuries and illnesses go to the EDs expecting the best care in the fastest time. With limited emergency resources (mainly manpower), EDs are responsible to direct the right attention to the right patients at the right time. But with the significant increase of patients visiting EDs yearly, serving everyone promptly becomes a challenging mission. Patients present to EDs without prior appointment, either on their own or by an ambulance. Due to the unplanned nature of patients visits, the ED provides initial treatment for a broad spectrum of illnesses and injuries, some of which may be life-threatening and require immediate intervention. EDs often become important entry points for those without other means of access to medical care (Safety Net).

EDs offer access 24 hours a day, 365 days a year. ED staff include paramedics, nurses, technicians, reception and administrative staff, porters, security guards, and emergency medicine physicians. The medical staff are highly trained in all aspects of emergency medicine.

Objectives:

Every patient visiting the ED is entitled to:

- Access to emergency care
- Quality emergency services
- Safety

Topics:

- Clinical (patient care pathway)
- Administration (management)
- Professional
- Education and Training

ED.1. The hospital ensures the physical space supports the access to emergency care.

ED.1.1. The decontamination space in the ED is accessed from outside the hospital directly and is located reasonably close to the walk-in entrance of the emergency department.

ED.1.2. The EDs decontamination space has appropriate disposal of runoff water.

ED.1.3. The emergency department has a minimum of one airborne/negative isolation room with an anteroom and a restroom

ED.1.4. All areas of the emergency department are accessible by wheelchair.

ED.1.5. The ED has a waiting room with sufficient bathrooms for patients and families.

ED.1.6. Access to the ED is controlled using physical barriers such as access controlled doors.

ED.1.7. The ED has a staff lounge with appropriate amenities and a rest room for staff.

ED.1.8. Patient care areas have sufficient toilet rooms with sinks for patients and families.

Explanations:

To ensure the safety of hospital staff and patients and prevent exposure to radiation, a decontamination space is accessible from outside the hospital and reasonably close to the walk-in entrance.

It is important to have a defined procedure to safely dispose of runoff water from decontamination areas.

This procedure is stated in a policy, a contract or a set of agreed upon and published procedures.

Due to the possibility of receiving a patient with a communicable disease in the ED, it is important that the ED has a pathway to safely manage and isolate such patients.

The ED cater to special needs people by providing safe and easy access to receive care.

The ED has sufficient amenities needed for staff as well as patients. A good rule is to have one bathroom for every 6 patient beds and one bathroom for every 10 staff members.

The ED is a safe environment for delivering patient care. One important element of safe care is to control access to the area through automatic closing doors.

The ED provides a private space for staff to rest, socialize and eat. The lounge is close to the ED facilitating the ability to quickly mobilize staff in case of an emergency.

The ED has the amenities needed for staff as well as patients in appropriate numbers. A good rule is to have one bathroom for every 6 patient beds and one bathroom for every 10 staff members. Male and female bathrooms are properly identified.

ED.2. The design of the emergency department is aligned with the patient journey.

ED.2.1. The entrance of the emergency department has a nursing station for visual triage.

ED.2.2. The main triage area is designed in a way that allows healthcare providers to see, with or without camera use, outside of the department as well as the waiting room.

ED.2.3. The emergency department has a separate entrance for EMS patients.

ED.2.4. The hospital has a policy and processes for immediate access to the Operating Room, catheterization lab and radiology department.

Explanations:

Patients who are entering the emergency department are seen by a qualified healthcare provider who can triage them to determine the urgency of service they need.

Patients in the waiting room need to be viewed by a healthcare provider to identify any serious physical or psychological patient deterioration. A camera that looks directly at the waiting room can be used to see outside the department.

EMS patients need to have a separate point of entry from the regular ED entrance to ensure safe and quick unloading of patients who have received initial medical care.

Moving critically sick patients out of the emergency department is easy and effective to ensure quick service provision of needed services.

ED.3 The hospital ensures the required resources are available for accessible emergency care.

ED.3.1. Approved and required equipment is available at all times in the ED area and for the patient population.

ED.3.2. The hospital maintains an identified list of equipment and supplies, for all relevant areas, available at all times and in sufficient quantities required for trauma care.

ED.3.3. All identified and listed emergency medications required for crash carts, resuscitation, and time-sensitive medications are immediately available and located within the ED.

ED.3.4. All identified and listed essential ED consumables are located within the ED or immediately available to the ED.

Explanations:

The unique operation and flow of emergency departments require the listed equipment to be available within the ED or immediately available.

The ED has equipment lists for the following:

- General Emergency Department
- Resuscitation areas
- Ortho/Cast
- Minor procedures
- Ambulance
- Patient transfer bag
- Treatment rooms
- Pediatric (appropriate size even in non-pediatric EDs)
- Delivery and Neonatal, including incubator (even non-maternal EDs)

The unique operation and flow of emergency departments require the listed medications to be properly stored and available within the ED or immediately available.

Time sensitive – anti SZ, and antibiotics

The ED has consumable lists for the following:

- General Emergency Department
- Resuscitation areas
- Ambulance
- Patient transfer bag
- Treatment rooms
- Pediatric appropriate size (even in non-pediatric EDs)
- Delivery and Neonatal, including incubator (even non-maternal EDs)

ED.4. The emergency department applies the concept of the universal bed in all its clinical care areas.

ED.4.1. The ED has all its designated treatment areas ready to deliver emergency care for all patients.

ED.4.2. The ED has the capability to immediately move critical care equipment to all the beds in the emergency department.

ED.4.3. The ED can immediately move specialized equipment to any bed in any area of the emergency department.

Explanations:

The ED does not assign specific areas for specialized care based on physicians' specialties such as medicine, surgery, trauma, ophthalmology, Ear, Nose and Throat, orthopedics, or wound care. Rather the ED has mobile carts with specialized equipment that will facilitate the fulfilment of this substandard.

The ED can handle any type of emergency at any ED bed and resuscitation equipment is easily portable to all beds in the ED. The ED has mobile carts with specialized equipment that will facilitate the fulfilment of this substandard.

The ED is required to handle special situations cases at any ED bed.

Specialized care equipment such as orthopedic, dental, wound, procedures, ear, nose and throat cases or ophthalmology can be mobilized to all beds in the emergency department. Having mobile carts with specialized equipment will facilitate the fulfilment of this substandard.

ED.5. The hospital has qualified emergency department physician leadership and medical staff.

ED.5.1. The ED Head of Department is an Emergency Medicine Board Certified consultant physician.

ED.5.2. A minimum of one Emergency Medicine Board Certified (EMBC)/Pediatric Emergency Medicine Fellowship Certified physician is available at all time.

ED.5.3. All non-EMBC physicians working in the ED have advanced life support (per the ages served and scope of service) and additional emergency and trauma training and certification.

ED.5.4. A daily accurate, updated list of on-call specialties for emergency care is accessible at all times for all ED clinicians.

Explanations:

The unique operation and flow of emergency departments require specialized skills that are acquired during EM training to provide safe and effective leadership management.

Emergency departments are staffed 24/7 by at least one (1) qualified Emergency Medicine Board Certified (EMBC)/Pediatric Emergency Medicine Fellowship Certified physician with valid SCFHS licensing to provide safe appropriate emergency care. Note that specialized hospitals such as ophthalmology, mental health, obstetrics, or other specialized hospitals are exempted from having EMBC physicians.

Physicians working in the ED that are not EMBC (except learners) have specific and appropriate resuscitation training based on the scope of service they provide. This training includes Advanced Cardiovascular Life Support (ACLS) certification, Pediatric Advanced Life Support (PALS) certification, Neonatal Resuscitation Program (NRP) certification, Advanced Trauma Life Support, and/or procedural sedation, etc. (as appropriate).

To ensure safe transition of care; an updated list of available on-call specialties with contact information is always available.

ED.6. The hospital has ED qualified nurses, allied health and non-clinical staff.

ED.6.1. The nurse manager/head nurse of the ED holds a baccalaureate degree in nursing and SCFHS as a specialist or higher.

ED.6.2. A minimum of one nurse specialist is available at all time in ED.

ED.6.3. All nurses working in the ED have advanced life support (per the ages served and scope of service) and additional emergency and trauma training and, as applicable, certification.

ED.6.4. Emergency medical service (EMS) providers are qualified according to their assigned roles, and have advanced life support (per the ages served and scope of service).

ED.6.5. The ED has an administrative coordinator and sufficient security guards are available at all time a week in ED.

Explanations:

Emergency departments are staffed by at least one (1) Nurse Specialist with valid SCFHS licensing to provide safe appropriate emergency nursing care.

All ED nurses working in the ED (except learners hold a valid SCFHS license. Additionally, nurses have specific and appropriate resuscitation training based on the scope of service they provide. These trainings include: ACLS, PALS, NRP, ATCN, Triage Course and/or procedural sedation, etc. (as appropriate).

All EMS providers (Specialist/Technicians) working in the ED (except learners) hold a valid SCFHS .

Additionally, EMS providers have specific and appropriate training on the safe operation of an emergency vehicle, such as the Emergency Vehicle Operators Course (EVOC)

The unique operation and flow of emergency departments require a dedicated administrative coordinator and sufficient security guards to ensure effective delivery of care.

ED.7. The hospital ensures ED patient care meets national and cited international standards of care.

ED.7.1. The hospital a policy and processes specific to the ED/emergency care patient for handover, change of shift, transition of care and endorsement of patients.

ED.7.2. The hospital has a policy and processes specific to vulnerable/high risk cases in the ED, inclusive of dependent abuse and neglect, psychiatric conditions, drug abuse, domestic violence, medical, legal and ethical situations).

Explanations:

The unique operation and flow of emergency departments require a handoff/over policy to ensure safe, continuity of care. Handoff/handover is performed between the most responsible physicians/nurses.

The unique operation and flow of emergency departments require a variety of policies and procedures to be available to staff.

ED.8. The hospital has effective and efficient resources management processes.

ED.8.1. The hospital has a policy and processes for triaging the emergency patient using a validated triage system.

ED.8.2. The hospital has a policy and processes for consultations inclusive of service and MRP acceptance, transition of care, consultation and ED disposition time frames, escalation process and conflict resolution.

ED.8.3. The hospital a policy and processes specific to the ED/emergency care patient for the transfer of patients within the hospital or outside the hospital.

ED.8.4. The hospital has a policy and processes for emergency care admission, transfer, discharge, inclusive of both “left without being seen”, AMA and absconded cases.

ED.8.5. The hospital has a policy and processes for ED overcrowding and bypass mechanisms.

Explanations:

The unique operation and flow of emergency departments require an effective triaging system. Every patient, regardless of their eligibility has documented and retrievable clinical triage notes (different than visual triage). The triage is performed by a privileged and trained healthcare provider.

The unique operation and flow of emergency departments require a consultation policy to ensure safe transition of care of the patient.

Consultation is documented and retrievable and the escalation process yields conflict resolution within the established time frame. The chain of escalation includes the hospital administration.

BEST PRACTICE 4 hours

The emergency departments require a patient transfer policy to ensure safe patient transfer either within the hospital or transfer to another facility outside the hospital.

The hospital has a document plan that involves hospital administration and different layers of activation.

ED overcrowding is an expected incidence; therefore, the hospital has a policy that involves hospital administration and different layers of activation.

ED.9. The hospital leadership establishes an effective clinical governance framework.

ED.9.1. The hospital I maintains a list of crash carts and their required locations, by scope of service.

ED.9.2. Crash carts are standardized and equipped with age specific initial advance life support interventions, per scope of service.

ED.9.3. Crash carts are readily available for use in the clinical areas.

ED.9.4. Crash carts are checked by designated staff at the beginning of each shift, after each use and replenished as indicated.

ED.9.5. The Pharmacy department determines the emergency drugs for the crash carts and emergency medical bags in compliance with the current Saudi Heart Association recommendations.

ED.9.6. Crash carts have breakaway locks.

Explanations:

XXX

ED.10. The hospital has sufficient ambulance service at all times in accordance with national rules and regulations.

ED.10.1. The hospital ensures sufficient ambulance services either through hospital-owned ambulances or outsourced services.

ED.10.2. The ambulance driver holds a valid driver's license appropriate to the type of vehicle being operated and conducts daily functional vehicle checks.

ED.10.3. Ambulances are maintained in state of readiness with required equipment, medication, supplies and personal protective equipment to meet the specific individualized needs of patients of all age groups and scope of service.

ED.10.4. The hospital has two-way communication with ambulances at all times.

ED.10.5. The patient's clinical condition determines the number and qualifications of EMS/EMT staff assigned for the to the patient transfer.

ED.10.6. A standardized EMS/EMT patient care record is completed for each patient. The emergency medical services handover report, includes (MIST): Mechanism of injury, Injury pattern (injury suspected), Sign (Vitals) and symptom and Treatment.

ED.10.7. The ambulances are cleaned and sanitized in accordance to established infection prevention and control practices.

Explanations:

XXX

DRAFT

STROKE READINESS (SR)

Stroke is the 2nd leading cause of death and a leading cause of disability in Saudi Arabia. Its clinical, economic and emotional impacts are enormous. The one-year mortality of stroke in Saudi Arabia is between 14-27%. Stroke is the 2nd leading cause of dementia. The incidence of stroke is expected to increase by 60% over the next 10 years. Saudi Arabia could save 2.8 billion Saudi Riyals if stroke services were optimized.

Due to fragmented care, stroke patients in Saudi Arabia do not adequately utilize clinical services that are proven to reduce morbidity and mortality, like admission to stroke units, emergency thrombolysis (IV TPA and endovascular thrombolysis) and rehabilitation. A significant gap is present between hospitals with excellent stroke care and those with sub-optimal care, due to deficiencies in staffing, infrastructure and lack of immediate predefined transfer protocols. This leads to lower utilization of intravenous and endovascular thrombolytic use, lower rates of admissions to stroke units, which have been proven to lower morbidity, mortality and the need for transfer to long term care. Many first and recurrent strokes are preventable by treating known vascular risk factors, such as hypertension, smoking, hypercholesterolemia, diabetes mellitus, obesity, inactivity and an unhealthy diet. There is a significant disparity between current stroke prevention services and optimal care. Urgent TIA (transient ischemic attack) clinics have been shown to reduce the risk of subsequent strokes by 80%.

Education of the community, the patient and healthcare workers about stroke symptoms and management have also been associated with higher use of thrombolytics, and better compliance to stroke prevention interventions.

The objectives of the development of national stroke readiness standards are to increase the use of preventative and acute management protocols and systems to prevent and treat strokes.

We aim to reduce the burden of stroke & TIA on the Kingdom of Saudi Arabia by reducing mortality and morbidity, improving the patient experience and controlling the cost of stroke care.

National stroke standards will achieve Vision 2030s triple aim of improving population health, experience of care and lower per capita health costs.

The national stroke standards will increase the utilization of proven stroke therapies and streamline the stroke patients journey from detection of symptoms to reintegration back to society.

DRAFT

SR.1. The hospital has a stroke program.

SR.1.1. The stroke program has policies, processes, and the required infrastructure and resources.

SR.1.2. The stroke program has and qualified, accountable program director with a scope of service which covers all patients and visitors in all locations (ED, ambulatory care and inpatient areas) at all times.

SR.1.3. The stroke program is operated by qualified, competent stroke-trained staff/team.

Explanations:

Stroke is a medical emergency, and definitive stroke care is not readily available in all hospitals or regions. All hospitals should be able to provide essential life stabilizing measures and transfer eligible patients to receive definitive care in higher level hospitals, immediately. All hospitals should be classified as either Acute Stroke Ready Hospitals, Primary Stroke Hospitals or Comprehensive Stroke Hospitals and connected to each other to form a regional stroke network that ensure rapid access to life and limb (brain) saving procedures. Stroke directors in each hospital must ensure consistent provision of rapid, safe, streamlined stroke care for all suspected and confirmed stroke patients.

Acute Stroke Ready Hospitals (ASRH) that are far from Primary Stroke Hospitals (PSH) and Comprehensive Stroke Hospitals (CSH) can have capabilities to identify acute ischemic stroke by CAT scan and give thrombolytics, by tele-stroke prior to transferring a patient to a PSH or CSH. ASRHs that are close (less than 60 km or 45 minutes) will quickly identify possible strokes and rapidly ship patients to PSHs or CSHs.

Reliable management to support the stroke patient through his/her stroke journey throughout a stroke network.

SR.2. The hospital has primary and secondary stroke prevention programs.

SR.2.1. The hospital's ambulatory care has evidence-based person-centered stroke prevention care.

SR.2.2. The stroke program has primary and secondary prevention screening and clinical pathways which identify patients who have stroke risk factors.

SR.2.3. All identified at-risk stroke patients have a documented stroke prevention plan based on their specific risk factors.

SR.2.4. All stroke patients and families are educated regarding activities, medications, stroke risks and risk factor modifications and have follow-up for lifestyle modifications.

Explanations:

To ensure that all stroke prevention measures are available at all levels.

To prevent recurrent stroke and supports patients to pursue an independent healthy lifestyle.

To prevent stroke or recurrent stroke by managing risk factors e.g.: hypertension, dyslipidemia, diabetes management, weight loss, etc.

To refer patients to a smoking cessation program

SR.3. The hospital has stroke awareness and education for patients, families, the community and staff.

SR.3.1. The stroke program participates in community education regarding stroke awareness, recognition and prevention including EMS activation, risk factors, and lifestyle modifications.

SR.3.2. The stroke program provides patients and families user-friendly access to information about health and healthcare services related to stroke.

SR.3.3. Multidisciplinary stroke education is based on needs assessment to all healthcare providers and staff.

Explanations:

Stroke is preventable and the best defense against stroke is to increase awareness about stroke prevention and how its treated.

Community stroke education includes recognition of stroke symptoms, activation of Emergency Medical Services (EMS), management of stroke symptoms, reduction in risk factors and promoting healthy lifestyle changes to prevent stroke. The objectives of stroke education are:

- To provide the community with accurate information on stroke recognition and access to stroke program services.
- To ensure community education resources are available and accessible, and education is ongoing through various channels utilizing providing easy to understand information on how to access stroke care.
- To ensure community perspectives are considered as a partner in healthcare decision-making processes, respecting expectations.
- To provide patient education in an easily understandable language.
- To ensure patients educational needs are assessed and documented, considering patients' willingness for learning. Barriers to learning are identified and these findings are utilized to plan stroke education.
- Continuous staff education is provided to maintain up-to-date staff stroke competencies, establish professional conduct of all staff, and ensure the quality of service provided by stroke staff is in line with their job descriptions and privileges.
- To verify that stroke unit mandatory competencies are identified by the hospital policy and include safe administration and management of thrombolytic therapy, training on preparing and administering thrombolytics, and monitoring for complications post thrombolytic therapy as well as other stroke competencies such as cardiac monitoring.
- To ensure that general practitioners and community healthcare providers receive education on how to refer patients to stroke and TIA services, and the types of patient conditions that can appropriately treated.
- To improve public awareness of stroke risk factors and early symptoms of stroke.
- To improve competency of all the hospitals in the stroke network.

SR.4. All patients with suspected or confirmed Transient Ischemic Attack (TIA) or acute stroke have rapid recognition, assessment, management and, if required, transfer.

SR.4.1. All patients with suspected TIA or stroke have a rapid initial evaluation by all clinicians for airway, breathing, circulation and basic neurological assessment utilizing the standardized tool FAST and, when applicable, NIHSS by trained health care providers.

SR.4.2. The hospital has a standardized TIA and acute stroke management protocol in the emergency department and all clinical units/areas.

SR.4.3. A designated stroke team assesses and manages all TIA and acute stroke patients and is available at all times.

SR.4.4. Tele-stroke is used for hospitals with limited in-house stroke expertise for diagnosis, treatment, stabilization and transfer of stroke patients, if hospital is more than 45 minutes or 60 km away from nearest higher stroke care hospital.

SR.4.5. The hospital has a protocol to transfer suspected or confirmed TIA and stroke patients to a higher level of care.

SR.4.6. Patients presenting within 24 hours of suspected ischemic stroke are immediately assessed and investigations are conducted to establish a diagnosis, rule out stroke mimics, and determine eligibility for reperfusion therapy.

SR.4.7. Suspected or confirmed TIA or acute stroke patients have blood glucose, complete blood count, chemistry studies, coagulation profile, pregnancy testing, and ECG on an immediate basis and reported within 45 minutes from the recognition presentation of stroke symptoms.

SR.4.8. Patients with suspected acute stroke undergo door or recognition-to-image time in less than 25 minutes, with non-contrast CT or MRI brain imaging.

SR.4.9. All hospitals capable of administering thrombolytic treatment thrombolysis medications have an evidence-based protocol with indications, contraindications, post thrombolysis care and complication management.

SR.4.10. In hospitals with capacity to perform thrombolysis, all eligible patients with disabling ischemic stroke, who are within 4.5 hours from the onset of stroke symptoms, under door-to-needle intravenous thrombolysis within 60 minutes.

SR.4.11. Patients eligible for endovascular thrombectomy undergo immediate noninvasive vascular imaging with CT angiography or MR angiography.

SR.4.12. In hospitals with capacity to perform thrombolysis, all eligible patients with disabling ischemic stroke, who are within 4.5 hours from the onset of stroke symptoms, under door-to-needle intravenous thrombolysis within 60 minutes.

Explanations:

In the last two decades acute stroke care has been transformed due to results from multiple trials that demonstrated that ischemic stroke can be effectively treated with reperfusion therapy (intravenous and intra-arterial). The phrase "Time is brain", indicates the earlier the treatment is started the better. The window for intervention is very short, thus it is essential to have a pre-defined pathway and protocol to facilitate prompt recognition of stroke and expedite management or transfer.

Stroke is a medical emergency requiring rapid recognition and management. Many strokes will lead to death or disability if not treated promptly. Standardized medical care results in better outcomes and less variability in healthcare provision. Each patient with acute stroke should be viewed as a medical emergency and a potential candidate for reperfusion therapy, and should have rapid assessment to determine eligibility. Tele-stroke services can be utilized to increase access to acute stroke care for hospitals with limited in-house expertise or prolonged transfer time.

** The FAST score is a rapid screening test used for acute stroke, and stands for Face, Arm, Speech and Time (the Arabic version عاجل is occasionally used for stroke education). (في انحراف ا, التخاطب او الفهم في عسر ع). ((تتاخر لال, الجسم من ضعيفة جهة ج, الفم زاوية)). FAST can be used by the public, community first responders or hospital triage areas, and it is highly effective for diagnosing strokes. The National Institutes of Health Stroke Score (NIHSS) is a commonly used scoring system to classify stroke severity. It is the most commonly used scoring system to make diagnostic decisions as well as prognosticating recovery.

*** Acute Stroke Ready Hospitals (ASRH) that are far from Primary Stroke Hospitals (PSH) and Comprehensive Stroke Hospitals (CSH) may have capabilities to identify acute ischemic stroke by CAT scan and give thrombolytics through tele-stroke, prior to transferring a patient to a PSH or CSH. ASRHs that are close to a PSH or CHS (less than 60 km or 45 minutes) can quickly identify possible strokes and rapidly transfer the patients.

SR.5. All patients suspected of acute ischemic stroke are rapidly assessed to determine eligibility for thrombolysis.

SR.5.1. Adult patients presenting within 24 hours of suspected ischemic stroke are immediately assessed and investigations are conducted to establish a diagnosis, rule out stroke mimics, and determine eligibility for reperfusion therapy.

SR.5.2. All hospitals capable of administering thrombolysis have an evidence-based protocol outlining indications, contraindications, post thrombolysis care and complication management.

Explanations:

Intravenous thrombolytic therapy is the primary pharmacological therapy for acute ischemic stroke and is proven to significantly improve functional outcome. Intravenous thrombolytic therapy increases patient survival rates up to fifty percent. However, there is also a 3-6% increased risk of intracerebral hemorrhage with intravenous thrombolytic therapy. The benefit and risk percentage are dependent upon the time that has elapsed from stroke onset to treatment and the earlier treatment is started the better the outcomes. Currently, IV thrombolysis is approved for all eligible ischemic stroke patients if initiated within 4.5 hours from the last time the patient was known to be well; or in selected patients using advanced imaging after 4.5 hours.

Intent:

- To ensure that timely intravenous thrombolytic therapy is delivered to stroke patients who can benefit from it.
- To ensure that intravenous thrombolytic therapy is delivered safely in an evidence-based manner by qualified staff in appropriately equipped facilities.

Explanation for substandard point 3 (labs) * (which includes: random glucose, coagulation status (INR, aPTT), complete blood count (CBC), electrolyte and creatinine. IV r-tPA should not be delayed due to pending lab results unless there is a clinical suspicion of a contraindication. Point of care testing is recommended for glucose, Direct Oral Anti-Coagulants (DOACs) and INR)

SR.6. The hospital has a policy for the management of subarachnoid hemorrhages (SAH) and intracerebral hemorrhages (ICH).

SR.6.1. The hospital has a protocol for the prompt identification, assessment and investigation of SAH and ICH, inclusive of blood pressure control and reversal of coagulates.

SR.6.2. The hospital ensures immediate access to neurosurgical expertise.

SR.6.3. The patient is admitted to a hyperacute stroke unit or an intensive care unit with neurocritical care expertise.

SR.6.4. If required, the patient undergoes immediate access to surgical intervention (i.e., ventricular drain and hemicraniectomy).

SR.6.5. In hospital's without neurosurgical expertise and SAH or ICH surgical intervention capabilities, there is immediate transfer of SAH or ICH cases to a primary or comprehensive stroke hospital for definitive care.

SR.6.6. For hemorrhages suspected to be secondary to cerebral aneurysms and arteriovenous malformations, the patient is immediate transfer to a comprehensive stroke hospital for definitive care.

Explanations:

Intracerebral and subarachnoid hemorrhages are some of the most devastating forms of stroke, however management in a timely and proper manner saves lives and reduces morbidity. Intracerebral hemorrhages must be managed immediately in a well-equipped specialized center. Their treatment requires a highly trained team of healthcare practitioners, and specialized equipment following standardized patient-centered protocols, that can be mobilized immediately 24 hours a day.

All hospitals within a region must develop immediate triage and transfer systems based upon pre-arranged contracts with primary and comprehensive stroke hospitals for further treatment.

Primary and comprehensive stroke hospitals will provide immediate access to care for these patients.

Hemorrhages suspected to be secondary to cerebral aneurysms and arteriovenous malformations can only be managed in comprehensive stroke hospitals.

Epidural and subdural hemorrhages are not included in this standard.

SR.7. The Stroke Program Director monitors the program clinicians' performance through KPIs.

SR.7.1. The program directors identify and monitors key performance indicators (KPIs).

SR.7.2. The head of the department maintains a list the conditions considered as TIA/Stroke morbidity and mortality.

SR.7.3. KPIs and morbidity and mortality data are discussed in monthly departmental meetings to aid in staff awareness with continuous performance improvement and action plans.

Explanations:

Continuous Quality improvement is an essential component of providing high-quality patient-centered stroke care. Each step of the stroke pathway should be considered for quality improvement measures.

DRAFT

References:

Saudi Stroke Pathway Standards, version 1.9 (2019). Stroke Clinical Advisory Group. Vision Realization Office

Adeoye, O, etal. Recommendations for the Establishment of Stroke Systems of Care: A 2019 Update. A policy statement from the American Stroke Association. Stroke 2019;50:e187-e210

National Standards for Stroke Program Certification, Draft1. Saudi Central Board for Accreditation of Healthcare Institutions

Powers, W. J., Rabinstein, A. A., Ackerson, T., Adeoye, O. M., Bambakidis, N. C., Becker, K., ... & American Heart Association Stroke Council. (2019). Guidelines for the early management of patients with acute ischemic stroke: 2019 update to the 2018 guidelines for the early management of acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke, 50(12), e344-e418.

Coutts, S. B. (2017). Diagnosis and management of transient ischemic attack. CONTINUUM: Lifelong Learning in Neurology, 23(1), 82.

Gomez, C. R., Schneck, M. J., & Biller, J. (2017). Recent advances in the management of transient ischemic attacks. F1000Research, 6.

Johnston, S. C. (2002). Transient ischemic attack. New England Journal of Medicine, 347(21), 1687-1692.

Tamm, A., Siddiqui, M., Shuaib, A., Butcher, K., Jassal, R., Muratoglu, M., & Buck, B. H. (2014). Impact of stroke care unit on patient outcomes in a community hospital. Stroke, 45(1), 211-216.

Jones, S. P., Miller, C., Gibson, J. M., Cook, J., Price, C., & Watkins, C. L. (2018). The impact of education and training interventions for nurses and other health care staff involved in the delivery of stroke care: An integrative review. Nurse education today, 61, 249-257.

Guidelines for the Management of Aneurysmal Subarachnoid Hemorrhage. A Guideline for Healthcare Professionals from the American Heart Association/American Stroke Association. Stroke. 2012;43:1711-1737

Guidelines for the Management of Spontaneous Intracerebral Hemorrhage. A Guideline for Healthcare Professionals from the American Heart Association/American Stroke Association. Stroke. 2015;46:2032-2060

Samuels, O., Webb, A., Culler, S., Martin, K., & Barrow, D. (2011). Impact of a dedicated neurocritical care team in treating patients with aneurysmal subarachnoid hemorrhage. Neurocritical Care, 14(3), 334-340.

Kurtz, P., Fitts, V., Sumer, Z., Jalon, H., Cooke, J., Kvetan, V., & Mayer, S. A. (2011). How does care differ for neurological patients admitted to a neurocritical care unit versus a general ICU?. Neurocritical care, 15(3), 477-480

Harrison, D. A., Prabhu, G., Grieve, R., Harvey, S. E., Sadique, M. Z., Gomes, M., ... & Rowan, K. M. (2013). Risk Adjustment In Neurocritical care (RAIN)--prospective validation of risk prediction models for adult patients with acute traumatic brain injury to use to evaluate the optimum location and comparative costs of neurocritical care: a cohort study. *Health technology assessment (Winchester, England)*, 17(23), vii-350.

Kramer, A. H., & Zygun, D. A. (2014). Neurocritical care: why does it make a difference?. *Current opinion in critical care*, 20(2), 17

Raj, R., Bendel, S., Reinikainen, M., Hoppu, S., Laitio, R., Ala-Kokko, T., ... & Skrifvars, M. B. (2018). Costs, outcome and cost-effectiveness of neurocritical care: a multi-center observational study. *Critical Care*, 22(1), 1-10.

Moheet, A. M., Livesay, S. L., Abdelhak, T., Bleck, T. P., Human, T., Karanjia, N., ... & Chang, C. W. (2018). Standards for neurologic critical care units: a statement for healthcare professionals from the neurocritical care society. *Neurocritical care*, 29(2), 145-160.4-181.

Carolee J. Winstein, et al., (2016). *Guidelines for Adult Stroke Rehabilitation and Recovery. A Guideline for Healthcare Professionals from the American Heart Association/American Stroke Association. Volume 47, Issue 6, June 2016, Pages e98-e169.*

Tong, Y., Cheng, Z., Rajah, G. B., Duan, H., Cai, L., Zhang, N., Du, H., Geng, X., & Ding, Y. (2019). High Intensity Physical Rehabilitation Later Than 24 h Post Stroke Is Beneficial in Patients: A Pilot Randomized Controlled Trial (RCT) Study in Mild to Moderate Ischemic Stroke. *Frontiers in neurology*, 10, 113. <https://doi.org/10.3389/fneur.2019.00113>.

<https://www.jointcommission.org/-/media/tjc/documents/accred-and-cert/certification/certification-by-setting/disease-specific-care-certification/03---dsc-quick-guide---asrh-4-9-digital.pdf>

TRAUMA READINESS (TR)

In the Kingdom, road traffic accidents (RTAs) are the second highest cause of mortality for men³ and children, with incidence rising 8.5% in the period from 2005 to 2016⁴. Between 2001 and 2010 the most frequent type of injury was due to RTAs (52.0%), followed by falls (23.4%)⁵, with RTAs resulting in 7,661 fatalities in 2013 (88% M, 12% F)⁶. In Riyadh region in 2017, there were over 27,000 RTA related emergency admissions, and over 120,000 non-RTA related trauma admissions, emphasizing the scale of the problem.

The standards contained within this document are geared towards ensuring the provision of optimal care to injured patients within acute care facilities specializing in trauma care. Most acute care facilities within a region regularly provide care to patients with minor injuries but have no trauma care preparation or interaction with specialized trauma centers. However, these non-trauma center facilities receive more severely injured patients on occasion, especially if the transport time to a specialized trauma center is significant. A uniform approach by all acute care facilities to provide consistent, high-quality care to the injured is essential, whilst a dedicated network-based trauma system, allows for the most seriously injured patients to be diverted to specialized trauma centers. That is the purpose of this document.

Objectives:

- 1- Prehospital care of injured patient.
- 2- Provision of safe timely hospital care of injured patient.
- 3- Provision of needed support services or multidisciplinary team.
- 4- Preventing of unnecessary death and disability.
- 5- Post hospital care.
- 6- Transfer trauma patient.
- 7- Involvement in regional and clusters system.
- 8- Quality improvement program.
- 9- Effective leadership on trauma services.

TR.1. The hospital has a trauma readiness program.

TR.1.1. The hospital's trauma readiness program has an identified, qualified, accountable trauma readiness program director and a defined scope of service.

TR.1.2. The hospital has policies and processes for the maintenance of services essential to trauma coverage in the hospital at all times.

TR.1.3. The hospital has trauma code activation criteria.

TR.1.4. The hospital's trauma readiness program includes a hospital-level disaster plan.

TR.1.5. The hospital has an identified catchment area to be served in collaboration with the Emergency Medical Service Provider.

TR.1.6. The hospital has ongoing communication with the Emergency Medical Service Provider.

TR.1.7. The hospital has agreements and ongoing communication with the regional control center for acceptance and diversion of trauma victims, inclusive of a regional disaster plan.

TR.1.8. The hospital has agreements and protocols for the rapid transfer of trauma patients to a higher or lower level of care, including intermediate care in the closest hospital for urgent treatment.

Explanations:

XXXXX (incomplete)

The trauma director is a general surgeon who is administratively responsible for all issues related to trauma care. The trauma director needs to be empowered by the hospital to develop and enhance trauma care in the hospital.

This standard ensures optimum care for trauma patient by ensuring availability of dedicated surgeon with trauma qualification as his specialty. It ensures coverage is maintained 24/7. It ensures optimum coverage even in case of multiple casualties.

TR.2. The hospital has qualified on-duty and on-call staff for nursing, surgical and non- surgical services to provide trauma care at all times.

TR.2.1. The hospital has the required physicians, nurses, and allied health staff, qualified by education, training, experience, and certification in ATLS, ATCN, or equivalent on the roster, on-duty and on-call to provide trauma care at all times.

TR.2.2. The hospital ensures qualified primary and back- up trauma and/or general surgery consultant surgeon is on-call at all times to manage all trauma code patients in the trauma resuscitation area within 30 minutes of the patient's arrival.

TR.2.3. A qualified anesthesia consultant is on-call or in house at all times to respond to all trauma patients within 30 minutes of the call with qualified anesthesia physician staff in-house at all times for immediate, primary trauma coverage.

TR.2.4. The hospital has qualified specialty consultant surgeons on-call at all times, for neurosurgery/spine, orthopedics, vascular, plastic/hand surgery, urologic, thoracic, cardiac, obstetric/gynecologic, oral/maxillofacial, and otorhinolaryngology to manage all trauma code patients in the trauma resuscitation area within 30 minutes of call.

TR.2.5. The hospital has qualified cardiology, infectious disease, internal medicine, nephrology, pathology, radiology, neurology, critical care medicine, gastroenterology, hematology, psychiatry, and pulmonary medicine consultant physician on-call coverage, with the ability to be on-site within 30 minutes from the call.

TR.2.6. The trauma team leader ensures all referrals are made as required for diagnosis and/or management, with all consultations available within 30 minutes of the call/notification.

Explanations:

XXX

TR.3. The assessment and re-assessment of trauma patients meet national and cited international standards of care.

TR.3.1. The hospital has age-specific policies and processes outlining the initial assessment and re-assessments for all disciplines, including the trauma team, physicians, including consultations, nurses, respiratory therapists, physiotherapists, social services.

TR.3.2. Every trauma patient receives initial trauma care until the arrival of the specialty consultant(s) to provide stabilization, diagnostic procedures, or definitive **XXX**.

TR.3.3. ED staff and the trauma team are knowledgeable regarding the triage system used by the emergency medical service provider.

TR.3.4. The hospital has a structured system to document the assessment **of** the emergency medical service provider, the appropriateness of transfer to the hospital based on the trauma **filed** triage system, and the treatment delivered pre-arrival to the hospital.

TR.3.5. The emergency medical services have a standardized handover report including (MIST): Mechanism of injury, Injury pattern (injury suspected), Sign (Vitals), and symptom and Treatment.

TR.3.6. The Primary Survey uses the ABCDE approach: A medical history (obtained utilizing AMPLE -Allergies, Medications, Past Illnesses, Last Meal, and Events/Environment/Mechanism).

TR.3.7. The Secondary Survey is a complete head-to-toe history and physical and additional or specialized assessments completed as indicated by the patient's condition.

TR.3.8. A list of injuries should be generated and documented as a provisional diagnosis from the assessments before transfer from the trauma room.

Explanations:

XXX

TR.4. Trauma care meets national and cited international standards of care.

TR.4.1. The hospital has age-specific policies and processes for the most common trauma management decisions and injuries, outlining the management of open fractures, pelvic fractures, brain injury, and spinal cord injury.

TR.4.2. The hospital has age-specific policies and processes for vulnerable/high-risk trauma patient populations' inclusive of geriatric, pediatric, and pregnant patients.

TR.4.3. The hospital has age-specific policies and processes for trauma patients inclusive of airway management, POC ultrasound, hemorrhage control, massive blood transfusion, mitigation of IV access failure, reversal of anticoagulation, administration of hemostatic agents, resuscitative thoracotomy, and damage control surgery.

TR.4.4. The hospital has age-specific policies and processes for invasive blood pressure monitoring of trauma patients in the emergency room, the operating room, and the intensive care unit.

Explanations:

XXX

TR.5. The trauma readiness program director monitors the hospital, departmental and clinicians' performance through KPIs.

TR.5.1. The multidisciplinary, full stakeholder trauma readiness program committee is chaired by the trauma readiness program director and reports directly to the hospital CEO.

TR.5.2. The trauma readiness program director identifies and monitors key performance indicators (KPIs).

TR.5.3. The hospital maintains a trauma registry, properly coded, with the required minimum data for every trauma case, inclusive of the patient's MRN, mechanism of injury, injury severity score, discharge diagnoses, and discharge data.

TR.5.4. Required trauma TAT KPIs include prehospital transfer Time from scene to ED, time from ED to trauma center (interfacility), the response time of the trauma surgeon/general surgeon to ED from trauma activation code, time to OR, 30 min. TAT from all on-call/consultations.

TR.5.5. Required trauma registry and KPIs: all admissions per hospital trauma code activation, ICU and OR admissions for traumatic injury, any trauma transfer into or out of the hospital, all trauma-related deaths, including trauma resuscitation area, unplanned hospital re-admission, readmitted or unplanned admission to the ICU, quadriplegia or vegetative state related to trauma.

TR.5.6. KPIs and morbidity and mortality data are discussed in hospital level committee meetings, ED, OR and ICU, and other relevant stakeholders' monthly departmental meetings to aid awareness with continuous performance improvement and action plans.

Explanations:

XXX

DRAFT

ACUTE CORONARY SYNDROME READINESS (ACS)

Ischemic heart disease (IHD) is the leading cause of death worldwide. Estimates indicate that around 126 million people are living with IHD at the time being and around 10.6 million new cases are diagnosed yearly at the global level. IHD contributes to around 9 million deaths yearly and causes 165 million YLL and 5.3 million YLD worldwide.

In Saudi Arabia IHD causes around 30% of the total mortalities and its acute presentation to our healthcare facilities causes a huge burden to our healthcare system as it is estimated that we have around 100,000 admissions yearly with the diagnosis of Acute Coronary Syndrome (ACS).

ACS results from a sudden blockage of blood flow to the heart typically caused by a blood clot or an atherosclerotic plaque or a combination of both that gradually or suddenly reduces blood supply to a portion of heart muscle. If the blockage is severe enough it could lead to injury or death of the heart muscle – Acute Myocardial Infarction for which we have 2 types – ST Elevation MI STEMI and Non-ST Elevation MI NSTEMI. ACS also includes unstable Angina UA – Chest pain due to restricted blood flow to the heart muscle increasing in nature or severity over time which indicates the need of more evaluation and probable intervention as it could be predisposing to a more serious and lethal myocardial infarction.

Objectives:

The aim of the Acute Coronary Syndrome Readiness standards is to assure that our healthcare provision facilities and systems are optimized to provide the population of Saudi Arabia with the highest quality of care and increase the likelihood for the desired health outcomes in a manner consistent with current professional knowledge by focusing on transforming our care of ACS patients to be more effective, safe, equitable, timely, efficient and patient centric.

We started by differentiation of care facilities into tier 1 (T1) which are hospitals that cannot provide definitive therapy and tier 2 (T2) which are hospitals that can provide definitive therapy.

The aim of these standards is

- Enhance ACS readiness in all hospitals in the kingdom of Saudi Arabia

- Promote the adaptation of nationally and internationally recognized clinical practice guidelines, protocols and pathways in ACS management
- Unify and standardize the way we manage and measure ACS patient's diagnosis, treatment and outcome measurements.

Topics:

What are the standard topics to be covered?

(Limited to the topics that are directly related to the objectives)

ACS 1 – Facility and Organization

ACS 2 – Clinical Pathway

ACS 3 – Quality and Outcome indicators/measurements

ACS service provision classification

Tier 1 hospitals (T1)

- Do not have a cardiac catheterization lab
- Is not the final destination for essential services for ACS patients
- Should have an open ER to both walk ins and ambulance services
- Capable of diagnosing different types of ACS and administering thrombolytic therapy when indicated
- Part of a network with other facilities that have interventional capabilities

Tier 2 Hospitals (T2)

- Has Cardiac Catheterization capabilities
- Covering a defined catchment area with a clear network of referring hospitals
- Has a 24/7 open cathlab covered by a certified interventional cardiologist
- Has access to cardiac surgery either onsite or with a written agreement with another hospital within not more than an hour drive.

ACS.1. The hospital is a part of an inter-hospital network with protocols and clinical pathways for rapid management of ACS patients, including transfer and acceptance of ACS patients.

ACS.1.1. The hospital has a policy and processes for transferring patients to a CT angiogram-equipped and cath-capable hospital, as indicated.

ACS.1.2. Hospitals with no in-house cardiac surgery capability have an active contractual agreement with a cardiac surgery-capable hospital.

ACS.1.3. The hospital has either an ICU or CCU bed to admit ACS patients with continuous monitoring and management of the critically ill ACS patient or the ability to rapidly transfer the patient to a higher level ICU -CCU capacity hospital.

ACS.1.4. The hospital has a documented network in a clear catchment area to be served in collaboration with the Emergency Medical Service Provider.

Explanations:

XXX

ACS.2. The hospital has a protocol for patients presenting with chest pain.

ACS.2.1. A qualified nurse or healthcare provider that is Chest Pain Clinical Pathway- competent is present in the ED triage area at all times.

ACS.2.2. The patient is triaged with vital signs monitoring and immediate ECG, with Door-to-ECG time, read and interpreted, within 10 minutes of arrival.

Explanations:

XXX

ACS.3. The ED has the infrastructure, staffing, diagnostic capabilities and medications to accurately diagnose and initially manage ACS patients.

ACS.3.1. At least one physician, qualified by education, training, and experience to accurately diagnose and manage ACS patients, is on duty in the ED at all times.

ACS.3.2. All hospitals have basic diagnostic testing, inclusive of ECG, laboratory, troponin, radiology, and echocardiogram available at all times.

ACS.3.3. All hospitals have the required medications to manage ACS available in the ED at all times, inclusive of Thrombolytics (tPA), Aspirin, antiplatelets, anticoagulants vasodilators (Nitroglycerine, hydralazine, B-Blockers) ACLS medications (adrenaline, noradrenaline, vasopressin, atropine), and Statins.

ACS.3.4. Required equipment includes Echocardiogram, Intra-Aortic Balloon Pump (IABP), Pericardiocentesis kits, and pacing (trans cutaneous and/or trans venous) are available at all times.

Explanations:

XXX

ACS.4. All hospitals have a clinical pathway and guidelines for STEMI, NSTEMI and UA based on national or cited international standards of care.

ACS.4.1. All STEMI patients have diagnosis-to-cathlab activation within 10 min or activate transfer to external CT angiogram-equipped and cath-capable hospital, as indicated.

ACS.4.2. All STEMI patients undergo Door-to-Needle receiving thrombolytic therapy within 30 minutes.

ACS.4.3. All applicable STEMI patients undergo door-to-balloon within 90 minutes in cath-lab capable hospitals and within 120 minutes for patients transferred patients.

ACS.4.4. The clinical pathway details ECG and repeat ECG times, troponin and repeat troponin times inclusive of monitoring and actioning negative or equivocal findings.

ACS.4.5. All applicable patients receive a pre-discharge evaluation of LVEF.

ACS.4.6. NSTEMI patients have a documented evidence-based assessment of their risk of adverse events with medical management.

ACS.4.7. All patients have a written plan for secondary prevention, communicated to the patient and family.

ACS.4.8. All applicable patients receive a referral to cardiac rehabilitation.

ACS.4.9. All applicable patients, receive a referral to smoking cessation clinic and/or counselling for smoker cessation.

ACS.4.10. All patients receive discharge medications, inclusive, if applicable, dual antiplatelet therapy, B-Blocker and ACE/ARB/ARNI, with patient and family discharge instructions and education.

Explanations:

XXX

ACS.5. The ED and Cardiology heads of department monitors the departments' and clinicians' ACS readiness performance through KPIs.

ACS.5.1. The heads of department identify and monitor key performance indicators (KPIs) for ACS readiness.

ACS.5.2. Required KPIs include: ACS patients' care guided by ACS pathway, Door-to ECG, Door-to Needle, door -to-balloon time, NSTEMI with documented assessment and risk stratification, proportion of patients High risk NSTEMI that have an coronary angiography within 72 hours, ACS discharges with dual antiplatelet therapy, LVEF evaluation done prior to discharge, discharged on B-Blocker and ACE/ARB/ARNI for reduced LVEF ACS patients, secondary prevention plan, patient records entered into the national ACS registry, proportion of patients diagnosed with ACS Readmitted after discharge within 30 days, and Crude/risk adjusted mortality.

ACS.5.3. he heads of the department maintain a list the conditions considered as morbidity and mortality.

ACS.5.4. ACS and MI KPIs and morbidity and mortality data are discussed in monthly departmental meetings to aid in staff awareness with continuous performance improvement and action plans.

Explanations:

XXX

DRAFT

Venous Thromboembolism (VTE)

Acute venous thromboembolism (VTE) is associated with high morbidity and mortality. It has been reported to be responsible for about 11.3% of deaths worldwide, with a 30% risk of developing post-thrombotic syndrome (PTS) 10-20 years after the incidence. (1) PTS is the most common chronic complication of VTE, which causes chronic limb pain, swelling, and leg ulcers. Internationally, the true incidence of VTE is approximately 25,000 cases per year, with a fatality rate of 6-10 percent. Venous thromboembolism (VTE) is of two types, deep vein thrombosis (DVT), and pulmonary embolism (PE), and is a relatively common disease affecting approximately 100 per 100,000 people per year. (1, 3) Hence, it is estimated that around 25,000 people are involved in Saudi Arabia (KSA) annually.

The main risk factors for the development of VTE are age, surgery, antenatal, cancer, immobility trauma, puerperium, hormonal use, obesity, and inherited and acquired hypercoagulable states. (3) VTE is considered a significant risk for many types of patients, i.e., the elderly, surgical patients, antenatal patients, and patients in intensive care units.(4) For example, the incidence of hospital acquired VTE is 10-40% among surgical patients.(5) In one study conducted locally at a tertiary-care hospital in Saudi Arabia, investigators identified 500 confirmed cases of VTE in one year with a fatality rate of 20.8%; with two-thirds of those patients being in surgical wards and one third in the medical wards.(5) The study also indicated that only 44.1% of surgical patients and 21.7% received appropriate thromboprophylaxis. (5)

However, another study, conducted at seven major hospitals in Saudi Arabia, found 1241 confirmed VTE cases over a 12 months period (6). Most (58.3%) of the VTE cases were DVT only, 21.7% were PE, and 20% were DVT and PE (6). In this study, the majority of the confirmed VTE cases occurred in medical patients (78.6%), but only 40.9% of the cases received appropriate thromboprophylaxis (63.2% for surgical patients and 34.8% for medical patients; $P < 0.001$). (6) The mortality rate was 14.3% which represented 1.6% of total hospital deaths. (6)

These studies might reflect the variations in the practice and the underutilization of thromboprophylaxis for at-risk patients. Also, these studies indicated that the available guidelines might not be adequately implemented. Non-adherence to the available guidelines can be attributed to several factors that include underestimating the risk of VTE and the absence of formal national guidelines on VTE prevention. These concerns were highlighted by the Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) leading to the creation of a unified, up-to-date National standard for identification, management and treatment of VTE to be used as the guideline for all healthcare organizations in Saudi Arabia. Hence, this project aims to provide a standard of care for VTE screening, prophylaxis, and management.

DRAFT

VTE.1. The hospital has a policy and processes for venous thromboembolism (VTE) care based on national and cited international standards and guidelines.

VTE.1.1. All patients are screened for the risk of VTE and assessed for bleeding risk with evidenced-based tools in designated time frames in all clinical areas.

VTE.1.2. Identified at-risk VTE patients are managed per an evidenced-based clinical pathway or guidelines within designated timeframes.

VTE.1.3. Re-screening and reassessments are completed with the designated time frames in all clinical areas.

VTE.1.4. All at-risk VTE patients and their families are educated regarding risks, medications, interventions, and management.

VTE.1.5. Multidisciplinary VTE education is based on needs assessment to all healthcare providers.

Explanation

A comprehensive policy shall address all potential clinical settings and facility areas and detail the processes and responsibilities of every staff member. The policy should be easily accessible to all staff and is updated regularly.

The policy includes standardized implementation tools that facilitate proper implementation. Evidence-based timing guidelines for screening, reassessment, and management are defined in the policy, and are implemented, observed and monitored.

Proper supply chain management should ensure the adequate presence of all needed supplies and medications used in VTE prophylaxis. This would facilitate prompt interventions when indicated.

VTE prophylaxis policies and procedures should be an integral component of designated healthcare workers' orientation programs. Periodic retraining and focused training are documented in the staff's personnel file.

The policy and procedures need to include provisions for patient and family education regarding VTE risk and management, provided to all patients, irrespective of their risk profile or score. Implementation is documented in patients' records. Discharged patients receive information about VTE risk, signs and symptoms and further action if needed. Those on therapy need comprehensive education regarding bleeding risks and effort.

VTE.2. The hospital and all heads of departments monitor the departmental and clinicians' VTE performance through KPIs.

VTE.2.1. A designated hospital-wide committee and the heads of the department identify and monitor key VTE-related performance indicators (KPIs).

VTE.2.2. Required KPIs include: compliance with VTE and bleeding risk assessment upon admission and reassessments, percent of patients receiving appropriate VTE Prophylaxis, VTEs, unexpected in-hospital VTE-related deaths, VTE readmissions, and compliance with patient and family VTE education, including on discharge.

VTE.2.3. VTE -related KPIs and morbidity and mortality data are discussed in the hospital-wide committee and monthly departmental meetings to aid in staff awareness with continuous performance improvement and action plans.

Explanations:

XXX

Glossary

- Standardized tool:

Validated, an objective assessment tool for identifying at-risk for VTE.

- VTE Guidelines:

Evidence-based recommendations for health care providers on how to care for people with VTE.

- Unexpected in-hospital deaths:

Not directly related to original condition or treatment.

References

- Næss IA, Christiansen S, Romundstad P, Cannegieter S, Rosendaal FR, Hammerstrøm J. Incidence and mortality of venous thrombosis: a population-based study. *Journal of thrombosis and hemostasis*. 2007;5(4):692-9.
- Nishimoto Y, Yamashita Y, Morimoto T, Saga S, Amano H, Takase T, et al. Risk factors for post-thrombotic syndrome in patients with deep vein thrombosis: from the COMMAND VTE registry. *Heart and vessels*. 2019;34(4):669-77.
- Al-Hameed FM, Al-Dorzi HM, Al-Momen AM, Algahtani FH, Al-Zahrani HA, Al-Saleh KA, et al. The Saudi Clinical Practice Guideline for the treatment of venous thromboembolism: Outpatient versus inpatient management. *Saudi medical journal*. 2015;36(8):1004.
- White RH. The epidemiology of venous thromboembolism. *Circulation*. 2003;107(23_suppl_1):I-4-I8.
- Abo-El-Nazar Essam GS, Al-Hameed F. Venous thromboembolism-related mortality and morbidity in King Fahd General Hospital, Jeddah, Kingdom of Saudi Arabia. *Annals of thoracic medicine*. 2011;6(4):193.
- Al-Hameed F, Al-Dorzi H, Qadhi A, Shaker A, Al-Gahtani F, Al-Jassir F, et al. Thromboprophylaxis and mortality among patients who developed venous thromboembolism in seven major hospitals in Saudi Arabia. *Annals of thoracic medicine*. 2017;12(4):282.
- Health Nif, Excellence C. Venous Thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism. NICE guideline [NG89]. National Institute for Health and Care Excellence London, UK; 2018.
- Darzi A, Abou-Jaoude EA, Agarwal A, Lakis C, Wiercioch W, Santesso N, et al. A methodological survey identified eight proposed frameworks for the adaptation of health-related guidelines. *Journal of clinical epidemiology*. 2017; 86:3-10.

Perioperative Safety (POR)

The term 'Perioperative' period refers to the journey of the surgical patient, namely, preoperative, intraoperative and postoperative periods. The outcome of the surgery is not only about the surgical procedure, but a series of events leading up to, during and after the surgery (1).

The incident of adverse events varied from 3% to 17% during hospitalization (2,3). Although Most of the adverse events were resulted in minor or temporary disability, but a proportion of the adverse events, 4% to 21%, contributed to death (4). All these studies have shown that a high percentage of adverse events are attributable to surgical specialties, ranging from 51% to 77% (5), with range of 50 % of the adverse events are ruled to be preventable (4). In famous surgical events systematic review, that included 16,424 surgical patients, Anderson et al (6) concluded the following:

Adverse events occurred in 14.4% of patients and potentially preventable adverse events occurred in 5.2%. The consequences of 3.6% of adverse events were fatal, those of 10.4% were severe, those of 34.2 were moderate, and those of 52.5% were minor. Errors in nonoperative management caused more frequent adverse events than errors in surgical technique.

The operating room is unique area in which multi background specialties health care workers available with rapid pace actions, different reporting structure and advance technology and equipment. All those factors will play role in distraction of health care workers forcing for errors.

List of possible preventable perioperative adverse events include:

Incomplete preparation of surgery	Medication errors
Incomplete patient charting	Home medication not prescribed
Blood units not available	VTE prophylaxis not assessed
DVT / Pulmonary Embolism	Antibiotics not administered
Postoperative infections	Wrong surgery site

Retention of foreign body	Mislabeled or lost specimens
Required equipment not available	Miscommunication

Perioperative safety depends largely on the regulatory requirements that mandate skill levels, documentation standards, monitoring and well-maintained equipment and devices (7).

The regulatory requirements demand strategies to improve perioperative safety which include:

- Implementation of standardized practices to reduce variations in care provision, decreases the risk of human error and miscommunication. Perioperative standardized practices will include use of checklists, structured handover reports and policies & procedures to guide perioperative practices.
- Continuous medical education is required to ensure health care professionals are knowledgeable in these policies, practices and protocols, as well as new equipment and techniques.

In the other hand, developing effective communication techniques and facilitating teamwork training has demonstrated better performance and improved clinical outcomes (1). It's essential for every perioperative department to own Clinical indicators which will assess perioperative structures, processes, and outcomes, and can provide a quantitative basis for quality improvement.

Objectives:

- To adapt efficient safe surgery protocols
- To ensure the design of operating room will support smooth and safe patients flow
- To ensure proper monitoring of surgical patients during sedative and anesthetic effects
- To reduce the incidence of health care associated infections.
- To maintain wellbeing of perioperative health care workers
- To ensure proper documentation of the patient's trip through the operative process (pre-op, intra-op and post-op)

POR.1. The hospital ensures operating rooms and remote procedural area rooms meet national and cited international standards and regulations.

POR.1.1. Operating and remote procedural rooms meet the minimum requirements for their specific service(s).

POR.1.2. The layout of the operating room and remote procedural rooms are designed to consider patient flow, traffic patterns, the types of procedures performed, equipment storage, and movement logistics.

POR.1.3. The hospital has a policy and processes for maintaining operating rooms' three levels of unrestricted, semi-restricted, and restricted.

POR.1.4. Operating and remote procedural area rooms have heating, ventilation, temperature, and humidity monitored with defined mechanisms to mitigate out-of-range requirements.

POR.1.5. The hospital has policies and processes that are OR/remote procedural areas specific to medical gas pipeline systems, including low-pressure connecting assemblies, pressure regulators, and terminal units, are certified, checked regularly and have strict compliance.

POR.1.6. Connections in medical gas systems are non-interchangeable between different gases.

Explanation:

- Unrestricted areas may include the preoperative holding area, staff lounge, booking office, or manager's office.
- Semi-restricted areas include supply rooms, storage areas, scrub sink areas, and corridors leading to restricted areas. Personnel wear appropriate surgical attire and cover their head and facial hair in semi-restricted areas.
- Restricted areas include any area where scrub personnel are present or where sterile supplies are opened. Surgical attire and facemasks are required in restricted areas.

POR.2. The hospital ensures the safety of surgical and anesthesia equipment and devices.

POR.2.1. All surgical equipment and medical devices are used per manufacturers' instructions.

POR.2.2. Surgical equipment, medical devices, and supplies are regularly calibrated, maintained and 'ready for safe use.'

POR.2.3. The surgical and anesthesia teams ensure all equipment, devices, and supplies are available and functional prior to use.

POR.2.4. The hospital has a policy and processes for surgical counts for all surgical instruments, sponges, sharps and miscellaneous items.

POR.2.5. Equipment that fails or breaks during a procedure, is removed from circulation, and all pieces of the item are accounted for, and the event is documented and reported.

POR.2.6. The hospital has policy and processes for permanent implanted medical devices.

Explanation:

The process of equipment and device maintenance includes identifying and communicating equipment alerts and recalls appropriately throughout the team with regular checkup by the biomedical engineers. Testing equipment includes confirming that all components are properly connected and inspected to ensure that all parts are present and functional. The surgical instruments counting process is standardized and includes instruments, sharps, sponges, and others as applicable. When a surgical miscount is identified, a procedure is followed that includes recounting, using imaging technologies, notifying the surgeon and other providers, and documenting the miscount. Documentation includes noting the correct/incorrect count, completing an incident report, and documenting all actions taken in the client record. The count record is signed by all personnel involved in the count. A record is kept for the proper storage, handling and management of expired supply according to the manufacturers' instructions. Formal procedures are followed for containing used items and transporting them to and from the area where they are reprocessed. Reports on equipment failures should clearly identify the piece of equipment; the type of failure and date, time, and action taken to ensure the equipment is repaired or replaced before its next use.

The proposed implanted device is selected based on the current data from the literature. Availability of the device and functionality of equipment is confirmed before the patient enters the operating room and the infection prevention and control considerations are maintained.

POR.3. The operating room and anesthesia department have qualified physician and nurse leadership.

POR.3.1. The head of department for the operating room is a qualified, practicing consultant surgeon or anesthesiologist.

POR.3.2. The nurse manager/head nurse of the operating room holds a baccalaureate degree in nursing and SCFHS as a specialist or higher.

POR.3.3. The nurse manager/head nurse of the recovery room/PACU holds a baccalaureate degree in nursing and SCFHS as a specialist or higher.

Explanation:

The head of the operating room will:

- Supervise the development and implementation of the policies and procedures related to the OR
- Enforce the implementation of infection control guidelines inside the OR.
- Administer the workload in the OR in accordance with the hospital's license and scope of services

The nurse manager in charge of the operating room is a qualified registered nurse with training, education, and experience in operative care. The nurse manager of the operating room develops and collaborates with other disciplines for developing all required and related policies and procedures.

POR.4. The hospital ensures standardized processes and protocols for all procedures, interventions, sedation, and anesthesia based on national and cited international standards.

POR.4.1. The hospital has a policy and processes for the acceptance of the patient to the operating room.

POR.4.2. The hospital has a policy and process for day surgery procedures.

POR.4.3. The hospital has policies and procedures for patient care specific to the operating room and remote procedural/interventional areas, inclusive of emergency, massive blood transfusion, maternal hemorrhage, malignant hyperthermia, local anesthesia systemic toxicity, and moderate sedation protocols

POR.4.4. The hospital has policies and processes specific to the OR/remote procedural areas for infection prevention and control standards with strict compliance.

POR.4.5. The hospital has policies and processes that are OR/ remote procedural areas specific to medication safety, inclusive of secured locked medications, high alert medications, narcotics, controlled medications, antibiotics, crash carts, and smart infusion pumps.

Explanation:

The policy for the acceptance of the patient to the operating room must ensure the following:

- Patient identification by name and medical record number as listed on the patient's ID band.
- The consent forms are checked for completion.
- The operation/procedure and the surgeon's name are checked.
- The site of surgery and its preparation and whether it is marked or not are according to the WHO surgical safety checklist.
- The laboratory and radiology results and pregnancy test as appropriate are checked.
- The pre-anesthesia sheet is checked for completion.
- The history and physical examination are checked for documentation, as in standard.
- The requisition for blood is verified to ensure blood is reserved in the blood bank, if needed.

The day surgery policy defines the types of surgical procedures that are performed as "day surgery". This policy addresses the categories of patients who are not candidates for day surgery. It defines a process for patients who are admitted to the hospital from the day surgery unit. The primary physician writes the discharge order. The policy defines clear discharge criteria. Patients are discharged in the company of a responsible adult who assumes responsibility and can take care of the patient. Patient/family education and follow-up care instructions are provided prior to discharge.

Availability of specialized emergency protocols as standardized protocol, is shown to be safe and effective in enhancing emergency patient care, enhancing workflow and improving coordination with reduction in variation of care.

Infection prevention and control measures should include, but are not limited to:

- The operating room environment is kept clean at all times.
- There is minimal use of storage cabinets in the operating room.

- There is a policy for traffic control in the operating room.
- Only operating room scrub clothing is allowed inside the restricted areas of the operating room.
- Scrubbing sinks are available at the entry of the operating room.
- Standard precautions are strictly implemented in the operating room with particular emphasis on hand hygiene and the appropriate use of gloves, gowns, masks, and other barriers to infection.
- There are clear procedures for cleansing and disinfecting operating rooms by housekeeping after surgical procedures.
- There are clear procedures for cleaning and disinfecting anesthesia machines after each case and toward the end of working hours by anesthesia technicians.
- The storage area of the operating room is well maintained with respect to the infection prevention and control standards.
- Waste management protocols in the operating room maintain the safety of patients and healthcare workers.
- Patients with transmissible diseases are handled properly, according to infection control protocols, inside the operating rooms.
- Infected cases are scheduled towards the end of the operating list.
- There is an implemented policy to handle patients with air-borne transmitted disease inside the operating room.
- There is an implemented policy for contact and droplet transmission-based precaution in the recovery room.

High alert medications such as concentrated electrolytes or insulin should be prepared by a pharmacy to ensure that the syringes and infusions have a standardized concentration and label.

The following conditions should be applied when prescribing and administering high alert medication:

- Accurate age and weight of patients should be documented.
- The route of administration should be clearly identified.
- Dose adjustments should be considered when prescribing and administering for patients with preexisting clinical conditions (such as renal or hepatic impairment).
- High alert medications should not be stored as part of routine OR stock medications. If stored for timely care reasons a clear visual label is applied to these medications.

Perioperative medication errors have the potential to cause serious patient harm. The hospital policy focuses on reducing errors such as inadvertent drug administration, wrong route, miscalculation of

dilution or failure to dilute, mis-programming of infusion pumps, administering a known allergic drug, and failure to flush a line after a drug.

The OR medication cart policy includes:

- Standardization of anesthesia medication carts to avoid the proximity of look-alike or sound-alike medications.
- Use of color-coded labels or prefilled syringes.
- Use of multi-dose vials are discouraged.
- Removal of outdated and expired medications
- Clear segregation of regional anesthetic solutions from intravenous medication, preferably in a regional anesthesia cart.
- Segregation of topical or irrigation fluids from intravenous fluids.

Narcotics and controlled medication are kept in a locked cabinet. All empty used vials and ampoules are disposed of with a completed signed and cosigned narcotics and controlled prescription form as per SFDA policy.

POR.5. The hospital ensures standardized, documented person-centered processes for all procedures, interventions, sedation, and anesthesia in the OR and remote procedural areas.

POR.5.1. All patients for invasive procedures/interventions have a comprehensive medical assessment, plan of care, and determination of 'fit for surgery.'

POR.5.2. All patients for procedures/interventions have a comprehensive anesthesia evaluation, an anesthesia pre-operative, intra-operative, and post-operative plan of care (including pain, nausea, and vomiting), and determination of fit for anesthesia/sedation.'

POR.5.3. All applicable patients have surgical, procedural, or intervention informed consent and an anesthetic or sedation informed consent completed and signed, per hospital policy, by the patient or legal guardian.

POR.5.4. Patients and families receive comprehensive pre, intra and post procedural/surgery instructions.

POR.5.5. All patients have a pre-operative or pre-procedural checklist.

POR.5.6. Medication Reconciliation is completed prior to patient transfer to the OR.

POR.5.7. The hospital has a policy and processes for site marking, inclusive of patient and family participation.

POR.5.8. The hospital has a policy and processes for Time Out, inclusive of patient participation, if the patient has not received sedation.

POR.5.9. All patients for sedation or anesthesia have complete anesthesia/sedation record.

POR.5.10. All tissues or specimens removed during an intervention are sent for pathological evaluation.

POR.5.11. The operative, procedure, or intervention report is completed immediately after the intervention and available with the patient/medical record prior to patient transport.

POR.5.12. The patient has a post-operative plan of care written by the most responsible physician prior to the patient leaving PACU/ recovery room, or recovery area.

Explanation:

Preoperative assessment documentation aims to minimize patient risk by assessing the patient's readiness for surgery.

Prior to surgery, the primary physician performs a medical assessment and ensures documentation of the following:

- Preoperative diagnosis and planned procedure
- Medical and surgical history
- Medication history
- Allergies
- Nutritional status and needs
- American society of anesthesiologist classification (ASA)
- Previous perioperative complications.
- Diagnostic tests (laboratory, radiology, etc.) as appropriately ordered.

In emergency situations where a complete medical assessment cannot be documented, a brief note is written by the primary physician.

A preanesthetic evaluation is conducted to assess the risks and develop a plan for anesthesia. This evaluation specifically identifies the risks of the anesthesia encounter and is the sole purview of an anesthesia professional.

Prior to the delivery of anesthesia care, the anesthesiologist is responsible for:

- Reviewing the available medical record.
- Interviewing and performing a focused examination of the patient to discuss the medical history, including previous anesthetic experiences and medical therapy.
- Ordering and reviewing pertinent available tests and consultations as necessary for the delivery of anesthesia care.
- Ordering appropriate preoperative medications.
- Ensuring that consent has been obtained for the anesthesia care.
- Documenting in the chart that the above has been performed.

The informed consent should include the following information:

- The patient's name and medical record number.
- The intervention.
- The site if applicable.
- Possible complications.
- The physician's name and signature.

Tissues or specimens removed during surgery have pathological examination unless exempted by a hospital policy and surgical specimens are accurately identified. The report of the examination is signed by the pathologist and made part of the medical record.

The postoperative plan of care includes:

- Postoperative monitoring parameters and its frequency.
- Wound care.
- Care of drains and catheters when applicable.
- Special patient positioning requirements when indicated.
- Nutritional instructions.
- When to start mobilization.

- Special referrals as indicated (e.g., physical therapy, respiratory therapy)
- A new order for all required medications including analgesia and VTE when indicated.
- Any other postoperative care needed.
- Each patient is assessed after surgery and reassessed at intervals appropriate to the patient's condition. This assessment must be documented and the postoperative plan updated accordingly.

POR.6. Anesthetic monitoring meets national and cited international standards.

POR.6.1. A qualified anesthesiologist remains present in the room throughout all anesthetic care.

POR.6.2. Patient status is continuously monitored during all anesthetics care, using appropriate monitoring equipment.

POR.6.3. All patients are continuously monitored during the recovery period/post-anesthesia care unit (PACU).

POR.6.4. Patient monitoring is continued during the recovery period until the patient is stable and safely discharged by a qualified physician, meeting evidenced-based, defined PACU discharge criteria.

Explanation:

To ensure that the hospitals meet the basic Anesthetic Monitoring Requirements, to reduce the risks of incidents by detecting the consequences of errors, and by giving early warning that the condition of a patient is deteriorating.

A qualified anesthesiologist includes physician anesthesiologists, at the level of consultants, registrars, or residents. During administration of anesthesia, the patient can undergo rapid and sudden changes; thus, a qualified anesthesia physician is continuously present to monitor the patient and provide continuous anesthesia care in response to changes in patient status.

To ensure adequate oxygen concentration in the inspired gas and the blood throughout anesthesia administration, the hospital use the following equipment:

- An oxygen analyzer, with a low oxygen concentration limit alarm.
- Pulse Oximetry

- To ensure adequate ventilation of the patient throughout anesthesia administration, the hospital uses A capnography, capnometry or mass spectroscopy and a device that can detect disconnection of any of the components of the breathing system.
- To ensure the adequacy of the patient's circulatory function during all anesthetics the hospital uses:
 - An electrocardiogram
 - Arterial blood pressure and heart rate monitor that measures at least every five minutes.
 - An Intra-arterial pressure monitor should also be available in the OR if needed.

To aid in the maintenance of appropriate body temperature during all anesthetics, the hospital ensures that every patient receiving anesthesia should have their body temperature monitored.

To determine onset of neuromuscular blockade, maintain the required depth of muscle relaxation during the surgical procedure, and assess an appropriate dose of the reversal agent, the hospital must use neuromuscular monitoring to monitor inadequate reversal of neuromuscular blockade.

Patients are recovered from anesthesia in a designated area to ensure a safe transition from the intraoperative period to assess and manage the patient's vital signs, analgesic recovery and general preparedness for safe and optimal recovery. Qualified nursing staff monitor the patients till they meet the locally agreed discharge criteria to leave the PACU. Qualified anesthesia physicians are always available when patients are managed in the PACU.

Recommended monitors for evaluating the physiological parameters include:

- Pulse oximeters
- RR (Respiration Rate) monitors.
- NIBP (Noninvasive Blood Pressure) monitor
- ECG (Electrocardiogram)
- Temperature monitors

POR.7. The OR head of department monitors the departmental and clinicians' performance through KPIs.

POR.7.1. The head of department identifies and monitors key performance indicators (KPIs).

POR.7.2. The head of the department maintains a list the conditions considered as morbidity and mortality.

POR.7.3. KPIs and morbidity and mortality data are discussed in monthly departmental meetings to aid in staff awareness with continuous performance improvement and action plans.

Explanations:

XXX

References

The Patient Safety Education Program PSEP – Canada Module 12a: Interventional Care: Perioperative Care [2017]

Available at:

<https://www.patientsafetyinstitute.ca/Pages/PageNotFound.aspx?requestUrl=https://www.patientsafetyinstitute.ca/en/education/patientsafetyeducationprogram/%20patientsafetyeducationcurriculum/document/module12a-Interventional%20Care-Perioperative%20Care.pdf>

Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, Etchells E, Ghali WA, Hébert P, Majumdar SR, O'Beirne M, Palacios-Derflingher L, Reid RJ, Sheps S, Tamblyn R: *The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. CMAJ. 2004, 170: 1678-86. 10.1503/cmaj.1040498.*

Gawande AA, Thomas EJ, Zinner MJ, Brennan TA: *The incidence and nature of surgical adverse events in Colorado and Utah in 1992. Surgery. 1999, 126: 66-75. 10.1067/msy.1999.98664.*

Zegers, M., de Bruijne, M.C., de Keizer, B. et al. *The incidence, root-causes, and outcomes of adverse events in surgical units: implication for potential prevention strategies. Patient Saf Surg 5, 13 (2011).*

<https://doi.org/10.1186/1754-9493-5-13>

Kable AK, Gibberd RW, Spigelman AD: *Adverse events in surgical patients in Australia. Int J Qual Health Care. 2002, 14: 269-76. 10.1093/intqhc/14.4.269.*

Anderson O, Davis R, Hanna GB, et al *Surgical adverse events: a systematic review. Am J Surg 2013; 26:253–62.*

Watson DS. *Perioperative Safety, In: Perioperative Safety E-Book 2011, 1st Edition. By Mosby, Inc, ISBN: 978-0-323-06985-4. Available at: <http://www.elsevier.com/permissions>. Chazapis M et al. Perioperative structure and process quality and safety indicators: a systematic review. British Journal of Anaesthesia, 120(1): 51e66 (2018)*

Perioperative Services and Invasive Procedures, Accreditation Canada; 2019.

<https://store.accreditation.ca/products/perioperative-services-and-invasive-procedures>

Perioperative care in adults, NICE guideline, August 2020. Available at:

<https://www.nice.org.uk/guidance/ng180>

Basic Standards for Preanesthesia Care, American Society of Anesthesiologists (ASA). Available at:

<https://asahq.org/standards-and-guidelines/basic-standards-for-preanesthesia-care>.

Guidelines for perioperative pain management: need for re-evaluation. British Journal of Anaesthesia 119(4):720–2 (2017).

Ward WH, et al. Optimal preoperative assessment of the geriatric patient. Perioper Care Oper Room Manag. 2017

Dec;9:33–38. Available at: <https://doi.org/10.1016/j.pcorm.2017.11.005>.

Kumar C, Salzman B, Colburn JL. Preoperative assessment in older adults: A comprehensive approach. Am Fam Physician.

2018 Aug 15;98(4):214–220.

Goldberg, J.L. & Feldman, D.L. (2012). Implementing AORN Recommended Practices for Prevention of Retained Surgical Items. AORN Journal, 95(2): 205-216.

Joint Commission International publishes International Accreditation Standards for Hospitals, 7th edition, 2020.

<https://www.jointcommissioninternational.org/news-and-support/news/2020/04/joint-commission-international-publishes-international-accreditation-standards-for-hospitals/>

<https://store.accreditation.ca/products/perioperative-services-and-invasive-procedures>

World Health Organization-World Federation of Societies of Anaesthesiologists (WHO-WFSA) International Standards for a Safe Practice of Anesthesia. Can J Anesth/J Can Anesth (2018) 65:698–708. <https://doi.org/10.1007/s12630-018-1111-5>.

SFDA Recognized Standards Supporting Medical Device Premarket Submissions; 2020.

https://www.sfda.gov.sa/ar/saudi_standards_lists.

NICE guideline for Perioperative care in adults. Published: 19 August 2020. <https://www.nice.org.uk/guidance/ng180>

Association of perioperative Registered Nurses. (2013). Perioperative Standards and Recommended Practices. Beaulieu, D.,

Barkun, A.N., et al. (2013). Endoscopy reporting standards. Canadian Journal of Gastroenterology, 27(5):286-292.

Infection Prevention and Control Guidelines for Anesthesia Care; 2018. [https://www.aana.com/docs/default-source/practice-aana-com-web-documents-\(all\)/professional-practice-manual/infection-prevention-and-control-guidelines-for-anesthesia-care.pdf?sfvrsn=850049b1_4](https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/professional-practice-manual/infection-prevention-and-control-guidelines-for-anesthesia-care.pdf?sfvrsn=850049b1_4)

Medication safety in the operating room: literature and expert-based recommendation. British Journal of Anaesthesia, 118 (1): 32–43 (2017)

Perioperative Medication Errors: Uncovering Risk from Behind the Drapes (pa.gov). In: The Pennsylvania Patient Safety Advisory. Pa Patient Saf Advis 2018 Dec;15(4).

Medication Safety Strategies for the Perioperative Setting Medication Safety Strategies for the Perioperative Setting: October 2010 - Pharmacy Purchasing & Products Magazine. Available at: http://www.pppmag.com/article/767/october_2010.

Standards for Basic Anesthetic Monitoring Committee of Origin: Standards and Practice Parameters (Approved by the ASA House of Delegates on October 21, 1986, last amended on October 20, 2010, and reaffirmed on December 13, 2020). Available at: <https://www.asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/standards-for-basic-anesthetic-monitoring.pdf>.

Recommendations for standards of monitoring during anaesthesia and recovery 2015; Association of Anaesthetists of Great Britain and Ireland. Available at: <https://www.rcoa.ac.uk/system/files/PUB-SafeSedPrac2013.pdf>.

Well-being at work: creating a positive work environment (Literature Review) European Agency for Safety and Health at Work ISSN: 1831-9351. Available at: <https://osha.europa.eu/en/publications/well-being-work-creating-positive-work-environment>

Management of occupational exposure to blood and body fluids, 2017 Queensland Health. Available at: https://www.health.qld.gov.au/_data/assets/pdf_file/0016/151162/qh-gdl-321-8.pdf

A Guide for Hospital and Health System Leaders, May 2019 American Hospital Association. Available at: <https://www.aha.org/>

Statement on the Anesthesia Care Team, Approved by ASA House of Delegates, Oct. 2019. [file:///C:/Users/user/Downloads/Statement%20on%20the%20Anesthesia%20Care%20Team%20\(1\).pdf](file:///C:/Users/user/Downloads/Statement%20on%20the%20Anesthesia%20Care%20Team%20(1).pdf)

American College of Surgeons. Statements on Principles, Code of professional conduct 2016. Available at: <https://www.facs.org/about-ac/s/statements/stonprin>

Balik, B. (2012). Patient- and Family Centeredness: Growing a Sustainable Culture. Healthcare Quarterly 15: 10-12.

Balik, B., J. Conway, L. Zipperer & J. Watson. (2011). Achieving an Exceptional Patient and Family Experience of Inpatient Hospital Care. IHI Innovation Series White Paper. Cambridge, Massachusetts: Institute for Healthcare Improvement. Available at: <http://www.ihl.org/>

Chow, S., Teare, G., & Basky, G. (2009). Shared decision making: Helping the system and patients make quality health care decision. Saskatoon: Health Quality Council. Available at: <http://www.hqc.sk.ca>

Safe Operating Room Saudi Patient Safety Center (SPSC), JULY 2017;15:10-12. Available at: <http://www.spsc.gov.sa>.

Australian and New Zealand College of Anaesthetists. Guidelines on sedation and/or analgesia for diagnostic and interventional medical, dental or surgical procedures.[accessed on 2019 January 31]. Available at: <http://www.anzca.edu.au/documents/ps09-2014-guidelines-on-sedation-and-or-analgesia>.

Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018: a report by the American Society of Anesthesiologists Task Force on Moderate Procedural Sedation and Analgesia, the American Association of Oral and Maxillofacial Surgeons, American College of Radiology, American Dental Association, American Society of Dentist Anesthesiologists, and Society of Interventional Radiology. Anesthesiology. 2018;128:437–479.

ASA Committee on Standards and Practice Parameters. Standards for basic anesthetic monitoring, [accessed on 2019 January 31]. Available at: <https://www.asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/standards-for-basic-anesthetic-monitoring.pdf>.

Academy of Medical Royal Colleges. Safe sedation practice for healthcare procedures: standards and guidance.[accessed on 2019 January 31]. Available at: <https://www.rcoa.ac.uk/system/files/PUB-SafeSedPrac2013.pdf>.

DRAFT

Safe labor and birth (SLB)

CBAHI advocates for the provision of excellent maternity care which is comprehensive and flexible to respond to the clinical and social needs of women and their families across the Kingdom of Saudi Arabia. It is understood that many women will undergo normal and uncomplicated pregnancies and childbirths. However, the service must also be able to respond appropriately to those who may require highly specialized care for existing medical problems, social circumstances and any common or rare complications that may develop.

In 2018, the maternal mortality rate in Saudi Arabia reached 11.9 per 100,000 live births (MOH 2019). Therefore, the importance of setting standards for maternity care has been recognized through the inclusion of a mandatory, Safe Labor and Birth Standard in CBAHI to minimize preventable maternal and neonatal morbidity and mortality.

For the development of these standards, the committee has come up with several expert recommendations whilst seeking guidance from reputable internationally recognized sources and benchmarks based on the most recent evidence-based practices.

This set of standards is developed to provide the guidelines for safe and quality care that should be followed by healthcare providers and hospital administrators to benefit women and their families.

These standards for maternity care will aim to facilitate the development of equitable, safe and high-quality care for mothers and their babies by providing a structured framework for both urban and rural maternity services whilst incorporating a smooth transfer and liaison of interdepartmental multidisciplinary services wherever applicable.

These standards will cover every step of the care process for women from pregnancy to childbirth across all the regions of the Kingdom of Saudi Arabia.

SLB.1. The hospital has an obstetric unit with physical structures that facilitate safe labor and birth practices.

SLB.1.1. Labor and birth rooms have a minimum clear floor area of 30 square meters and include a newborn stabilization and resuscitation space with a minimum clear floor area of 3.7 square meters.

SLB.1.2. A newborn care area, with facilities for a neonatal warmer and resuscitation, is available within the labor room and obstetrics operation theatre ancillary area, with a minimum clear floor area of 3.7 square meters.

SLB.1.3. The dimensions between the bed and any fixed obstruction are a minimum of 1.82 m from the foot of the bed, 1.52 m on the transfer side of the bed, and 1.22 m on the non-transfer side of the bed.

SLB.1.4. A minimum of one fully equipped operating room is readily available for obstetric procedures at all times.

SLB.1.5. The cesarean birth room has a minimum clear floor area of 40.85 square meters and includes a newborn resuscitation space with a minimum clear floor area of 7.4 square meters.

SLB.1.6. Newborn resuscitation space, when provided in a separate room, is immediately accessible room with a minimum clear floor area of 13.94 square meters.

Explanations:

XXX

SLB.2. The physical structure of the obstetric unit ensures a safe, clean and healthy environment.

SLB.2.1. The hospital has policies and processes labor and delivery specific to infection prevention and control and building standards.

SLB.2.2. Labor and delivery units have clean supply workroom, separate from with no connection to the soiled workroom, that contains a work counter, a hand-washing sink, and storage facilities for clean and sterile supplies.

SLB.2.3. The hospital has policies and processes labor and delivery specific to medical gases, including the availability and accessibility of oxygen, medical air, and a vacuum system.

SLB.2.4. The hospital ensures Point of Care (POC) testing is available for urgent obstetric investigations.

Explanations:

XXX

SLB.3. The hospital ensures the privacy, safety, and security of newborns, parents and staff and minimizes the risk of newborn abduction and exchange.

SLB.3.1. The obstetrical unit is designed and located to prohibit unnecessary traffic into and through the unit and is secured with controlled access.

SLB.3.2. Cesarean birth rooms located on the obstetrical unit have restricted access to ensure no staff or patients move through the cesarean birth area to access other areas or services.

SLB.3.3. The hospital ensures an identification tagging process for mothers and newborns immediately after birth.

SLB.3.4. Auditory and visual privacy is ensured in all areas.

SLB.3.5. The newborn stabilization and resuscitation space is a dedicated area within the birthing room, distinct from the mother's area, and facilitates easy access to neonatology staff while respecting the mother's privacy.

Explanations:

XXX

SLB.4. The hospital ensures the safe and timely transport and transfer related to labor and birth.

SLB.4.1. There is an emergency department registration area and a registration clerk for obstetric cases.

SLB.4.2. The hospital has an available, functioning ambulance service equipped and supplied with medication and instruments for obstetrical and neonatal emergency care and transport.

SLB.4.3. The hospital ensures a dedicated obstetrics triage at points of entry for laboring women, in labor and delivery, ambulatory care, and the emergency department available with processes and resources to support all stages of labor.

SLB.4.4. The hospital has an alerting process for urgent transfer to the operating room.

SLB.4.5. The hospital ensures the transport time from the labor/birth room to an obstetric Operating Room (OR) does not exceed three minutes.

SLB.4.6. Transport pathways are clear to provide and maintain safe patient mobilization and transfer.

SLB.4.7. Designated exits and pathways are not obstructed by any object that is not movable.

Explanations:

XXX

SLB.5. The hospital has qualified obstetric department leadership, medical, midwife and nursing staff.

SLB.5.1. Qualified obstetricians are physically present in the labor and delivery at all times and available for out of labor and delivery births.

SLB.5.2. An on-call neonatologist/pediatrician and anaesthetist are available to provide obstetric services coverage at all times.

SLB.5.3. The labor and delivery manager/head nurse/midwife holds a baccalaureate degree in nursing or midwifery and SCFHS as a specialist or higher.

SLB.5.4. Qualified midwives are physically present in the labor and delivery and provide midwifery care to women per the national scope of midwifery practice.

SLB.5.5. Nurses provide nursing care to women in labor, at all times, including present to receive the newborn during birth.

SLB.5.6. Maternity/healthcare/midwife assistants have a defined scope and competencies in maternity and newborn care and are supervised by a nurse/midwife at all times.

SLB.5.7. Obstetricians, nurses, and midwives are certified in obstetric emergencies, and electronic fetal monitoring courses such as Advanced Life Support in Obstetrics (ALSO), Obstetrics Emergency and Trauma Workshop (OBERT), K2 fetal monitoring, and at least one certified obstetrician and nurse/midwife is assigned and present on duty every shift.

SLB.5.8. Obstetricians, paediatricians/neonatologists, nurses, and midwives are certified in the Neonatal Resuscitation Program, and at least one certified obstetrician, paediatrician/neonatologist, and nurse or midwife are assigned and present on duty every shift.

Explanations:

XXX

SLB.6. The hospital identifies the obstetrics admission and discharge criteria based on the level of care provided.

SLB.6.1. The departmental scope of service details the services provided and the level of cases accepted and includes screenings, physical assessment, risk assessment, and the criteria for transfer.

SLB.6.2. The obstetrics department implements specific criteria for admission and discharge. The criteria are collaboratively developed by the obstetricians and other relevant departments, based on the gestational age of mothers, the department's design, and the available resources.

Explanations:

XXX

SLB.7. The hospital has standardized processes, protocols, and resources to ensure safe labor and birth based on national and cited international standards.

SLB.7.1. Mandatory policies and processes specific to labor and birth: Labor/postpartum care, CTG, Partogram, Induction, Augmentation, Analgesia, Instrumental deliveries, LSCS, Emergency hysterectomy, Obstetric/Medical Emergencies, VTE, Preterm Labor (PTL), multiple births, perineal trauma, newborn identification, code pink, blood transfusion and The hospital has a policy to provide the necessary blood products for obstetric procedures.

SLB.7.2. The hospital implements have a standard for care for all unbooked mothers which includes screening, obstetric, medical, surgical, and medications history, vital signs, physical examination, fetal ultrasound scan, CTG, documentation of adverse events, and women and family education.

SLB.7.3. The hospital implements a standardized set of laboratory workup for all unbooked mothers inclusive of blood type and screen with cross-match, Ferritin, Fibrinogen, CBC, RBS, Rubella IgG, HBsAg, HCV, HIV, and urine analysis.

SLB.7.4. For booked and unbooked :The hospital has policies and processes labor and delivery specific area specific to medication safety, inclusive of the to administer the necessary

medication to prevent alloimmunization during and after pregnancy to the identified at-risk patients and identifies the population requiring with documentation of the anti-D dose given.

SLB.7.5. The obstetrics department floor medications includes the following drugs: MgSO₄, Labetalol, Hydralazine, Nifedipine, calcium gluconate, Oxytocin, Methergine, Misoprostol, Prostaglandins, uterine tamponade balloons, low molecular weight heparin, unfractionated heparin, Atosiban and antibiotics.

SLB.7.6. The hospital provides the necessary vaccinations before, during, and after pregnancy including Influenza, Tdap, MMR, and Varicella vaccinations.

SLB.7.7. The obstetrics equipment checklist includes: a CTG machine, a Doppler machine, a vitals monitor, delivery beds, infusion pumps, light sources, amnihooks, vacuum and forceps, newborn resuscitation setup, ultrasound, catheters, vaginal birth sets, obstetric emergency care boxes for Postpartum Haemorrhage (PPH) and PET.

Explanations:

XXX

SLB.8. The hospital identifies and clears preventable obstacles that may delay urgent management of obstetrics cases.

SLB.8.1. There is clear documentation of delivery time, the time the urgent delivery requirement or intervention is declared necessary and the time the required intervention is actually performed.

SLB.8.2. The department identifies any obstacles to urgent intervention and applies an action plan based on these circumstances.

Explanations:

XXX

SLB.9. Physicians and midwives provide documentation for indications of any obstetric intervention undertaken: caesarean section, instrumental birth, episiotomy, and others.

SLB.9.1. Patients' medical records include information before discharge from the labor and birth ward documenting the maternal assessment and reassessment, Partogram, secured CTG or documented nursing or midwifery record of FHR by Doppler, initial neonatal assessment and birth summary.

SLB.9.2. The birth summary includes labor progress, method, birth date and time, name of the clinician who conducted the birth and any assistants, type of anesthesia, neonatal outcome, perineal trauma, any complications, the status of the placenta and membranes, and postpartum observations and instructions.

Explanations:

XXX

SLB.10. The obstetric head of department monitors the department's and clinicians' performance through KPIs.

SLB.10.1. The head of department identifies and monitors key performance indicators (KPIs) for safe obstetric practice.

SLB.10.2. Required KPIs include rate of emergency, primary and elective Lower Segment Caesarean Section (LSCS), Vaginal Birth After Caesarean (VBAC), shoulder dystocia, episiotomy, 3rd-4th degree tears, PPH ≥ 500 ml at Normal Vaginal Delivery (NVD), ≥ 1000 ml at LSCS, instrumental delivery, induction before 39 weeks without indication, and birth conducted by obstetricians/midwives.

SLB.10.3. The head of the department maintains a list the conditions considered as morbidity and mortality.

SLB.10.4. KPIs and morbidity and mortality data are discussed in monthly departmental meetings to aid in staff awareness with continuous performance improvement and action plans.

Explanations:

XXX

Glossary

Transfer of care: A transfer of care occurs whenever there is a change in the most responsible physician for a particular patient. This can take place with movement of patients between health care locations, providers or different levels of care within the same location as their conditions and care needs change

Clearance: the required minimum distance between a specified object (eg., a patient bed or exam table) and any fixed or immovable element of the environment. Note: movable equipment and furniture that do not interfere with functions or could be easily moved out of the way are not used to calculate minimum clearance.

Clear dimension: an unobstructed room dimension exclusive of built-in casework and equipment and available for functional use.

Clear floor area: the floor area of a defined space that is available for functional use excluding toilet rooms, closet, lockers, wardrobes, cubicles, hallways, anterooms, and axillary work areas. Note: door swings and floor space below sinks, counters, cabinets, modular units, or other wall-hung equipment that is mounted to provide usable floor space count toward "clear floor area". Space taken up by minor fixed encroachments that do not interfere with room functions can be included in calculating clear floor area.

Midwife: is a person who has successfully completed a midwifery education program that is based on the ICM Essential Competencies for Basic Midwifery Practice and the framework of the ICM Global Standards for Midwifery Education and is recognized in the country where it is located; who has acquired the requisite qualifications to be registered and/or legally licensed to practice midwifery and use the title 'midwife' by Saudi Commission for Health Specialties (SCFHS); and who demonstrates competency in the practice of midwifery" (Adopted from ICM international definition of the Midwife, 2017).

Midwife scope of practice: The midwife is recognised as a responsible and accountable professional who works in partnership with women to give the necessary support, care and advice during pregnancy, labor and the postpartum period, to conduct births on the midwife's own responsibility and to provide care for the new-born and the infant. This care includes preventative measures, the promotion of normal birth, the detection of complications in mother and child,

the accessing of medical care or other appropriate assistance and the carrying out of emergency measures. The midwife has an important task in health counselling and education, not only for the woman, but also within the family and the community. This work should involve antenatal education and preparation for parenthood and may extend to women's health, sexual or reproductive health and childcare. A midwife may practise in any setting including the home, community, hospitals, clinics or health units." (ICM Scope of Midwifery Practice, 2017).

Clean supply room: a room used only for storage and holding as part of a system for distribution of clean and sterile supplies does not require a work counter or a hand-washing station.

References

The Facility Guidelines Institute (2018) Guidelines for Design and Construction of Hospitals
<https://fgiguideines.org/guidelines/2018-fgi-guidelines/>

CBAHI Standards (L&D, nursing care)

International health facility guidelines (2017)

Renfrew MJ, McFadden A, Bastos MH, Campbell J, Channon AA, Cheung NF, et al. Midwifery and quality care: findings from a new evidence-informed framework for maternal and newborn care. Lancet. 2014;384(9948):1129–45.

Tunçalp Ö, Were WM, MacLennan C, Oladapo OT, Gülmezoglu AM, Bahl R, et al. Quality of care for pregnant women and newborns – the WHO vision. BJOG. 2015;122(8):1045–9. [PMC free article]

Intrapartum care for healthy women and babies. NICE clinical guideline 190. London: National Institute for Health and Care Excellence; 2014 (http://www.geburtshaus.ch/documents/upload/NICE_clinical_guideline_190_dec2014.pdf).

The health and care of pregnant women and babies in Europe in 2010. European Perinatal Health Report. Euro-Peristat Project; 2013 (<http://www.europeristat.com/images/doc/Peristat%202013%20V2.pdf>).

Rapid Response System (RRS)

Healthcare practitioners strive to achieve best practice and excellence in outcomes. However, some patients will deteriorate even with appropriate and timely care. This deterioration is commonly due to complications of the primary illness, progression of an acute illness, or the complications of correct treatment despite best practice preventive measures.

Acute deterioration is often time-critical, arising over minutes or hours rather than days or weeks. These may lead to medical emergencies, including unplanned admission to the intensive care unit (ICU), in-hospital cardiac arrest and death [1–4]. When occur, the risk of death is greater than 80 percent after in-hospital cardiopulmonary resuscitation (CPR) for cardiac arrest as indicated in several studies [5, 6].

Life threatening emergencies and events do not happen without warning. Several studies indicate that almost all critical inpatient events are preceded by warning signs for an average of 6–8 hours. [2,7,8]. In multicenter, prospective cohorts, clinical antecedents, such as a change in vital signs, are present in the majority of patients (60 to 70 percent) before in-hospital cardiac arrest occurs [3, 7] and such severe changes in vital signs were found to be associated with a 6.8-fold increase in mortality (95% CI 2.7-17.1) [9]. Simultaneously, studies in the US, Canada, Australia, and the UK[1-12] estimate that adverse events occur in 10% of hospitalized patients with a mortality rate of 5–8%,[8,9].

Unfortunately, as many as 50-70% of these adverse events are judged to be preventable. [8, 13] Of the avoidable cases, 35 percent had a delay in nursing staff communicating with the physician, and 29 percent had a delay in the physician responding to the nurse's request [13].

Another important factor affecting patient outcome in hospitals is Delay in ICU transfer for the critically ill in the wards, which is not uncommon [14] and leads to higher mortality when patient transfer to higher levels of care is delayed [15, 16]. In addition, some critically ill patients are either inappropriately admitted to the general ward, rather than to the ICU, from the emergency department or decompensate rapidly shortly after admission. Therefore, these patients' outcome would improve if they were identified and transferred earlier to the required higher level of care to facilitate timely interventions and treatment.

For those hospitalized patients experiencing clinical deterioration outside the intensive care unit (ICU), a mismatch between an acute increase in a patient's needs and available resources occur [17]. Recognizing these patients early, represent a window of opportunity in which to rescue deteriorating patients before irreversible morbidity or mortality occurs. This concept of "rescue" for the hospitalized patient has led to the development of rapid response systems (RRS) designed to identify and respond to deteriorating patients by moving critical personnel, diagnostics, and interventions to the bedside. In

2004, the Institute for Healthcare Improvement (IHI) began its “100,000 Lives Campaign,” which called for all United States hospitals to deploy rapid response teams [18]. Subsequently, the Joint Commission mandated that United States hospitals should establish RRSs as part of the 2008 National Patient Safety Goals [19] Most recently, the 2015 American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care continue to recommend RRSs, especially in general care wards [20].

Rapid response systems (RRS) are put in place to improve the safety of hospitalized patients whose condition is deteriorating quickly by identifying them by timely notification upon early signs of deterioration, bring the expertise (team of responders) capable of providing critical care resources and interventions at the patient’s current location to the patients in timely manner, rapid intervention by the response team, and ongoing evaluation of the system’s performance and hospital-wide processes of care leading to Preventing deterioration leading to life threatening events, prompt therapy and resuscitation as needed and transfer to higher level of care while promoting education and higher patient safety culture.

Generally, RRS are multidisciplinary and comprised of four limbs: 1) an afferent limb, which is the calling criteria and the method of activation, 2) an efferent limb, which is the Rapid Response Team (RRT) itself, 3) an administrative limb, which is responsible for the day-to-day running of the RRS and 4) the quality improvement and governance limb which addresses system and clinical factors contributing to deterioration [17].

In the majority of the studies, the introduction of a RRS resulted in an overall reduced rate of unexpected cardiac arrest outside ICU, unscheduled critical care admissions and hospital mortality [21-25] such as 46% reduction in cardiac arrest rates; a 54% reduction in cardiac arrest related mortality rates; a 19% reduction in hospital mortality; a 35% decrease in failure to rescue rates [26]. Similarly, delay in activation of the RRS for decompensating patients is independently associated with increased mortality [27].

Implementation of an RRS was associated with a significant decrease in hospital mortality (relative risk [RR]= 0.88, 95% confidence interval [CI]: 0.83-0.93, I(2) = 86%, 3,478,952 admissions) and a significant decrease in the number of non-ICU cardiac arrests (RR = 0.62, 95% CI: 0.55-0.69, I(2) = 71%, 3,045,273 admissions) [25,28].

In Saudi Arabia, there is published literature regarding the impact of RRS application. The hospital mortality rate dropped from 7.8 to 2.8 per 1000 hospital admission and Hospital cardiopulmonary arrest rate has dropped from 10.53 per 1000 hospital admissions to 2.58[28]. In another local study involving more than 1000 rapid response activation over a year of study period, there was low mortality rates in those RRS were activated for and have identified the risk factors higher age (>70 years). While low oxygen saturation and level of consciousness were the higher criteria for transfer to the ICU [29].

Therefore, the aim of this national priority is to establish high quality RRT service for in-patients in the Saudi hospitals which will improve patient safety, decrease in-hospital serious events and death by ensure timely evaluation/intervention for the critical ill in-patients outside the critical care areas by bringing the expertise to the in-patient bedside in timely manner.

Objectives:

1. Establish rapid response system in hospitals across Saudi Arabia.
2. Facilitate early intervention and stabilization to prevent clinical deterioration of any critically ill in-patient prior to cardiopulmonary arrest or other potentially life-threatening event.
3. Decrease the number of preventable cardiopulmonary arrest that occurs outside the ICU.
4. To facilitate timely and appropriate ICU admissions.
5. Encourage end-of-life discussions and decision-making with primary health care providers to avoid unnecessary ICU admission of terminally ill patients.
6. Encourage continued call to RRT by responding promptly and using every patient encounter as an opportunity to facilitate shared learning as well as promoting an improved culture of care.
7. Establish quality measures and ongoing audits to improve the service provided by the RRS to enhance patient safety culture.

RRS.1. The hospital has a rapid response program.

RRS.1.1. The hospital has a rapid response committee chaired by a qualified ICU consultant physician, meets regularly, and reports directly to the CEO.

RRS.1.2. The rapid response committee membership includes relevant stakeholders, including critical care, nursing, pharmacy, respiratory care, and quality and patient safety.

RRS.1.3. The rapid response committee collects, analyses, evaluates, and disseminates rapid response-specific measures benchmarked with internal and external data.

RRS.1.4. Required rapid response KPIs include: rates of activation per 1000 hospital admissions, response times, percentage transfer to ICU, transfer time, decision-to-intervention time, patient outcome(s), CPR rates with and without rapid response activation, and clinician documentation compliance.

RRS.1.5. The rapid response committee findings are incorporated into the hospital's quality and patient safety programs and are disseminated at the relevant departmental meetings with action plans for continual performance improvement.

Explanations:

Engagement of senior leadership in hospital is an essential role to assure successful implementation and continuity of rapid response team. This shows an explicit organization commitment to improve care delivery and improve outcome measures within hospitals. The involvement of leadership and establishment of a committee send a clear message to hospital staff about nature and usefulness of such team in the day-to-day clinical work. The major role of the committee is to oversee all activities related to establishing, implementing and measuring effectiveness and outcome. This will help in facilitating all recommendation modifications reflected by the KPI and quality improvement projects. The committee establishment will ensure availability of required equipment/supplies, continuous formal training and education of hospital staff and accurate monitoring of the related documentation process in the hospital.

RRS.2. The hospital has a rapid response team (RRT).

RRS.2.1. The hospital has a policy and processes for standardized rapid response activation criteria at all times, with defined response time frames for all RRT members (within 15 minutes or less) and termination criteria.

RRS.2.2. The hospital outlines the qualifications, roles, responsibilities of the RRT, comprised at a minimum with ICU physicians, ICU nurses, and RTs.

RRS.2.3. The hospital outlines the roles and responsibilities of the patient's primary nurse, most responsible physician, and the patient's 'on duty' physician.

RRS.2.4. Rapid response activation is simple, standardized, easily accessible, and recognized by all relevant staff via an overhead loudspeaker or standardized electronic system.

RRS.2.5. The hospital's rapid response system's activation criteria are based on age and condition-appropriate early warning signs (EWS, Pediatric-PEWS, Neonatal- NEWS, and Maternal -MEWS) inclusive of parameters for all vital signs as well as mental status, urine output, oxygenation requirements, and other relevant evidenced-based criteria.

RRS.2.6. The hospital's staff and RRT identify sepsis early through evidence-based sepsis early warning signs (SEWS), including qSOFA and/or SIRS.

RRS.2.7. The hospital's RRT identifies stroke, ACS/MI, and VTE early through evidence-based screening and assessment.

RRS.2.8. Any staff can activate the rapid response/RRT in any patient location in the hospital, even if the patient does not meet the EWS criteria, based solely on staff's concern or clinical judgement without any negative consequences or retaliation.

Explanations:

Typically, the afferent limb of Rapid response system is a protocolized process where a call for activation is based on the detection of physiological abnormality from the routine patient vital signs taken by in-patient nursing staff or qualitative criteria such as staff or family concern which may be of particular importance in the pediatric setting with parents detecting subtle change in a child's condition. Emergency

medication should be readily available to the RRS team for immediate use as needed and important medication to be prepared and delivered by different faster route than regular inpatient medication.

RRS.3. The hospital has policies, processes, and standardized documentation specific to rapid response.

RRS.3.1. Members of the patient's primary team document the rapid response activation in the patient's medical record, including the activation reason, signs, time, and RRT team response time on a designated rapid response form.

RRS.3.2. The RRT communicates with the primary care team about their concerns for the patient, activation, and co-develops a documented management plan including assessments, treatments, medications, interventions, and disposition status and time on a designated rapid response form.

RRS.3.3. The RRT assesses, diagnoses, and stabilizes clinical situations, including stroke ACS/MI, and VTE, per standards of care and regulations, initiating emergency care and transfer to a higher level of care, as indicated.

RRS.3.4. The RRT assesses, diagnoses, and stabilizes sepsis per standards of care and, as indicated, indicated the Hour-1 Sepsis Bundle, emergency care, and transfer to a higher level of care.

RRS.3.5. The hospital has a policy and processes for standardized and timely medication ordering, dispensing, and administration for rapid response cases.

RRS.3.6. The hospital has a policy and processes for the management and continuity of care of rapid response cases that remain in the general ward, with defined time frames by the RRT and primary nurse and physician team.

RRS.3.7. The RRT's responding physician has the authority to transfer the patient to a higher level of care and ensures clinical stability and patient monitoring during transport.

RRS.3.8. The RRT participates in end-of-life discussions, decision-making with the primary team, patient and family, and has the authority to independently refer the patient and or family to the EOLC team, as indicated.

Explanations:

Efferent limb of rapid response system is the responding team to the RRS activation. Once arrived to the bedside within the target time, handover from the primary team nurse and physician should be taken. Communication tool could be chosen as SBAR. To minimize potential clinical inefficiencies, fragmented patient care and sub-optimal handover, the care plan should be discussed with the primary team especially if the patient is to be kept in the ward. In the case of patients with terminal illness, the RRS team discuss goals of care with the treating team to avoid unnecessary ICU admission or chest compression for those who wouldn't benefit from it due to flutily.

Standardized RRS form facilitate comprehensive assessment and close follow up along with feasible way to facilitate auditing, quality review, and communication between the stakeholders.

RRS.4. The hospital has specific awareness and training for staff, patients, and families.

RRS.4.1. All hospital healthcare providers and staff receive education and training for rapid response activation, their roles, responsibilities, and awareness of no retaliation policies for activation.

RRS.4.2. All patients and families are educated on admission and ongoing about the hospital's rapid response system and their role and responsibilities related to patient deterioration.

RRS.4.3. The RRT members have specific qualifications, including valid advanced life support for all ages served.

RRS.4.4. The RRT members have specific initial and ongoing education, training courses, and as applicable, simulations and competencies for the initial management of common scenarios and emergencies encountered, including stroke, sepsis, ACS/MI and VTE, effective communication, conflict resolution, and EOLC.

RRS.4.5. The rapid response activation criteria are easily accessible and universally distributed to hospital staff, patients, and families based on the target populations.

Explanations:

Because of the wide variety of skills, knowledge and behaviour required to train a staff in the elements of RRS assessment, management and team management and leadership, there is a need to use a variety of training techniques. The structure of teaching should include both theoretical and practical components.

DRAFT

References

- Kohn LT, Corrigan JM, Donaldson MS. *To Err is Human: Building a Safer Health System*. Washington DC: National Academy Press, 2000.
- Hillman K, Parr M, Flabouris A, Bishop G, Stewart A. *Redefining in-hospital resuscitation: the concept of the medical emergency team*. *Resuscitation* 2001;48:105-10.
- Hillman KM, Bristow PJ, Chey T, Daffurn K, Jacques T, Norman SL, et al. *Duration of life-threatening antecedents prior to intensive care admission*. *Intensive Care Med* 2002;28:1629-34.
- Kause J, Smith G, Prytherch D, Parr M, Flabouris A, Hillman K, et al. *A comparison of antecedents to cardiac arrests, deaths and emergency intensive care admissions in Australia and New Zealand, and the United Kingdom--the ACADEMIA study*. *Resuscitation* 2004;62:275-82.
- Braithwaite RS, DeVita MA, Mahidhara R, Simmons RL, Stuart S Foraida M, et al. *Use of medical emergency team (MET) responses to detect medical errors*. *Qual Saf Health Care* 2004;13:255-9.
- Ehlenbach WJ, Barnato AE, Curtis JR, et al. *Epidemiologic study of in-hospital cardiopulmonary resuscitation in the elderly*. *N Engl J Med*. 2009;361(1):22-31. doi:10.1056/NEJMoa0810245
- Peberdy MA, Kaye W, Ornato JP, et al. *Cardiopulmonary resuscitation of adults in the hospital: a report of 14720 cardiac arrests from the National Registry of Cardiopulmonary Resuscitation*. *Resuscitation*. 2003;58(3):297-308. doi:10.1016/s0300-9572(03)00215-6
- Schein RM, Hazday N, Pena M, Ruben BH, Sprung CL. *Clinical antecedents to in-hospital cardiopulmonary arrest*. *Chest* 1990;98:1388-92.
- Goldhill DR, White SA, Sumner A. *Physiological values and procedures in the 24 h before ICU admission from the ward*. *Anaesthesia* 1999;54:529-34.
- Buist M, Bernard S, Nguyen TV, Moore G, Anderson J. *Association between clinically abnormal observations and subsequent in-hospital mortality: a prospective study*. *Resuscitation*. 2004;62(2):137-141. doi:10.1016/j.resuscitation.2004.03.005
- Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, et al. *The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada*. *CMAJ* 2004;170:1678-86.
- Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. *The quality in Australian health care study*. *Med J Aust* 1995;163:458-71.

McQuillan P, Pilkington S, Allan A, Taylor B, Short A, Morgan G. et al. Confidential inquiry into quality of care before admission to intensive care. *BMJ* 1998;316:1853-8.

Hodgetts TJ, et al. Incidence, location and reasons for avoidable in-hospital cardiac arrest in a district general hospital. *Resuscitation* 2002; 54:115.

McQuillan P, Pilkington S, Allan A, et al. Confidential inquiry into quality of care before admission to intensive care [published correction appears in *BMJ* 1998 Sep 5;317(7159):631]. *BMJ*. 1998;316(7148):1853-1858. doi:10.1136/bmj.316.7148.1853

Sprung CL, Geber D, Eidelman LA, et al. Evaluation of triage decisions for intensive care admission. *Crit Care Med*. 1999;27(6):1073-1079. doi:10.1097/00003246-199906000-00021

Young MP, Gooder VJ, McBride K, James B, Fisher ES. Inpatient transfers to the intensive care unit: delays are associated with increased mortality and morbidity. *J Gen Intern Med*. 2003;18(2):77-83. doi:10.1046/j.1525-1497.2003.20441.x

DeVita MA, Bellomo R, Hillman K, et al. Findings of the First Consensus Conference on Medical Emergency Teams. *Crit Care Med*. 2006; 34(9):2463-2478. [PubMed: 16878033]

Berwick DM, Calkins DR, McCannon CJ, Hackbarth AD. The 100,000 Lives Campaign. *JAMA*. 2006; 295(3):324. [PubMed: 16418469]

The Joint Commission. [Accessed February 15, 2018] National patient safety goals. 2008. http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/08_hap_npsgs.htm

Kronick SL, Kurz MC, Lin S, et al. Part 4: Systems of care and continuous quality improvement: 2015 American Heart Association guidelines update for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2015; 132(18):S397-S413. [PubMed: 26472992]

Chan PS, Jain R, Nallmothu BK, Berg RA, Sasson C. Rapid response teams: A systematic review and meta - analysis. *Arch Intern Med*. 2010;170(1):18-26.

Al-Qahtani S, Al-Dorzi HM, Tamim HM, Hussain S, Fong L, Taher S, et al. Impact of an intensivist - led multidisciplinary extended rapid response team on hospital - wide cardiopulmonary arrests and mortality. *Crit Care Med*. 2013;41(2):506-17.

Winters BD, Weaver SJ, Pfoh ER, Yang T, Cuong J, Dy SM. Rapid - response systems as a patient safety strategy: A systematic review. *Ann Intern Med*. 2013;158(5 PART 2):417-25.

Maharaj R, Raffaele I, Wendon J. Rapid response systems: A systematic review and meta - analysis. *Crit Care*. 2015;19(1):254.

Solomon RS, Corwin GS, Barclay DC, Quddusi SF, Dannenberg MD. Effectiveness of rapid response teams on rates of in - hospital cardiopulmonary arrest and mortality: A systematic review and meta - analysis. *J Hosp Med.* 2016;11(6):438–45

Jack Chen, Lixin Ou, Arthas Flabouris et al; Impact of a Standardized Rapid Response System on Outcomes in a Large Healthcare Jurisdiction. August 2016 *Resuscitation* 107. DOI: 10.1016/j.resuscitation.2016.07.240

Boniatti MM, Azzolini N, Viana MV, et al. Delayed medical emergency team calls and associated outcomes. *Crit Care Med.* 2014;42(1):26-30. doi:10.1097/CCM.0b013e31829e53b9

Jack Chen, Lixin Ou, Arthas Flabouris et al; Impact of a Standardized Rapid Response System on Outcomes in a Large Healthcare Jurisdiction. August 2016 *Resuscitation* 107. DOI: 10.1016/j.resuscitation.2016.07.240

Al-Omari et al. *International Journal of Emergency Medicine* (2019) 12:31

Alhaidari A, Busuhail M, Alsultan S, Alshammari S, Alshimemeri A. Exploring factors affecting critical care response team service at a tertiary hospital in Riyadh: A retrospective cohort study. *Saudi Crit Care J [serial online]* 2020 [cited 2021 Apr 5];4:123-9. Available from: <https://www.sccj-sa.org/text.asp?2020/4/4/123/305823>

CBAHI standards 2016 3rd edition

Joint Position Statement on Rapid Response Systems in Australia and New Zealand and the Roles of Intensive Care. (http://cicm.org.au/CICM_Media/CICMSite/CICM-Website/Resources/Professional%20Documents/IC-25-Joint-ANZICS-and-CICM-Rapid-Response-Systems-Position-Statement.pdf)

https://www.cicm.org.au/CICM_Media/CICMSite/Files/Professional/IC-8-Guidelines-on-Quality-Improvement.pdf

Jones DA, DeVita MA, Bellomo R. Rapid-response teams. *N Engl J Med* 2011; 365:139.

Patient Transfer (PT)

One of the main strategic objectives of Saudi Arabia's Vision 2030 is to ease access to care and improve the quality and efficiency of healthcare services. The wide variability of healthcare services and population across the Kingdom has made patient transfer an essential part of achieving these objectives. The Kingdom of Saudi Arabia (KSA) has numerous healthcare facilities which include but are not limited to hospitals, medical cities, and specialized centers. As highly specialized care is currently available mainly in the big cities, the accessibility for such services is very challenging in peripheries without appropriate patient transfer guidelines. Based on Ministry of Health (MOH) data, there were around 354,275 transfer requests through the Saudi National Referral System (EHALA) in 2020. Therefore, the Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) identified patient transfer as a national health priority.

Patient transfer is a frequently performed task during care of hospitalized patients. Patient transfer is an essential part of patient care that is usually undertaken to improve patient management. Transfers may be due to various reasons such as patients requiring specialized care not available in the referring location or a need for advanced diagnostic skills or equipment. Specialized care that requires transfer could include, for instance, pediatrics neuroscience, spinal injury burns, or a variety of other specialties.

Furthermore, patients are often transferred within the same hospital. This may involve transferring patients between hospital units for diagnostic or therapeutic procedures, or even for consultation. Patients may come from the Emergency Department (ED), Operating Rooms (OR), Critical Care Units (CCU), wards, or any other hospital areas. During all types of transfers, the main aim is to maintain the continuity of medical care. Patient transfer is particularly challenging when patients are moved to a new environment with different care settings and staff. In addition, the transfer of an ill patient can induce various alterations of the clinical status, such as deterioration of physiological parameters including hemodynamic instabilities or other vital parameters, or displacement or malfunctioning of tubes, lines or equipment which can also adversely affect the status of the patient. Therefore, the transfer process should be reviewed thoroughly, and it should be initiated

systematically and according to the evidence-based guidelines. The critical elements of safe transfer involve appropriate decision to transfer and proper communication, pretransfer preparation, stabilization, suitable escorts and personnel accompanying the patient, choosing the proper mode of transport, monitoring equipment during the transfer, accurate and comprehensive documentation and correct hand-over at the receiving hospital or other facility.

Incorrect transfer mechanisms and dynamics can put the patient in a potentially dangerous environment and has the potential for multiple miscommunication risks. Moreover, the transferring team is mainly operating independently. Hospitals that conduct patients' transfers should ensure proper protocols, personnel, equipment, training, and support to ensure the patient's optimal health and wellbeing during the transfer process. It is essential that a standardized and complete approach is taken to patient transfer; beginning with the transfer decision until handover of the patient to the receiving unit.

Multiple guidelines have been proposed to perform the patient transfer safely. The various professional bodies have formulated guidelines for safe patient transfer, including the Ministry of Health (MOH), American College of Critical Care Medicine, American Society of Critical Care Medicine, Association of Anesthetists of Great Britain and Ireland, American Society of Anesthesiologist. The guidelines emphasized different key elements; however, all the guidelines maintain the principal goal of a safe transfer.

Written transfer protocols and interfacility agreements should be in place, especially when patients' transfer is part of a regional plan to provide optimal care at a specialized medical facility.

Patient transport is an essential part of a patient-centered approach of care and positive patient experience. The transfer decision should be undertaken when the benefits of transfer outweigh the risks. The choice of receiving hospitals should be based primarily on specialized care availability and proximity to the referring hospital. The aim is to seek transfer to a nearby hospital that provides a high level of quality care. The level of care provided during patient transport should be based on the patient's clinical status, national standards and regulations and any anticipated problems. The transport team should have policies and procedures to direct their practice. Documentation of the

transport process should be initiated once the transfer decision is made and continued until the transport process is completed. The transport team should be capable of evaluating the patient's response during the transport. It is known that education and proper preparation are key to any safe transfer.

The Operating Room (OR) is a critical area in all healthcare facilities with high financial value and significant impact. OR transfers require a specific patient's handling process for perioperative patient transfer to maintain efficient flow and proper bed utilization. Furthermore, the OR handles all patient categories, from different locations, regardless of their current medical condition. Transfers to the OR may come from a variety of locations including Intensive Care Unit (ICU), Pediatric Intensive Care Unit (PICU), Neonatal Intensive Care Unit (NICU), Emergency Department (ED) or other specialty areas, thus this variety necessitates a standardized protocol for bidirectional communication and transfer processes.

In addition, the transfer process in OR should maintain a procedure to reduce human factors affecting the transfer and patient safety. The goal is to maintain proper situational awareness, proper communication channels, and closed-loop communication between healthcare providers.

Transporting a critically ill patient is usually associated with significant complications. For any hospital to reduce the patient's risks, such transports should be appropriately organized, accompanied by the proper personnel and equipment and efficiently done. Guidelines and Protocols for transferring critically ill patients should be fully used across all healthcare facilities. In addition, care provided during transportation and at the site of the procedure or diagnostic testing should be equivalent to the care delivered in the originating unit.

It is known that timely transfer of patients from the ICUs to the wards is one aspect of proper hand-over, which positively affects overall patient care. Although optimal patient flow is critical to ensure quality patient care, there is no clear evidence regarding the best way to achieve a safe and efficient patient transfer from the ICUs, particularly in the pediatric population.

Another consideration to keep in mind is critically ill neonates. Neonates may have absent or small physiological reserves, which makes them very susceptible to a life-threatening situation. Such

threats may result in adverse physiological changes in these patients during intra- or inter-hospital transport. Ventilator-dependent and hemodynamically unstable patients are at notably higher risk.

Careful planning is always required to move these critically ill patients between the different hospital units such as ICUs, operating theatres, medical imaging rooms, emergency departments, and general wards. Although, most intra-hospital transfers (defined as transferring patients between hospital units) are elective, the need for urgency should always be anticipated such as moving the patient to the operating theatres after a diagnostic procedure.

Interfacility transport is defined as the transport of patients between two healthcare organizations. The process is generally accomplished through ground transportation. Interfacility transfers, either for a stable (not urgent) or a critical (urgent) patient, is a crucial part of today's healthcare system that allows hospitals to transfer patients needing specialized care which cannot be adequately performed in their current facility.

This document and standards aim to provide standardized transfer procedures that will ensure the safest inter and intra facility transfers for all patients while maintaining a continuum of care. It aims to minimize risks and maximize patient safety during transfers based on the current evidence-based practice and agreed upon recommendations in this regard.

PT.1. The hospital has policies and processes for all patient transfers.

PT.1.1. The hospital has a policy and processes for internal patient transfers between units/clinical areas, including to and from procedural/investigation areas.

PT.1.2. The hospital has a policy and processes for external patient transfers, accepting and receiving patients to and from external hospital.

PT.1.3. The hospital has patient transfer criteria for all categories of patients, including vulnerable/high-risk patients, urgent cases, critically ill patients, ED and trauma patients, all age groups, newborns, pregnant women, women in labor, and prisoners.

PT.1.4. Hospital policies outline the minimum time between vital signs completed and patient transfer based on patient categories and type of transfer.

PT.1.5. The MRP/sending physician remains responsible for the patient throughout the entire patient transfers until, when applicable, the receiving physician/hospital accepts the patients and the transfer of responsibility of patient care is completed for both internal and external patient transfers.

PT.1.6. There are acceptance processes and structured handover communication tools between the sending unit/clinical area or hospital and the accepting unit/clinical area or hospital, including ambulance EMS/EMT handover.

PT.1.7. Morbidity and mortality data related to patient transfers are discussed in relevant monthly departmental meetings with continuous performance improvement and action plans.

Explanations:

Each hospital ensures the availability of a policy to guide and standardize patient transfer across all its units. This policy is accessible, maintained and followed by all concerned staff. In addition, there is a justified clinical indication for each transfer. The transfer is based on the patient's medical needs for the care continuum and the resources' availability.

The policy indicates the minimum required patients' information for a safe and efficient admission process. The minimum information includes full patient name, age, and gender, referring hospital contact details, current patient location, receiving location, attending physician contact details, infection control status, and all relevant clinical notes. The minimum information also includes the patient's current status including mental status, vital signs, use of oxygen and type, allergies and any medication that cannot be stopped during the transfer.

Referring physicians assess the stability of the patient and continuity of care and ensure that all required resources, including appropriate staff, functioning equipment, needed medication and/or blood that is required are available as needed. To maintain the continuity of care there is a team lead that is responsible for the patient throughout the transfer.

PT.2. The hospital ensures the availability of required equipment for safe patient transfers.

PT.2.1. The hospital has a policy and processes to ensure all equipment for patient transfer is readily available and regularly checked and maintained, with identified, dedicated equipment secured at all times for emergency or critical care patient transfer.

PT.2.2. A transport incubator is utilized for all neonatal transfers determined at risk for hypothermia.

PT.2.3. The equipment is durable, and trolley-linked devices are able to enter lifts and pass through all doorways en route.

Explanations:

The patient transfer process is part of patient care and continuity of a high quality of care during the transfer is essential. To achieve continuity of care, appropriate equipment is always available and ready to be used based on each patients' conditions. This equipment is dedicated for use in the transfer process and includes a minimum of basic items including ECG monitors, heart rate monitors, blood pressure monitors and oxygen saturation monitors (pulse oximetry).

Additional equipment for critical and ventilator-dependent patients is available, such as end-tidal Co2 monitors, defibrillator, suctioning device, portable ventilator with a disconnect alarm, manual resuscitator

bag, infusion pumps, fully charged batteries with spare packs for all electrically driven devices, age-appropriate equipment to secure airways, emergency drugs, analgesics, sedatives and muscle relaxants.

For external transfers, the hospital ensures the ambulance is equipped with standardized supplies and equipment to provide the safest and highest level of patient care. The minimum required equipment and supplies necessary to stock the ambulance adequately includes but is not limited to intubation and ventilation equipment/supplies, vascular access supplies, portable battery-operated monitor/defibrillator, glucometer or blood glucose measuring device, ambulance stretcher, portable suction with required supplies, ventilator, immobilization devices, intraosseous drill, adequate oxygen cylinder with a regulator, airway supplies, emergency medications, obstetrical kit, infection control supplies, bandages, gloves and emesis bags. All equipment is periodically checked by biomedical engineering, and records are maintained. Equipment supports direct clinical monitoring and no equipment is placed on the patient during the transfer process.

PT.3. The hospital has pre-transfer processes.

PT.3.1. The transfer of patient responsibility from one physician to another or from one healthcare provider to another is guided by a hospital policy and is documented in the patient's medical record.

PT.3.2. Transfer of patient care responsibility between physicians requires the receiving physician acceptance of the patient prior to the patient's departure, with written agreement documented in the medical record.

PT.3.3. The receiving unit/clinical area/hospital staff are notified and accepts the patient for transfer, prior to the patient's departure.

PT.3.4. Prior to departure, the minimum number of staff and their qualifications, including ACLS, PALS, NRP as appropriate for patient age and clinical condition are determined by the primary medical and/or nursing team.

PT.3.5. The patient has a documentation/checklist as part of the medical record inclusive of allergies, code status, fall risk level, oxygen requirements, isolation status, NPO status, and vital signs when there is a transfer of patient care responsibly.

PT.3.6. The medical record, all required equipment and imaging films are sent with the patient, as per documentation/checklist.

PT.3.7. The time the patient leaves the sending clinical area is documented.

PT.3.8. The sending unit/clinical area/hospital sends communication of any new update or change in patient's condition, prior to departure.

PT.3.9. A complete and updated medical report and patient care report, with a recent full assessment, is sent with the patient for all external patient transfers.

Explanations:

XXX

PT.4. Continuity of care is maintained during transfer.

PT.4.1. The most efficient route for the transfer is planned and selected in advance.

PT.4.2. Lifts are secured or reserved prior to patient transfer, for critically ill patients, patients being transferred from OR or PACU and as determined by the medical team prior to transport.

PT.4.3. Patients in transit are continuously monitored. Any change in the patient's condition, unexpected event, or incident that occurs during the transfer is acted upon immediately, communicated with, the MRP, and, as applicable, with the receiving unit/clinical area/hospital.

PT.4.4. Adequate communication tools are available during transit and at the destination with communication about the patient's condition or the need for additional qualified staff able to be secured, as needed.

Explanations:

Continuity of care during transfer promotes patient safety and assures quality of care. Inappropriate patient transfer can significantly contribute to morbidity and mortality. The receiving facility provides the patient with equal quality of care and monitoring as his point of origin to avoid any deterioration or negative impact on the overall patient's clinical status.

PT.5. The hospital has on-arrival processes.

PT.5.1. The patient is assessed when the equipment, new monitors, ventilators (if used), gas and power supplies are established.

PT.5.2. Existing medical devices, lines, tube and drains, are verified in the presence of the sending and receiving staff.

PT.5.3. The transport staff remain with the patient until the receiving staff acceptance, and when applicable, handover and transfer of care responsibility with arrival date/time documented.

PT.5.4. For external hospital transfer, a standardized patient care report is signed by the receiving team upon accepting the patient.

Explanations:

XXX

PT.6. There are Operating Room (OR)/remote procedural area patient transfer processes.

PT.6.1. A pre-operative/pre-procedural checklist is completed for all OR patients prior to transfer including in the handover, as per policy, with emergencies being exempt.

PT.6.2. Patients transferred to the recovery room/ICU are accompanied by a qualified member of the anesthesia team.

PT.6.3. All posts-op newborns are transferred directly form the operating room (OR) to the NICU accompanied by a NICU nurse, pediatric anesthesia physician with complete in-person handover to NICU medical team.

PT.6.4. The patient is evaluated and accepted by the receiving team upon arrival at the recovery/PACU/ICU.

Explanations:

When the patient arrives at the OR, a checklist is completed by preoperative nursing staff; the checklist uses the "Yes," "No," and "Not Applicable" format.

The assigned nurse endorses all the preoperative Checklist findings to the receiving nurse in the operating room. In the operating room the receiving nurse reviews all the preoperative checklist findings with the assigned nurse and confirms them in writing.

The nursing preoperative checklist contains the following elements as a minimum: evidence of completed relevant consents, history and physical examination by medical and nursing staff, site marking, results of requested investigations, requested blood or blood products, removal of dentures and loose objects such as eye lenses, eyeglasses, removal of jewelry and the patient's valuables. Prior to conducting transfers in the hospital, a clear written policy to regulate the (bidirectional) mechanism of communication between the operating rooms and PACU is in place to ensure the readiness of both locations prior to each transfer. Shifting the patient within the OR needs to be minimized to reduce harm to the patients.

PT.7. There are newborn and neonatal specific patient transfer processes.

PT.7.1. All newborns transferred from an external hospital are directly admitted from the ambulance to NICU without any stops in other areas.

PT.7.2. Any newborn or neonate with surgical intervention under general anesthesia is admitted directly from the OR to level 3 NICU.

PT.7.3. Any newborn or neonate less than 28 days old or <28 days old and identified as at-risk for hypothermia is transported in an incubator with appropriate warming and regular temperature measurements.

PT.7.4. All NICU admissions require vital signs with temperature immediately upon arrival with full assessment and blood gases including lactate level, if on respiratory support.

Explanations:

XXX

DRAFT

References

Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) 3rd Edition

Ministry of Health, Kingdom of Saudi Arabia

Minimum standards for intrahospital transport of critically ill patients, Australasian College for Emergency Medicine, Australian and New Zealand College of Anaesthetists, Joint Faculty of Intensive Care Medicine

American Society of Anesthesiologists

The Association of Anaesthetists of Great Britain and Ireland

Appropriate Interhospital Patient Transfer, Annals of Emergency Medicine, Volume 54, Issue 1, 2009, Page 141, ISSN 0196-0644, <https://doi.org/10.1016/j.annemergmed.2009.04.012>.

(<https://www.sciencedirect.com/science/article/pii/S019606440900403X>)

Bowen SL. Transport of the mechanically ventilated neonate. Respir Care Clin N Am. 2002 Mar;8(1):67-82. DOI: 10.1016/s1078-5337(02)00017-5. PMID: 12184658.

Lin SJ, Tsan CY, Su MY, Wu CL, Chen LC, Hsieh HJ, Hsiao WL, Cheng JC, Kuo YW, Jerng JS, Wu HD, Sun JS. Improving patient safety during intrahospital transportation of mechanically ventilated patients with critical illness. BMJ Open Qual. 2020 Apr;9(2):e000698. DOI: 10.1136/bmjopen-2019-000698. PMID: 32317274; PMCID: PMC7202726

Knight PH, Maheshwari N, Hussain J, et al. Complications during intrahospital transport of critically ill patients: Focus on risk identification and prevention. Int J Crit Illn Inj Sci. 2015;5(4):256-264. doi:10.4103/2229-5151.170840

Ali H, Kazzaz Y, Alshehri A, et al. Reducing unnecessary delays during the transfer of patients from the paediatric intensive care unit to the general ward: a quality improvement project. BMJ Open Qual. 2019;8(3):e000695. Published 2019 Sep 4. doi:10.1136/bmjopen-2019-000695

Rafa Janowicz 2017 IOP Conf. Ser.: Mater. Sci. Eng. 245 052088, Ergonomic Aspects of Transport of Patient through the Operating Theatre

Jt Comm J Qual Patient Saf. 2016 September ; 42(9): 400–414. Operating Room–to-ICU Patient Hand-overs: A Multidisciplinary Human-Centered Design Approach

Ashish Kulshrestha and Jasveer Singh. Inter-hospital and intra-hospital patient transfer: Recent concepts. Indian J Anaesth. 2016 Jul; 60(7): 451–457. DOI: 10.4103/0019-5049.186012

Nicole Blay , Michael Roche , Christine Duffield , Xiaoyue Xu. Intrahospital transfers and adverse patient outcomes: An analysis of administrative health data. J Clin Nurs 2017 Dec;26(23-24):4927-4935. DOI: 10.1111/jocn.13976. Epub 2017 Oct 10. PMID: 28748563

*Despoina G. Alamanou 1 , Hero Brokalaki. Intrahospital transport policies: The contribution of the nurse. HEALTH SCIENCE
JOURNAL VOLUME 8 (2014),ISSUE 1*

DRAFT

Intensive Care Units (ICC)

Critical illness is the most severe and devastating stage of any acute disease. The ability of any medical system to provide measures and therapies to improve outcomes depends on the presences of good critical care service. Critical or intensive care provided in specific units are called critical or intensive care units (ICUs). Critical illness has been crudely estimated to result in several million deaths globally each year. The outcomes of them depends on the standards of care of units hosting patients. The importance of ICU becomes clear with the advance of medical and surgical therapies for different illness. During disaster and pandemics, the pressure on ICU and the need for organ and lives saving measures paly a measure and pivotal role in the success to manage such situation and reduce mortalities.

Establishing an ICU in every institution must match the services, patients' population, and complexity of care. A minimum standard in every ICU is essential to provide safe and efficient care. In addition, recognizing the vital role of ICU make a focus on the ICU in the health system as a national health priority to set a required standard to ensure ability of any health care facility to provide the expected role and services, to contribute to the accommodation and management of any unforeseen situation facing the whole system, and setting a standard that matches the level of care provided in each ICU and guide the institution to provide best quality care.

It is essential to develop these standards for critical care services in relation to healthcare providers, hospital space, tools utilized and processes of coordination among all these aspects.

As the nature and delivery of intensive care services are evolving with great speed. With both increased in complexity of treatments being delivered and, in the types / levels of facilities to accommodate changes in service delivery. Patients in critical care units require complicated care plans, rapid decision making, close monitoring, and constant support from highly trained workforces specialize in caring for the sickest of patients.

The annual cost is a challenging aspect of medical care, particularly in critical care units. It was estimated to represent an average of 13% of the actual health care costs worldwide. While a lot of these expenses are attributed to waste, some of them were related to lack of knowledge of what are the minimum requirements to run a safe practice. Hence, a lot of resources are consumed to cover up pitfalls and retrospective catch up.

In fact, evidence confirms that the likelihood of serious complications and mortality rates increases when fewer workforces especially registered nurses assigned to patient care. Similarly, a considerable amount of research indicates healthy work environments and better patient outcomes when a higher percentage of patient care delivery provided by registered nurses.

It is important to note different levels of critical care services provided by different critical care units. While this is essential to create a level of challenge among ICUs to provide the right level of care, it also helps to know what is needed to reach advanced care.

In this document, we will discuss the minimum required standard of care according to each ICU levels. These standards are to be met on minimum basis and they would specify the level that needs to coincide with the level of service provided. In addition, will review the current CBAHI version (V3)- AICU- standards with a huge emphasis on staffing, equipment, design and structure, handover and safe transfer, and delivery of safer care domains and link it with appropriate level of care.

DRAFT

ICC.1. The hospital ensures sufficient adult and pediatric intensive and critical care bed capacity and care capabilities.

ICC.1.1. Hospitals with adult and pediatric intensive care capabilities have a minimum of 5-6 ICU beds for the hospital or have dedicated 5-10% of its total number of hospital beds number as ICU beds, for both adult and pediatric patients.

ICC.1.2. The provision of safe critical care and standards of care are equitable to all critically ill patients, all ages, regardless of the patient's physical location, in or out of an ICU unit, with care coordinated among the MDCT.

ICC.1.3. The critical care patient or ICU patient, all ages, regardless of the patient's physical location, is visualized at all times inside their bed area.

ICC.1.4. The hospital has policies, processes and network agreements for surge capacity and internal and external staff augmentation strategies.

Explanations:

XXX

ICC.2. The physical structure and design of the ADULT ICU room provides a safe environment to care for the critically ill patient.

ICC.2.1. Each patient area is a minimum of 20 m² for a shared room and >25 m² for a single room and the clear area floor/traffic area is least 2.5 meters beyond the bed.

ICC.2.2. Each ICU bed, on both sides of bed, has an adequate electrical outlet according to the level of care: a minimum 6 outlets (L1), a minimum 10 outlets (L2) and a minimum of 16 outlets (L3).

ICC.2.3. Each ICU bed has a minimum of 2 oxygen outlets, with each Level 3 ICU bed having 3 oxygen outlets.

ICC.2.4. Each bed has adequate compressed air outlets according to the level of care; Minimum 1 compressed air outlet and 2 compressed air outlets.

ICC.2.5. Each bed has adequate vacuum outlets according to the level of care; Minimum 1 to 2 vacuum outlet, Minimum 2 vacuum outlet and Minimum 3 vacuum outlet.

Explanations:

XXX

ICC.3. Adult and pediatric ICUs have critical care monitoring and care.

ICC.3.1. ICU has monitors telemetry observation of the cardiac rhythm for each ICU patient inclusive with the minimum requirements of oxygen saturation with waveform, arterial line waveform and systolic and diastolic blood pressure mean calculation.

ICC.3.2. A sufficient number of ICU telemetry monitors have the capability provide pulmonary artery (PA) catheter waveform, carbon dioxide (CO2) capnography waveform, or pulse pressure variation (PPV), via the appropriate inserted devices.

ICC.3.3. Infusion pumps for critically ill patients allow for the titration of vasopressors, the infusion of different intravenous fluids, and the transfusion of blood products.

Explanation

These standard highlights the importance of having functioning equipment that support the care of critically ill patient.

ICC.4. Adult and pediatric critical care units are equipped with the required resources.

ICC.4.1. ICU beds have adjustable angles, heights, and positions to prevent HAI pneumonias, while temporarily allows flattening for procedures and care interventions, inclusive of Trendelenburg, and reverse Trendelenburg positions.

ICC.4.2. Each patient's bed has flow meters, with up titration to 15 Liters per minute of oxygen flow available at all times.

ICC.4.3. Critical care noninvasive ventilators provide continuous positive airway pressure (CPAP): single leveled positive airway pressure on a continuous manner and double leveled positive airway pressure (BIPAP) via inspiratory (IPAP), and expiratory pressure (EPAP).

ICC.4.4. Critical care invasive mechanical ventilation (MV) provides volume controlled, pressure controlled, or pressure supported modes of MV with adjustable pressure and volume settings, fraction of inspired oxygen delivered controls and respiratory rate provided, and humidifying capacity.

ICC.4.5. The minimum respiratory equipment for all levels of critical care units, available at all times in identified sufficient quantities, includes direct functional laryngoscopy, endotracheal tubes with different sizes, bag-valve-mask devices, and oropharyngeal and nasopharyngeal airways.

ICC.4.6. All higher-level critical care unit have, available at all times in identified sufficient quantities video laryngoscopy device(s) and its relevant supplies.

ICC.4.7. Level 3 critical care units have at all times and in identified sufficient quantities, percutaneous Tracheostomy insertion kits, various tracheostomy tube sizes for exchange, bronchoscopy devices and their sterilization, difficult airway kits, cricothyrotomy kits, and laryngeal mask airways.

ICC.4.8. Mouth airway clearance suction devices and tubes are available close to at the bed of the patient.

ICC.4.9. All ICUs have suction ports through the wall of the room available at all times, portable suction devices, in sufficient quantity per level of care.

Explanation

This standard indicates a mandatory presence of noninvasive ventilation machines to provide positive airway pressure, as well as mechanical ventilation for patients who are endotracheally intubated or have tracheostomy tube placed. It outlines needed basic features for any functioning critical care unit. It also mentions what upgraded features if available to correlate with what level of critical care unit function Guide: Regardless of all detailed specifications, surveyors should look for basic features for respiratory support machines that have to be there for assessing ICUs.

ICC.5. The intensive care units have qualified physician and nurse leadership and staff.

ICC.5.1. The adult intensive care unit head of department is a qualified board certified in critical care adult intensivist consultant physician.

ICC.5.2. The pediatric intensive care unit head of department is a qualified pediatric consultant physician.

ICC.5.3. For both pediatric and adult ICUs, a minimum of two full-time consultants per unit is employed at all times.

ICC.5.4. All medical staff working in the ICU who are not board certified in critical care hold training on fundamental critical care support (FCCS) or equivalent.

ICC.5.5. The nurse manager/head nurse of the adult ICU holds a baccalaureate degree in nursing and SCFHS as a specialist or higher.

ICC.5.6. The nurse manager/head nurse of the Pediatric ICU holds a baccalaureate degree in nursing and SCFHS as a specialist or higher.

Explanations:

XXX

ICC.6. The adult and pediatric intensive care units have admission and discharge criteria.

ICC.6.1. The admission and discharge criteria for adults and pediatric patients are defined physiological parameters and per scope of service, with specific admission and co-management guidelines for pediatric patients with height, weight, and developmental considerations.

ICC.6.2. The hospital has policies and process for ICU MRP, co-management, inclusive of the primary services physician a member of the MDCT while the patient is admitted in the ICU, and ICU physician coverage outside of the critical care units, as applicable.

ICC.6.3. The ICU physician and the primary physician jointly make the decision to admit and discharge patients from the ICU.

Explanations:

XXX

ICC.7. The hospital ensures standardized processes and protocols for adult and pediatric critical care based on national and cited international standards.

ICC.7.1. The hospital has policies and procedures for patient care specific to adult and pediatric critical care, inclusive of medical and nursing initial assessments and re-assessments minimum requirements, including time frames and guidelines for monitoring patient circulation, respiration, and oxygenation.

ICC.7.2. There are evidence-based criteria for intubation, weaning off ventilator and sedation and extubation.

Explanations:

XXX

ICC.8. The hospital has a policy and processes to identify and notify Saudi Center for Organ Transplantation (SCOT) of potential organ donors.

ICC.8.1The hospital in collaboration with the intensive care unit establishes communication and collaboration with the Saudi Center for Organ Transplantation (SCOT).

ICC.8.2The hospital has criteria to identify, notify, document, and manage potential donors based on the registry of organ donation and transplantation in Saudi Arabia.

ICC.8.3The hospital reports all cases of potential deceased Donors after Brain Death (DBD) to SCOT within the time frames.

ICC.8.4The hospital reports all cases of potential deceased Donors after Circulatory Death (DCD) to SCOT within the time frames.

ICC.8.5The hospital establishes and uses criteria that support the effectiveness of the donation process (patient factors, time since perfusion of the tissue stopped, maintenance of viability by appropriate care of the body between death and donation).

Explanations:

XXX

ICC.9. The critical care units' heads of department monitor the departments and clinicians' performance through KPIs.

ICC.9.1. The heads of the department identify and monitor key performance indicators (KPIs).

ICC.9.2. Required KPIs include: XXX

ICC.9.3. The heads of the department maintain a list the conditions considered as morbidity and mortality.

ICC.9.4. KPIs and morbidity and mortality data are discussed in monthly departmental meetings to aid in staff awareness with continuous performance improvement and action plans.

Explanations:

XXX

DRAFT

Neonatal Care Safety (NIC)

It is estimated that every year, worldwide 2.7 million babies die during the first 28 days of life and 2.6 million babies are stillborn. Lower perinatal and neonatal mortality have been achieved in the developed and high-income countries following advancement of neonatal care, introduction of high technologies, and better knowledge of pathophysiology of the newborn infants. Studies clearly indicate that countries with high maternal, perinatal, and neonatal mortality have inadequate and poor-quality health services and this can be associated with reduced utilization of health care services. As such, increased emphasis is being placed on the need for standards of care, as well as mechanisms which address the barriers to provision and use of quality care.

There is a global movement to end preventable maternal and newborn deaths and stillbirths. To reach 2030 national targets for neonatal mortality and stillbirth rates of ≤ 12 per 1000 births, high and equitable coverage of the evidence-based interventions is needed.

Neonatal care occurs in environments that are extremely dynamic and complex, and the nature of the work performed in those environments requires that correct decisions be made, and appropriate interventions be carried out, often while working as a member of a multidisciplinary team in the context of intense time pressure. quality deficits in the neonatal intensive care setting is the widespread birth of inappropriate care—defined as underuse, overuse, and misuse of interventions. Examples include the underuse of hand hygiene by NICU personnel, the overuse of antibiotics, and the misuse of medications because of medical errors.

It is the right of every newborn to the highest attainable standard of health and health care to ensure every newborn has the chance to live a healthy and productive life.

The birth of safe, effective, and efficient care to ill neonates is the goal of every neonatologist. In this new era, health professionals in neonatology must learn how to evaluate themselves and learn how they will be evaluated by others, including policy makers, hospital administrators, regulators, payers, and the families and public they serve.

Getting this early care right is the responsibility of the national health system at all levels.

Safe, effective, and organized neonatal care can make a lifelong difference to premature and sick newborn babies and their families.

The Standards for Maternal and Neonatal Care can represent a useful tool for facilitating a systematic approach to evaluate and improve the care provided by maternal and neonatal health services.

Utilizing document review, observational, and staff interview for reviewing structures, processes, and outcomes in the health care institutions to ensure safe Newborn Care in the following elements:

1. Ensure clear Newborn identification process.
2. Prevent Newborn Abduction.

3. Availability of safe NICU Structure, Equipment, medications & NICU workforce
4. Availability of safe in and out Newborn transfer
5. Availability of safe operating room for newborns
6. Implementing all mandated Newborn Screening & Preventive measures
7. Implementing Neonatal clinical guidelines and Policies
8. Ensure Follow up and continuity of care & Care at the End of Life
9. Availability of Allied Health Professionals (Multidisciplinary Team) (Dietitian, Health Educator, Occupational Therapy and Physiotherapy in the NICU, Speech & Language Therapy, Social Services, clinical Pharmacists.
10. Ensure implementing newborn individualized developmental care and measuring the family Satisfaction.(NIDCAP)
11. Follow up with neonatology clinic and High Risk Program clinics

DRAFT

NIC.1. The hospital provides a secure newborn environment.

NIC.1.1. The hospital has continuous monitoring at all times of all doors/entrances. All hospital.

NIC.1.2. All levels of neonatal care have only 1 main entrance with locked, restricted access control.

NIC.1.3. The hospital has a locked, restricted access control system to newborn neonatal care areas and exits, with exit doors monitored by video surveillance cameras at all times with date/time stamp capability.

NIC.1.4. The hospital limits visitors to neonatal care areas at all times with monitoring of the unit's main entrance.

NIC.1.5. The hospital has an identification process of all visitors entering neonatal and postpartum areas with no individual allowed entrance to the areas without proper identification.

NIC.1.6. All healthcare workers handling newborns are well identified with a unique uniform and a hospital identification badge.

NIC.1.7. All newborns in bassinets are transported by 1 staff and newborns in incubators are transported by two staff (one being a nurse or midwife) with newborns NEVER 'carried' or left unattended without direct supervision in any area.

NIC.1.8. A well-baby healthy newborn is either under the direct responsibility of the mother or the newborn nursery staff/OB GYNE/, if for any reason the mother is unable to care for the newborn.

NIC.1.9. Verification of the mother's identity is done every time the newborn is endorsed the care to the newborn or returned to well-baby nursery.

NIC.1.10. After mother identification verification is completed, the mother is encouraged to visit her newborn and participate in the newborn's care and management.

Explanations:

XXX

NIC.2. The hospital has a policy and processes to prevent newborn abduction.

NIC.2.1. The hospital has an infant abduction code and code activation system.

NIC.2.2. The hospital has a functional infant security tag or abduction alarm system that can trigger alarms, locks doors, and freezes elevators if the infant comes within 1.2 meters of an exit or elevator prior to transfer for all neonatal care areas/ well-baby nursery levels entire hospital.

NIC.2.3. The hospital has a tracking system to document the infant's location at all times.

NIC.2.4. The hospital conducts, at minimum, twice yearly unannounced infant abduction mock codes.

NIC.2.5. The hospital provides staff education and training on abduction prevention procedures across the continuum of care and an infant abduction critical incident response plan.

NIC.2.6. The hospital has a parent and family educational program on preventing infant abduction upon birth, admission, postpartum, and at discharge.

Explanations:

XXX

NIC.3. The hospital has a policy and processes for newborn identification that prevents newborn exchanges from birth, admission, to discharge.

NIC.3.1. The hospital ensures correct identification of all newborns in all levels of care inclusive of mother's full legal name, mother's and father's national ID/iqama, mother's fingerprint, newborn DOB, time of birth, order of birth, gender, MRN, and footprint.

NIC.3.2. All born-before-arrival newborns have two ID bands placed immediately at the point of entry.

NIC.3.3. All newborns transferred from external hospitals have two ID bands placed prior to transport that remain secured during transport.

NIC.3.4. Verification of newborn identity occurs at specific times and events, inclusive of at birth, on admission, prior to any transfer, prior to any separation from the mother, at handover, prior to any intervention, and at discharge.

NIC.3.5. Two nurses or midwives secure wrist and ankle identification bands to both mother and newborn prior to the initial separation, with the first band signed by the two staff with the mother's required information and second with the newborn's information.

NIC.3.6. The mother is fingerprinted and the newborn footprinted prior to the newborn's transfer from the birthing area or the initial separation from the mother.

NIC.3.7. The hospital creates the new permanent medical record for every newborn within 60 minutes after birth.

NIC.3.8. There is a verification process of mother and newborn identification bands and security clearance approval prior to removal of identification bands and discharge from hospital.

Explanations:

XXX

NIC.4. The hospital ensures the required physical design, equipment and resources for safe neonatal care.

- NIC.4.1. There are no toilets or soiled utility rooms inside neonatal care areas.
- NIC.4.2. A minimum of one negative pressure isolation room in all levels or only NICU L3.
- NIC.4.3. Each bed has wall fixed medical gases including medical air, oxygen, and vacuum.
- NIC.4.4. The neonatal care areas include one medication room and breast-feeding room.
- NIC.4.5. The main entrance of the unit has a deep sink for scrubbing up to elbows.
- NIC.4.6. The utility room located outside patient care area has a deep sink sufficient in depth to cleaning incubators.
- NIC.4.7. A hands-free hand washing sink within 6 meters from the bed position.
- NIC.4.8. Approved and required equipment is available at all times, for all level of neonatal care, inclusive of ADD.

Explanations:

XXX

NIC.5. The hospital has qualified neonatal care area physician and nurse leadership and staff.

- NIC.5.1. The NICU level 3 head of department is a board-certified neonatologist consultant physician.
- NIC.5.2. A certified consultant neonatologist is present or provides on call coverage to level 3 NICU at all times.
- NIC.5.3. Level 3 NICU has certified pediatric anesthesia, neurosurgery ENT ophthalmology, cardiology and surgery consultants, available ON CALL/ at all times.
- NIC.5.4. The NICU levels 1&2 head of department certified consultant pediatrician with any endorsement coverage by a neonatologist.
- NIC.5.5. A certified consultant pediatrician is present or provides on call coverage LEVEL 1 & 2 NICU at all times, its cover by neonatologist only.

NIC.5.6. A Certified pediatric/neonatal registrar is on duty in the all-neonatal care levels NICU 1&2.

NIC.5.7. The nurse manager/head nurse of the NICU level 3 holds a baccalaureate degree in nursing and SCFHS as a specialist or higher.

Explanations:

XXX

NIC.6. The hospital ensures standardized, person-centered processes for neonatal care meeting national and cited international standards of care.

NIC.6.1. The hospital has policies and procedures for neonatal admission until discharge and transfer, including direct admission to NICU from an external hospital, based on gestational age and birth weight by level of care.

NIC.6.2. Any newborn with surgical intervention in OR with general anesthesia for neonates must be admitted directly from OR to level 3 NICU.

NIC.6.3. Any newborn or neonate less than 28 days old or identified at risk for hypothermia is transported in an incubator with appropriate warming and regular temperature measurements.

NIC.6.4. The hospital has policies and processes for medical, midwife, and nurse assessment and re-assessments, with specific time frames, including minimum assessment requirements to be completed prior to transfer from the birthing area.

NIC.6.5. Newborn physical examination is done within 2 hours of birth prior to the newborn's transfer from the birthing area or separation of the mother.

NIC.6.6. The hospital should ensure a full assessment of every newborn on arrival to NICU which including temperature (for all newborns) and blood gases including lactate level for Newborns on respiratory support.

NIC.6.7. The newborn is provided appropriate developmental individualized care: ADD.

NIC.6.8. The hospital has the WHO's Baby Friendly Hospital Initiative (BFHI), inclusive of implementing the 10 steps to successful breastfeeding.

NIC.6.9. The hospital has policies and process specific to the neonatal care, per level, inclusive of, mechanical, ventilation, resuscitation and stabilization, Hypoxic-ischemic encephalopathy (HIE) Hypoglycemia, group B streptococcus (GBS), Hyperbilirubinemia, RDS, feeding, High-risk baby's policy.

NIC.6.10. The hospital has policies and processes specific to the neonatal care for infection prevention and control standards inclusive of Central line insertion, care, and maintenance Policy VAP/VAE.

NIC.6.11. The hospital neonatal resuscitation capabilities are available in neonatal resuscitation including birth room attendance for any high-risk delivery, with all required team members and equipment available in birthing room, operating room, postal natal ward, and ED, at all times.

NIC.6.12. The hospital implements a comprehensive neonatal early warning signs (NEWS) and maternal early warning signs (MEWS) hospital-wide.

Explanations:

XXX

NIC.7. The neonatal care area heads of department monitor the departmental and clinicians' performance through KPIs.

NIC.7.1. The heads of the department identify and monitor key performance indicators (KPIs).

NIC.7.2. Required KPIs include: In-born mortality rates, mortality rates by birth weight, birth trauma, hypoxic-ischemic injury (all stages), admission hypothermia, advanced ROP Cases, IVH Grade 3& 4 cases, inborn NICU admission rate, neonatal sepsis, NICU Breast milk rates.

NIC.7.3. The heads of the department maintain a list the conditions considered as morbidity and mortality with all newborn codes analysed.

NIC.7.4. Neonatal/pediatric departments conducts monthly mortality and morbidity meetings.

NIC.7.5. KPIs and morbidity and mortality data are discussed in monthly departmental meetings to aid in staff awareness with continuous performance improvement and action plans.

Explanations:

XXX

DRAFT

End-of-Life Care (EOL)

Patients at the end-of-life (EOL) have unique and complex healthcare needs which are at risk of being ignored. End-of-life is defined as a phase of life when a person is living with an illness that will worsen and eventually cause death. It is not necessarily limited to a short period of time when the person is moribund. EOLC as a part of palliative care is person and family-centered care provided for a person with an active, progressive, advanced disease, who has little or no prospect of cure and who is expected to die: and for whom the primary treatment goal is to optimize the quality of life.

"Palliative care is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering through early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual." (WHO DEFINITION). Worldwide, there is a major population of adults in need of palliative care who have chronic diseases such as cardiovascular diseases (38.5%), cancer (34%), chronic respiratory diseases (10.3%), AIDS (5.7%) and diabetes (4.6%). Many other conditions may require palliative care, including kidney failure, chronic liver disease, multiple sclerosis, Parkinson's disease, rheumatoid arthritis, neurological disease, dementia, congenital anomalies, and drug-resistant tuberculosis. Today, Saudi Arabia (SA) has a total population of over 32.3 million, and the majority are Saudis based on 2016 statistics. The percentage of the population living in urban areas is 82.3% and the life expectancy at birth is 76 years. The burden of disease (2016) attributable to communicable diseases is 11%, non-communicable diseases 73.0% and injuries 16%. The total deaths are over 114,000 and non-communicable diseases are accounted for 73% of these deaths. This population can benefit tremendously if they were managed by palliative care services when access is guaranteed for them before death. Distressing symptoms (e.g., breathlessness, pain, fatigue, and anxiety) will be controlled, and individuals will be able to die with dignity, with their wishes respected; and families are also more likely to report satisfaction with care. Numerous, well-defined symptoms are associated with end-of-life, if unrelieved, are distressing to both the patients and their families and preclude any possibility of relieving biopsychosocial suffering, improving quality of life, or completing life closure. This requires a multidisciplinary, total-person approach to achieve relief from symptoms complexity. The numbers of end-of-life patients will increase in line with

demographic and societal trends, reflecting the global situation. The societal and economic arguments for delivering effective EOLC are powerful. Unplanned emergency hospital admissions are common because the end-of-life period is not well managed. If such admissions could be reduced through improved EOLC, inpatient care would be reserved for the acutely ill, reducing the burden on the health service. Symptom assessment in children may be more complex than in adults because of variable developmental stages and communication abilities and reliance on parental symptom evaluation. Many of the 20,000 US children (age 1 to 19 years) who die annually from serious illness and their caregivers do not receive high-quality EOLC. A study of children with advanced cancer revealed that 48% had pain, 46% fatigue, and 37% irritability. The circumstances and details of pediatric death can be different from those for the death of an adult, partly because of higher hospital death rates in pediatrics. Less than 7% of hospital deaths occur in patients younger than age 45 years, and most children with chronic conditions die in the hospital. Measures to evaluate in-hospital EOLC are also needed and may include access to nursing for dying children, private rooms for patients, and relaxed visitor policies to allow for visits by young siblings and visits after hours. Bereaved parents represent another vulnerable group with high rates of psychological distress. Psychological distress and caregiving burden also have financial implications; 24% of bereaved families of children with cancer face significant economic hardship because of their child's illness. End-of-life care should be multidimensional, culturally relevant, respecting of religious sensitivities, and focused on respecting patient's wishes. Families of patients have the right to grieve and be supported in the bereavement phase. Pain assessment and management, including safe opioid prescribing, is identified as an organizational priority. The pain experience is unique, complex, challenging for professionals, and has biopsychosocial implications, which require best management delivered by a multidisciplinary team. "Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage or both" (International Association for the Study of Pain, 1994).

The wide range of clinical disorders with progressive illness leading to death demands that improved care for patients at end-of-life becomes the focus of all medical specialists who will encounter dying patients during their practice. As there are different phases in the end-of-life process depending on the underlying health status of the patient and the nature of the terminal illness; different specialties

may encounter different aspects and varying needs regarding the care of dying patients and their families. Different specialties agree on the basic principles underlying their roles and responsibilities in EOLC. This will ensure that practicing physicians are equipped with the knowledge, skills, and education necessary to provide the best possible care for patients and their families. Pediatric EOLC providers must be trained in developmental and age-appropriate assessment in all hospital settings needed to ensure that all children receive appropriate management of their symptoms.

The Operational Objectives for EOLC are:

- To provide better care for patients at the end of life.
- To guide those who are caring for patients living with a terminal illness.
- To recognize and respect the patients' unique needs; to make the end of life dignified and compassionate.

DRAFT

EOL.1. The hospital has person- centered processes for EOLC decision-making for adult and pediatric patients.

EOL.1.1. The hospital ensures a multidisciplinary, person centered approach for decision-making at the end-of-life (adult and pediatric patients).

EOL.1.2. The hospital ensures EOLC decisions are made in a culturally sensitive manner, in consultation with and respectful of patient/child and the family/parent preferences.

EOL.1.3. The hospital ensures a structured framework for conducting family meetings and documenting EOLC decisions.

EOL.1.4. The hospital ensures all relevant healthcare providers demonstrate the required communication skills to perform sensitive communication at the end-of-life for adult and pediatric patients.

EOL.1.5. The hospital ensures “Do-Not-Resuscitate” decisions are made and documented as per national guidelines for adult and pediatric patients.

EOL.1.6. The hospital ensures sufficient patient/child and family/parent education at the time of poor prognosis, terminal diagnosis or life-threatening situations during the ELOC & DNR discussions.

Explanation:

This standard intends to ensure that the hospital recognizes the unique challenges that EOLC presents in terms of ethical decision-making while being sensitive and relevant to the cultural, social, religious, and moral values and beliefs of the patient and family.

EOL.2. The hospital has person-centered adult and pediatric identification process for patients at end-of-life.

EOL.2.1. The hospital has criteria to define and identify patients at end-of-life for services from consultation to ELOC care, inclusive of patient/child and family/parent requests for ELOC.

EOL.2.2 The hospital has standard adult and pediatric assessment tools to perform a comprehensive assessment for the identification of patients at end-of-life.

EOL.2.3. The patient and their caregivers work in partnership with the team to communicate, plan, set goals of care and support informed decisions about the care plan.

EOL.2.4. The hospital has standard adult and pediatric tools to assess the physical, psychological, social, cultural and spiritual needs of patients at end-of-life.

EOL.2.5. The hospital ensures a multidisciplinary approach throughout the EOLC assessment process. (psychological, social, cultural, spiritual assessment in addition to physical assessment at end-of-life.)

Explanation:

This standard intends to ensure that the hospital has systems in place to make sure that patients at end-of-life are identified, not missed, and are appropriately referred to EOLC teams.

EOL.3. The hospital has person-centered adult and pediatric processes for referring patients requiring EOLC.

EOL.3.1. The hospital has a referral system for patients identified for EOLC and ensures all healthcare providers' compliance.

EOL.3.2. The hospital ensures a multidisciplinary clinical team (MDCT) leads the delivery of EOLC.

EOL.3.3. The hospital ensures the patient/child and family members/parents are supported during the transition of care to the EOLC & MDCT.

EOL.3.4. The hospital ensures EOLC is provided in all settings, inclusive of inpatient acute care, home care and hospice settings.

Explanation:

This standard intends to ensure that the hospital has a referral system for patients requiring EOLC, and their family, to EOLC multidisciplinary teams; either in the hospital or to other hospitals where EOLC is available.

EOL.4. The hospital ensures the availability and accessibility of adult and pediatric bereavement services.

EOL.4.1. Bereavement support services are available to patients, caregiver, family members, as well as healthcare providers.

EOL.4.2. The hospital ensures sufficient patient/child and family/parent education and ensures the care of the bereaved family members.

Explanation:

This standard intends to ensure that, the hospital has a system for early integration of palliative care multidisciplinary service to patients and their families facing life-threatening illnesses; with a primary focus on providing physical, emotional, and spiritual care, regardless of diagnosis or prognosis. The service, while recognizing that death is an inevitable part of life is not directed at either hastening or delaying death.

EOL.5. The hospital processes for pain assessment and management for adult and pediatric patients during EOLC.

EOL.5.1. The hospital has age-appropriate pain screening, assessment and re-assessment as well as a pain management/plan of care specific to EOLC.

EOL.5.2. The hospital ensures the availability and accessibility of EOLC pain medications and delivery modalities with monitoring systems.

EOL.5.3. The hospital educates patients and families about pain management and involves them in decision-making throughout EOLC.

Explanation:

This standard intends to ensure that, the hospital has a system to recognize that pain assessment and management is a particular integral component of patient right for EOLC and should include an expanded scope of pain management in terms of utilizing assessment tools, determine the most recent types and doses of analgesia, the role of the multidisciplinary team in the process of management, patient and family involvement, and understand how the management of pain affects the patient's quality at end-of-life.

EOL.6. The hospital has processes for symptom management for adult and pediatric patients during EOLC.

EOL.6.1. The hospital has an age- appropriate evidence-based symptom standardized tools for symptom, assessment and management during EOLC.

EOL.6.2. The hospital educates patients/children and families/parents about symptom management and involves them in decision-making throughout ELOC.

EOL.6.3. The hospital has EOLC standing order sets and an imminent death protocol.

Explanation:

This standard intends to ensure that the hospital has a system to explore the significant burden of unrelieved symptoms among end-of-life patients, which necessitate a need for more widespread institution symptom identification and management strategies that enable palliation with proven effectiveness. This includes additional investigation into treatment availability of common symptoms other than pain (pain is covered with standalone standard) for which few effective treatment strategies are known.

EOL.7. The hospital has education and training of staff regarding EOLC.

EOL.7.1. The hospital ensures that multidisciplinary staff training is maintained for effective decision-making in EOLC for pediatric and adult patients.

EOL.7.2. The hospital ensures that multidisciplinary team members receive training on EOLC pain, symptom management, treatment and shared decision-making.

EOL.7.3. The hospital participates in public education about EOLC.

Explanation:

This standard intends to ensure that, the hospital has a system to demonstrate a range of interpersonal and communication skills to enable compassionate interactions with the patient, family and caregivers at the end of life. Develop a range of skills and care strategies with multi-professional groups to promote best-practice in the delivery of high-quality End-of-life care.

DRAFT

Blood Transfusion Safety (BTS)

Blood transfusion saves lives, improves health, and it is one of the most performed clinical procedures in healthcare today. However, many patients requiring transfusion do not have timely access to safe blood products. Providing safe and adequate blood products always should be an integral part of our country's national health care priorities. According to WHO, the risk of transmission of serious infections, including HIV and hepatitis, through unsafe blood and chronic blood shortages brought global attention to the importance of blood safety and availability. (needs citation)

Because blood donors are the only source of blood and blood components, which is vital for public health security, the supply of quality-assured blood components should be maintained effectively, along with ensuring quality and judicious use of blood and blood products, so only patients who genuinely need the blood will receive it.

Another aspect is to address transfusion-related alloimmunization and pregnancy-related Rh D hemolytic disease of the fetus and newborn (HDFN). Even more than 50 years later, Rh (D) immune globulin's regulatory approval in 1968 remains an issue globally and in Saudi Arabia, leading to families affected by repeated miscarriages and stillbirths and neonatal hyperbilirubinemia-related adverse outcomes. It is estimated that ~50% of the pregnant women worldwide who need Rh(D) immune globulin do not receive it, amounting to ~2.5 million women each year.

This blood transfusion safety initiative will add standards and guidance on maintaining an adequate and safe blood supply —gaining the community's trust by delivering top-quality blood products. We will also promote Patient Blood Management (PBM approach), an evidence-based, patient-centered strategy that aims to optimize the use of blood products and improve patients' outcomes.

Besides, we will implement standards that emphasize eliminating transfusion-related alloimmunization and prevent pregnancy-related RhD HDFN.

BTS.1. The hospital ensures the availability of blood products for clinical use.

BTS.1.1. The blood bank has a donor recruitment program.

BTS.1.2. The blood bank and transfusion medicine services have a policy and processes to manage blood product inventory.

BTS.1.3. The blood bank and transfusion medicine services have contingency plans as part of the hospital's business continuity to address blood supply shortages, in emergencies and disasters.

Explanation

The aim is to have a recruitment and retention process of voluntary non-remunerated donors, ensuring blood safety standards meanwhile boosting blood collection.

Donor Recruitment program focus on six main functions:

1. Designating recruitment staff with good organizational, marketing, and communication skills
2. Establishing a mode of contacting potential donors through a donor database by calling, texting, or the use of social media
3. Promoting and Education on the importance of blood donation
4. Ensuring pleasant experience during blood donation
5. Implementing Incentive programs as per locally approved regulations

Effective Organization of bloodmobile drives in the community.

Hospital transfusion medicine services should implement an effective blood inventory program to ensure sufficient blood products to meet clinical needs while keeping wastage rates at a minimum.

Preparedness for disasters is an integral part of blood banking and transfusion services. Unplanned disasters always stress the healthcare system due to the nature and type of the situation (earthquakes, accidents, fire, terrorism.). Risk mitigation strategies, clear policies, and procedures help to navigate through such disasters. However, planned disasters such as pandemics create different challenges since they might limit blood donation and blood product availability. The policy and procedures should include clear internal communication plans to alert the leadership and raise awareness of the blood shortage across the organization. As well as alerting the external stakeholders and Blood Bank to overcome the disasters.

BTS.2. The blood bank has donor selection and acceptance criteria according to the national rules and regulations.

BTS.2.1. The blood bank develops donor qualification acceptance criteria according to national Allogeneic Whole Blood Collection regulations.

BTS.2.2. The blood bank develops acceptance criteria for plasma-apheresis and cytapheretic donors.

BTS.2.3. The blood bank has a process for donor identification and delivering pre-donation education to prospective blood donors.

BTS.2.4. All blood donors complete a signed informed consent, per hospital policy.

Explanation

There are policies and procedures to ensure proper donor identification.

There are policies and procedures for linking the donor identification information to existing donor history (records) on each donor encounter including off-site and mobile blood drives.

The policies and procedures ensure that donors receive appropriate information/education materials regarding the donation process, infectious diseases transmitted by blood transfusion, Importance of providing accurate information, Importance of withdrawing themselves before, during and after the donation process if they believe that their blood is not suitable for transfusion.

Donors' acknowledgement of reading and understanding the educational materials is documented.

The blood bank implements a process for consenting blood donors to ensure that prospective donors are receiving explanation of the donation procedure and answer any concern raised by the donor.

The blood bank implements a process for consenting blood donors to ensure that prospective donors are being informed about the risks of the procedure including risk of transmission of infectious diseases.

BTS.3. The blood bank ensures safe, person-centric blood donation processes.

BTS.3.1. The blood bank has evidence-based standards of care and processes before, during, and after the blood donation, inclusive of initial immune-hematological testing of blood donor samples.

BTS.3.2. The blood bank has a policy and processes for donor notification of significant findings.

BTS.3.3. The blood bank has a policy and processes for managing adverse donation events.

Explanation

There is a policy and a detailed procedure for venipuncture site preparation to reduce the risk of bacterial contamination of the collected blood/blood component.

The blood bank has sufficient provisions for providing appropriate care for blood donors during and after the procedure.

Donors are given proper written post donation instructions.

Supplies and equipment needed for donors' care are available.

Personnel are trained and competent in recognition and handling of adverse donor reactions.

The blood bank has a process for confidential self-unit exclusion and handling post donation information.

The blood bank develops a policy and procedure for donor notification of significant findings detected during donor screening or after performing laboratory testing.

The policy and procedure mandate the provision of proper education, counseling, and referral for donors with significant findings.

The blood bank has a policy and procedure for managing adverse donation events that covers recognition, reporting and handling of adverse donation events
Donor adverse event classification should follow international classification if national classification does not exist.
Blood Donor Specimen is properly labeled and crosschecked with the collected product label.
Blood Donor Specimen is stored under appropriate and controlled conditions.
There are policies and procedures mandating that a sample of blood obtained from the donor during blood/ blood component collection is subjected to initial immune-hematological testing.
Testing must include Determination of the donor's forward ABO group (RBC grouping).
Testing must include Determination of the donor's reverse ABO group (serum grouping).
Testing must include Determination of the donor's Rh-D type (including a test for weak-D).
Testing must include Detection of unexpected antibodies to red cell antigens (antibody screening).
There is a confirmation of agreement between the donor's current and historical group/type
Discrepancies are solved before releasing any blood/blood components.

BTS.4. The blood bank ensures standardized manufacturing conditions.

- BTS.4.1. The blood bank has a policy and processes for validation of collected blood volume regulators.
BTS.4.2. The blood bank has a policy and processes to identify and discard unacceptable blood/blood products.
BTS.4.3. The blood bank has a policy and processes for labeling blood and blood components.
BTS.4.4. The blood bank and transfusion medicine services use appropriate blood and blood components storage devices.
BTS.4.5. The blood bank and transfusion medicine services have processes for reagents quality control.

Explanation

The blood bank implements a process for check/adjustment of blood volume regulators (blood shakers) to ensure that checking and adjustments are performed at regular intervals, on every day of use, and after activities that may alter the calibration.

Calibration and adjustment procedures conform to the manufacturer's instructions.

The process mandates two qualified staff members to perform and document this activity.

The process mandates discarding unacceptable components before the labeling of blood and blood components.

There are policies and procedures to ensure that blood and blood components are not labeled before completion of the donor testing.

There are policies and procedures to ensure that blood and blood components are not labeled before the discard of unacceptable units.

Blood components labeling should include identification of the collecting facility, product name, unit number, ABO/Rh and expiration date, and time.

The blood and blood components storage devices are designed for the intended use, equipped with continuous temperature monitoring system (temperature recording) and are equipped with audio/visual alarm systems.

The device's alarm and monitoring system conforms with the following: Activates at a temperature that allows for intervention before the contents reaches unacceptable temperature, activates at an area staffed 24 hours a day, seven days a week, Connected to a separate or DC power supply.

The alarm system is checked weekly.

Alarm activation temperatures are checked quarterly.

The inner temperature of blood storage devices is monitored and recorded at least once a day using a standardized thermometric device.

In the event of failure of continuous temperature monitoring, temperature recording, or alarm systems, the inner temperature is monitored and recorded every four hours.

Policies and procedures ensure performance of reagents quality control on each day of use.

Policies and procedures ensure results are reviewed and reagents are approved before use for patient testing.

Corrective actions are taken for unacceptable results.

BTS.5. The blood bank ensures the preparation, storage, transportation, and quality control of all manufactured blood products.

BTS.5.1. The blood bank and transfusion medicine services have a policy and processes for the preparation, storage, transportation, quality control and transfusion of Red Blood Cells (RBC) and Leukocyte-Reduced Red Blood Cells (LR-RBC) components.

BTS.5.2. The blood bank and transfusion medicine services have a policy and processes for the preparation, storage, transportation, quality control and transfusion of Platelet Concentrates (PC), Leukocyte-Reduced Platelet concentrates (LR-PC) and platelet apheresis components.

BTS.5.3. The blood bank and transfusion medicine services have a policy and processes for the preparation, storage, transportation, quality control and transfusion of Fresh Frozen Plasma (FFP).

BTS.5.4. The blood bank has a policy and processes for the preparation, storage, transportation, quality control and transfusion of Cryoprecipitate (CRYO).

BTS.5.5. The blood bank and transfusion medicine services have policies and processes for the preparation, storage, transportation, quality control and transfusion irradiated cellular bloods.

BTS.5.6. The blood bank and transfusion medicine services have policies and processes for the preparation, storage, thawing, transportation, quality control and transfusion of Fresh Frozen Plasma (FFP) units.

BTS.5.7. The blood bank and transfusion services have policies and processes for the preparation, storage, thawing, transportation, quality control and transfusion of thawed CRYO units.

Explanation

Policies and procedures ensure that RBC components are prepared by separating the RBC from the plasma proteins

Policies and procedures ensure that LR-RBC units are prepared by a method known to retain 85% of the RBC in the original product and a residual WBC count of less than 5×10^6 WBC/ unit.

Policies and procedures ensure that RBC components are stored under properly controlled conditions between 1 and 6°C.

Policies and procedures ensure that RBC components are transported in properly insulated containers between 1 and 10°C.

Policies and procedures ensure that RBC components are assigned an expiration date according to the manufacturer's recommendations

Policies and procedures ensure that 1% of the monthly production- but not less than 4 units every month- are subjected to quality control testing. All tested RBC units have a hematocrit of less than 80% (RBC in additive solutions are exempted from quality control requirement).

Policies and procedures ensure that 1% of the quarterly production -but not less than 12 units every three months- are subjected to quality control testing. All tested LR-RBC units have an RBC recovery rate of more than 85% and a residual WBC count of less than 5×10^6 WBC/unit in all subjected units.

Blood product quality should be in accordance with the approved national rules and regulations.

PC components are prepared by separating the platelets from whole blood within eight hours of collection.

Policies and procedures ensure that LR-PC units are prepared by a method known to retain 85% of the platelets in the original product and a residual WBC count of less than 8.3×10^5 WBC/ unit or 5×10^6 WBC/pool of six units.

Platelet apheresis units are prepared by separating the platelets from whole blood using an apheresis machine

PC components are stored under properly controlled conditions between 20 and 24°C with continuous agitation.

PC components are transported in properly insulated containers as close as possible to 20 and 24°C.

PC components are assigned an expiration date of twenty-four hours to five days from the day of whole blood collection according to the manufacturer's recommendations or four hours of opening the PC unit.

Policies and procedures ensure that 1% of the monthly production of (PC) but not less than four units every month are subjected to quality control testing. On the expiration date or at issue, 90% of the subjected units have a platelet count of 5.5×10^{10} platelets/unit or more and a minimum

Policies and procedures ensure that 1% of the quarterly production of (LR-PC)-but not less than twelve units every three months- are subjected to quality control testing. All tested LR-PC units have a platelets recovery rate of more than 85% and a residual WBC count of less than 8.3×10^5 WBC/unit or 5×10^6 WBC/pool of six units.

Policies and procedures ensure that 1% of the monthly production of (Plateletpheresis) -but not less than 4 units every month- subjected to quality control testing. On the expiration date or at issue, all the subjected units must have a platelet count of 3.0×10^{11} platelets/unit or more, a minimum pH of 6.2, and a residual WBC count of 5×10^6 WBC/ unit.

Blood product quality should be in accordance with the approved national rules and regulations.

FFP components are prepared by separating and freezing the plasma from the whole blood within eight hours of collection and within six hours for plasma collected by apheresis.

FFP components are stored under properly controlled conditions below -18°C .

During transportation, FFP units are maintained at frozen state in properly insulated containers.

FFP components are assigned an expiration date of one year from the day of whole blood collection.

If cryoprecipitate is not prepared at least quarterly, 1% of the FFP quarterly production - but not less than twelve units every three months- are subjected to quality control testing. More than 75% of the tested units must have a minimum factor VIII level of 700 IU/L. Blood product quality should be in accordance with the approved national rules and regulations.

CRYO components are prepared by separating cold insoluble proteins from Fresh Frozen Plasma and refreezing of the product within one hour of preparation.

CRYO components are stored under properly controlled conditions below -18°C .

During transportation, the CRYO units are maintained at frozen state in properly insulated containers.

Policies and procedures ensure that 1% of the quarterly production- but not less than twelve units every three months- are subjected to quality control testing. More than 75% of the tested units must have a minimum factor VIII level of 80 IU/unit and 150mg of fibrinogen/bag.

Blood product quality should be in accordance with the approved national rules and regulations.

Policies and procedures ensure that irradiated cellular blood products are prepared by a method known to ensure that irradiation has occurred at each time of use.

Policies and procedures ensure that the preparation method used is known to deliver a minimum of 25 GY to the central part of the canister and a minimum of 15 GY at any point. Verification of dose delivered must be performed and evaluated annually

Policies and procedures ensure that irradiated RBC components assigned an expiration date not exceeding twenty-eight days from the date of irradiation or the original assigned expiration date (whichever occurs first).

Policies and procedures ensure that irradiated platelet components retain their original expiration date.

Thawed FFP units are stored under properly controlled conditions between 1 and 6°C .

Thawed FFP units are transported in properly insulated containers between 1 and 10°C .

Thawed FFP units are assigned an expiration time of twenty-four hours from the thawing time.

Requirements for FFP preparation, storage, transport, and expiration apply.

Thawed CRYO units are prepared by thawing CRYO units between 30 and 37°C without direct contact with the water.

Thawed CRYO units are stored and transported at room temperature (between 20 and 24°C).

Thawed CRYO units are assigned an expiration time of six hours from the thawing time for individual units and four hours from the thawing time of pooled units.

Requirements for CRYO preparation, storage, transport, and expiration apply.

BTS.6. Transfusion medicine services ensures valid and safe transfusion testing.

BTS.6.1. Transfusion medicine services has a process to confirm the ABO/Rh-D of donated blood.

BTS.6.2. Transfusion medicine services has a process for pre-transfusion testing of the recipient.

BTS.6.3. The transfusion services establish a process for compatibility testing.

BTS.6.4. Transfusion medicine services develops a process to prevent infectious disease transmission.

Explanation

There is a process to confirm the ABO/Rh-D of donated blood which mandates that segment from RBC components is subjected to testing:

Testing must include Determination of the donor's forward ABO group (RBC grouping).

Testing must include Determination of the donor's Rh-D type.

ABO/Rh-D conformation is performed after labeling.

Discrepancies are solved before releasing any blood/blood components.

Pre-transfusion testing is performed on a specimen collected from the recipient with every admission and within three days of the scheduled transfusion time.

There is a consistency between patient's current and historical records (including group/type, antibody screening). Discrepancies are resolved before performing compatibility testing.

When there is no history for the patient in the transfusion services records or computer system, two determinations of the patient's ABO/RhD must be made on two specimens collected during the current admission.

Pre-transfusion testing includes the following: Determination of the patient's forward ABO group (RBC grouping), Determination of the patient's reverse ABO group (Serum Grouping), Determination of the patient's Rh-D type, Detection, and Identification (if applicable) of unexpected antibodies to red cell antigens.

There is a process to ensure the detection of ABO incompatibility between the recipient's serum/plasma and the donor's RBC.

The process ensures the compatibility testing is performed on integrally attached segments from the donor's RBC unit.

The process ensures the checking for presence, now or in the past, of clinically significant antibody in the patient's serum.

The process ensures the proper labeling of cross-matched units with patient's name, patient's identification number and patient is ABO /Rh-D.

There are policies and procedures mandating that a sample of blood obtained from the donor during blood/ blood component collection is subjected to the following infectious diseases testing: HBsAg, Anti-HBc, Anti-HCV, Anti-HIV-1/2, Anti-HTLV-I/II, HIV-1 RNA, HCV RNA, HBV DNA, Serological test for syphilis and Other additional or supplemental tests as mandated by relevant health authorities.

There are policies and procedures to detect bacterial contamination (using sensitive methods to detect significant bacterial contamination) or use pathogen reduction technology in all platelets components.

BTS.7. Transfusion medicine services ensures the selection and release of blood products under routine and emergency circumstances.

BTS.7.1. The transfusion medicine services have a policy and processes for the selection of blood/blood products for transfusion.

BTS.7.2. The transfusion medicine services have a policy and processes for the release of blood/blood component for transfusion.

BTS.7.3. The transfusion medicine services have a policy and processes to prevent the release of units that are not suitable or unacceptable for transfusion.

BTS.7.4. The transfusion medicine services have a policy and processes for the release of incompletely tested blood/blood components.

BTS.7.5. The transfusion medicine services have a policy and processes for the emergent release of uncross-matched or incompletely cross-matched blood.

Explanation

The selected red blood cells component is ABO group-specific or ABO group-compatible with the recipient's plasma.

Only Rh-D negative red blood cell components are transfused to Rh-D negative patients.

Identification of the conditions for the release of Rh-D positive red blood cells components to Rh-D negative patients.

The selected plasma component is ABO group-specific or ABO group-compatible with the recipient's RBC. Conditions for the release of ABO-incompatible plasma are identified.

In the presence of clinically significant antibodies in the donor's plasma, the recipient red cells must lack the corresponding antigen.

If the plasma components are visually contaminated with red blood cells (more than 2 ml of RBC), RBC selection criteria apply.

There are policies and procedures for the selection of blood/blood components for patients with special requirements that address the use of leukocyte-reduced cellular blood components, The use of irradiated-cellular blood components, Transfusion of known Hemoglobin-S patients and Massive transfusions.

There is a process for the issue of blood/blood components to ensure accurate identification of the intended recipient and the required blood components.

The process ensures the integrity of the donor unit identification label and the recipient identification label.

The process ensures confirmation that the donor's ABO/Rh is identical with the recipient's or marked compatible.

The process ensures proper documentation of the release event.

Policies, processes, and procedures ensure the accuracy and legibility of identification information.

Policies, processes, and procedures ensure the agreement of the identification information (records and donor units).

Policies, processes, and procedures ensure the performance of visual inspection for discoloration, clots, hemolysis, and adequacy of seal.

Policies, processes, and procedures ensure two qualified staff members perform and document this activity.

There are implemented policies, processes, and procedures to ensure that incompletely infectious diseases tested blood/blood components can be released under the following circumstances: For urgent need only and Upon the discretion of the medical director of the transfusion medicine, the agreement of the attending physician and the consent of the patient or next of kin, when applicable.

The release of incompletely tested blood/blood components is approved only for a particular patient and one transfusion event.

The released blood products are conspicuously labeled to this effect.

Testing of the blood/blood components must be completed and reported promptly to the attending physician.

The transfusion services develop a process for emergency release of uncross-matched or incompletely cross-matched blood.

The process considers age and sex factors.

The process ensures ABO/Rh-D and labeling of the selected blood.

The process ensures subsequent compatibility testing and notification of the results.

The process ensures documentation of the release event (including the ordering physician signature).

BTS.8. Transfusion medicine services ensures the availability of therapeutic procedures and the selection and release of blood products under patient and population- specific circumstances.

BTS.8.1. The transfusion medicine services have a policy and processes for neonatal testing and transfusion.

BTS.8.2. The transfusion medicine services have a policy and processes for intrauterine transfusion.

BTS.8.3. The transfusion medicine services have a policy and processes to prevent RhD sensitization for RhD negative females with childbearing potential.

BTS.8.4. The transfusion medicine services have a policy and processes for request, approval, and execution of therapeutic procedures.

Explanation

There is a process for neonatal testing and transfusion that entails determination of the neonate ABO/Rh.

The process entails performance and interpretation of Direct Antiglobulin Test (DAT).

The process describes conditions for omitting re-typing and serological crossmatch.

The process considers the clinically significant antibodies of maternal origin.

The process describes selection of RBC and plasma components for top-up and exchange transfusion.

There is a process for intra-uterine testing and transfusion that entails determination of the fetal ABO/Rh.

All exp.

The process entails performance and interpretation of Direct Antiglobulin Test (DAT).

The process describes conditions for omitting re-typing and serological crossmatch.

The process considers the clinically significant antibodies of maternal origin.

The process describes selection of RBC transfusions.

The process ensures all therapeutic procedures are ordered and justified by an authorized physician.

The process ensures the blood bank medical director or designee is responsible for reviewing therapeutic procedures orders for appropriateness and evaluating patient clinical and laboratory data before approving the procedure.

The process ensures that blood/ blood components are discarded immediately after collection.

Rh Immunoglobulin (RhIG) is given to prevent alloimmunization for RhD negative patients in case of exposure to Rh positives cells. Potential RhIG candidates include transfusion, pregnancy termination through delivery or abortion, amniocentesis, invasive obstetric procedures, and abdominal trauma during pregnancy. The hospital must ensure that all Rh-negative patients receive the maximum protection against Rh alloimmunization.

The procedure should address the RhIG candidacy of women of childbearing age including variants RhD typing. Maternal RhIG candidacy assessment must include the identification of variants-D phenotype of the new-borns.

RhIG candidates must be evaluated for fetomaternal hemorrhages with standard methods (Kleihauer-Braun-Betke or flow cytometry). The method should be used to calculate the recommended dosage of RhIG. Standardized formulas must be used for translating the mL of fetal blood into vials of RhIG.

Patients with fetomaternal bleed should receive the recommended dose of RhIG as soon as possible (preferably within 72 hours), except if the foetus is Rh-negative or the patient is known to be alloimmunized to the D antigen.

- The transfusion service shall have a policy for RhIG prophylaxis for Rh-negative patients who have been exposed to Rh-positive cells.
- There is a written procedure to identify all potential candidates for Rh immune globulin with appropriate dosing.
- There is a written procedure ensure urgent screening and quantification of fetomaternal bleed.
- There is a written procedure to ensure that an adequate dose of Rh immune globulin is administered to all identified candidates within 72 hours of a Rh alloimmunization event, whenever possible.

BTS.9. Hospital proactively manages its blood transfusion services to avoid shortages of any blood products.

BTS.9.1. The hospital has assessment methods and management of patients undergoing elective surgeries to minimize perioperative transfusions.

BTS.9.2. Transfusion medicine services has evidence-based transfusion guidelines for all blood products to advocate for restrictive transfusion strategies.

BTS.9.3. The hospital has a policy and processes to limit iatrogenic blood loss.

Explanations:

The prevalence of preoperative anemia ranges from 5% to 75 & of the patients. The most significant risk factor for an intraoperative blood transfusion is pre-existing anemia, coagulopathy, and hemostasis abnormality. In addition to the optimization of hemoglobin level and hemostasis, it is essential to investigate the source of anemia and hemostasis.

Patient preoperative anemia evaluation must include relevant causes such as iron deficiency, folate deficiency, and vitamin B12 Deficiency.

Hemostasis should be evaluated preoperatively; if there is documented bleeding tendency, then consulting the relevant specialties is required.

The clinical rationale for RBC transfusion is to restore oxygen delivery to hypoxic tissues. Accordingly, physicians are challenged daily to select from among patients, those who could benefit from RBC transfusions without exposing others to RBC transfusion-related risks. Health care providers will be monitored through key performance indicators to ensure safe transfusion practice. The Medical Director of Transfusion Services Develops and implements Evidence-Based Guidelines with Triggers for Blood Products Transfusion.

Blood loss may be reduced by implementing policies for.

1. Elimination of unnecessary laboratory studies
2. POCT program
3. Hemorrhage management and recovery and reinfusion of shed blood

Pharmacologic enhancement of Hemostasis.

- Identify patients with anemia and or at risk of bleeding.
- There are guidelines to optimize preoperative anemia and coagulopathies.
- Quality metrics for preoperative transfusion appropriateness is in place and reported.
- The transfusion committee must regularly review preoperative transfusion appropriateness
- Massive transfusion Protocol
- Critical care transfusion guideline
- Obstetric transfusion guideline
- Neonatal and Pediatric transfusion guideline
- Medical and surgical transfusion guidelines
- There are approved policies and procedures to minimize blood draws.
- There is an established point of care testing (POCT).
- There are approved policies and procedures to minimize intraoperative blood loss.

BTS.10. The hospital communicates and collaborates with internal and with external stakeholders to ensure blood product availability.

BTS.10.1. Blood bank and transfusion medicine services has a policy and processes for receiving and sending blood and blood products with external hospitals.

BTS.10.2. Transfusion medicine services participates (through the blood transfusion committee) in the development of a process for the management of adverse or suspected transfusion events.

BTS.10.3. Transfusion medicine services participates (through the blood transfusion committee) in the development and implementation of a process for the investigation of suspected cases of post-transfusion infection.

Explanation

There are written blood supply/exchange agreements with outside facilities covering the following requirements: Agreement conditions (including accreditation status), Agreement on adequate blood/blood components inventory, Role of the involved parties in look back and transfusion transmitted diseases investigation, Release of blood, blood components or information to a third party, Validity of agreement and agreement review schedule and Resolving disputes.

There is a written procedure describing the process for requesting or releasing blood from or to outside facilities.

Policies and procedures on receipt and inspection of incoming blood/blood components including: Evaluation and verification of the shipping condition of each blood component, checking for meeting predefined acceptance criteria for each blood component received, Evaluation and verification of the agreement of units' identification information (unit numbers, ABO/Rh-D and Expiration dates), Conformation of ABO/Rh-D for RBC components and Actions taken for unsatisfactory consignment.

The process covers Recognition and handling of adverse transfusion events.

The process covers Reporting and monitoring of adverse transfusion events.

There is a process for management of suspected transfusion reactions covering Clerical check of the identification information and records, Visual inspection of the blood product, pre and post transfusion samples, Initial immune-hematological testing, and conditions for performing additional testing (minor/major crossmatch, urine analysis, biochemistry, microbial culture) and Conclusion and instructions for future transfusion.

Transfusion reaction reports are reviewed by the transfusion services medical director and the transfusion committee.

Transfusion adverse event classification should follow international classification if national classification does not exist.

There is a process for the investigation of suspected cases of post-transfusion infection ensures Prompt identification of the implicated donors, Prompt notification of the collecting facility (if applicable), Prompt quarantine of available components from the implicated donors, Investigating the implicated donors, assigning appropriate deferrals to the implicated donors, and Reporting the investigation results (internally and externally), as applicable.

The process for investigation of donors subsequently found to have transfusion transmissible disease (Look Back) ensures Prompt quarantine of available components from the same donor, Prompt identification of the recipients, Prompt notification of the facility where the transfusion was conducted (if applicable), Prompt notification of the patient's physician and/or infection control, Investigation, and follow-up of recipients.

The process for investigation of suspected cases of post-transfusion infection ensures Reporting the investigation results (internally and externally), as applicable.

BTS.11. The blood transfusion committee and heads of departments monitor departmental and clinicians' blood transfusion safety performance through KPIs.

BTS.11.1. A Blood transfusion committee and the heads' of the department identify and monitor key performance indicators (KPIs) as related to blood transfusion safety.

BTS.11.2. Required KPIs include: XXX

BTS.11.3. Blood transfusion safety KPIs and morbidity and mortality data are discussed in the Blood transfusion committee and monthly departmental meetings to aid in staff awareness with continuous performance improvement and action plans.

Explanations:

XXX

DRAFT

Medication Safety Standards (MM)

Medication therapies are fundamental for disease management and they constitute the most common intervention in healthcare setting. Medication error represents a major issue leading to hospitalization, especially in adult and elderly patients. Medication errors are a leading cause of avoidable harm in health care systems across the world. The Institute of Medicine (IOM) Committee on Identifying and Preventing Medication Errors estimates a hospitalized patient experiences at least one medication error per day. Furthermore, the IOM reports estimated at least 25 percent of all medication-related injuries are preventable. In the United States alone, at least 1.5 million preventable adverse drug events (ADEs) occur each year. Mortality rates attributed to ADEs range between 1 and 2.45 percent. Several studies evaluated the cost of medication error in the healthcare sectors, one study estimated the cost to be up to 5.6 million US dollar per hospital. Another study suggests the cost associated with medication errors has been estimated at US\$ 42 billion annually, the IOM reported that medication related injuries contributed to a cost of over, 3.5 billion (2006) dollars.

In a local study done in Saudi Arabia estimated the incidence of adverse drug event in hospitalized patient 8.5 per 100 admission and 30% were preventable (Al Jadhey et al, 2013a).

The objectives of medication safety national health priority are:

- To promote medication safety culture within healthcare institutions
- To Identify the most important medication safety challenges in KSA health care system
- To Recommend an evidence based/ consensus based safe medication practices and medication use standards that shall be applied across the KSA healthcare systems.
- Minimize the occurrence and prevent risk of patient harm that result from the misuse of medications.
- Reduce the financial burden resulting from medication errors.

MM.1. The hospital has a safe and secure system for the storage of medications.

MM.1.1. There are multidisciplinary policies and processes for the safe storage of refrigerated and non-refrigerated medications, frozen medications, biologicals, and vaccines in the main stores, pharmacies, patient care areas, and, if available, automated dispensing cabinets.

MM.1.2. Medications are safely and securely stored in the required temperature, humidity ranges, and light protection, with proper labeling and organized arrangement. The storage area is clean, with limited access only to authorized personnel.

MM.1.3. Vaccine refrigerators and freezers are equipped with functioning thermometers for 24-hour/7days-a-week temperature recording, connected to an emergency power source, and with electric outlets marked accordingly, with defined mechanisms to mitigate electrical power outages and out-of-range requirements.

MM.1.4. Vaccine storage areas are clearly identified and labeled, and vaccines are segregated from other medications.

MM.1.5. The hospital has multidisciplinary policies and processes to maintain an update-to-date list of the hospital's hazardous drug and materials and ensures the safe storage based on the dosage form and the type of preparation, dispensing, transport, storage, and administration.

MM.1.6. The hospital has multidisciplinary policies and processes to safely handle expired, discontinued, recalled, damaged, or contaminated medications.

MM.1.7. The Pharmacy head of department develops and oversees mechanisms for monthly inspection of all medication storage areas, including patient care units and ambulances, with actions plans implemented for identified areas for improvement.

Explanations:

Proper storage of pharmaceuticals is extremely important from the time it is received in the hospital until it reaches the patient. The loss of potency during storage may influence the efficacy and safety of pharmaceuticals. Proper environmental control must be maintained wherever drugs are stored

anywhere in the hospital. Proper labeling and storage to avoid mixing are very crucial for medication safety.

Vaccination is among the greatest public health achievements of the twentieth century, and it resulted in the worldwide prevention and eradication of multiple diseases. However, errors with vaccine storage, prescribing, preparation, and administration are still threatening the safe use of vaccines and could result in patient harm or inadequate immunization or protection.

Several errors were reported worldwide that resulted in serious patient harm. Errors related to vaccines included wrong vaccine administration, wrong medication administration (instead of vaccine), wrong preparation technique, and administration of expired or deteriorated vaccine due to improper vaccine storage.

Many drugs may be considered hazardous because they are potent (small quantities produce a physiological effect) or cause irreversible effects. As the use and number of these potent drugs increase, so do opportunities for hazardous exposures among healthcare workers. Standard precautions shall be taken while handling hazardous drugs to ensure the safety of healthcare workers.

Expired, discontinued, recalled, damaged or contaminated medications constitute risks if inadvertently administered to the patients thus the hospital shall have a robust process to handle these medications to promote patient safety.

Inspection on medication storage areas can spot issues related to medication handling in different medication storage areas. Improvements shall be conducted based on the findings detected during the inspection of medication storage areas.

MM.2. The hospital has a system that detects and oversees medication errors, near misses, hazardous situations, and adverse drug reactions.

MM.2.1. The hospital has a multidisciplinary Pharmacy and Therapeutics Committee that oversees quality and safety across the entire medication-use process, inclusive of medication safety reported incidents, the Adverse Drug Reaction (ADR) reporting program, trends and patterns, risk-mitigation, error-reduction strategies and continuous improvement performance.

MM.2.2. The hospital has a dedicated pharmacist as the Medication Safety Officer(s) with verified experience, certification and/or training qualifications.

MM.2.3. At all stages of the medication-use process, generic names are used.

MM.2.4. The hospital has an electronic pharmacy system with electronic alerts.

MM.2.5. The hospital has multidisciplinary policies and processes for managing reported medication safety events, unsafe hazardous drug or materials situations, and adverse drug reactions.

MM.2.6. The hospital has a standard safety reporting system, manual or electronic with all medication-use process incident report analyses detailing the event, outcomes, and severity level.

MM.2.7. The hospital has active reporting by all individuals who have roles in the medication-use process for any medication errors, near misses, or unsafe hazardous drug or materials situations in all stages of the medication-use process.

Explanations:

Incident reporting is one of the most widely used strategies for system improvement in healthcare and there are many examples to substantiate the benefits of learning and improvement following incident reporting. However, the hospital should aim for an established mechanism to detect and report medication errors, near misses, and other medication safety risks. A multidisciplinary team, consisting of members involved in the medication-use processes (preferably including a full-time medication safety officer), is responsible for conducting proactive measures (e.g., trigger tools, self-assessment, Failure Mode and Effect Analysis) as well as analysis of internal and external reported events or hazards. A policy and procedure is developed by the multidisciplinary team in collaboration with Quality and Patient Safety Department (or equivalent), to define medication safety related terms and taxonomy, standardize reporting format and analysis process, and promote a just culture that facilitates incident reporting.

Data and information obtained from reported incidents are utilized to identify system-based vulnerabilities and customize risk-reduction strategies to prevent similar errors in the future.

Active reporting system ensure that all individuals who have roles in the medication-use process (e.g., physicians, dentists, pharmacists, pharmacy technicians, nurses, laboratory technicians, respiratory therapists, etc.), who were either involved, witnessed, or discovered an event, are encouraged to report the incident regardless of the event outcome severity (e.g., National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Category A to I) or the stage of the medication-use process (e.g. selection and procurement, storage, prescribing, preparing, dispensing, administration, and monitoring)

Hospitals should ensure appropriate detection, documentation, management, reporting, and analysis of Adverse Drug Reactions (ADRs). Reported ADRs are analyzed for trending and the information gained is used for staff education and development of preventive measures, if any.

MM.3. The hospital has a system to ensure the identification, labeling, safe use, handling, and administration of high-alert medications.

MM.3.1. The hospital has multidisciplinary policies and processes that identify annually, or more often, an updated list of high-alert medications.

MM.3.2. The hospital has multidisciplinary policies and processes that specify and communicate error-reduction strategies, inclusive of labeling and independent double-checking to ensure safe use and handling of high-alert medications. throughout all stages of the medication-use process.

MM.3.3. Healthcare providers responsible for total parenteral nutrition and chemotherapy medications throughout the entire medication-use process undergo baseline and annual training and competency assessment.

MM.3.4. There is a hospital policy regulating the use of identified and approved concentrated electrolytes allowed in patient care areas, detailing their necessity, clinical indication, inclusive of immediate use with storage in a separate locked cabinet, proper signage, drug specific electrolyte replacement guidelines, and independent double-checking.

MM.3.5. The hospital prepares and dispenses vinca alkaloids ONLY in minibags of compatible solution; NEVER in a syringe.

MM.3.6. All methotrexate orders include therapeutic indications. Daily methotrexate orders are for oncology indications ONLY and the hospital has implemented strategies to mitigate methotrexate-associated risks.

MM.3.7. The hospital clearly identifies areas where neuromuscular blockers (NMBs) are stored and ensures NMBs are segregated from other medications and properly labeled as follows: "WARNING: CAUSES RESPIRATORY ARREST – PATIENT MUST BE VENTILATED".

MM.3.8. Antidotes and reversal agents for opioids, benzodiazepines, and, insulin, are available and readily accessible in all areas where these high-alert medication(s) are available, stored, and might be administered.

Explanation:

High-Alert Medications are those medications that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. Defining a list of high-alert medications available in the hospital is the first step in guiding customized, robust, and sustainable risk-reduction strategies to eliminate harm associated with their use.

The designed risk-reduction strategies should aim to prevent errors, make errors visible, and/or mitigate harm if an error happened. Each identified high-alert medication/class should be studied for potential risks and the underlining cause of errors to properly layer the system-focused interventions.

Newly hired healthcare providers who are involved in total parenteral nutrition and chemotherapy medications prescribing, preparing, dispensing, administering, or monitoring undergo baseline competency assessment to ensure their familiarity with the system and assess their knowledge, and an annual training thereafter to share information on internal and external reported risks or error, and developed risk-reduction strategies.

This standard aim is to focus on selected high-alert medications/classes and risk-reduction strategies to eliminate errors associated with their use that continue to be reported despite several published warnings and recommendations.

Reported fatalities resulting from direct administration of concentrated electrolytes (e.g., potassium chloride, potassium phosphate, sodium chloride, magnesium sulfate) have encouraged several organizations to endorse eliminating the storage of their concentrated forms from all patient care units and recommend that they are to be prepared and supplied from the pharmacy. If this is not possible, other strategies to ensure their safe use need to be considered.

Vinca alkaloid can lead to fatal neurological damage if administered intrathecally. Dispensing them in minibags of compatible solution can eliminate the risk of inadvertent intrathecal administration.

Several instances of death resulting from inadvertent administration of daily dosing of methotrexate have been reported. Pharmacists shall verify that all daily doses of methotrexate are for oncology indications

only and the hospital can implement many different strategies to reduce the risk associated with methotrexate.

Administering neuromuscular blockers (NMBs) to patients who are not receiving proper ventilator support have led to numerous cases of death or permanent harm. Several risk-reduction strategies can be implemented to ensure safe use and management of NMBs.

Appropriate reversal agents and antidotes for opioids, benzodiazepines, and insulin (i.e., naloxone, flumazenil, and glucagon/dextrose) should be available and readily accessible in areas where offending high-alert medication(s) might be administered to mitigate harm and minimize the consequences of errors.

MM.4. The hospital has a system for the safe use of look-alike and sound-alike medications.

MM.4.1. The hospital has multidisciplinary policies and processes on safe handling of look-alike and sound-alike medications that includes look-alike and sound-alike error prevention strategies throughout all stages of the medication use process.

MM.4.2. The hospital reviews and updates annually, and more often if required, its list of similar-sounding or similar-looking medication, which include look-alike and sound-alike medication name pairs that are available in the hospital formulary. Healthcare providers have access to the look-alike and sound-alike medications updated list at all times.

MM.4.3. The hospital has a look-alike and sound-alike medication error prevention strategies inclusive of, indication-based prescribing, electronic pharmacy system with electronic alerts, listing of both brand and generic names, separate non-alphabetical storage, TALL-MAN lettering, auxiliary labels, and if available, barcode scanning.

MM.4.4. The hospital ensures patients receive comprehensive counseling upon dispensing look-alike medications packages highlighting their differences and the safety actions to be taken.

Explanation:

Pharmaceutical companies sometimes choose drug names that are spelled or pronounced like other names on the market. Unfortunately, similarly named medications can have very different therapeutic uses. Patients have sometimes suffered from serious adverse drug events caused by incorrect medications that were inadvertently prescribed or administered due to name confusion. The same problem occurs with different medications that are packaged in similar ways.

One of the most common global causes of medication errors is the presence of many confused drug names. Currently, there are thousands of drugs on the Saudi market and the potential for error due to confusing drug names is significant.

Therefore, hospitals should identify medications that are at risk of error by reviewing local data on errors and the list of confused drug names published by the Institute for Safe Medication Practices (ISMP). The identified approved look-alike and sound-alike list is required to be updated annually.

In addition, the hospitals should implement look-alike and sound-alike error preventive strategies in all stages of the medication management system to reduce the chance of adverse drug events.

These strategies can include but are not limited to:

- Segregation of look-alike and sound-alike drugs to not be stored near each other.
- Improved access to information, alerts, limiting access or use, and redundancies.
- Using both brand and generic names when appropriate.
- Using tall-man lettering.
- Including the indication for use on orders.
- Limiting the use of verbal orders.
- Using read-back processes to minimize errors by spelling the medication name and stating the intended purpose.
- Implementing barcode technology for the preparation, dispensing, and administration of medications when applicable.

The involved healthcare providers should be aware about all medication errors reported and related to look-alike and sound-alike medications and corrective actions plans should be implemented accordingly.

MM.5. The hospital establishes and implements an effective process for conducting medication reconciliation on admission, on transfer between all levels of care, between services, and at the time of discharge.

MM.5.1. The hospital has multidisciplinary policies and processes for prescriber-led medication reconciliation upon patient admission, at the time of transfer between levels of care or between clinical services, and at discharge that outlines the processes, responsibilities, and time frames.

MM.5.2. Medication reconciliation is done upon transfer to the OR and upon transfer from the OR/RR, keeping necessary medications pre-op and during OR. including the discontinuation of all medications prior to OR.

MM.5.3. The defined responsible prescriber conduct medication reconciliation by identifying the medications currently prescribed and any-nonprescription medication or supplements being taken by the patient and comparing them to newly prescribed medication orders, clarifying and resolving all discrepancies and concerns.

MM.5.4. The hospital provides patients with a current medications list upon discharge and conducts medication discharge counseling.

MM.5.5. The hospital monitors the compliance with medication reconciliation and continually implements action plans for areas of improvement, required improvements, as needed, as well as providing feedback to prescribers.

MM.5.6. The hospital has processes to reduce the risks associated with polypharmacy.

Explanation:

A good medication history is critical for patient safety. Medication history errors account for up to 75% of all potential harmful medication discrepancies in admission and discharge orders. Barriers to accurate medication history-taking include the complex and fragmented healthcare system, lack of interoperability of medication history sources, lack of patient understanding of their medication, and polypharmacy.

Medication Reconciliation is the process of creating the most accurate list possible of all medications the patient is taking, including drug name, dosage, frequency, and route, and comparing that list against the physician's admission, transfer, and/or discharge orders, with the goal of providing correct medications to the patient at all transition points within the hospital.

Providing patients with current medication lists upon discharge can help patients and families keep track of everything they take to ensure continuity of care and keep them healthy. Patient counseling is an essential aspect of patient care; providing patient education about discharge medication improves safe-use and patients' adherence to their medication.

Regular monitoring of the process should continue to support sustained consistent performance, provide feedback to organization leadership, and identify opportunities to improve the process.

Polypharmacy is the concurrent use of multiple medications. Although there is no standard definition, polypharmacy is often defined as the routine use of five or more medications. This includes over the counter, prescription and/or traditional and complementary medicines used by a patient, and constitutes patient safety risks, especially for vulnerable patients. Hospitals shall implement measures to reduce the risks associated with polypharmacy such as the medication order review process, deprescribing to manage inappropriate medication use and polypharmacy, potential adverse drug reaction, assessment of potential drug-drug interaction, and not to prescribe medications for patients currently on five or more medications, or continue medications indefinitely, without a comprehensive review of their existing medications.

MM.6. The hospital implements measures to ensure safe handling of compounded sterile preparations, including chemotherapy and total parenteral nutrition.

MM.6.1. Sterile compounded preparations are performed by department of pharmacy in a designated, functionally separate, clean room, as per national or international regulations and standards.

MM.6.2. The compounding of sterile medications outside the pharmacy is minimized. When necessary, there are appropriate preparation areas that prevent contamination and clear procedures for aseptic technique. A qualified pharmacist regularly inspects sterile product preparation areas outside the pharmacy.

MM.6.3. The hospital develops and implements a comprehensive, formulary-based, and current (up-to-date) set of compatibility and stability guidelines for parenteral medications.

The hospital ensures the availability and utilization of current (up-to-date) intravenous push medications guidelines.

MM.6.4. An independent double-check policy is implemented at each stage of compounding parenteral nutrition, chemotherapy and high-alert parenteral products.

MM.6.5. If not immediately administered after preparation, the hospital label for compounded sterile preparations includes patient identification information, the name and amount of all ingredients, beyond-use date, and the initials of the person who prepared the sterile product.

MM.6.6. The hospital conducts training and competency assessment for healthcare providers involved in preparing sterile products inside and outside pharmacy sterile admixture rooms.

MM.6.7. When parenteral nutrition or/and chemotherapy products are compounded by an outside vendor, the pharmacy department maintains a copy of the annually renewed contract and ensures the ongoing compliance of the vendor with quality and safety standards.

Explanation:

With more than 70% of hospitalized patients receiving some form of intravenous drug therapy, errors in the preparation or administration have a significant impact on many individuals. Sterile compounding is a risky process as there is a risk of infection, wrong calculations, and the risk of introducing particulates into patient's bloodstream. Clean room design, equipment and cleanliness are all prerequisites for aseptic technique. Proper selection and maintenance of equipment prevent any laminar break-through in aseptic procedure. The pharmacy regularly monitors the performance of laminar airflow hoods (LAFH) and maintains updated certification. The chemotherapy admixture area is completely separated from regular IV area.

Pharmaceutical care services shall conduct a monthly inspection and continuous monitoring of non-pharmacy staff handling sterile products and the areas where sterile products are prepared. This quality assurance process shall be documented and utilized to improve the process and enhance patient safety.

Aseptic technique is a set of specific work practices performed to minimize contamination; performing aseptic technique in a disciplined and consistent fashion is a cornerstone of sterile compounding.

Designating areas for sterile compounding and keeping those areas clean is crucial to maintain the compounding processes' requirements.

When multiple IV medications are mixed, the risk of complication is serious, and incompatibility can diminish the efficacy of one or more drugs. Understanding the requirements of evidence-based intravenous compatibility and stability guidelines ensures consistency and safety. A double check policy is important at each stage of compounding of the final parenteral nutrition, chemotherapy and high-alert parenteral products.

Medication labeling provides the necessary information to facilitate appropriate and safe administration to the patient. This process can be facilitated using preprinted labels.

Training, competency monitoring, and holding staff accountable are essential elements to ensure the compounding process is appropriately done to guarantee patients receive safe and sterile medications. Patients rely on healthcare practitioners to perform the highest standards for their safety and wellbeing.

MM.7. The hospital has a system that ensures safe prescribing and transcribing of medication orders, including specific types of medication orders.

MM.7.1. The hospital has a multidisciplinary policy and processes that ensure safe prescribing and transcribing of medication orders, inclusive of specific types or classifications of medications. Medication orders that require transcription into the Medication Administration Records (MAR) are double-checked for accuracy by two qualified clinicians.

MM.7.2. Prescribers have access to all essential patient-specific information inclusive of patient's age, gender, height, weight, current medications, diagnoses, co-morbidities, laboratory values, and allergies.

MM.7.3. The authority to order medication is based on prescribing privileges, on formulary restrictions, and policy and procedures.

MM.7.4. The hospital has a multidisciplinary policy and processes on specific types of medication orders, including non-formulary, off-label, as needed (PRN), standing, automatic

stop (ASO), titrating, tapering, range, weight-based, body surface area-based medication orders, and discharge or transfer orders.

MM.7.5. The hospital has a multidisciplinary policy and processes on telephone and verbal orders for medications that indicate under which circumstances telephone and verbal orders are permitted, required documentation, and the time frames for prescriber co-signature.

Explanation:

To ensure safe prescribing and transcribing of medication orders and prevent prescribing errors, the hospital should establish a policy and procedure on safe prescribing and transcribing of medication orders, including the process to place limits, when appropriate, on the ordering practices of healthcare practitioners such as controlled substances, chemotherapy agents, or radioactive and investigational medications.

Only those healthcare providers approved by the hospital and relevant national licensure, laws, and regulations are allowed to order medications. The approved prescribing privilege list should be known to the pharmacists and others healthcare practitioners who dispense medications.

Any electronic medication order should include the name of the drug, the dose, the frequency, route of administration and the duration. Also, it should contain all essential patient specific information. The information includes, but is not limited to, the following: patient's age and gender, current medications, indication, diagnoses, co-morbidities, laboratory values, allergies, body weight and height. In addition, all authorized prescribers should have access to all essential patient specific information.

To improve standardization and improve patient safety, the hospital policy defines the required elements for processing specific types of medication orders that include writing indications for use with any PRN order, standing, automatic stop (ASO), titrating, tapering, range, weight-based, body surface area-based medication orders, and discharge or transfer orders. Blanket orders such as resume preoperative medication should be prohibited to improve patient safety.

Accurate transcription of medication orders is very important to reduce the chance of medication errors. Therefore, when the medication has been ordered and dispensed, the nurses should ensure accurate and timely transcription of the medication onto the correct Medication Administration Record (MAR).

Since not all medications could be made available in the hospital formulary, a limited formulary list is defined by each hospital. When a clinical need arises to obtain a non-formulary drug, a process must be in place to prescribe and obtain the required medication in a reasonable time. Whenever standard therapeutic modalities are tried and have failed or when there is no established treatment for a medical illness, the need may arise to try an approved formulary drug for an unapproved indication (Off-label). The pharmacy and therapeutics committee could allow such practice by developing policies and procedures.

Miscommunication is a known contributing factor for medication errors between healthcare providers, therefore the hospital should develop and implement a policy and procedure on verbal and telephone orders and ensure that safe practices for effective communication include limiting the verbal and telephone medication orders to emergent and urgent situations, respectively.

MM.8. The hospital has a medication order appropriateness review prior to medication dispensing.

MM.8.1. The hospital has a multidisciplinary policy and processes that defines a complete medication order, inclusive of, patient information, medication regimen, and prescriber's information.

MM.8.2. The hospital has a multidisciplinary policy and processes that defines the roles, responsibilities, and processes of medication appropriateness review, inclusive of the medication regimen, therapeutic duplication, drug/food interactions, contraindications, related laboratory values, allergies, and pregnancy status.

MM.8.3. Healthcare providers involved in all stages of the medication-use process have access to the medical record and MAR to facilitates medication appropriateness review prior to medication dispensing.

MM.8.4. A qualified healthcare provider with verified education, training, and competency, reviews all medication orders before dispensing.

MM.8.5. Relevant and current (up-to-date) drug information resources are readily available and accessible to all healthcare providers involved in all stages of the medication-use process.

MM.8.6. The hospital has a multidisciplinary policy and processes to clarify with the prescriber issues and concerns related to medication orders with changes documented before medication dispensing.

Explanation:

Medication errors is one of the common causes of adverse events with prescribing errors being the most common in the hospital setting. Sixty percent of medication errors occur during the ordering or prescribing stage. Typical errors include the healthcare provider writing the wrong medication, wrong route or dose, or the incorrect frequency.

Therefore, hospitals are required to use a safe and reliable mechanism for ordering medications such as a computerized prescriber order entry system (CPOE). The CPOE has emerged as a valuable tool to improve medical efficiency and to decrease medication errors and ADEs. It has proven to be a secure way of transferring physician orders electronically thus enabling hospitals and physicians to practice a more effective and better quality of care.

Safe medication ordering and the medication order review process should be guided by hospital policies and procedures. The policy must be developed and monitored by medical, nursing, pharmacy, and administrative staff to ensure appropriate medication order review before medications dispensing.

The process to conduct an appropriateness review for an order or prescription prior to dispensing includes evaluation of the following items: medication regimen, indication, therapeutic duplication, drug/food interactions, contraindication, related laboratory values, allergy, and pregnancy status. The healthcare provider should document the review.

A complete medication order must include the following:

- Patient information (patient full name, medical record, weight, and height).
- Medication regimen (medication name, dose, route, frequency, and duration).
- Prescriber Information (signature of the ordering prescriber and contact number/pager).

The hospital must specify the process by which the appropriateness review is conducted. For example, the appropriateness review may be conducted by individuals competent to do so by virtue of education and training, such as licensed pharmacists.

The hospital should review and monitor all medication errors including pharmacy interventions that have been documented by the healthcare providers. Review of medication errors can prevent prescribing errors from recurrence and improve the medication safety accordingly.

To facilitate the appropriateness review, the involved healthcare practitioners should have access to the electronic patient's medication record as well as to the clinical information that is pertinent to the review process.

MM.9. The hospital ensures the preparation, labeling, and dispensing of medications to best practices.

MM.9.1. The hospital has a multidisciplinary policy and processes describing a standardized system for dispensing medications in the most ready-to-administer form possible (repackaged unit-doses) and keeping medications in the pharmacy or manufacturer's package until administration.

MM.9.2. All extemporaneously prepared medication formulas are available in a manual (formulation book) that is properly referenced and is documented in a logbook that includes preparation name, strength, dose, prepared quantity, batch number, preparation date, BUD, prepared and checked by.

MM.9.3. Multiple medications prepared for a single patient, such as those in the operating room or emergency room, are labeled with the medication's name and concentration.

MM.9.4. All individualized medications prepared by the pharmacy for inpatient use are labeled with the patient's name, medical record number, and location or are stored in a patient-specific cassette labeled with the hospital-approved patient identifiers.

MM.9.5. All patient-specific medications shall be labeled with the medication name, dosage form, strength, dose, directions for use, relevant cautionary instructions (e.g., refrigerate), preparation date, beyond-use date, and time (when beyond use date occurs in less than twenty-four hours).

MM.9.6. Oral liquid medications are strictly prepared and dispensed in oral syringes or other measuring devices that only display volume using the metric scale (mL) and are preferably distinctly marked as “Oral Use ONLY.”

MM.9.7. When automated dispensing cabinets are used, the hospital has a policy and procedure which details access, type of medication information, medication override, and medications stocking and refilling.

Explanation:

A unified system for dispensing medications is crucial for safe medication use in the hospitals. It is intended to standardize and streamline medication distribution and storage throughout the organization, and consequently will minimize unnecessary variation and confusion to nurses and decrease the likelihood of medication errors.

Although a unit dose medication distribution system is known and proven to be a safe system that will ensure pharmacist review and approval to medication orders when applicable, it will limit the availability of medications as floor stock in the nursing units. In addition, proper medication identification, labelling and checking before medication administration will result in a safer medication administration process.

This system shall include pharmacy dispensing the medication in the readiest to administer form as possible, as this will also facilitate administering the right medication with the right dose to the right patients. Some limited exceptions can be accepted based on the approved hospital processes for medications to be dispensed as bulk items or to be kept as a floor stock in the nursing units.

Although extemporaneous preparation has historically been a core component of the pharmaceutical profession, currently most medications are available from the manufacturer ready to use. However, there are still some circumstances where custom-made products are required for patients. Safe and accurate preparation of extemporaneous medication is an important component in the safe medication preparation and dispensing process.

Proper identification of patients' medication through a safe labeling process utilizing the hospital-approved patient specific identifiers is crucial for patient safety and to minimize wrong patient and wrong medication administration errors. Medication labelling shall include all the required information as explained in MM.9.3, MM.9.4, and MM.9.5.

Numerous medication administration errors and incidents were reported worldwide specifically related to inadvertent administration of oral liquid medications via parenteral route (e.g., Intravenously). These errors are considered a serious error that could result in significant patient harm. Investigation of these incidents revealed that using parenteral syringes or syringes that fit or connect to any type of parenteral tubing used within the hospital for measuring and preparing oral liquid medications is the main cause behind these errors.

Automated Dispensing Cabinets (ADC) technology is a high cost and safe medication distribution and management system for hospitals. These systems are intended to improve the safety and accessibility of medications through proper storage, dispensing and administration utilizing high technological techniques and processes such as electronic access control to medication (Biometric staff identification) and barcode scanning before medication refilling and stocking. These features vary from one system to another.

The safe and efficient use of Automated Dispensing Cabinets (ADC) technology can only be achieved through the adoption of standardized practices and processes that are directly associated with ADC design and functionality. This shall include:

- 1- ADC access control to provide and disable the access to ADC for different healthcare providers (ex. nurses, pharmacist and respiratory therapist).
- 2- Type of medication information to be utilized and displayed (i.e., medication name, dosage form, strength and selected important preparation and/or administration information).
- 3- The ADC integration or interface with the hospital health information system/ electronic prescribing system.
- 4- Medication override process.
- 5- Medication stocking and refilling process.

These elements are essential to ensure that the designed and intended outcome of the automated dispensing cabinet is achieved.

MM.10. The hospital ensures medication appropriateness review and verification prior to medication administration with monitoring after medication administration.

MM.10.1. The hospital has a multidisciplinary policy and processes for proper verification of dispensed medications prior to administration.

MM.10.2. The hospital has a policy and processes that defines the qualified healthcare providers who are authorized to administer medications with or without supervision, inclusive of restrictions by medication classifications, job title/role, training or competency.

MM.10.3. Relevant training and competency assessments of individuals authorized to administer medications are on file.

MM.10.4. The authorized healthcare providers verify all medication orders against the medication administration record (MAR) before administration.

MM.10.5. Oral liquid syringes or other metric measuring devices suitable to prepare patient-specific doses are available and used to administer all oral liquid medication. These devices shall not fit or connect to any type of parenteral tubing used within the hospital.

MM.10.6. The hospital maintains routinely updated guidelines for Beyond-Use Date of all types of multi-dose containers, including vials, oral liquid bottles, cream, ointment, and multi-dose inhalers.

MM.10.7. The hospital has a policy and processes for monitoring patient response to medication after administration for possible adverse drug reactions or allergies inclusive of immediate documentation of patient allergies in the patient medical record once identified and a comprehensive review by the most responsible physician and pharmacists for confirmation of allergy.

Explanation:

Medication administration and monitoring represents the final stages in the medication-use process. Given the complexity of the medication-use process and inherent vulnerability of those stages, developing strategies to capture errors and facilitate minimizing errors is a must. Using a mix of low-, medium- and high- leverage strategies is recommended, such as: patient education, judicious use of independent double checks, bar-code medication administration, and smart infusion pumps with Dose Error Reduction Software (DERS).

The hospital system must ensure accessibility to all elements of the complete order (specified in MM.8.1) at the time of administration, for all healthcare providers authorized to administer medications. Safe administration of medication includes verifying the dispensed medication, dose, frequency route of administration, as well as patient identity with the prescribed order.

The hospital must define individuals permitted, by licensing and regulatory organizations as well as their own hospital system, to provide care, treatment, and services with or without direct supervision. New practitioners who are involved in the administration of medication and are assigned to work independently undergo baseline competency assessment; and information about medications, medication-related risks, and errors that have occurred in the organization are shared with these practitioners for learning purposes.

Several medication administration errors were reported worldwide due to inadvertent administration of oral liquid medications intravenously. These errors are considered a serious error and could result in death or significant patient harm. Investigating reported incidents of this type revealed that using parenteral syringes, or syringes that fit or connect to any type of parenteral tubing used within the hospital, for measuring and preparing oral liquid medications is the main cause behind these errors.

Beyond-use date (BUD) is the date or time after which compounded preparations (sterile or non-sterile), opened multi-dose container, or repackaged medication may not be used and should be discarded. It is calculated from the date or time of compounding, opening, or repackaging, respectively. BUDs are assigned based on physical or chemical stability, microbial contamination, degradation and compatibility of the container–closure system. The hospital has to develop general guidelines, based on its need and according to published evidence, in order to guide the assignment of BUDs.

Despite the rigorous process and safety studies that every medication undergoes before it is marketed, there is no medication free of Adverse Drug Reactions (ADRs). The World Health Organization defines an ADR as “any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.” Using of screening tools (e.g., IHI Trigger tools), conducting clinical studies, and encouraging ADR reporting are essential in detecting and identifying them post-marketing. Proper documentation of ADR and allergies will assist in proper patient management and preventing medication errors in the future.

Radiation Safety (RS)

Hospital management endeavors to provide excellent healthcare services through high standards of patient care, proficient staff performance and efficient interdepartmental collaborations. Hospital accreditation schemes are mechanisms that can assist hospital management to improve health care services through the development of standards for safety, guidance and monitoring for continued support in clinical operations, technical development, communication skills and emergency preparedness aspects. The ultimate goal of hospital management is to respond equally to the expectations of patients for efficient health services and good quality care. Hospital accreditation provides a systematic system of promoting good health by putting into place the means to measure quality care and good management.

For the day-to-day activities in a medical institution, safety encompasses a wide realm of people, places, environment and facilities that require different approaches and degrees of safety. Practices, risk assessment and internal and external evaluation of safety for people, places, environment and facilities become part of the planning before and during hospital operations. Comprehensive and strategic assessment of tools, equipment and staff performance are all important aspects in the quality evaluation to ensure safety.

One facet of safety is the use of ionizing radiation in medicine. Ionizing radiation-based technologies are used as an essential tool for diagnosis and treatment purposes. Their benefit is immense and serves most departments within any healthcare facility. However, like many areas of medicine, the benefit is associated with a risk that must be kept as low as reasonably achievable. Conversely, the utilization of high dose imaging equipment like computed tomography (CT) has tripled in the last decade and studies have demonstrated that a significant percentage of these investigations show no useful information. In countries like the US, Europe and Canada, these are highly governed practices that still need improvement, optimization, and standardization. Currently, there is a worldwide concern on patient safety due to overutilization and misuse.

Early reports on the biological effects of ionizing radiation among watch dial painters, industrial workers, users in hospitals, victims of Hiroshima and Nagasaki bombings and nuclear power plant accidents confirm the harmful effects of radiation. In addition, injuries, and deaths in radiotherapy accidents demonstrated the need for protection of people and the environment. As a result, standards for the safe use of radiation and radioactive sources were developed and undergo continued review and revision. These standards were developed based on epidemiological studies, reports of the United Nation Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and recommendations of the International Commission on Radiological Protection (ICRP). They are basis of the International Atomic Energy Agency (IAEA) in its safety standards for protection. The IAEA first initiated the development of safety standards in 1958 and continue to develop updated standards for the many different applications of radiation to assess and control the risk of harmful effects from radiation.

The publication of the ICRP in 1990 included the stochastic effects (cancer induction and hereditary) and deterministic effects of radiation such as skin injuries, the short and long-term biological effects

and the risks associated with the exposure to ionizing radiation. The contributing features of radiological protection for patients and members of the public, namely justification, optimization and dose limitations, are being defined in the publication. Recommendations on the annual dose limits for occupationally exposed individuals and members of the public were issued by ICRP based on epidemiological studies and reports of accidents and these values were updated in the latest ICRP Publication 103 issued in 2005. Recommended dose limits to the fetus and recommendations for pregnant radiation workers and patients including patients who are breast-feeding are also contained in the ICRP publications. The new and current ICRP publication has updated the recommended radiation weighting factors based on new scientific studies and has included the protection of the environment. This publication has identified distinctions between two major health effects, namely skin injuries for deterministic effects and stochastic effects. The publication also highlighted radiation protection in emergency and unintended exposure situations.

The IAEA Basic Safety Standards and other safety standards are in harmony with the ICRP recommendations. It has also issued publications regarding the safety of radiation sources, management of hospital radioactive wastes and diagnostic reference levels. A specific publication on the safety of occupationally exposed individuals has been issued by IAEA. The IAEA standards of protection publication emphasizes the role of the government on regulating and setting up radiation protection infrastructure. It is then the responsibility of the national regulatory agencies of each country to formulate regulatory requirements on the safe use of ionizing radiation and regulate its uses through licensing of facilities for the different applications of ionizing radiation including medical uses.

In 2010, the US Food and Drug Administration (FDA) published a white paper on an initiative to reduce unnecessary radiation exposure from high radiation dose modalities like CT, fluoroscopy, and nuclear medicine examinations. This initiative was in response to the dramatic increase in the amount of radiation patients are currently being exposed to. Through this, the FDA aimed to promote the safe use of imaging modalities, the use of clinical decision support systems and guidelines and increased public awareness by defining the stakeholders responsible for safer applications.

In 2012, the IAEA and the World Health Organization (WHO) published a joint statement on the use of radiation in medicine during a scientific meeting in Bonn, Germany. The list of actions that concluded this meeting represents the Bonn Call for Action, listed below:

Action 1: Enhance the implementation of the principle of justification.

Action 2: Enhance the implementation of the principle of optimization of protection and safety.

Action 3: Strengthen the manufacturers' role in contributing to the overall safety regime.

Action 4: Strengthen radiation protection education and training of health professionals.

Action 5: Shape and promote a strategic research agenda for radiation protection in medicine.

Action 6: Increase availability of improved global information on medical exposures and occupational exposures in medicine.

Action 7: Improve prevention of medical radiation incidents and accidents.

Action 8: Strengthen the radiation safety culture in healthcare.

Action 9: Foster an improved radiation benefit-risk-dialogue.

Action 10: Strengthen the implementation of safety requirements globally.

These are essential actions and sub-actions in radiation protection that identify the stakeholders and their responsibilities to improve the practice of using ionizing radiation in medicine for the next decade. Reviewed every 5 years, these 10 actions have been adapted by different countries and by various scientific organizations and serve as guidelines for creating a radiation safety culture in healthcare facilities. In response to the Bonn Call for Action, the European Union and the European Society of Radiology established Euro safe Imaging in 2014 to strengthen the radiation safety culture in Europe. Euro safe Imaging been very active in conferences and research that promote best practice in radiation protection. Similarly, Canada, Japan, Latin American countries, and African countries have all established individual initiatives complimenting the Bonn Call for Action (i.e., Canada Safe, Japan safe, Latin Safe, and Afro Safe) supported by the International Society of Radiology (ISR), IAEA and WHO to facilitate the Bonn Call for Action implementation in each region. In 2017, all chairmen of radiological societies in the Arab World signed the establishment of Arab Safe in Marrakesh, Morocco; a radiation protection movement in Arab countries that aims to impact the current diagnostic imaging practice, support self-regulation, and increase awareness of radiation safety for patients.

Currently, the Saudi population is exposed to unknown amounts of ionizing radiation from medical applications. Over the years, the practice of using radiation in medicine (specifically in radiotherapy and nuclear medicine) has been regulated by local authorities, though some of them are no longer active. However, significant variation in safety standards among diagnostic imaging service providers locally is still a discernible problem. Diagnostic radiology practices in Saudi Arabia were not efficiently monitored, licensed or regulated until 2017. Recently, the Saudi Food and Drug Authority (SFDA) established a National Radiation Safety Committee, published a set of hospital safety requirements for radiation use, and conducts site visits to report misuse. In 2018, the Nuclear and Radiological Regulatory Commission (NRRC) was established to regulate, monitor, and protect people and the environment from the hazards of radiation. The NRRC published an extensive draft in 2020 that will serve as the regulation guideline for use of ionizing radiation in medicine. All these efforts aim to support users and make sure that the benefit from using imaging modalities is achieved while keeping the risk at minimum. Previously, neither government nor private health organizations that use ionizing radiation implemented a national standard for safe use of medical radiation in practice. Therefore, much effort is still needed to bring about a measurable impact on the current practice and to ensure the highest standards of patient safety are followed.

Additionally, non-ionizing radiation is used in some medical procedures which are associated with significant risk to humans. These procedures include the use of ultraviolet radiation, infrared radiation, and laser. Effects and safe uses are contained in the International Commission for Non-Ionizing Radiation Protection (ICNIRP) guidelines. The National Council for Laser Excellence (NCLE) is the only cross-industry board that provides standard and proctored examination certification of laser operators,

nurses and technicians. The basis of formalizing a laser safety program is set forth in the American National Standards Institute (ANSI) Z136.3 standards for safe use of lasers in health facilities. Legally, ANSI does not have the power to enforce these standards, therefore the standards remain voluntary and not a requirement. Practically, ANSI standards are implemented in healthcare facilities because of the enforcement of other agencies such as the Occupational and Safety Health Administration (OSHA). OSHA Publication 8.1-7 is an instructional handbook that lists the safety requirements based upon ANSI standards and evaluates safe laser practice. Locally, the SFDA has been regulating the applications of lasers in medicine to ensure minimum accidents and harm in healthcare facilities. Their effort in this field is very important especially in the private sector as they are the primary users of medical laser. In contrast, Magnetic Resonance Imaging (MRI) and ultrasound are two areas of medical imaging that use sound waves and magnetic fields, respectively. However, these modalities are both unmonitored practices from the safety point of view, which also do not comply with any safety standards and lack formal regulations. The American College of Radiology (ACR) came out with safe MR practice guidelines (ACR guidance document on MR safe practices), that has become the national standard of care for MR safe practices in the USA. The risk of producing bioeffects as a result of ultrasonographic acoustic energy has been studied with the support of the World Federation for Ultrasound in Medicine and Biology (WFUMB) where conclusions and recommendations have been accepted. Conversely, guidelines have been published by the National ultrasound safety committees. These recommendations and guidelines facilitate a safe application of diagnostic ultrasound. In the United States, the US Food and Drug Administration (FDA) regulates the acoustic output from ultrasound equipment.

This document, the CBAHI Radiation Safety Priority, contains standards for the safe use of ionizing and non-ionizing radiation in medical institutions. The standards are based on the recommendations and requirements of IAEA, ICRP and ICNIRP. It contains 7 priority standards that are focused on addressing the safe use of ionizing and non-ionizing radiation in diagnostic and therapy procedures and investigations. It has specific safety standards for patients, occupational workers and facilities. The document requires the participation of hospital management in radiation safety, particularly in giving radiation safety and protection the highest priority in its management decisions. The document includes the hospital's management role in radiation emergency response, optimization of protection of patients and occupational workers and patient dose optimization to ensure that doses of patients are as low as reasonably achievable (ALARA). Each standard provides the compliance requirements which will serve as the indicator that the medical institution has met the requirements of the specific standard. The intent of the standard, citations and references are listed for each standard. Also, this priority follows NRRC and SFDA requirements and all hospitals will have to comply with both in the coming years. Compliance with CBAHI Radiation Safety Priority should not pose any additional budget burden to the hospital.

The objective of this document is to evaluate the capability and assess the readiness of medical institutions to implement radiation safety requirements and to promote patient safety by enforcing standards of radiation protection as required locally and internationally.

RS.1. The hospital ensures a safe environment for diagnostic investigations and treatments.

RS.1.1. The hospital has processes to identify areas with ionizing radiation usage, ensuring its safekeeping and use.

RS.1.2. The hospital complies with national laws and regulations for radiation safety in all areas.

RS.1.3. The hospital has a system to maintain the security of radiation sources, as per national and international standards.

RS.1.4. The hospital has processes for radiation waste disposal and management.

RS.1.5. The hospital has radiation area monitors in the hot lab, injection room, radioactive waste areas, and waste decay storage areas.

RS.1.6. The hospital has a separate ventilation system for rooms hosting radioactive material (i.e., hot lab, injection room, radioactive waste storage) and negative pressure to prevent radioactive contamination in the air in the Nuclear Medicine areas.

RS.1.7. The hospital has a radiation dose management system that integrates with the Radiology Information System (RIS).

Explanations:

Radiation safety starts from the equipment that produces the ionizing radiation; therefore, the hospital has the responsibility to ensure appropriate procurement, installation, operation, maintenance, and replacement of all equipment that reach the retirement age. Records relating to these obligations are maintained.

RS.2. The hospital ensures culture of radiation safety.

RS.2.1. Hospital leaders are accountable for radiation safety in the hospital.

RS.2.2. The hospital grants radiation privileges to qualified healthcare providers.

RS.2.3. The hospital regularly conducts radiation safety assessments, with risk mitigate strategies.

RS.2.4. The hospital ensures continuing professional development, training, and competency in radiation protection for occupational radiation exposure.

RS.2.5. The hospital promotes radiation safety awareness as part of its orientation program and on an ongoing basis.

Explanations:

Radiation safety is a shared responsibility that starts with the leadership and involves all staff. Creating a radiation safety culture is a multidisciplinary task that involves hospital-wide efforts and commitment to actions that lead to safe use of radiation.

RS.3. The hospital has a process for the justification of medical radiation exposure.

RS.3.1. The hospital implements evidence-based referral guidelines to standardize imaging requests.

RS.3.2. There is an effective periodic internal audit of imaging requests with feedback communication to healthcare providers on their compliance.

RS.3.3. The hospital investigates the clinical indications of repeated imaging requests.

Explanations:

Patient exposure for the purposes of diagnosis or treatment has no limits according to international regulatory bodies but is governed by justification and optimization principles of radiation protection and evidence demonstrates that the hospital is working to implement both continuously.

RS.4. The hospital has a process for medical radiation exposure optimization.

RS.4.1. The hospital has a system to identify patient radiation doses.

RS.4.2. For the hospital's identified most common radiological examinations, the hospital sets investigation triggers when exceeding its typical values (or facilities diagnostic reference levels (FDRL) and benchmarks its practice with national or international dose reference levels (DRL).

RS.4.3. The hospital has a radiation quality assurance program, inclusive of its imaging equipment and PPM.

RS.4.4. The hospital ensures all radiation measuring tools, phantoms, and quality control equipment is reliable, suitable for their purpose, and calibrated.

RS.4.5. The hospital performs periodic room integrity and lead equivalent verification checks for all areas that include radiation sources, including equipment or radioactive sources.

RS.4.6. The hospital conducts scheduled periodic reviews of its adult and pediatric imaging protocols and ensures compliance with specified DRL quantities.

RS.4.7. The hospital has protective tools and shields that are tested periodically and has a system for disposal of defective items.

Explanations:

Patient exposure for the purposes of diagnosis or treatment has no limits according to international regulatory bodies but is governed by justification and optimization principles of radiation protection and evidence shows that the hospital is working to implement both continuously.

RS.5. The hospital has a system to continuously assess, evaluate and monitor occupational radiation exposure.

RS.5.1. There is continuous monitoring of occupational staffs' exposure to external and internal radiation.

RS.5.2. The hospital monitors the radiation doses of all pregnant workers.

RS.5.3. The hospital performs annual audits of radiation doses to staff.

Explanations:

The hospital implements the concept of as low as reasonably achievable to limit the occupational dose of radiation through continuous monitoring of all radiation workers.

RS.6. The hospital has a system to measure potential unintended radiation exposures.

RS.6.1. The hospital has a prompt response system to mitigate any consequences from unintended radiation exposure of patients.

RS.6.2. The hospital has a prompt response system to mitigate any consequences from unintended radiation exposure of staff.

RS.6.3. The hospital has a prompt response system to mitigate any consequences from unintended radiation exposure in the workplace.

Explanations:

Unintended radiation exposures lead to accidents that need to be handled professionally and mitigated by emergency plans with prepared scenarios, steps and regulations that are updated periodically with revised guidelines and recommendations.

RS.7. The hospital leaders ensure a safe environment for the application of diagnostic and therapeutic non-ionizing radiation.

RS.7.1. The magnetic resonance imaging (MRI) unit is located and designed in compliance with national and international safety standards and regulations.

RS.7.2. The hospital has an MRI quality assurance program that includes initial and ongoing specialized training of staff.

RS.7.3. The hospital has a laser safety program.

RS.7.4. The hospital has an ultrasound safety program.

Explanations:

There are potential risks in the non-ionizing radiation environment, not only for the patient, but also for the attending healthcare professionals, patient's family members and support personnel. The hazard from non-ionizing radiation may extend to fires, biological burns and conduction of biological eddy current. The hospital is responsible for maintaining a safe working environment, service application and safe use of equipment. -related safe use.

Central Sterile Service Department (CSS)

The Central Sterile Service (CSS) is responsible in reprocessing reusable medical devices and equipment's in all healthcare facilities, aiming to provide the highest care and handling towards patient's safety, staff protection, environment control and Preventing surgical site infection (SSI) and HAI. Centralizing the process is the safest, efficient and most cost-effective arrangement to perform the reprocessing medical device. The work areas should be physically divided into the following functional areas: receiving, cleaning, decontaminate, inspection, preparation, and packaging, sterilization, storage and distribution. There should be a clear unidirectional workflow, traffic control and controlled environment to minimize bioburden and prevent cross contamination.

The fundamental role of the CSS department is to receive, clean, decontaminate, package, sterilize and distribute safe reusable medical devices in compliance to infection control protocol, national and international standards.

The CSS personnel need numerous dimensions of knowledge and skills in providing a successful service by implementing the best practices in communication, technical skills, workplace safety and must be qualified and knowledgeable through orientation, training, competency and certification issued by authority (SCHFS). Potential infectious blood, fatty tissue, and body fluids transmission through contaminated medical device occurs in CSS by indirect mode. The risk of exposure to pathogenic microorganisms can be reduced by performing hand hygiene, wearing PPE and compliance to OSHA safety standard. The environmental cleaning in CSS also plays a huge role to prevent spread of infection.

At the end of each surgical procedure, end user must perform pre-treatment and safely transport as soon as possible from point of use to the CSS facility to prevent body substances from coagulating and making it more difficult to clean. Instruments should be kept moist with an enzymatic solution or hospital approved instrument gel and any lumens are flushed after used, the reusable medical device should be moved in closed containers or enclosed transport cart with biohazard label. Single use devices (SUD) must be discarded at point of use and prohibited to send to CSS facility.

The Removal of blood borne pathogens on instrument surface including cannulated/lumen type of Instrument is done through manual/mechanical cleaning following manufacturer's instruction for use. The cleaning brush standard considers a correct brush size in all lumen items and preferably single use. Due to risk of cross contamination, cleaning and disinfection of reusable brushes is required every after used. The automated washer disinfectant provides an efficient and validated process which enable to reduce CSS personnel in exposure to contamination and limit possible human error.

The clean zone (Inspection-Assembly-Packaging Zone), the CSS personnel prepare and inspect instruments in their cleanliness, functionality and possible defects followed by the arrangement and checking of quantities inside the tray for completeness using checklist. Labelling is essential in each package for it contains the information of the set, load number, name of staff and the date of sterilization. The CSS personnel may also consider factors in dealing with instruments such as the instrument type, manufacturer's recommendation, damaging factors, package materials and packaging techniques.

Steam and plasma sterilization process destroys all microorganisms including bacterial spores. High level disinfection is another method used for certain devices depending on its type as refer in Spaulding

classification. The principles of sterilization can be achieved by a correct sterilization methods and parameters. The efficacy of sterilization process can be affected by several factors like the type and number of bioburden/soils, cycle of sterilization including exposure (contact time), temperature and the type of sterilization process.

Instruments to be sterilized are monitored through chemical and biological means to determine the effectiveness of the sterilization process. Each sterilizer requires quality assurance monitoring test based on the manufacturer's instructions for use. Malfunction sterilizer and positive spore test result the staff should initiate a recall process including roles and responsibilities of each staff.

Storage spaces and shelving should have met the standard requirements to prevent damage and micro-tear to the package and maintain the sterility of the items. CSS personnel should follow the unloading protocol based on standard and ensures that in each surgical procedure the instruments are appropriate, packs are intact, not torn/opened, or wet and all indicators show sterilization prior to distribute to the end-user. The shelf life of sterile items should be event related or time related depending on healthcare facility policy and procedure. Transport cart or container used sterile items must be cleaned and decontaminated prior to use.

The outsources policies and procedure established to provide a clear process for transportation and reduce the cost associated with instruments reprocessing and improving patient's safety, personnel safety and hazard free environment. Moreover, the outsourcing provides high quality sterilization services on a timely manner in healthcare facilities.

The reprocessing zone in the endoscopy unit are physically separated from the endoscopy procedure rooms to prevent cross contamination of soiled endoscopes. Effective decontamination of endoscope will protect the patient from infection, ensure the quality of diagnostic procedures and taking samples and prolong the life span of the equipment. Manufacturers recommendation and standard procedure in decontamination process as well as performing verification of cleaning is essential and must be followed at all times.

Surgical site infection (SSI) is the most frequent type of healthcare associated infection (HAI) in low- and middle-income countries 68% of the world countries (low middle-income countries is considerably higher than in high income countries). Based on WHO report approximately 1 in 10 people who have surgery acquire SSI. The average SSI leads to approximately 1 week of additional hospitalization and increases the risk of death 2-to-11-fold compared to uninfected surgical patients. In addition to the risk and discomfort for the patient, surgical site infection dramatically increases the direct and indirect cost of treatment.

The most basic work to prevent hospital infections is usually by sterilizing reusable medical devices. Therefore, proper investment and creation of processes and necessary infrastructures for proper cleaning, disinfection and sterilization with optimal management in CSS will improve the quality of services and leads to the reduction and control of costs.

CSS.1. The hospital has CSSD services.

CSS.1.1. The hospital has central sterilization services to meet their operational needs, either in-house or externally contracted.

CSS.1.2. The hospital has a process for monitoring and management of contacted CSSD services, ensuring secured transportation of reusable medical devices to and from the outsourced facility.

CSS.1.3. The hospital's CSSD is access control restricted to the authorized personnel only at all times, with signage.

Explanation:

The hospital needs to centralize CSSD functions to ensure staff and patient safety, reduce cross-infection, create a hazard-free environment, and promote cost-effectiveness. Sterilization is a complex process requiring environmental controls (e.g., controlled air changes, heating, ventilation, and air conditioning [HVAC] parameters).

CSS.2. The hospital's central sterilization service physical design and work flow meets national and cited international standards and regulations.

CSS.2.1. The hospital has dedicated CSSD room(s) with a shower, a toilet facility, and staff lockers.

CSS.2.2. The hospital has a dedicated area for donning Personnel Protective Equipment before entering the CSSD.

CSS.2.3. The decontamination zone is physically separated from the clean zone with a unidirectional workflow.

CSS.2.4. The decontamination zone is under negative pressure with a minimum of 10 air exchanges/hour with exhaust to the outside, temperature between 18°C-23°C.

CSS.2.5. The clean zone is under positive pressure with a minimum 10 air exchanges/hour with temperature 20°C- 23°C, and the sterile store has 4 air exchanges per hour.

Explanation:

This standard guides the CSSD design and workflow to facilitate effective and efficient processing, and standardization of procedures to minimize environmental contamination and maintain the processed items' sterility.

CSS.3. The CSSD has qualified staff and essential resources to operate the Central Sterilization Service.

CSS.3.1. The CSSD/ CPP supervisor is licensed in medical sterilization from the Saudi Commission for Health Specialties.

CSS.3.2. Central sterilization services staff are qualified by education and training with 20% or 50% of the staff licensed in medical sterilization by the Saudi Commission for Health Specialties.

CSS.3.3. The CSSD staff are immunized as per hospital policy and the national immunization policy.

CSS.3.4. Required personal protective equipment is available and used during decontamination at all times.

CSS.3.5. The hospital has an approved list of required CSSD materials, solutions and equipment available at all times, with designated par levels for CSSD and hospital storage facilities.

Explanation:

To ensure efficiency and quality of sterilization services. The process should be conducted by qualified CSSD staff by experience, knowledge, and certification to ensure efficiency and quality of sterilization services. The competency assessment should be regularly evaluated maintained for all CSSD staff. All credentials, competencies, and job descriptions should be documented in CSSD staff personnel files and assessed during CSSD staff interviews. As for the workforce, CSSD should be staffed to cover 24 hours of operation the day. The staffing level and number meet the workload requirement, hospital bed capacity, and the number of operating rooms. The number of CSSD assigned staff should be presented in CSSD Organizational Chart and staffing plan.

CSS.4. The hospital has decontamination processing of approved re-usable medical devices.

CSS.4.1. The hospital has an evidence-based multidisciplinary policy and processes for processing re-usable medical devices.

CSS.4.2. Contaminated instruments are pretreated at the point of use and transported in closed containment with the biohazard sign.

CSS.4.3. Instruments are sorted, disassembled, cleaned & disinfected as per the manufacturer's instructions.

CSS.4.4. Manual cleaning is performed before loading in the washer-disinfector, ultrasonic cleaners, or manual disinfection; at least two sinks are used, one for soaking and cleaning and one for rinsing before the final wash with purified water.

CSS.4.5. Cleaning brushes are used as per the manufacturer's instructions.

CSS.4.6. Approved cleaning enzymatic detergent and disinfectant solutions are available at all times and used to clean and disinfect the instruments.

CSS.4.7. Automated washer-disinfector and ultrasonic machines are used according to the manufacturer's instructions for use, and efficacy tests are performed daily.

Explanation:

Decontamination removes contaminants on reusable medical devices for safe handling, which can be achieved by manual and mechanical processes. All reusable medical devices transported in the decontamination zone have biohazard label signs and are considered infectious. Standard precautions must be observed during handling, transporting, and reprocessing.

There must be a unidirectional flow from the receiving area in the decontamination area until the dispatching area.

Manufacturers' recommendations should comply during the manual and/or automated cleaning and disinfection process. Infection control must approve the disinfectants, detergent, and cleaning tools. The

PPE must ensure compliance with the ISO standard regarding the quality of the material that will be used. The CSSD must perform the cleaning verification test for ultrasonic, washer disinfectant and manual cleaning.

CSS.5. CSSD has inspection, assembly, and packaging before sterilization.

CSS.5.1. All Instruments are inspected for cleanliness and functionality before packing.

CSS.5.2. Lubrication is performed according to manufacturer's instructions.

CSS.5.3. Counting of items is conducted utilizing documented instruments' checklists.

CSS.5.4. The instrument tray weights less than 12 kg.

CSS.5.5. Type 5 or 6 chemical indicators are placed inside each package, according to manufacture instructions.

CSS.5.6. Packaging materials are compatible with the intended sterilization and the devices to be sterilized.

CSS.5.7. All packaged items are labeled before sterilization.

Explanation:

Clean items are received in the packaging zone to be inspected, assembled, and packaged for sterilization. It is essential to check reusable medical devices for cleanliness to assure sterility and functionality to avoid patient harm.

Lubrication should be performed after cleaning to maintain the instrument's integrity. Sets and trays of reusable medical devices must be counted against a checklist and assembled safely to assure the sterilization process.

Appropriate packaging materials and chemical indicators should be selected based on the sterilization method that will be used. Detailed Labelling must be maintained according to the standards.

CSS.6. The hospital ensures the quality of sterilization process.

CSS.6.1. Sterilizers have regular PPM.

CSS.6.2. A Bowie Dick test is performed daily for each steam sterilizer.

CSS.6.3. A biological indicator is used at least once a week for each steam sterilizer and daily for low-temperature sterilizers.

CSS.6.4. Any load containing implants require a biological indicator to be used.

CSS.6.5. A leak test is performed at least weekly, per the manufacturer's instructions.

CSS.6.6. All sterilization monitoring parameters records are kept as per national or international standards.

CSS.6.7. The hospital has a policy and processes to recall items.

Explanation:

Sterilization is the destruction of microorganisms, including bacterial spores.

All sterilizers must be functioning correctly; therefore, the hospital needs to perform preventative maintenance and regular servicing according to the manufacturer's instruction, and all reports are kept.

The sterilization procedure is monitored routinely by using a combination of quality controls, including chemical and biological indicators, Bowie-Dick test, leak test to ensure a successful process, and prevent infection transmission to the patient. Documentation must be kept for one year for each load, and for all quality controls of the sterilization process.

CSS.7. The hospital provides dedicated sterile storage(s).

CSS.7.1. Dedicated sterile storage(s) are maintained under positive pressure, with a minimum of 4 air exchanges per hour, temperature ranges from 20°C to 23°C, and relative humidity with a limit of 70%.

CSS.7.2. Sterile storage shelves are clearly labeled, free from dust and away from sprinklers and air vents.

CSS.7.3. Storage shelves are placed 40 cm from the ceiling, 20 cm from the floor, and at least 5 cm away from the wall.

CSS.7.4. Sterile items are arranged in the storage shelves, with lighter items on the top shelves and heavier items on the bottom shelves, in all areas within the hospital with sterilized item storage.

CSS.7.5. Distribution of sterile items adheres to the 'First in the First Out' (FIFO) principle.

CSS.7.6. A packaged item's sterility is event-related with a maximum of one year and all sterile items are tagged with the sterilization date.

Explanation:

Sterility maintenance is directly affected by packaging materials, storage methods and conditions, and methods of distribution. It is essential to ensure that all sterile products are maintained and stored to maintain sterility until a product is used. Sufficient storage space with specific engineering control measures (Positive pressure, air changes per hour, temperature, and humidity) are established to maintain the sterile items' sterility. The CSSD has sterile store(s) that meet the standard requirement to maintain sterility of sterile items.

CSS.8. The hospital reprocesses flexible endoscopes.

CSS.8.1. The endoscopy procedure room(s) and the reprocessing zone are physically separated.

CSS.8.2. The bronchoscopy procedure room is maintained under negative pressure with a minimum of 12 air changes per hour.

CSS.8.3. Contaminated endoscopes are transported safely to the reprocessing area in a suitable closed container with a visible biohazard label.

CSS.8.4. Leak testing is performed according to the manufacturer's requirements before manual cleaning, and the results are documented.

CSS.8.5. Cleaning verification and efficacy tests are performed and documented.

CSS.8.6. High-level disinfectants, approved by Infection Control Committee and routinely tested to ensure minimum effective concentration, are used for reprocessing.

CSS.8.7. Endoscopes are stored in a designated storage cabinet in accordance with the manufacturer's instructions.

Explanation:

The cleaning and disinfection process should maintain the same standards wherever they are performed in a hospital's designated area. All reprocessing should be carried out by trained staff in a traffic-controlled place and should be done according to the manufacturer's recommendations and international

standards. The hospital must ensure there is a written policy and procedure for reprocessing contaminated endoscopes.

CSS.9. The hospital has a process for discarding single-use devices (SUD) at the point of use.

CSS.9.1. The hospital has a policy and processes regarding single-use devices.

CSS.9.2. The hospital has processes to identify single-use devices.

CSS.9.3. The CSSD staff have a process in place to prevent reprocessing of single-use devices.

Explanation:

To prevent risk of cross-infection, single-use devices are not designed for reprocessing. A single use device is intended to be used on one patient only and then discarded and never reprocessed for use on another patient.

There are two risks associated with the reuse of reprocessed single-use devices: There is the potential for an increased risk of infection. There is also a risk that the device's performance may be inadequate or unacceptable after it is reprocessed. The reuse of reprocessed single-use devices carries significant risk, as many devices are complex in design and therefore difficult to clean, disinfect, or sterilize.

The hospital must have a system to ensure that devices under the category of a single-use device (SUD) will not be reprocessed.

CSS.10. The hospital has CSSD -specific Infection Prevention and Control Practices.

CSS.10.1. Hand hygiene facilities support hand hygiene practices in all CSSD zones.

CSS.10.2. Personnel Protective Equipment is available in different types and sizes with qualities approved by infection control, at all times.

CSS.10.3. Waste is segregated according to a hospital facility waste management policy.

CSS.10.4. The CSSD has a process to handle biological and hazardous material spills.

CSS.10.5. Environmental cleaning is conducted by dedicated, competent environmental service staff on a regular basis according to the hospitals environmental cleaning policies and procedures.

CSS.10.6. CSSD staff disinfect the workstations, medical equipment, counters using approved disinfectant before starting the work and at the end of the shift.

CSS.10.7. Designated surgical attire/scrub suit, dedicated shoes/shoe covers and head and facial hair covers are available and used by staff according to the CSSD attire policy.

Explanation:

CSSD played a significant role in patient/staff safety, preventing healthcare-associated infection/surgical site infection and environmental contamination.

The central sterilization supply department (CSSD) is performed reprocessing of reusable medical devices with best practice compliance.

Dumb dusting and cleaning at the beginning and end of each shift will maintain cleanliness, reduce microorganism transmission and staff safety.

Healthcare-Associated Infections (HAI)

Healthcare-associated infections (HAIs) are infections acquired by the patient due to direct or indirect exposure to the healthcare system environment or the medical care provided. HAIs are one of the most alarming public health problems worldwide with serious adverse effects. Moreover, they are associated with increased morbidity and mortality rates and prolonged hospital length of stay, leading to an increase in healthcare costs, which will increase the burden on patients, healthcare workers, and the healthcare system.

Some HAIs are related to the use of invasive devices such as a central line that could lead to central line-associated bloodstream infection (CLABSI), Foley catheters leading to catheter-associated urinary tract infection (CAUTI), and ventilators leading to ventilator-associated pneumonia (VAP) and ventilator-associated event (VAE). On the other hand, some HAIs are iatrogenic but non-device associated, including bloodstream infections (BSI), urinary tract infections (UTI), and pneumonia; or procedure-related, including surgical site infections (SSI), and other HAIs are associated with the dialysis procedures.

The increasing antimicrobial resistance poses a challenge to surveillance systems and raises concerns about multidrug-resistant organisms' impact on patient safety. By controlling HAIs, infection or colonization by multidrug resistance microorganisms could be decreased. Regular and vigilant surveillance of HAIs, with timely reports to stakeholders, is an essential component of patient safety and healthcare improvement initiatives. Furthermore, surveillance will provide baseline data for assessing the progress of preventive measures.

The reported case-fatality rate of HAIs ranges from 2.3% to 14.4%, depending on the infection type. Hospitals need to develop a monitoring system for HAIs to collect data using standardized collecting methods and unified definitions based on the most used commonly used references worldwide (CDC's, National Healthcare Safety Network NHSN). The aim is to estimate unit-specific HAIs rates and device utilization ratios with benchmarking of results against recognized regional and international rates including those published by the National Health Safety Network (NHSN), the International Nosocomial Infection Control Consortium (INICC) and the Gulf Cooperation Council (GCC).

Risk Reduction Strategy:

1. Annual Risk Assessment and Plan:

Rates of Healthcare-Associated Infections are calculated, analyzed and interpreted regularly based on the hospital scope of service and patient type. Infection control risk assessment (ICRA) (i.e., processes, procedures, and devices identified by the IC practitioners to be associated with risk of HAIs in a specific healthcare setting) is an essential element for a structured infection control program that must lead to the development of the annual plan.

The ICRA uses monthly reports of HAI surveillance, patient types, environmental circumstances, training needs, emerging infections, and shortage in supplies to identify risks specific to the hospital and prioritize improvement projects.

Annual IC Plan: A written, risk-based document with goals and measurable objectives, strategies, evaluation methods, and regular follow-up.

Risk Assessment: Describe the overall process or method used to identify and evaluate risk factors that can cause harm to the patients, staff, visitors, and family members.

Why perform an Annual Risk Assessment?

The aim of an annual risk assessment is to focus activities on essential tasks related to reducing critical infection risks:

- Identify the risks that are unique for every hospital
- Improved patient safety.
- Improved staff safety.
- Improved efficacy (desired results)
- Identify training issues.
- Understanding of disease transmission and prevention
- Implementation of new interventions

2. Care Bundles:

Care “bundles” in infection prevention and safety are simple sets of evidence-based practices that, when implemented collectively, improve the reliability of their delivery and improve patient outcomes. Several specific bundles are available that can be implemented at hospitals in resource-limited settings. These packages of care contribute to infection prevention, reduce unnecessary antibiotic prescribing, and may limit the development of antibiotic resistance in hospitals.

General principles:

- a. The implementation of care bundles can assist in enhancing compliance to evidence-based quality process measures to improve patient care.
- b. Care bundles include a set of evidence-based measures (where possible backed by level 1, randomized controlled trial evidence) that when implemented together have shown to produce better outcomes and have a greater impact than that of the isolated implementation of individual measures.
- c. Bundles also help to create reliable and consistent care systems in hospital settings since they are simple (three to five elements), clear, and concise.
- d. In addition to creating safer patient care environments, the implementation of bundles also promotes multidisciplinary collaboration since they are developed collaboratively and consensus is obtained with strong clinician engagement and endorsement.
- e. For bundle implementation to be successful, each element of the bundle is implemented collectively with complete consistency to achieve the most favorable outcomes (“all or none” approach).
 - The effective implementation of a care bundle requires that the measures are adapted to the local setting; appropriately followed; entrenched in the patient care culture and recorded and evaluated to ensure compliance by all members of the health care team involved.

- f. Healthcare providers are advised to continuously follow each bundle element for every patient. This aims to develop and promote a positive habit-forming behavior among providers and ultimately a reliable care process.
- g. Bundled interventions are an effective way to implement change and improve the “culture” of patient safety by promoting teamwork, measuring compliance, and providing feedback and accountability to frontline teams and hospital leadership to improve care.

3. Antimicrobial Stewardship:

ASP: The antimicrobial stewardship program (ASP) is a coordinated program that promotes the appropriate use of antimicrobials (including antibiotics), improves patient outcomes and reduces microbial resistance by preventing the misuse of antibiotics. This program plays an essential role in optimizing antibiotics prescribing, leading to better patient outcomes and decreasing healthcare costs. The ASP has both process indicators and outcome indicators to assess the efficacy of the program.

Multidrug-Resistant Organisms (MDROs) Surveillance: MDROs surveillance targets clinical relevance microorganisms that are resistant to one or more antibiotics class.

The hospital collects indicator data for one of the following pathogens, in accordance with the definitions outlined below:

1. Methicillin-resistant Staphylococcus aureus (MRSA)
2. Vancomycin-resistant Enterococci (VRE)
3. Clostridium difficile infection (diarrhea) (C. difficile)
4. Multidrug-resistant Pseudomonas aeruginosa (P. aeruginosa)
5. Carbapenem-resistant Enterobacteriaceae (CRE), For Escherichia coli (E. coli) and Klebsiella pneumoniae (K. pneumoniae).
6. Other pathogens important to the hospital’s environment (i.e., based on risk/volume – rationale must be provided)

Antibiogram: An antibiogram is an overall profile of antimicrobial susceptibility testing results of a specific microorganism to a variety of antimicrobial drugs.

Local and global statistics in the most common ICU surveillances according to recent published reports and studies:

	NHSN	GCC	INICC	MOH
CLABSI				
Adult Medical Surgical	0.8	2.6	4.93	2.55
Paediatric Medical Surgical	1.2	3.1	6.07	1.45
Neonatal ICU	1.12	5	5.17	2.93
CAUTI				
Adult Medical Surgical	1.71	3.3	5.34	1.06
Paediatric Medical Surgical	2.5	N/A	5.6	0.25
VAP				
Adult Medical Surgical	1.09	5.4	16.5	2.66
Paediatric Medical Surgical	0.7	2.4	7.9	0.32
Neonatal ICU	0.81	1.8	9.54	0.85

NHSN: National Health Safety Network

GCC: Gulf Cooperation Council

INICC: International Nosocomial Infection Control Consortium

MOH: Ministry of Health

4. Hand Hygiene:

Cleaning hands with alcohol hand rub or antimicrobial soap eliminates potential pathogens from spreading in the healthcare setting. In 1847, Ignaz Semmelweis demonstrated hand disinfection's effectiveness in cutting nosocomial infections. Healthcare workers' hands are repeatedly in contact with patients and their surroundings, making hand surfaces the most at risk for contamination with microorganisms during the delivery of care and potentially the vehicles for transferring microorganisms. Hand hygiene is a vital element of infection control, crucial to safeguard patients' safety in hospitals. It is the base for Infection Prevention and control (IPC) standard precautions. Nonetheless, compliance with appropriate hand hygiene practices is often lacking. Cost estimations of healthcare-associated infections significantly exceed those related to hand hygiene. Training on hand hygiene is multimodal and focus on:

- 1) Preventing the transmission of microorganisms
- 2) Factors that have been found to influence hand hygiene behavior
- 3) Proper hand hygiene techniques.
- 4) Training also includes recommendations about when to clean one's hands, based on the "five moments for hand hygiene":
 1. Before initial contact with the patient
 2. Before a clean/aseptic procedure
 3. After body fluid exposure risk
 4. After touching a patient.
 5. Before or after initial contact with the patient environment.

Hand hygiene is a broad term that covers handwashing, hand antisepsis, and actions taken to maintain healthy hands and fingernails. One hand hygiene method is handwashing; removing soil and transient microorganisms from the hands using soap and water. An alternative hand hygiene technique is hand antisepsis, which includes removing or killing resident and transient microorganisms on the hands using an antiseptic agent by either rubbing the hands with alcohol

or handwashing with an antiseptic soap. This latter process has also been referred to as antiseptic hand wash, antiseptic hand-rubbing, and hand disinfection. The use of an alcohol-based hand rub (ABHR) is the preferred method of hand hygiene in healthcare settings unless exceptions apply (i.e., when hands are visibly soiled with organic material or if exposure to norovirus and potential spore-forming pathogens such as *Clostridioides difficile* is strongly suspected or proven, including outbreaks involving these organisms).

Hand hygiene performed with an ABHR may reduce the impact of some of the identified barriers to handwashing, including lack of time, inaccessibility of designated handwashing sinks, inadequate supplies for handwashing (e.g., hand towels, soap).

Hand hygiene at Point-of-care: This refers to the place where the following three factors join: the patient, the healthcare provider, and treatment/care, that mandate contact with the patients or their surroundings. WHO recommends that this scenario "enforces the need to perform hand hygiene at recommended moments precisely when care delivery takes place". This requires that hand hygiene products (e.g., alcohol-based hand rub, if available) be easily accessible and as close as possible - within arm's reach of where patient care or treatment is taking place. Point-of-care products are accessible without having to leave the patient zone.

In addition, the role that patients' families and visitors play in transmitting infection is also well documented in the literature. The hospital's hand hygiene program targets patients and their families and visitors, including education on entry and the posting of reminders.

Assessing compliance with hand hygiene practices allows hospitals to improve education and training regarding hand hygiene, evaluate hand hygiene facilities and benchmark compliance practices across the hospital. Studies have shown that improvements in compliance with hand hygiene practices have decreased the number of healthcare-associated infections. The best method for measuring compliance with accepted hand hygiene practices is to use direct observation (audits). Direct observation involves watching and recording the hand hygiene behaviors of staff and observing the work environment.

Compliance to hand hygiene policies and procedures during aseptic techniques, and as part of respiratory etiquette can be assessed through education and regular supervision by the infection control team.

HAI.1. The hospital has a comprehensive hand hygiene program.

HAI.1.1. The hospital has infection control and prevention policies and processes for hand hygiene, including types, indications, supplies, techniques, and monitoring.

HAI.1.2. Hand washing station/sink and supplies are available and easily accessible. In critical care areas and labor and delivery (one sink outside of the rooms for every 2-4 beds) and in all inpatient areas (at least one sink inside each patient room).

HAI.1.3. Alcohol-based hand rub dispensers are available in adequate numbers, one dispenser per patient's bed, one at every nursing station and in any service areas.

HAI.1.4. Hand hygiene compliance rates are regularly monitored, and the results disseminated throughout all levels of the hospital and at the infection prevention and control committee with corrective actions and action plans for improvement.

HAI.1.5. The hospital has visual alerts for hand hygiene and staff are knowledgeable about them.

HAI.1.6 Staff perform hand hygiene using the appropriate technique and following the recommended duration.

HAI.1.7. WHO hand hygiene improvement strategy tools are applied to improve the quality of hand hygiene.

Explanations:

Hand hygiene is a critical component of patient and staff safety.

Effective patient safety and infection prevention programs require that healthcare personnel be familiar with hand hygiene recommendations and consistently adhere to them.

Education alone seldom leads to adequate adherence to hand hygiene in healthcare.

Multimodal, multidisciplinary strategies are more likely to lead to change and improve hand hygiene practices.

The complex dynamic of behavioral change requires a combination of education, motivation and system change.

The hand hygiene self-assessment framework is a systematic tool to obtain a situation analysis of hand hygiene promotion. Hospitals can track their progress in hand hygiene resources, promotion, and activities, plan their actions, and aim for improvement and sustainability using the WHO Hand Hygiene Self-Assessment Framework.

The Hand Hygiene Self-Assessment Framework is divided into five components and 27 indicators. The five components reflect the five elements of the WHO Multimodal Hand Hygiene Improvement Strategy, and the indicators have been selected to represent each component's key elements.

The hospital has a process to select and review products for hand hygiene including alcohol-based hand rubs and hand soaps.

HAI.2. The hospital has a comprehensive healthcare-associated infections (HAIs) surveillance system that is integrated with the hospital's quality and patient safety programs.

HAI.2.1. The hospital has continuous surveillance of healthcare-associated infections.

HAI.2.2. The hospital has policies and processes for the implementation and compliance of infection control practices including hand hygiene, environmental cleaning, medical equipment cleaning, standard precautions and contact isolation precautions.

HAI.2.3. The hospital defines the data collection methods and sources ensuring the methodology and analyses are conducted by trained and competent staff.

HAI.2.4. The hospital selects surveillance data indicators based on internal and external benchmarking.

HAI.2.5. The hospital uses risk, rate and trend information to design or modify processes to reduce healthcare-associated infections to the lowest possible level.

HAI.2.6. The hospital has continuous improvement plans for the identified epidemiologically relevant infections or infections of concerns, processes and devices that are associated with risk of healthcare-associated infections.

HAI.2.7. The results of infection monitoring in the hospital are regularly communicated to staff, clinicians, and hospital leaders (the board to the ward).

HAI.2.8. Healthcare-associated infections surveillance reports are regularly submitted to the infection prevention and control committee and all relevant departmental meetings for review and action.

Explanations:

The hospital identifies hospital acquired infections by site of infection, and associated devices, procedures, and practices to direct the efforts in preventing and reducing incidence.

A risk-based approach assists hospitals to identify on which practices and infections on to focus their efforts to reduce healthcare-associated infections.

The hospital utilizes HAIs surveillance as a vital component for collecting and analyzing the data that guides the risk assessment.

Hospitals gather and evaluate data on the below related infections, devices and sites:

- Urinary tract—including the invasive procedures and medical devices associated with indwelling urinary catheters, urinary drainage systems, their care, and so on.
- Intravascular invasive devices—such as the insertion and care of central venous catheters, peripheral venous lines, and similar devices.
- Surgical sites—including care and type of dressing and associated aseptic procedures.
- Respiratory tract—including the procedures and medical equipment associated with intubation, mechanical ventilator support, tracheostomy, and other similar devices.

Implementing the scientific knowledge related to the prevention and control of infections through the use of clinical practice guidelines, programs to reduce hospital-associated infections, and initiatives to decrease the use of unnecessary invasive devices can significantly reduce the rates of infection.

To reduce the risk of hospital acquired infections, the hospital proactively identifies risks, rates and trends in healthcare-associated infections.

A hospital can best use measurement data and information by understanding rates and trends in other similar hospital settings and contributing data to infection-related databases.

HAI.3. The hospital implements an evidence-based strategies and preventive care bundles to reduce the risk of Healthcare Associated Infections (HAIs).

HAI.3.1. The hospital implements evidence-based interventions to prevent ventilator-associated pneumonia (VAP) and ventilator-associated events (VAE).

HAI.3.2. The hospital implements evidence-based interventions to prevent surgical site infection (SSI).

HAI.3.3. The hospital implements evidence-based interventions to prevent catheter associated urinary tract infection (CAUTI).

HAI.3.4. The hospital implements evidence-based interventions to prevent central intravascular catheter-associated blood stream infection, vascular catheter-associated blood stream infection (CLABSI).

HAI.3.5. The hospital implements evidence-based interventions to prevent Dialysis Event (DE).

HAI.3.6. The hospital implements evidence-based interventions to prevent pressure injury/wound healthcare associated infections.

HAI.3.7. Data on each implemented care bundle is regularly collected, analyzed and evaluated at the infection control committee and relevant departmental meetings.

HAI.3.8. Care bundles' compliance reports are regularly submitted to the infection prevention and control committee and all relevant departmental meetings for continual performance improvement/action plans.

Explanations:

Patients' care bundles are the series of evidence-based practices / interventions related to devices or processes of care that, when implemented together, will achieve significantly better outcomes than when implemented individually.

Care bundles are an implementation tool aiming to improve the care process and patient outcomes in a structured manner. Care bundles comprise a small, straightforward set of evidence-based practices that have been proven to improve patient outcomes when performed collectively and reliably.

To verify patient safety and to reduce the risk of HAIs, the hospital has a policy for care bundles for prevention of VAP/VAE, SSI, CAUTI, CLABSI and DE. All concerned hospital staff are fully oriented about the elements of the respective care bundle(s). The hospital regularly collects and analyses the data and assess implemented care bundles compliance rates for performance improvement.

HAI.4. The hospital has a comprehensive system for investigation and management of outbreaks of infectious diseases.

HAI.4.1. The hospital has a comprehensive outbreak management plan that addresses determination, investigation and control of outbreaks as per national and cited international laws and regulations.

HAI.4.2. The hospital has a multidisciplinary outbreak management team that is approved by the infection prevention and control committee.

HAI.4.3. The infection prevention and control department lead the investigation and control of outbreaks in coordination with the outbreak management team.

HAI.4.4. The outbreak management team members are qualified with training, experience and skills to detect and mitigate outbreaks. The team conducts regular meetings to review the surveillance, laboratory data, bundles results and antibiogram.

HAI.4.5. The hospital has processes for outbreak notification to hospital leaders and higher authorities, as per required time frames by national laws and regulations.

HAI.4.6. At the conclusion of the outbreak, a final outbreak summary report is prepared and communicated with hospital leaders and higher authorities.

HAI.4.7. The final outbreak summary report, including the results of an investigation of the outbreak, is presented at the infection prevention and control committee to evaluate infection control measures and to avoid further recurrence.

Explanations:

HAIs Outbreak: An outbreak refers to an increase in the number of hospital-acquired or any other healthcare facility-acquired cases of a disease among patients or staff over and above the expected number of cases. However, in Saudi Arabia, if there are more than 2 cases of HAIs with the same organism, linked to the same exposure, at any given time or location within three (3) days, it will be considered an outbreak. (In some situations, one (1) case is considered an outbreak e.g., Candida Auris, and respiratory pathogens).

Outbreaks in hospitals are often multifactorial including breaches in infection control or clinical practices, contaminated devices, infected or colonized patients and /or healthcare workers.

Providing a management protocol for a hospital outbreak assists in early detection of an outbreak and initiates immediate control measures that prevent further disease transmission.

For proper management of an outbreak, the hospital implements the following:

- o Develop a policy and procedure for investigation and management of an outbreak.
- o Formation of an outbreak team that is led by the IPC Team.
- o Identification of the outbreak, establishment of a case definition and search for any additional cases.
- o Determining the steps of an outbreak investigation and implementation of infection prevention and control measures.
- o Monitor and evaluate the outbreak control measures.
- o Documentation of all activities of the outbreak team in ICC meetings minutes.

HAI.5. The hospital has an Antimicrobial Stewardship Program (ASP).

HAI.5.1. The hospital has a policy and processes to restrict antibiotics based on the ASP committee reports on antimicrobial utilization, cost, patients' outcomes, length of hospital stays, MDROs rates and microbial side effects.

HAI.5.2. Hospital leaders provide the required human, financial and information technology resources to support the ASP.

HAI.5.3. The hospital has a multidisciplinary ASP committee co-chaired by a physician and a pharmacist that meets regularly.

HAI.5.4. Membership of the ASP Committee includes pharmacist(s), microbiologist(s), IPC practitioner(s), and the heads of critical care units, infectious diseases department, surgical department, nursing department and, as applicable, any additional other clinicians and non-clinicians, as needed.

HAI.5.5. The hospital monitors and tracks antibiotic prescriptions and resistance patterns with the data generated, analyzed, and actioned via continuous performance improvement through the ASP committee.

HAI.5.6. The hospital regularly prepares an antibiogram report with action plan(s) and interventions to improve the use of antimicrobials developed through the ASP committee.

HAI.5.7. The ASP committee provides regular updates to prescribers, pharmacists, nurses, and hospital leadership on the process and outcome measures that address both national and local issues, including the antibiotic resistance pattern.

Explanations:

Misuse and overuse of antimicrobials is one of the world's most pressing public health problems.

Infectious organisms adapt to the antimicrobials designed to kill them, making the drugs ineffective.

People infected with antimicrobial-resistant organisms are more likely to have longer, more expensive hospital stays, and may be more likely to die as a result of an infection.

ASP promotes limiting inappropriate antibiotic use and optimizing antimicrobial selection, dosing, route and duration of therapy to maximize clinical cure or prevention of infection.

Hospital leadership commitment is of utmost importance to emphasize the necessity of antimicrobial stewardship programs to ensure availability of the necessary human, financial and information technology resources.

Antimicrobial stewardship continues to grow as a recognized and required need of hospitals and health systems.

Implementation of an effective coordinated ASP program will promote the appropriate use of antimicrobials (including antibiotics), improve patient outcomes, reduce microbial resistance and decrease the spread of infections caused by multidrug-resistant organisms.

HAI.6. The hospital has evidence-based strategies to reduce MDROs.

HAI.6.1. The hospital conducts MDRO surveillance as a part of the hospital surveillance plan.

HAI.6.2. The hospital has processes for immediate notification regarding relevant MDRO laboratory values.

HAI.6.3. The hospital has evidence-based interventions to prevent MDROs, including drug specific care bundles.

HAI.6.4. Data on the care bundle for prevention of MDROs is regularly collected, analyzed evaluated, and action with continuous improvement interventions/action plans.

HAI.6.5. The infection prevention and control committee use ASP's data and reports to evaluate the effectiveness of MDROs preventive strategies.

HAI.6.6. Data on each implemented care bundle is regularly collected, analyzed and evaluated at the infection prevention and control committee and all relevant departmental meetings for continual performance improvement/action plans.

Explanations:

MDROs are defined as microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents. Although the names of certain MDROs describe resistance to only one agent (e.g., MRSA, VRE, CRE), these pathogens are frequently resistant to most available antimicrobial agents.

Prevalence of MDROs varies temporally, geographically, and by healthcare setting.

The type and level of care also influence the prevalence of MDROs. Critical care areas such as ICUs, especially those at tertiary care facilities, may have a higher prevalence of MDRO infections than do non-ICU settings.

Once MDROs are introduced into a hospital, transmission and persistence of the resistant strain is determined by the availability of vulnerable patients, selective pressure exerted by antimicrobial use, increased potential for transmission from larger numbers of colonized or infected patients ("colonization pressure") and the impact of implementation and adherence to prevention efforts.

The hospital administration ensures that appropriate strategies are fully implemented, regularly evaluated for effectiveness, and adjusted such that there is a consistent decrease in the incidence of targeted MDROs.

Fire Safety (FS)

FS.1. The hospital complies with all Civil Defense and national codes and regulations for fire safety across all hospital areas.

- FS.1.1. Emergency exits and escape routes are designated per code throughout the hospital.
- FS.1.2. Evacuation plans, emergency exits, staircases, and escape routes are located per travel distance requirements, with the size, illumination, signages, and directions per code.
- FS.1.3. Escape routes are clear from any obstructions and lead to designated assembly areas with proper signage.
- FS.1.4. Emergency exits are not locked and are unobstructed at all times.
- FS.1.5. Emergency lighting is adequate for the safe evacuation of the hospital.

Explanations:

XXX

FS.2. The hospital's buildings have passive fire prevention measures.

- FS.2.1. The hospital has fire and smoke compartmentation per code.
- FS.2.2. Fire-rated doors are per code, including fire rating, hardware, labeling, and frame.
- FS.2.3. Fire and smoke dampers are installed across compartmentation zones.
- FS.2.4. There are no voids in any fire compartmentation above and under a false ceiling.
- FS.2.5. Fire-rated stop materials are used to seal any penetrations between assigned fire zones and smoke compartments.

Explanations:

XXX

FS.3. The hospital has a functional fire alarm system.

- FS.3.1. The hospital fire alarm system covers all hospital areas and as per code.
- FS.3.2. The fire alarm system is functioning at all times without any faults, including all components, inclusive of the panel, ceiling, ducts, detectors, strobes, and manual call points.
- FS.3.3. The fire alarm system is tested regularly with documented results.
- FS.3.4. The fire alarm system is interfaced with other systems, including elevators, HVAC systems, fire and smoke dampers, fans, access control, magnetic doors, and fire suppressions systems.

Explanations:

XXX

FS.4. The hospital has fire extinguishers positioned and distributed per code.

- FS.4.1. Fire extinguishers are adequate in number and type as per Saudi Building Code requirements.
- FS.4.2. Fire extinguishers are distributed and positioned throughout the hospital, as per Saudi Building code requirements.
- FS.4.3. Fire extinguishers are inspected monthly for functionality.

Explanations:

XXX

FS.5. The hospital has fire suppression systems matching the area's specific code requirement.

- FS.5.1. The hospital has a functional sprinkler system in all areas of the facility, as per code.
- FS.5.2. The hospital has a clean agent suppression system.
- FS.5.3. The hospital has wet chemical suppression system.
- FS.5.4. The hospital has sufficient fire hose cabinets, standpipes, and hydrants.
- FS.5.5. Fire suppression systems are regularly inspected, tested, and maintained.
- FS.5.6. Fire pumps are functional with stand-by pumps of the required flow.
- FS.5.7. There is designated and sufficient water for fire protection inspected regularly and without any debris or fungal residue.

Explanations:

XXX

FS.6. The hospital has qualified and sufficient fire and safety personnel.

- FS.6.1. The fire & safety department has qualified and sufficient staff.
- FS.6.2. The fire & safety department has a clear chain of command to the executive management.
- FS.6.3. All fire and safety specialized personnel hold the necessary certifications/equivalency.
- FS.6.4. The fire & safety department is involved in all hospital project's five phases, study, design, execution, testing and commissioning, and handover.

Explanations:

XXX

FS.7. The hospital's fire and safety program include utilities and facilities systems' continuous maintenance and optimal operation.

- FS.7.1. The hospital's utility systems are well maintained to prevent fire and accidents.
- FS.7.2. The hospital has policies and processes for system failures and work permits with the safety department's approval.
- FS.7.3. The hospital addresses all external inspection authorities' concerns and provides action plans.
- FS.7.4. All permits with risk assessment is done before commencing any project with infection prevention and control and safety department approval.

Explanations:

XXX

FS.8. The hospital ensures electrical safety.

- FS.8.1. The hospital has a policy and processes for the utilization of extension cords and adapters, with the use of extension cords in the inpatient areas prohibited.
- FS.8.2. All medical equipment is tested using a calibrated with regularly conducted PPM.
- FS.8.3. Electrical Safety Analyzer.
- FS.8.4. All electrical loads are properly distributed on the breakers.
- FS.8.5. Thermal photography is conducted annually on the electrical panels.

Explanations:

XXX

FS.9. The hospital's ongoing fire and safety training supports continual readiness.

FS.9.1. Annual and more frequent if needed, hospital fire and safety training is conducted for all levels, specialized, individual, team, and hospital-wide).

FS.9.2. Fire and safety education and training include RACE, PASS, emergency codes, and evacuation procedures.

FS.9.3. All fire and safety training is conducted by trained and certified fire and safety personnel.

FS.9.4. All staff and contractors individually attend annually fire and safety training which includes (RACE, PASS, Codes, and Evacuation Procedure).

FS.9.5. Fire drills are scheduled and conducted annually in each department to cover all staff on all shifts with corresponding documentation.

FS.9.6. An annual full hospital fire drill is conducted in conjunction with civil defense, with the drill documented, evaluated, and with action plans.

FS.9.7. All designated fire & safety staff have the required specialized training, inclusive of basic and advanced life support, hazardous materials safety, firefighting, rescue, inspection, codes, investigation, RCA, TOT, and risk assessment).

Explanations:

XXX

FS.10. The hospital's leaders are accountable for fire safety.

FS.10.1. Hospital leaders' commitment to fire safety is demonstrated in resource allocation, assigned authorities, hospital compliance, and continuous monitoring and performance improvement.

FS.10.2. All fire safety risks and concerns are raised without retaliation and addressed directly by executive management and the fire and safety department.

FS.10.3. The hospital conducts fire and safety risk assessments, at a minimum annually and as required, with programs, plans, policies, and processes adjusted per assessments and continuous staff feedback and concerns.

FS.10.4. Hospital leaders monitor fire and safety KPI's.

FS.10.5. The hospital has a hazardous material plan to control of and reduce exposure to hazardous materials.

FS.10.6. Any renovation, reconstruction, modification, or change of utilization is with consultation and approval from the safety department and all clinical and non-clinical stakeholders.

Explanations:

XXX

FS.11. Hospital leaders emulate and foster a culture of safety and fire prevention at all times.

FS.11.1. Staff at all levels are fire and safety cautious in knowledge, awareness, behaviors, and practices).

FS.11.2. The hospital promotes a culture of safety with all staff through orientation, continuous fire & safety training, policies and processes, actionable feedback, and measurable compliance.

FS.11.3. The hospital has a the Defend in Place (DIP) fire strategy.

FS.11.4. The hospital develops a multidisciplinary active facility safety and risks committee which oversees, monitors, and provides oversight of the Fire & Safety and KPIs.

Explanations:

XXX

DRAFT

Housing (HOU)

Employees who receive housing as part of their employment contract are provided housing that is safe and adequate with a reasonable level of decency, comfort and hygiene. (ILO, 1961). The hospital complies, at all times, with the national as well as agreed-upon international, laws and regulations related to staff tenant housing.

DRAFT

HOU.1. The hospital has a Housing Department with clear roles and responsibilities.

HOU.1.1. The housing department has a qualified Head of Department (HoD).

HOU.1.2. The hospital ensures there is Planned Preventive Maintenance (PPM) in place for all hospital-owned and staff-owned utilities, equipment, appliances, and hospital-owned furniture.

HOU.1.3. There are resource utilization processes to ensure staff tenant housing is safe, adequate in quantity, usable, maintained in a good, functional state not in need of repair and meets needs of the staff.

HOU.1.4. The hospital ensures the cleanliness of common areas of staff housing.

Explanations:

To ensure that the role and authority of the Housing Department is clearly defined.

HOU.2. The hospital has a multidisciplinary Housing Committee which oversees all staff housing-related matters.

HOU.2.1. The housing committee is comprised of representatives from all relevant staff stakeholders and reports to the Chief Executive Officer (CEO).

HOU.2.2. The housing committee conducts an annual housing risk assessment and has a mitigation plan.

HOU.2.3. The housing committee ensures practical measures for the distribution of tenants taking into consideration job title/role, working shifts/hours, and duties.

HOU.2.4. The housing committee has processes and mechanisms to receive and address all staff tenant housing-related concerns and complaints.

HOU.2.5. The housing committee conducts periodic internal audits to ensure the implementation of the housing policies.

Explanations:

To ensure there is an official forum to address all aspects related to staff housing.

HOU.3. The hospital complies with Civil Defense and national laws and regulations for staff housing for facility-owned and/or rented property.

HOU.3.1. Staff housing complies with structural and fire safety as per national laws and regulations.

HOU.3.2. There is a system to address employees' safety, security and privacy without restricting the personal freedom of the staff tenants.

HOU.3.3. Staff housing is in close proximity to the hospital.

HOU.3.4. The hospital provides sufficient transportation to and from all facility-owned and/or rented property for work duties and basic necessities.

Explanations:

To ensure the laws and regulations applicable to staff housing are established, standardized and implemented.

HOU.4. Staff housing complies with relevant national and international health safety regulations.

HOU.4.1. There are adequate laundry facilities that accommodate 1 washer/dryer per 25 individuals.

HOU.4.2. There are adequate kitchen and sanitation facilities: one (1) toilet, one (1) washbasin, and (1) one tub/shower per each six (6) persons.

HOU.4.3. The minimum space requirements for one (1) single-staff sleeping accommodation are 6m². Any additional staff in the shared area requires an additional 4m² per person.

HOU.4.4. There is adequate ventilation and lighting (both artificial and natural), in compliance with national and international IPC laws and regulations.

HOU.4.5. Staff housing is kept free from infestation and mold.

HOU.4.6. There are adequate heating and cooling systems along with clean cold and hot running water.

Explanations:

To ensure that the hospital is providing an adequate and healthy living environment to the employees.