# JCI Accreditation Standards for Hospitals and Academic Medical Centers (AMC), 8th Edition

Draft Standards for Field Review

Proposed New Standards and Requirements

**Note:** This document does not include all standards for Hospitals and Academic Medical Centers (AMC), 8th Edition. The standards in this document are the proposed requirements in the Assessment of Patients (AOP) and Care of Patients (COP) chapters only. To participate in the field review of other chapters of the hospital and AMC standards, please refer back to the JCIA website.

As a reminder, the field review focuses on newly added or significantly revised requirements. To identify the difference:

- Standards, measurable elements, intents, and guidance that are new or have undergone significant changes that have impacted the intent of the requirement are in **RED font**.
- Standards, measurable elements, intents, and guidance that are in **BLACK font** may have undergone changes, but the intents remained the same.

Prior to the publication, a complete summary of changes will be included in the manual along with an updated and complete reference list for each chapter.

**Field Review Questionnaire:** To participate in the field review of this chapter, please complete the survey below:

https://www.surveymonkey.com/r/ZT92NBW

Field Review Period: **October 23- November 13, 2023**

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

# Assessment of Patients (AOP)

## Overview

The goal of assessment is to determine the care, treatment, and services that will meet the patient's initial and continuing needs. An effective patient-assessment process results in decisions about the patient's treatment needs for emergency, elective, or planned care, even when the patient's condition changes. Patient assessment is an ongoing, dynamic process that takes place in many inpatient and outpatient settings and departments and clinics. Patient assessment consists of three primary processes:

1. Collecting information and data on the patient's physical, psychological, and social status, and health history
2. Analyzing the data and information, including the results of laboratory testing, diagnostic imaging, and physiologic monitoring, to identify the patient's health care needs
3. Developing a plan of care to meet the patient's identified needs

Patient needs must be reassessed throughout the course of care, treatment, and services. Reassessment is key to understanding the patient's response to the care, treatment, and services provided and is essential in identifying whether care decisions are appropriate and effective.

Assessment activities may vary between settings, as defined by the hospital's leaders. Information gathered at the patient's first contact may indicate the need for more data or a more intensive assessment. At a minimum, the need for further assessment is determined by the care, treatment, and services sought and the patient's presenting condition(s).

Patient assessment is appropriate when it considers the patient's condition, age, health needs, and requests or preferences. These processes are most effectively carried out when the various health care practitioners responsible for the patient work together.

## Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, Guidance, and Measurable Elements.

AOP.1 All patients have their health care needs identified through an assessment process that has been defined by the hospital. ?

- AOP.1.1 The initial assessment includes a health history and an assessment of the patient's physical, psychological, spiritual/cultural, social, and economic needs.
- AOP.1.2 The hospital has a process for accepting initial assessments from outside sources. ?
- AOP.1.3 Patients are screened for nutritional, functional, and other special needs and are further assessed when indicated by the screening.
- AOP.1.4 All patients are screened for pain and assessed when pain is present.

AOP.2 The hospital develops and implements a process to reduce the risk of falls, and patient harm resulting from falls. ?

AOP.3 All patients are reassessed at intervals based on their condition and treatment. ?

### Laboratory Services

AOP.4 Laboratory services are available to meet patient needs, and all laboratory services meet applicable local and national standards, laws, and regulations.

- AOP.4.1 A qualified individual(s) is responsible for managing the clinical laboratory service or pathology service, and all laboratory staff are qualified to perform the tests and interpret the results.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

AOP.4.2 The hospital has defined requirements for the oversight and supervision of the point-of-care testing program.

AOP.4.3 Laboratory results are reported within time frames defined by hospital policy.

AOP.4.4 All laboratory testing equipment is regularly inspected, maintained, calibrated, and appropriate records are maintained for these activities.

AOP.4.5 Essential reagents and supplies are available, and all reagents are evaluated to ensure accuracy and precision of results.

AOP.4.6 Procedures for collecting, identifying, handling, safely transporting, and disposing of specimens are established and implemented.

AOP.4.7 Established norms and ranges are used to interpret and to report clinical laboratory results.

AOP.4.8 The hospital has implemented processes for quality control and proficiency testing of laboratory services.

AOP.4.9 The hospital ensures the quality of services provided by contracted laboratories.

### Blood Bank and/or Transfusion Services

AOP.5 A qualified individual is responsible for blood bank and/or transfusion services and ensures that services adhere to laws and regulations and recognized standards of practice.

### Radiology and Diagnostic Imaging Services

AOP.6 Radiology and diagnostic imaging services are available to meet patient needs, and all services meet applicable local and national standards, laws, and regulations.

AOP.6.1 A qualified individual(s) is responsible for managing the radiology and diagnostic imaging services, and individuals with proper qualifications and experience perform diagnostic imaging studies, interpret the results, and report the results. ?

AOP.6.2 A radiation and/or diagnostic imaging safety program for patients, staff, and visitors is implemented and is compliant with applicable professional standards, laws, and regulations. ?

AOP.6.3 Radiology and diagnostic imaging study results are available in a timely way as defined by hospital policy. ?

AOP.6.4 All equipment used to conduct radiology and diagnostic imaging studies is regularly inspected, maintained, and calibrated, and appropriate records are maintained for these activities. ?

AOP.6.5 The hospital has implemented quality control procedures for radiology and diagnostic imaging services. ?

AOP.6.6 The hospital ensures the quality of services provided by all outside contracted sources of radiology and diagnostic imaging services.

AOP.7 When applicable, the hospital establishes and implement a nuclear medicine safety program that complies with applicable professional standards, laws, and regulations.

# Standards, Intents, Guidance, and Measurable Elements

---

## Standard AOP.1

All patients have their health care needs identified through an assessment process that has been defined by the hospital.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

## Intent of AOP.1

The effective assessment process drives decisions about the patient's needs for care, treatment, and services. Because decisions are made based on assessments, the assessment process is ongoing throughout patient care.

## Guidance for AOP.1

Patient assessments determine care needs, even when the patient's condition changes. It is an ongoing, dynamic process that continues throughout the care continuum. Patient assessment includes three primary processes:

1) Collecting information and data on the patient's health history and their physical, psychological, and social needs
2) Analyzing the assessment data, including any diagnostic tests, to identify the patient's health care needs
3) Using the information to develop a plan of care specific to the patient's needs

Hospital policies define the minimum content of assessments for clinical staff to include in their assessments and in all care settings. The hospital identifies any specific assessment data that must be included by various clinical staff.

Assessments are performed by each discipline within its scope of practice, licensure, applicable laws and regulations, or certification. Only qualified individuals conduct the assessments.

All the content from assessments must be available when treatment is initiated.

## Measurable Elements of AOP.1

- ❑ 1. The hospital policy defines the minimum content of assessments for patients for each clinical staff that performs assessments
- ❑ 2. The hospital defines the required elements of the history and physical examination.
- ❑ 3. The hospital identifies the information to be documented for the assessments.

---

# Standard AOP.1.1

The initial assessment includes a health history and an assessment of the patient's physical, psychological, spiritual/cultural, social, and economic needs.

## Intent of AOP.1.1

The initial patient assessment is critical to identifying patient needs and planning the patient's care.

## Guidance for AOP.1.1

A complete assessment is performed related to the chief complaint at the time of admission or registration. Hospital policies define what information is needed at the time of admission or registration, who is responsible for obtaining and documenting this information, and how this information is documented.

The initial assessment provides information to

- understand the care the patient is seeking;
- select the best care setting for the patient;
- form an initial diagnosis; and
- understand the patient's response to any previous care.

The hospital policy outlines what assessments and history are required as part of the initial assessment.

Common elements of an initial assessment include

- Physical assessment
- Health history
- Medication history and allergies
- Psychological assessment
- Social and economic assessment

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

- Cultural and spiritual assessment

The psychological assessment determines the patient's perception, thought processes, and emotional status. The social and economic assessment is not intended to "classify" the patient; it is used to identify possible barriers to access and paying for care.

A patient's social, cultural, spiritual, family, and economic factors can influence their response to illness and treatment. Families can be very helpful in these areas of assessment and in understanding the patient's wishes and preferences.

The hospital policy also states

- What parts of the initial assessment each discipline is responsible for completing
- The minimum content for the initial medical assessment
- The minimum content for the initial nursing assessment
- The minimum content for other assessments, **for example,** physical therapy, speech therapy
- The time frame for completion of the initial assessment
- The documentation requirements for the initial assessment

The initial assessment of the patient does not need to be completed by one person. The hospital policies define which disciplines are responsible for which parts of the initial assessment. The hospital policies outline the minimum content of the initial medical and nursing and other assessments, the time frame for completion of assessments, and the documentation requirements for assessments.

The initial assessment of some patient populations requires that the assessment process be modified. The modification is based on the unique characteristics or needs of each patient population. Each hospital identifies those special patient populations and modifies the assessment process to meet their special needs. The assessment of these patients responds to their needs and condition in a culturally acceptable and confidential manner. The assessment of special populations is modified to be consistent with local laws and regulations and professional standards.

The assessment is complete, available to those caring for the patient, and results in an initial diagnosis and an understanding of the patient's medical and nursing needs so care and treatment can begin.

The initial medical and nursing assessments are completed within 12 hours of admission to the hospital. However, the hospital may identify situations where an assessment needs to be documented sooner than 12 hours or when limited assessments are acceptable.

In an emergency, the initial medical and nursing assessments may be limited to the patient's apparent needs and condition. In cases where an emergency patient requires surgery, a brief note and the preoperative diagnosis are documented before surgery.

The hospital defines what information must be documented as part of the patient's initial assessment. Common elements of an initial assessment include

- Physical assessment
- Health history
- Medication history and allergies
- Psychological assessment
- Social and economic assessment
- Cultural and spiritual assessment

The hospital must identify, in writing, special populations that it serves and require a modified assessment process. **Examples** of special patient populations include

- Infants, children, and adolescents
- Frail elderly
- Terminally ill/dying patients
- Patients with intense or chronic pain
- Women in labor or experiencing terminations in pregnancy
- Patients with emotional or psychiatric disorders
- Patients suspected of drug and/or alcohol dependency
- Victims of abuse or neglect
- Patients with infectious or communicable diseases
- Patients whose immune systems are compromised

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

The hospital requires the patient's initial assessment be completed and documented within 24 hours of admission. The hospital may identify situations where an assessment may be needed sooner, or a limited assessment is acceptable. These situations include

- when a patient's condition indicates, **for example,** an unstable patient, a patient scheduled for surgery in less than 24 hours after admission, or when a transfer is imminent
- the immediate assessment of emergency patients or other groups identified by the hospital
- or when an emergency patient is sent for emergent surgery

### Measurable Elements of AOP.1.1

❑ 1. All patients have an initial assessment that is consistent with the requirements defined in hospital policy.

❑ 2. The assessment includes

a) A physical examination
b) A health history
c) A medication history and known allergies
d) An initial psychological assessment as indicated by the patient's condition
e) An initial social and economic assessment, as indicated by the patient's needs
f) An initial spiritual and cultural assessment, as indicated by the patient's needs

❑ 3. The hospital outlines requirements about who is responsible for the initial assessment and the timeliness of the assessment, including

a) What parts of the initial assessment each discipline is responsible for completing
b) The minimum content for the initial medical assessment
c) The minimum content for the initial nursing assessment
d) The minimum content for other assessments, for example, physical therapy, speech therapy, social services
e) The time frame for completion of the initial assessment
f) The documentation requirements for the initial assessment

❑ 4. The hospital identifies, in writing, those patient groups and populations it serves that require modifications to their initial assessment.

❑ 5. The initial assessment for special patient populations is modified to reflect their needs.

❑ 6. The initial medical and nursing assessments are performed and documented within the first 24 hours of admission or sooner as required by patient condition.

❑ 7. The initial assessment results in an initial diagnosis or diagnoses that require treatment and monitoring.

❑ 8. The initial nursing assessment results in a list of specific nursing needs or conditions that require nursing care, interventions, or monitoring.

❑ 9. There is at least a brief note and preoperative diagnosis documented for patients requiring emergency surgery.

---

## Standard AOP.1.2

The hospital has a process for accepting initial assessments from outside sources.

### Intent of AOP.1.2

There must be a process to accept initial assessments from outside sources that includes validation of the information included in the assessment because correct and current information is needed to provide safe patient care.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

## Guidance for AOP.1.2

An initial assessment may be conducted by an outside source**. Examples** of outside sources include

- a health care practitioner's office
- a primary care or ambulatory care center
- a consulting or referring practitioner

Common reasons for initial assessments by outside sources include

- referral to a specialist employed by the hospital
- direct or scheduled admissions to the hospital
- referral for a scheduled outpatient or same-day procedure

The initial assessment completed by an outside source must be within the previous 30 days.

When an assessment is partially or entirely completed by an outside source, the information in the assessment is reviewed and verified by a qualified individual. If there are any changes to the assessment, the health record is updated and identifies any additional testing that may be needed related to the change.

If the initial assessment is greater than 30 days old at the time of admission or registration, the medical history must be updated and the physical examination repeated.

For initial assessments performed and documented 30 days or less prior to admission or registration, the information in the history and assessment is reviewed and verified. This review includes

- the patient's medical history and assessment findings
- laboratory and other diagnostic test results
- the proposed plan of care and treatments

Any changes in the patient's condition since the assessment, or "no change" if appropriate, are documented at admission.

## Measurable Elements of AOP.1.2

- ❑ 1. Initial medical assessments accepted are less than or equal to 30 days old.
- ❑ 2. For initial assessments less than or equal to 30 days old, the assessment is reviewed and validated; any changes in the patient's condition since the assessment or "no change" are documented in the patient's health record at the time of admission or registration.
- ❑ 3. If the initial assessment is greater than 30 days old at the time of admission or registration, the medical history is updated and the initial assessment is repeated in accordance with the hospital's initial assessment policy.

---

# Standard AOP.1.3

Patients are screened for nutritional, functional, and other special needs and are further assessed when indicated by the screening.

## Intent of AOP.1.3

Initial screenings for nutritional, functional, and other special needs identify patients who may require additional interventions for safe, quality care.

## Guidance for AOP.1.3

These screenings may be conducted at the initial medical or nursing assessment. The hospital uses a screening tool to screen patients for nutritional, functional, and other special needs. The information gathered through the screening determines if the patient needs further assessment.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

The screening process is very simple and high-level and identifies whether a risk or problem exists. If the screening identifies a risk or a problem, an assessment is then completed. The hospital refers the patient for further assessments, either within the hospital or through the community, to address risks or problems identified by the screening.

The screening tools are implemented consistently throughout the hospital and are used by trained clinical staff.

The screening tools are developed by qualified individuals able to further assess any identified risks. Various clinical staff may be trained on how to use the tools and complete screenings with patients. When indicated by the screening, qualified individuals complete the assessment and identify interventions or a plan to address the patient's needs. **Examples** include

- Nutritional risk
  - A screening tool for nutritional risk may developed by the hospital's nurses
  - Nurses, physicians, and dieticians are trained to use the tools
  - Dietitians then complete a nutritional assessment and supply the recommended dietary intervention
  - Nutritionists integrate nutritional needs identified by the assessment with the other needs of the patient.
- Functional status
  - A functional status screening tool, including physical ability, vision, and hearing, may be developed by the hospital's occupational therapists
  - Nurses, occupational, physical, and speech therapists are trained use the screening tool
  - Occupational, physical, and speech therapists complete a functional assessment
  - Physical medicine and rehabilitation physician orders functional therapy to address the needs identified in the assessment

Other specialized needs may be identified through routine care, **for example**, clinical staff may observe that a patient has difficulty seeing or hearing and refer the patient for the necessary assessments.

Assessments are completed using evidence-based tools and used by trained clinical staff to determine the level of risk or severity of a problem and to develop specific interventions to address the risk or problem.

A screening tool is used to evaluate for the presence of a risk or a problem and generally results in a "yes or no" response.

Screening tools can be developed by a qualified individual to screen for a risk or problem. Creating a brief questionnaire for the patient are useful screening tools. **For example**,

- Asking a patient "Have you lost or gained more than 2kg in the last 30 days" to screen for nutritional risk
- Asking a patient "Are you able to complete daily hygiene tasks without difficulty or assistance?" to screen for functional risk
- Asking a patient to complete a brief whisper test to screen for hearing deficits

Assessment tools are used to complete an in-depth assessment of patient risk or problems and are used to develop specific interventions to address the risk or problem.

Assessment tools are

- Appropriate to the risk or problem being evaluated
- Appropriate to the patient population being evaluated, **for example,** pediatric, adult, or geriatric
- Evidence-based and validated in the population being evaluated

## Measurable Elements of AOP.1.3

- ❑ 1. Evidence-based screening tools are used to identify patients who require further nutritional assessment, and the tools are implemented consistently throughout the hospital.
- ❑ 2. Patients whose screening indicates a nutritional risk or problem receive a nutritional assessment.
- ❑ 3. Screening tools are used to identify patients who require further functional assessment, and the tools are implemented consistently throughout the hospital.
- ❑ 4. Patients whose screening indicates a functional risk or problem receive a functional assessment.
- ❑ 5. When the need for additional specialized assessments is identified, patients are referred within the hospital or outside the hospital.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

# Standard AOP.1.4

All patients are screened for pain and assessed when pain is present.

## Intent of AOP.1.4

Pain greatly impacts a patient's quality of life, affects healing, and can impact physical, psychological, and social wellbeing.

## Guidance for AOP.1.4

A screening is used to identify patients with pain. The screening process is simple and high-level and identifies whether a risk or problem exists. If the screening identifies a risk or a problem, an assessment is then completed. A screening for pain may consist of one or more simple questions that can be asked by trained clinical staff. The results of the pain screening are documented in the patient's health record.

The information gathered through the screening determines if the patient needs further assessment.

> **NOTE on screening versus assessment:** While screening has a narrow scope, the scope of assessment is more comprehensive. Screening can be done by a non-specialist (**for example,** a nurse conducting a nutritional "screening"). Assessment has to be done by a specialist (**for example,** nutritional assessment done by nutritionist for those patients who screened positive.

If the planned care, treatment, or services may result in pain, this would also indicate the need for a pain assessment.

The pain assessment is appropriate to the patient, including

- Patient age
- Patient condition, **for example,** sedated or alert
- Any barriers, **for example,** inability to speak or hear or developmental delays

The pain assessment is a more in-depth evaluation of the patient's pain and is used to develop to specific interventions to address the pain. The pain assessment is documented in the patient's health record.

The patient's pain is addressed immediately and may include referral or transfer to a different care setting. **For example,** an outpatient with severe pain may be admitted to as an inpatient to further assess and treat their pain or an inpatient in the general medical unit may need to be transferred to an intensive care unit for monitoring if an epidural is needed to treat their pain.

A screening tool is used to evaluate for the presence of a risk or a problem and generally results in a "yes or no" response.

**Examples** of questions that may be used in a screening include:

- Are you having pain right now?
- Does pain keep you from sleeping at night?
- Does pain keep you from participating in activities?
- Do you experience pain every day?

If the planned care, treatment, or services may result in pain, this would also indicate the need for a pain assessment.

The pain assessment is appropriate to the patient's age and condition. Evidence-based tools are used to measure the severity of the patient's pain. **Examples** of pain severity scales include

- Wong-Baker Faces Scale
- FLACC (Face, Legs, Arms, Crying Consolability)
- COMFORT Scale
- Behavior Pain Scale

The pain assessment also evaluates pain intensity and quality, including

- Pain character, **for example,** sharp, dull, or burning
- Frequency
- Location

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

- Duration
- Pain history, **for example,** when did the pain start, what activities cause the pain, what treatments has the patient tried to relieve the pain
- What makes pain better or worse
- What are the patient's goals for pain relief, **for example**, zero pain or enough relief to complete or participate in specific activities

Pain assessments, including which assessment tool is used, are documented in the patient's health record to allow the care team to easily identify trends in the patient's pain and pain relief interventions.

### Measurable Elements of AOP.1.4

- ❑ 1. All patients are screened for pain and the screening is documented.
- ❑ 2. When pain is identified by the screening, a pain assessment is performed and documented.
- ❑ 3. Patients are reassessed for pain following any pain management interventions.
- ❑ 4. If needed, the patient is referred or transferred to a care setting that has the capabilities and resources to treat the patient's pain.

## Standard AOP.2

The hospital develops and implements a process to reduce the risk of falls, and patient harm resulting from falls.

### Intent of AOP.2

Many injuries in hospitals to both inpatients and outpatients are a result of falls, so a comprehensive falls prevention program is needed to prevent injuries to patients.

### Guidance for AOP.2

The risk for falls is related to the patient, the situation, and/or the location. Risks associated with patients include, but are not limited to

- age
- medical history
- patient history of falls,
- medications use,
- substance consumption,
- other comorbidities
- gait or balance disturbances, visual impairments,
- altered mental status
- environmental hazards such as slippery floors, poor lighting, and cluttered rooms

Patient falls are a significant safety concern and can result in serious injuries such as fractures, head injuries, lacerations, and death.

Patients who have been initially assessed to be at low risk for falls may have a change in fall risk during hospitalization or between outpatient visits. Reasons for change in fall risk include

- surgery and/or anesthesia,
- sudden changes in patient condition,
- adjustment in medications.

Many patients require reassessment during their hospitalization due to these changes in condition and fall risk.

Fall risk criteria screenings and assessments identify the patients who are considered at high risk for falls. Screenings, assessments, and any interventions applied are documented in the patient's medical record.–(No need to state why it is required to be documented. It is self-evident)

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

The hospital establishes a fall risk reduction program based on appropriate policies and/or procedures. If a fall occurs, the hospital evaluates the fall, takes action to reduce the risk of future falls, and reduces the risk of injury. A fall risk reduction program includes risk assessment and periodic reassessment of a particular patient population and/or of the environment in which care and services are provided (such as those conducted during periodic safety tours). Measures and interventions are implemented to reduce fall risk for patients, situations, and locations assessed to be at risk.

Specific situations can pose a risk for falls. **For example,** a patient arriving at the outpatient department from a long term care facility by ambulance for a radiologic examination. The patient may be at risk for falls in that situation when transferring from ambulance cart to exam table or when changing positions while lying on the narrow exam table.

Specific locations may present higher fall risks because of the services provided. **For example**, a physical therapy department (inpatient or outpatient) has many types of specialized equipment used by patients that may increase the risk for falls, such as parallel bars, freestanding staircases, and exercise equipment. When specific locations are identified as areas at higher risk for falls, organizations may determine that all patients visiting those locations are considered at risk for falls and implement general measures to mitigate fall risks that are applicable to all patients.

All inpatients are assessed for fall risk using evidence-based assessment tools and/or methods appropriate for the hospital's patient population(s). **For example**, pediatric patients require a pediatric fall risk assessment tool, such as the Humpty Dumpty Score or GRAF-PIF tool.

The hospital leaders conduct a risk assessment to identify high-risk services and patient populations to screen for fall risk in the outpatient department(s). However, the hospital may either choose to either screen all outpatients, or those departments that are inherently higher risk for fall, based on condition, diagnosis, situation, and/or location. **Examples** could include

- all patients in a physical therapy outpatient department,
- all patients arriving from long term care facilities by ambulance for outpatient procedures,
- patients scheduled for outpatient surgery involving procedural sedation or anesthesia,
- patients with gait or balance disturbances or who use an ambulation device
- patients with visual impairments,
- pediatric patients under the age of two

If fall risk is indicated from the screening, evidence-based interventions are implemented to reduce fall risk for those patients.

Screening generally involves performing a simple evaluation of the patient to determine if they are at risk for a falls. Screening tools are commonly used and include questions or items that are used to identify fall risk patients. **For example**, the questions may require a simple yes/no answer, or the tool may involve assigning a score to each item based on the patient's responses. Organizations may determine how the screening process occurs. **For example**, screening may be performed by registration clerks, or patients may be allowed to self-screen, such as at a kiosk upon entering the outpatient department. **Examples** of simple screening questions may include "Do you feel unsteady when standing or walking?"; "Do you worry about falling?"; "Have you fallen in the past year?"

### Measurable Elements of AOP.2

- ❑ 1. The hospital implements a comprehensive program for screening and assessing all inpatients for fall risk and uses evidence-based assessment tools appropriate for the patient population
- ❑ 2. The hospital implements a process for screening all outpatients or outpatients whose condition, diagnosis, situation, or location may put them at risk for falls and uses screening tools appropriate for the patients being served.
- ❑ 3. The hospital implements a process for the reassessment of patients who may become at risk for falls due to a change in condition or are already at risk for falls based on the documented assessment.
- ❑ 4. Interventions to reduce fall risk are implemented for those identified patients, situations, and locations within the hospital assessed to be at risk. Patient interventions are documented.

---

## Standard AOP.3

All patients are reassessed at intervals based on their condition and treatment.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

## Intent of AOP.3

Reassessment is key to understanding how patients respond to treatment and to understand if care decisions are effective.

## Guidance for AOP.3

Patients are reassessed throughout the care process at intervals based on their condition and treatment as defined in hospital policies. The results of these reassessments are documented in the patient's health.

The hospital policy defines how often reassessments occur by various members of the health care team. A physician must assess patients with acute care needs at least daily, including weekends, and when there is a significant change in the patient's condition.

The hospital policy defines how often patients are reassessed by a nurse. This will vary greatly based on the patient's needs, condition, and treatment. **For example,** newly intubated patients may require a nursing reassessment every hour, whereas a stable, chronically ill patient with an established airway may require a nursing reassessment every four hours.

The hospital policy defines how often patients are reassessed by other members of the care team, including

- Respiratory therapists
- Physical, occupational, and speech therapists
- Social workers or other social services

Reassessments occur in accordance with the hospital policy. Reassessments are completed and results are documented in the patient's health record

- at defined intervals by various members of the care team, including physicians, nurses, and others
- daily by a physician for acute care patients;
- in response to a significant change in the patient's condition
- if the patient's diagnosis has changed and the care needs require revised planning; and
- to determine if medications and other treatments have been successful and the patient can be transferred or discharged.

Some non-acute patients may not need daily physician assessments; **for example**, a stable psychiatric patient receiving group therapy sessions, or a patient who is past the acute phase of illness or surgery and who is receiving only rehabilitative treatment. The hospital policy identifies patients who do not require daily physician assessments.

## Measurable Elements of AOP.3

❑ 1. The hospital policy defines how often patients are reassessed by various members of the health care team and other circumstances when a reassessment is required, including

a) Physicians
b) Nurses
c) Other clinical staff (for example, therapists and social workers)
d) When there has been a significant change in patient condition
e) When the diagnosis has changed and plan of care needs to be revised
f) To determine if the patient is ready for transfer or discharge

❑ 2. A physician reassesses patients at least daily, including weekends, during the acute phase of their care and treatment.

❑ 3. The hospital policy identifies patient populations who may not require a daily assessment and defines the minimum reassessment interval for these patients.

❑ 4. Reassessments are documented in the patient health record.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

# *Laboratory Services*

*Laboratories that are required to have specific recognition by local laws and regulations (for example, ISO15189) may present verification of this recognition as evidence of compliance with relevant requirements to surveyors during the JCI Hospital Accreditation Survey. Evidence of compliance must include all specialties and subspecialties provided by the hospital laboratory. JCI survey includes laboratory specialties and subspecialties (for example, blood bank) that are not within the scope of the existing laboratory recognition.*

## Standard AOP.4

Laboratory services are available to meet patient needs, and all laboratory services meet applicable local and national standards, laws, and regulations.

### Intent of AOP.4

Laboratory services are essential to the diagnostic and treatment process and therefore must meet requirements to ensure the quality of data from laboratory tests.

### Guidance for AOP.4

The hospital has a system for providing laboratory services based on patient needs.

The laboratory services are organized and provided in a way that meets applicable local and national standards, laws, and regulations. Laboratory services are available after normal hours for emergencies.

Laboratory services may be provided within the hospital, by agreement with another organization (**for example**, contracted laboratory), or both. The hospital identifies and contacts experts in specialized diagnostic areas, such as parasitology, virology, or toxicology, when needed.

Outside sources are convenient for the patient to access. The hospital selects outside sources based on the recommendation of the laboratory's leader or other individual responsible for laboratory services. Outside sources of laboratory services meet applicable laws and regulations and have an acceptable record of accurate, timely services. Patients are informed when an outside source of laboratory services is owned by the referring physician.

### Measurable Elements of AOP.4

- ❑ 1. Laboratory services, including outside sources of laboratory services, meet applicable local and national standards, laws, and regulations.
- ❑ 2. Laboratory services meet the needs of the patients and other services the hospital provides, including a process to access laboratory services after hours and for emergency needs.
- ❑ 3. Experts in specialized diagnostic areas are contacted when needed.

## Standard AOP.4.1

A qualified individual(s) is responsible for managing the clinical laboratory service or pathology service, and all laboratory staff are qualified to perform the tests and interpret the results. ?

### Intent of AOP.4.1

Clinical laboratory services are managed by an individual who is qualified to ensure the laboratory and its services meet patient needs, laws, and regulations. Qualified laboratory staff perform tests and interpret results to ensure that the data collected through laboratory services is accurate.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

## Guidance for AOP.4.1

Clinical laboratory services are under the direction of an individual who is qualified through documented education, training, experience, and the requirements of laws and regulations. This individual is responsible for the laboratory facility, the services provided in the laboratory, and tests performed outside the laboratory, include point-of-care testing.

The oversight of services outside the laboratory does not include daily supervision of those activities. Daily supervision remains the responsibility of the leaders of the department or unit in which the testing is conducted.

When this individual provides clinical consultation or medical opinion, they are a physician, preferably a pathologist. Specialty and subspecialty laboratory services are under the direction of appropriately qualified individuals.

Laboratory staff are oriented to their work and are given work assignments consistent with their training and experience. The laboratory implements a staffing program that allows staff to perform tests promptly and to ensure laboratory staffing during all hours of operation and for emergencies.

The hospital identifies a qualified laboratory leader to oversee laboratory services. Oversight responsibilities include those services that are provided within and outside the laboratory.

The oversight of services outside the laboratory includes ensuring consistent hospital-wide policies and practices, including

- training
- supply management
- Inspection and maintenance of equipment
- Oversight of the point-of-care-testing program

Laboratory staffing requirements include

- Education, training, qualifications, and experience of laboratory staff members performing and interpreting laboratory tests,
- Identifying staff approved to perform point-of-care testing.
- Identifying staff who direct or supervise other staff who perform testing.

## Measurable Elements of AOP.4.1

❑ 1. The clinical laboratory, and other laboratory services throughout the hospital, are under the direction and oversight of one or more qualified individuals.

❑ 2. Responsibilities of the qualified laboratory leader include

a) developing, implementing, and maintaining policies and procedures;
b) administrative oversight of laboratory services;
c) maintaining any necessary quality control programs;
d) developing and implementing a staffing program;
e) recommending outside sources of laboratory services; and
f) monitoring and reviewing all laboratory services.

❑ 3. All laboratory staff have the required qualifications to perform and interpret tests.

❑ 4. A laboratory staffing program is implemented so staff can perform tests promptly and provide staffing during all hours of operation and during emergencies.

❑ 5. Laboratory supervisory staff are identified and have the proper qualifications and experience for the role.

---

# Standard AOP.4.2

The hospital has defined requirements for the oversight and supervision of the point-of-care testing program.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

## Intent of AOP.4.2

The hospital must have a clearly defined and well-structured approach to POCT to ensure that it is performed safely and correctly and that the results generated are accurate and reliable.

## Guidance for AOP.4.2

*Point-of-care testing* (POCT) is testing performed at sites outside the traditional laboratory environment, usually at or near where care is delivered to the patient.

The individual responsible for laboratory services or other qualified designee is responsible for the oversight and supervision of the POCT program.

The hospital develops a program for POCT that includes

- Selecting tests to be performed
- Identifying staff who perform the test(s)
- a protocol for reporting abnormal test results
- A process for reporting critical results.
- A process to include representatives of clinical staff in developing and evaluating the POCT program

Staff performing POCT require training for each test being performed. Staff must complete a competency evaluation for each test to confirm they know how to perform the test and to ensure that results are accurate. Staff performing the POCT understand the process to report abnormal and critical results.

Quality control tests and their documentation are required to be performed according to manufacturer guidelines. All staff performing POCT adhere to quality control procedures and know what actions to take if a quality control sample is out of the test range specified by the manufacturer. The results of the quality control testing and any corrective actions are documented.

The POCT program is monitored and evaluated to ensure that the program is meeting the needs of patients and health care providers

Point-of-care tests include those performed and interpreted at or near the patient. **Examples** of point-of-care tests include

- POCT blood glucose tests
- POCT blood gas tests
- Pregnancy test
- Urinalysis
- Fecal occult tests
- Rapid infection tests, including strep and COVID

Point-of-care tests do not include tests that are performed at or near the patient but are processed or interpreted in another location.

Quality control testing occurs based on manufacturer guidelines. **Examples** of when quality control testing occurs include

- Once daily
- Once per week
- Between new batches of test kits

POCT program evaluation may be accomplished by one or more of the following methods

- developing and monitoring quality improvement measures,
- through patient or surveys
- reviewing of quality control and proficiency testing results
- reviewing utilization reports.

## Measurable Elements of AOP.4.2

- ❑ 1. Staff performing point-of-care testing have the required qualifications and training and are competent to perform POCT
- ❑ 2. The POCT program includes a defined process reporting abnormal test results, including reporting critical results.
- ❑ 3. The POCT program includes requirements for quality control performance and documentation.
- ❑ 4. The POCT program is monitored, evaluated, and included in quality improvement activities.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

## Standard AOP.4.3

Laboratory results are reported within time frames defined by hospital policy.

### Intent of AOP.4.3

Timely result reporting is vital to the prompt assessment and diagnosis of patients.

### Guidance for AOP.4.3

The hospital defines the time frame for reporting laboratory test results. Results are reported within a time frame based on patient needs, services offered, and clinical staff needs. Emergent or stat tests and after-hours and weekend testing needs are included.

The hospital monitors whether results are reported within the time frame. Results from urgent tests or emergent tests are given special attention in the quality measurement process. If the results are not reported in accordance with the hospital's time frame, the hospital identifies barriers to meeting this goal and implements corrective actions.

In addition, when laboratory services are by contract with an outside organization, the reports are also timely, as set forth by hospital policy or the contract.

### Measurable Elements of AOP.4.3

- ❑ 1. The hospital establishes the expected report time for routine, urgent, and emergent test results.
- ❑ 2. The hospital monitors whether urgent and emergent tests are reported within the expected time frame
- ❑ 3. The hospital monitors whether routine laboratory results are reported within the expected time frame.
- ❑ 4. When laboratory results are not reported within the expected time frame, the hospital takes corrective action.

---

## Standard AOP.4.4

All laboratory testing equipment is regularly inspected, maintained, calibrated, and appropriate records are maintained for these activities.

### Intent of AOP.4.4

The proper maintenance and calibration of laboratory equipment is essential to ensuring accuracy of test results.

### Guidance for AOP.4.4

Laboratory staff ensure that all equipment, including medical devices used for point-of-care testing, function properly. The laboratory implements a program to manage equipment. Testing, maintenance, and calibration frequency are completed according to the manufacturer's guidelines or more frequently based on the laboratory's use of the equipment and documented history of service.

The program to manage laboratory equipment includes

- selecting and acquiring laboratory equipment and medical equipment;
- identifying and taking inventory of laboratory equipment and medical equipment;
- assessing laboratory equipment use through inspection, testing, calibration, and maintenance;
- monitoring and acting on laboratory equipment hazard notices, recalls, reportable incidents, problems, and failures; and
- documenting the management program.

### Measurable Elements of AOP.4.4

- ❑ 1. The laboratory implements program to manage laboratory equipment, including a process for how equipment is selected and acquired.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

- ❑ 2. There is a documented inventory of all laboratory equipment.
- ❑ 3. Laboratory equipment is inspected and tested when new and according to manufacturers' guidelines; the inspections are documented.
- ❑ 4. Laboratory equipment is calibrated and maintained according to manufacturers' guidelines, and the calibration and maintenance are documented.
- ❑ 5. The hospital has a system in place for monitoring and acting on laboratory equipment hazard notices, recalls, reportable incidents, problems, and failures.

---

# Standard AOP.4.5

Essential reagents and supplies are available, and all reagents are evaluated to ensure accuracy and precision of results.

## Intent of AOP.4.5

Reagents are a necessary component of laboratory testing, so the hospital creates a policy to ensure that essential reagents are available and meet their purpose for laboratory tests.

## Guidance for AOP.4.5

The hospital has identified reagents and supplies necessary to provide laboratory services to its patients. There is a process to order or secure essential reagents and supplies.

The laboratory develops and implements guidelines for the periodic evaluation of all reagents, to provide for accuracy and precision of laboratory test results. Reagent performance and adequacy are verified before use. All essential reagents are evaluated according to manufacturers' directives or packaging instructions. The hospital policy requires the complete and accurate labeling of reagents and solutions.

## Measurable Elements of AOP.4.5

- ❑ 1. Essential reagents and supplies are identified and available, and there is a process to address when essential reagents are not available.
- ❑ 2. All reagents are stored and dispensed according to manufacturers' instructions.
- ❑ 3. The laboratory establishes and follows the hospital policy for the evaluation of all reagents to ensure accuracy and precision of results.
- ❑ 4. All reagents undergo quality control testing as required by the manufacturer.
- ❑ 5. Records for reagents include the following information
  - a) identity of the reagent
  - b) the date of receipt or preparation
  - c) the lot number
  - d) the expiration date
  - e) the date put into use

# Standard AOP.4.6

Procedures for collecting, identifying, handling, safely transporting, and disposing of specimens are established and implemented.

## Intent of AOP.4.6

Proper management of specimens is required to ensure that test results accurately represent patient condition; specimens must be properly labeled to match the specimen and results to the correct patient.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

### Guidance for AOP.4.6

Procedures are established and implemented for

- ordering laboratory tests;
- collecting and identifying specimens;
- transporting, storing, and preserving specimens; and
- receiving, logging, and tracking specimens
- disposal of specimens

These procedures are observed for specimens sent to contracted laboratory services for testing.

### Measurable Elements of AOP.4.6

- ❑ 1. Procedures are established and implemented for the ordering of tests.
- ❑ 2. Procedures are established and implemented for the collection and identification of specimens.
- ❑ 3. Procedures are established and implemented for the transport, storage, and preservation of specimens.
- ❑ 4. Procedures are established and implemented for the receipt and tracking of specimens.
- ❑ 5. Procedures are established and implemented for the disposal of specimens.
- ❑ 6. The procedures are followed when contracted laboratory services are used.

---

## Standard AOP.4.7

Established norms and ranges are used to interpret and to report clinical laboratory results.

### Intent of AOP.4.7

Norms and ranges are needed to interpret test results; these norms and ranges are included with the test results so health care providers can interpret test results.

### Guidance for AOP.4.7

The laboratory establishes reference intervals or "normal" ranges for each test performed. The range is included in the medical record, either as part of the report or by including a current listing of such values approved by the laboratory leader. Ranges are provided when a contracted laboratory service performs the test. The reference ranges are appropriate to the hospital's geography and patient demographics. The reference ranges are reviewed and updated when testing methods change and to reflect current scientific evidence.

### Measurable Elements of AOP.4.7

- ❑ 1. The laboratory establishes reference ranges for each test performed.
- ❑ 2. The range is included in the health record at the time test results are reported.
- ❑ 3. Ranges are provided when tests are performed by contracted laboratory services.
- ❑ 4. Ranges are appropriate to the hospital's geography and patient demographics.
- ❑ 5. The laboratory reviews and updates ranges as needed.

---

## Standard AOP.4.8

The hospital has implemented processes for quality control and proficiency testing of laboratory services.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

## Intent of AOP.4.8

Well-designed quality control processes and proficiency testing are essential to providing accurate laboratory services.

## Guidance for AOP.4.8

Quality control procedures are used validate test methods and results. Quality control also includes daily surveillance to ensure testing is completed according to procedure. Rapid corrective actions are implemented when deficiencies are identified.

The laboratory participates in an approved proficiency-testing program or external quality assessment when available. Proficiency testing determines how well an individual laboratory's results compare with other laboratories that use the same methods. Proficiency testing can identify performance problems not recognized by internal mechanisms.

Quality control processes include

- validation of the test methods used for accuracy, precision, and reportable range;
- daily surveillance of results by qualified laboratory staff;
- rapid corrective action when a deficiency is identified; and
- documentation of results and corrective actions.

The laboratory participates in an approved proficiency-testing program when available. If an approved proficiency-testing program or external quality assessment is not available, the laboratory exchanges samples with a laboratory in another organization for purposes of peer comparison. Proficiency testing, or an alternative, is carried out for all specialty laboratory programs when available.

The laboratory maintains documentation of participation in a proficiency-testing process.[

## Measurable Elements of AOP.4.8

- ❑ 1. The hospital establishes and implements a quality control program for the clinical laboratory.
- ❑ 2. The program includes the validation of test methods for accuracy, precision, and reportable range.
- ❑ 3. The program includes the daily surveillance and documentation of test results.
- ❑ 4. The program includes rapid correction and documentation of deficiencies.
- ❑ 5. The laboratory participates in a proficiency-testing program or an alternative external quality assessments for all laboratory services and tests.
- ❑ 6. The laboratory's proficiency testing results meet satisfactory performance criteria in accordance with laws and regulations.

---

# Standard AOP.4.9

The hospital ensures the quality of services provided by contracted laboratories.

## Intent of AOP.4.9

The hospital has a responsibility to ensure that any service provided by a contracted services meets all licensing and legal requirements and meets quality expectations developed by the hospital.

## Guidance for AOP.4.9

If the hospital uses the services of a contracted laboratory, the hospital has a responsibility to make certain that the contracted laboratory is licensed, accredited, or certified by recognized authorities.

Contracted laboratories must participate in proficiency-testing to determine how the contracted laboratory's results compare with other laboratories that use the same testing methods.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

The hospital identifies measures to monitor the quality of services provided by all contracted laboratories. Qualified individuals review and act on the results of quality monitoring. This information is used to identify potential process improvements and to make decisions about future contracts with the contracted laboratories.

To be certain the contracted laboratory is licensed and accredited or certified, and participates in an outside proficiency-testing program, the hospital must obtain

- A copy of a license from a recognized licensing authority
- A copy of the certificate or letter of accreditation or certification from a recognized laboratory accreditation or certification program*
  Documentation that the contracted laboratory participates in an outside proficiency-testing program

The hospital defines what measures the contracted laboratory is required to collect and submit to the hospital, as well as how often data is submitted to the hospital. **Examples** of measures collected to evaluate contracted laboratories include

- Turnaround times for tests, meaning the time it takes for the laboratory to report a result following receipt of the specimen
- Critical results reporting
- Problems with specimens such as missing identifiers or specimen rejections.

### Measurable Elements of AOP.4.9

- ❑ 1. The hospital maintains a copy of the license certificate or letter of accreditation or certification, from recognized authority for all contracted laboratories used by the hospital.
- ❑ 2. The hospital maintains documentation that any contracted laboratory used by the hospital participates in proficiency-testing program.
- ❑ 3. The hospital determines the frequency and type of performance expectation data from contracted laboratories.
- ❑ 4. The individual responsible for the laboratory or a designee reviews the performance measure data from contracted laboratories and takes action based on the results.
- ❑ 5. An annual report of the data from contracted laboratories is provided to the leaders responsible for the management and renewal of contracts.

---

## *Blood Bank and/or Transfusion Services*

---

## Standard AOP.5

A qualified individual is responsible for blood bank and/or transfusion services and ensures that services adhere to laws and regulations and recognized standards of practice.

### Intent of AOP.5

Blood bank and/or transfusion services have unique risks to staff and patients. Proper oversight is required to minimize risks and to ensure optimal use of blood products.

### Guidance for AOP.5

Blood bank and/or transfusion services are under the direction of qualified individual. This individual assumes professional responsibility for all aspects of blood bank and transfusion services provided in the hospital.

Quality control processes for all blood bank and transfusion services are implemented and documented to ensure the safety and efficacy of blood bank and transfusion services. Blood donor and transfusion services are guided by laws and regulations and recognized standards of practice.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

The hospital monitors its use of blood products, outcomes, and availability of blood products. Many hospitals have implemented patient blood management programs to do this. Patient blood management programs include various clinical staff across disciplines and generally include staff from quality and risk management and infection control.

The hospital implements blood surveillance procedures known as *hemovigilance*. Hemovigilance covers the entire blood transfusion process, from donation of blood products through follow-up care for the blood product recipient. Monitoring includes any adverse events or near miss events through the blood bank and/or transfusion services. Once discovered, the hospital is responsible to take corrective action to prevent a repeat occurrence of the event.

The oversight of blood bank and/or transfusion services includes implementation and documentation of the processes for blood administration.

A formal patient blood management program may make oversight of the above processes more efficient. However, the hospital determines how its blood bank and/or transfusion services are monitored and how changes are implemented. The hospital monitors blood bank and/or transfusion services and makes improves on processes to

- Ensure optimal use of blood products
- Ensure optimal patient outcomes
- Maintain the supply of blood products

Hemovigilance processes include monitoring any adverse events or near miss events through the blood bank and/or transfusion services. When an adverse or near miss event is discovered that involves blood bank and/or transfusion services, the event is

- Investigated
- Reported to all required authorities, **for example**, hospital risk management committee or the local or regional blood bank

The hospital then takes corrective action based on monitoring data to prevent any future adverse or near miss events. **Examples** of these events include

- Transfusion to the wrong patient
- Mislabeled blood product
- Contaminated blood product

## Measurable Elements of AOP.5

❑ 1. A qualified individual is responsible for blood bank and/or transfusion services.

❑ 2. The blood bank has implemented, and documented processes for

a) blood donor selection;
b) blood screening for disease;
c) blood collection;
d) blood storage;
e) compatibility testing; and
f) blood distribution.

❑ 3. Quality control measures for all blood bank and transfusion services are implemented and documented.

❑ 4. The blood bank and transfusion services comply with applicable laws and regulations and recognized standards of practice.

❑ 5. The hospital has a process to monitor and improve blood product utilization throughout the hospital including

a) Optimal use of blood products
b) Safe transfusion practices
c) Availability of blood products

❑ 6. The hospital has hemovigilance surveillance program to monitor, investigate, and report any adverse events and near miss events involving blood bank and/or transfusion services.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

# *Radiology and Diagnostic Imaging Services*

## Standard AOP.6

Radiology and diagnostic imaging services are available to meet patient needs, and all services meet applicable local and national standards, laws, and regulations.

### Intent of AOP.6

Safe and accurate radiology and diagnostic services are needed to make accurate patient diagnoses and treatment plans.

### Guidance for AOP.6

The hospital has a process for providing radiology and diagnostic imaging services required by its patient population and scope of services. Radiology and diagnostic imaging services meet all applicable local and national standards, laws, regulations, and professional standards.

Radiology and diagnostic imaging services, including those required for emergencies, may be provided within the hospital, by agreement with another organization, or both. Radiology and diagnostic imaging services are available after normal hours for emergencies. In addition, the hospital may identify and contact experts in specialized diagnostic areas, hospital maintains a list of such experts. **Examples** of these specialized areas include

- radiation physics
- radiation oncology
- nuclear medicine
- interventional radiology
- neurointerventional radiology
- cardiac catheterization

Outside sources are convenient for the patient to access, and reports are received in a timely way to support patient care. The hospital selects outside sources based on the recommendation of the individual responsible for radiology and diagnostic imaging services. Outside sources of radiology and diagnostic imaging services meet applicable laws and regulations and have an acceptable record of accurate, timely services. Patients are informed when an outside source of services is owned by the referring physician.

### Measurable Elements of AOP.6

- ❑ 1. Radiology and diagnostic imaging services meet applicable professional standards local and national laws and regulations.
- ❑ 2. Radiology and diagnostic imaging services are available to meet the needs related to the hospital's patient population, scope of services, and emergency needs, including after normal hours.
- ❑ 3. The hospital maintains a list of experts in specialized diagnostic areas and ensures that the list is accessible to staff who need it.
- ❑ 4. Outside sources are selected based on recommendations of the individual responsible for radiology and diagnostic imaging services and have an acceptable record of timely performance and compliance with applicable laws and regulations.

## Standard AOP.6.1

A qualified individual(s) is responsible for managing the radiology and diagnostic imaging services, and individuals with proper qualifications and experience perform diagnostic imaging studies, interpret the results, and report the results. ⍰

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

## Intent of AOP.6.1

Radiology and diagnostic imaging services are managed by an individual who is qualified to ensure services meet patient needs, laws, and regulations. Qualified radiology and diagnostic imaging staff are needed to perform tests and interpret results to ensure that the data collected through these services is accurate.

## Guidance for AOP.6.1

Radiology and diagnostic imaging services, provided at any location in the hospital, are under the direction of an individual who is qualified by documented education, training, and experience, consistent with applicable laws and regulations. This individual assumes professional responsibility for the radiology and diagnostic imaging facility, equipment, and the services provided.

When this individual provides clinical consultation or medical opinion, they are a physician, preferably a radiologist. When special services are provided, they are under the direction of appropriately qualified individuals. **Examples** of special services include

- radiation therapy
- nuclear medicine
- interventional radiology
- neurointerventional radiology
- cardiac catheterization

The radiology and diagnostic imaging leader's responsibilities include

- developing, implementing, and maintaining policies and procedures;
- administrative oversight;
- overseeing quality control;
- developing and implementing a staffing program
- recommending outside sources of radiology and diagnostic imaging services; and
- monitoring and reviewing all radiology and diagnostic imaging services.

The hospital identifies which radiology and diagnostic imaging staff members

- perform diagnostic and imaging studies,
- who are qualified to interpret the results or to verify and report results, and those
- who direct or supervise the processes.

Supervisory staff and technical staff have appropriate and adequate training, experience, and skills and are oriented to their responsibilities. Technical staff members are given work assignments consistent with their training and experience. In addition, there is a sufficient number of staff to perform, to interpret, and to report studies within a time frame defined by hospital policy and to provide necessary staffing during all hours of operation and for emergencies.

## Measurable Elements of AOP.6.1

- ❑ 1. Radiology and diagnostic imaging services are under the direction of one or more qualified individuals.
- ❑ 2. Responsibilities of the individual managing radiology and diagnostic imaging services include
  - a) developing, implementing, and maintaining policies and procedures;
  - b) administrative oversight;
  - c) overseeing quality control;
  - d) developing and implementing a staffing program
  - e) recommending outside sources of radiology and diagnostic imaging services; and
  - f) monitoring and reviewing all radiology and diagnostic imaging services.
- ❑ 3. Staff with proper qualifications and experience perform diagnostic and imaging studies.
- ❑ 4. Staff with proper qualifications and experience interpret study results and verify and report the results within the time frame defined by hospital policy.
- ❑ 5. There is an adequate number of staff to meet patient needs and the hospital's scope of services.
- ❑ 6. Supervisory staff have proper qualifications and experience for the role.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

# Standard AOP.6.2

A radiation and/or diagnostic imaging safety program for patients, staff, and visitors is implemented and is compliant with applicable professional standards, laws, and regulations.

## Intent of AOP.6.2

Radiation exposure can post potential risk of long-term damage, so the hospital has a responsibility to implement a radiation safety program to protect patients, staff, and visitors from unnecessary or excessive exposure to radiation.

## Guidance for AOP.6.2

Radiation exposure can pose potential risks of long-term damage, depending on the dose of radiation delivered and the length and frequency of exposure to radiation. The higher the radiation dose, the greater the risk for long-term damage, and repeated doses have a cumulative effect presents greater risks. The diagnostic procedures most commonly associated with avoidable radiation doses are computed tomography (CT), nuclear medicine, and fluoroscopy. A radiation safety program is important in the safe use of ionizing radiation, including radioactive materials (RAM) and radiation producing machines.

Health care providers weigh the medical necessity of the exposure to radiation for diagnosis or treatment against the risks. Unnecessary exposure to radiation should be avoided. The hospital follows the principles of ALARA (maintain all radiation exposures As Low As Reasonably Achievable).

Diagnostic imaging, such as magnetic resonance imaging (MRI) and ultrasonography (US), does not use ionizing radiation and therefore the risks from radiation are not present. There are other risk related diagnostic imaging that need to be addressed. Hazards from MRI include

- exposure to a strong magnetic field
- presence of cryogenic gases used to cool the magnets of the MRI
- exposure to acoustic noise

The hospital has a radiation and diagnostic imaging safety program that includes all components of the hospital's radiology and diagnostic imaging services, including radiation oncology and the cardiac catheterization laboratory. The safety program addresses the risks and hazards encountered and implements safety practices and prevention measures for radiology and diagnostic imaging staff, patients, and visitors. The program is coordinated with the hospital's facility management and infection prevention and control programs.

The hospital follows the principles of ALARA (maintain all radiation exposures As Low As Reasonably Achievable). This includes

- Minimizing the amount of time staff, patients, and visitors are exposed to radiation
- Increasing the distance between the radiation source and any staff, patients, and visitors
- Using lead or other shields to reduce exposure to radiation

Hospitals must implement measures to address these hazards from diagnostic imaging. These measures may include

- clearly marking safety zones in the MRI area to indicate who can have access and what safety precautions are necessary in each zone.
- proper ventilation and appropriate staff training to address hazards related to cryogenic gases
- Ear protection to decrease discomfort and harm from acoustic noise during MRI examinations.
- restricting access to the MRI magnetic field area to only authorized staff and to patients accompanied by those staff
- posting signs in and around the area to identify hazards
- Completing a pre-imaging checklist to identify any risks or exclusion criteria for patients undergoing MRI, **for example,** metal implants, shrapnel, or pacemaker in place
- ensuring only special non-ferromagnetic equipment enters the MRI environment.

The radiation safety management program includes

- compliance with applicable professional standards, laws, and regulations
- orientation of all radiology and diagnostic imaging staff to safety procedures and practices
- training and ongoing education for new procedures, new equipment, and newly acquired or recognized hazardous materials

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

- availability of safety protective equipment and devices appropriate to the practices and hazards encountered; in radiology, protective devices and equipment include lead aprons, lead lining in the walls, and radiation badges (for staff), among others
- compliance with standards addressing facility management and infection prevention and control programs

### Measurable Elements of AOP.6.2

❑ 1. A comprehensive radiation and/or diagnostic imaging safety program for patients, staff, and visitors is implemented, and is compliant with applicable professional standards, laws, and regulations.

❑ 2. Radiology and diagnostic imaging staff are oriented to safety requirements and receive ongoing education and training for any new procedures, equipment, and hazardous materials.

❑ 3. Safety protective equipment and devices appropriate to the practices and hazards encountered from radiation and diagnostic imaging are available to staff, patients, and visitors, and in the area in which radiology and diagnostic imaging services are provided.

❑ 4. Radiation safety education includes the principles of ALARA and implementation of protocols that identify the maximum dose of radiation for each type of study.

❑ 5. Hazards from magnetic resonance imaging are addressed using industry standards and evidence-based guidelines.

❑ 6. The hospital designates an individual to serve as the radiation safety officer who is responsible for the following
a) ensuring radiologic services are provided in accordance with law, regulation, and organizational policy.
b) monitoring compliance with established radiation safety practices (including oversight of dosimetry monitoring)

❑ 7. The radiation and/or diagnostic imaging safety program is part of the organization's facility management and infection prevention and control programs and provides reports to those programs at least annually and when any safety events and infection control events occur.

---

## Standard AOP.6.3

Radiology and diagnostic imaging study results are available in a timely way as defined by hospital policy.

### Intent of AOP.6.3

Timely reporting of radiology and diagnostic imaging results is vital to the prompt assessment and diagnosis of patients.

### Guidance for AOP.6.3

The hospital defines the time frame for reporting diagnostic radiology and diagnostic imaging study results. Results are reported within a time frame based on patient needs, services offered, and clinical staff needs. Emergent or stat imaging and after-hours and weekend imaging needs are included.

The hospital monitors whether radiology and diagnostic imaging study results are reported within the time frame. Results from urgent or emergent radiology and diagnostic imaging studies are given special attention in the quality measurement process. If the results are not reported in accordance with the hospital's time frame, the hospital identifies barriers to meeting this goal and implements corrective actions.

Radiology and diagnostic imaging studies performed by outside contractors of services are reported according to hospital policy or contract requirement.

### Measurable Elements of AOP.6.3

❑ 1. The hospital establishes the expected report time for routine, urgent, and emergent radiology and diagnostic imaging results.

❑ 2. The hospital monitors whether urgent and emergent radiology and diagnostic imaging results are reported within the expected time frame.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

- ❑ 3. The hospital monitors whether routine radiology and diagnostic imaging results are reported within the expected time frame.
- ❑ 4. When radiology and diagnostic imaging results are not reported within the expected time frame, the hospital takes corrective action.

---

# Standard AOP.6.4

All equipment used to conduct radiology and diagnostic imaging studies is regularly inspected, maintained, and calibrated, and appropriate records are maintained for these activities. ⍰

## Intent of AOP.6.4

The proper maintenance and calibration of radiology and diagnostic imaging equipment is essential to ensuring accuracy of test results.

## Guidance for AOP.6.4

Radiology and diagnostic imaging staff ensure that all equipment used for radiology and diagnostic imaging program functions properly. The hospital a program to manage radiology and diagnostic imaging equipment. Testing, maintenance, and calibration frequency are completed according to the manufacturer's guidelines or more frequently based on the use of the equipment and documented history of service.

The program to manage radiology and diagnostic imaging equipment includes

- selecting and acquiring radiology and diagnostic imaging equipment and medical equipment;
- identifying and taking inventory of radiology and diagnostic imaging equipment;
- assessing radiology and diagnostic imaging equipment use through inspection, testing, calibration, and maintenance;
- monitoring and acting on radiology and diagnostic imaging equipment hazard notices, recalls, reportable incidents, problems, and failures; and
- documenting the management program.

## Measurable Elements of AOP.6.4

- ❑ 1. The hospital develops, implements, and documents a program to manage radiology and diagnostic imaging equipment, including how radiology equipment is selected and acquired.
- ❑ 2. There is a documented inventory of all radiology and diagnostic imaging equipment.
- ❑ 3. Radiology and diagnostic imaging equipment is inspected and tested when new and according to age, use, and each manufacturer's recommendations; the inspections are documented.
- ❑ 4. Radiology and diagnostic imaging equipment is calibrated and maintained according to each manufacturer's recommendations, and the calibration and maintenance is documented.
- ❑ 5. The hospital has a system in place for monitoring and acting on radiology and diagnostic imaging equipment hazard notices, recalls, reportable incidents, problems, and failures.

---

# Standard AOP.6.5

The hospital has implemented quality control procedures for radiology and diagnostic imaging services. ⍰

## Intent of AOP.6.5

Well-designed quality control processes and proficiency testing are essential to providing accurate radiology and diagnostic imaging services.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

## Guidance for AOP.6.5

Quality control also includes daily surveillance to ensure testing is completed according to procedure. Rapid corrective actions are implemented when deficiencies are identified.

Quality control processes include

- validation of the test methods used for accuracy and precision
- daily surveillance of results by qualified radiology and diagnostic imaging staff;
- rapid corrective action when a deficiency is identified; and
- documentation of results and corrective actions.

## Measurable Elements of AOP.6.5

- ❑ 1. The hospital establishes and implements a quality control program for the radiology and diagnostic imaging services.
- ❑ 2. Quality control includes validating test methods for accuracy and precision.
- ❑ 3. Quality control includes rapid correction and documentation when a deficiency is identified.

---

# Standard AOP.6.6

The hospital ensures the quality of services provided by all outside contracted sources of radiology and diagnostic imaging services.

## Intent of AOP.6.6

The hospital has a responsibility to ensure that any service provided by a contracted services meets all licensing and legal requirements and meets quality expectations developed by the hospital.

## Guidance for AOP.6.6

If the hospital uses the services of a contracted radiology or diagnostic imaging services, the hospital has a responsibility to make certain that the radiology or diagnostic imaging service is licensed and accredited or certified by recognized authorities.

The hospital identifies measures to monitor the quality of services provided by all contracted radiology and diagnostic imaging services. Qualified individuals review and act on the results of quality monitoring. This information is used to identify potential process improvements and to make decisions about future contracts with the contracted radiology and diagnostic imaging services.

The hospital defines what measures the contracted radiology or diagnostic imaging service is required to collect and submit to the hospital, as well as how often data is submitted to the hospital. **Examples** of measures collected to evaluate contracted radiology or diagnostic imaging service include

- Turnaround times for tests, meaning the time it takes for the radiology or diagnostic imaging to receive an order, obtain the imaging, and report the results
- Critical results reporting
- Problems with images such as missing identifiers or specimen rejections.

## Measurable Elements of AOP.6.6

- ❑ 1. The hospital maintains a copy of the license from recognized authority for all contracted radiology and diagnostic imaging services used by the hospital.
- ❑ 2. The hospital maintains a copy of the certificate or letter of accreditation or certification from a recognized authority for all contracted radiology and diagnostic imaging services used by the hospital.
- ❑ 3. The hospital determines the frequency and type of quality data from contracted radiology and diagnostic imaging services.
- ❑ 4. The individual responsible for the radiology and diagnostic imaging services or a designee reviews the performance measure data from contracted radiology and diagnostic imaging services and takes action based on the results.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

- ❑ 5. An annual report of the data from contracted radiology and diagnostic imaging services is provided to those who make decisions about management and renewal of contracts.

---

## Standard AOP.7

When applicable, the hospital establishes and implement a nuclear medicine safety program that complies with applicable professional standards, laws, and regulations.

### Intent of AOP.7

Nuclear medicine is a branch of medical imaging and treatment that uses small amounts of radioactive materials, known as radiopharmaceuticals, to diagnose and treat various diseases. Due to the use of radiation, strict safety standards and guidelines are in place to ensure the well-being of patients, healthcare professionals, and the general public.

### Guidance for AOP.7

Nuclear medicine practices are regulated by various national and international organizations, such as the International Atomic Energy Agency (IAEA), the Nuclear Regulatory Commission (NRC) in the United States, and the European Medicines Agency (EMA) in Europe. These bodies establish and enforce safety standards, including licensing requirements, training guidelines, and equipment regulations. Medical professionals working with radioactive materials in nuclear medicine, such as nuclear medicine physicians, radiologists, and technologists, must undergo specialized training to ensure they have the necessary knowledge and skills to handle radioactive materials safely. They should be trained in radiation safety, radiation protection, and proper handling and disposal of radioactive waste.

Nuclear medicine facilities are designed to minimize radiation exposure to staff and the public. Shielding materials, such as lead and concrete, are used to contain radiation within designated areas. Proper ventilation systems, monitoring equipment, and radiation shielding barriers are required to ensure safety. Quality assurance programs are established to ensure the accuracy and safety of nuclear medicine procedures. Regular equipment calibration, performance testing, and quality control measures are undertaken to maintain the reliability and effectiveness of imaging and treatment equipment.

Patients scheduled for nuclear medicine procedures receive specific instructions regarding preparation, such as fasting requirements or discontinuation of certain medications. Patients are educated about the benefits, risks, and safety precautions associated with the procedure. Informed consent is obtained, and patient concerns or questions are addressed. Radiation exposure is monitored for both patients and healthcare professionals involved in nuclear medicine procedures. Personal dosimeters are worn to measure the amount of radiation received. Regular monitoring helps ensure that radiation doses are within acceptable limits and that appropriate safety measures are followed.
Proper disposal of radioactive waste is crucial to prevent environmental contamination and ensure public safety. Nuclear medicine facilities follow strict protocols for the collection, storage, and disposal of radioactive materials and waste. These procedures are in accordance with local regulations and guidelines.

### Measurable Elements of AOP.7

- ❑ 1. Staff members are properly trained, qualified, and certified to perform their respective roles in nuclear medicine safety and procedures.
- ❑ 2. The hospital implements radiation safety protocols, including the use of appropriate shielding, personal protective equipment (PPE), and monitoring devices for both patients and staff.
- ❑ 3. Radiation doses administered to patients are optimized for diagnostic and therapeutic purposes and includes monitoring and minimizing radiation exposure while obtaining the necessary diagnostic information or therapeutic effect.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

- ❑ 4. The procurement, storage, handling, and disposal of radiopharmaceuticals is in compliance with regulations, professional and manufacturer guidelines.

- ❑ 5. Patients and family are informed about the procedures and safety precautions.

## References

### Assessment of Patients


Beach SP, et al. Screening and detection of elder abuse: Research opportunities and lessons learned from emergency geriatric care, intimate partner violence, and child abuse. *J Elder Abuse Negl.* 2016 Aug–Dec;28(4–5):185–216.

Blanch L, et al. Triage decisions for ICU admission: Report from the Task Force of the World Federation of Societies of Intensive and Critical Care Medicine. *J Crit Care.* 2016 Dec;36:301–305. https://doi.org/10.1016/j.jcrc.2016.06.014.

Fillingim RB, et al. Assessment of chronic pain: Domains, methods, and mechanisms. *J Pain.* 2016 Sep;17(9 Suppl):T10–T20. https://doi.org/10.1016/j.jpain.2015.08.010.

Nates JL, et al. ICU admission, discharge, and triage guidelines: A framework to enhance clinical operations, development of institutional policies, and further research. *Crit Care Med.* 2016 Aug;44(8):1553–1602. https://doi.org/10.1097/CCM.0000000000001856.

Özbilgin Ş, et al. Morbidity and mortality predictivity of nutritional assessment tools in the postoperative care unit. *Medicine (Baltimore).* 2016 Oct;95(40):e5038. https://doi.org/10.1097/MD.0000000000005038.

Pilapil M, DeLaet D. Health risk behaviors in adolescents and young adults with special health care needs. *Curr Opin Pediatr.* 2015 Feb;27(1):132–137.

Pilotto A, et al. Three decades of comprehensive geriatric assessment: Evidence coming from different healthcare settings and specific clinical conditions. *J Am Med Dir Assoc.* 2017 Feb 1;18(2):192.e1–192.e11.

Teixeira AF, Viana KD. Nutritional screening in hospitalized pediatric patients: A systematic review. *J Pediatr (Rio J).* 2016 Jul–Aug;92(4):343–352. https://doi.org/10.1016/j.jped.2015.08.011.


### Laboratory Services


Aykal G, et al. A model for managing and monitoring the quality of glucometers used in a high-volume clinical setting. *Biochemia Medica (Zagreb).* 2016;26(2):202–209. https://doi.org/10.11613/BM.2016.022.

College of American Pathologists (CAP). *Laboratory Accreditation Manual.* Northfield, IL: CAP, 2017.

ECRI Institute. Ask HRC: Best Practices for Specimen Handling. Jul 24, 2017. Accessed Jan 3, 2020. https://www.ecri.org/components/HRC/Pages/AskHRC072417.aspx.

Shaw JLV. Practical challenges related to point of care testing. *Pract Lab Med.* 2015 Dec 9;4:22–29. https://doi.org/10.1016/j.plabm.2015.12.002.

World Health Organization. *Safe Management of Wastes from Health-Care Activities,* 2nd ed. Chartier Y, et al., editors. 2014. Accessed Jan 3, 2020. https://apps.who.int/iris/bitstream/handle/10665/85349/9789241548564_eng.pdf;jsessionid=29E6B0CAE521C4997040A5E98E63D8E4?sequence=1.

World Health Organization. *Safe Management of Wastes from Health-Care Activities: A Summary.* Stone V, editor. 2017. Accessed Jan 3, 2020. https://apps.who.int/iris/bitstream/handle/10665/259491/WHO-FWC-WSH-17.05-eng.pdf;jsessionid=5C5B75D79DB233B0E2B679897CCBE5D6?sequence=1.


### Blood Bank and/or Transfusion Services


Carson JL, et al. Indications for and adverse effects of red-cell transfusion. *N Engl J Med.* 2017 Sep 28;377(13):1261–1272. https://doi.org/10.1056/NEJMra1612789.

Garraud O, et al. Improving platelet transfusion safety: Biomedical and technical considerations. *Blood Transfus.* 2016 Mar;14(2):109–122. https://doi.org/10.2450/2015.0042-15.

Sidhu M, et al. Report on errors in pretransfusion testing from a tertiary care center: A step toward transfusion safety. *Asian J Transfus Sci.* 2016 Jan–Jun;10(1):48–52. https://doi.org/10.4103/0973-6247.175402.

World Health Organization. Blood Safety and Availability. Jun 14, 2019. Accessed Jan 3, 2020. https://www.who.int/en/news-room/fact-sheets/detail/blood-safety-and-availability.


### Radiology and Diagnostic Imaging Services


Bacchim Neto FA, et al. Occupational radiation exposure in vascular interventional radiology: A complete evaluation of different body regions. *Phys Med.* 2016 Aug;32(8):1019–1024. https://doi.org/10.1016/j.ejmp.2016.06.014.

Ghadimi-Moghadam A, et al. Does exposure to static magnetic fields generated by magnetic resonance imaging scanners raise safety problems for personnel? *J Biomed Phys Eng.* 2018 Sep 1;8(3):333–336.



**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

International Commission on Non-Ionizing Radiation Protection. ICNIRP statement on diagnostic devices using non-ionizing radiation: Existing regulations and potential health risks. *Health Phys*. 2017 Mar;112(3):305–321.

The Joint Commission. Diagnostic Imaging Requirements. Aug 10, 2015. Accessed Jan 3, 2020. https://www.jointcommission.org/sitecore/media-library/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/ahc_diagimagingrpt_mk_20150806pdf/.

Kendrick DE, et al. Comparative occupational radiation exposure between fixed and mobile imaging systems. *J Vasc Surg*. 2016 Jan;63(1):190–197. https://doi.org/10.1016/j.jvs.2015.08.062.

Medicines and Healthcare Products Regulatory Agency. *Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use*. Mar 2015. Accessed Jan 3, 2020. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/476931/MRI_guidance_2015_-_4-02d1.pdf.

Roberts BW. Patient-centered radiation safety. *Radiol Technol*. 2017 May;88(5):499–514.

Salama KF, et al. Assessment of occupational radiation exposure among medical staff in health-care facilities in the Eastern Province, Kingdom of Saudi Arabia. *Indian J Occup Environm Med*. 2016 Jan–Apr;20(1):21–25.

## Falls

Agency for Healthcare Research and Quality. *Preventing Falls in Hospitals: A Toolkit for Improving Quality of Care*. AHRQ Publication No. 12-0015-EF. Jan 2013. Accessed Jan 3, 2020. https://www.ahrq.gov/sites/default/files/publications/files/fallpxtoolkit_0.pdf.

France D, et al. A multicomponent fall prevention strategy reduces falls at an academic medical center. *Jt Comm J Qual Patient Saf*. 2017 Sep;43(9):460–470. https://doi.org/10.1016/j.jcjq.2017.04.006.

Kafantogia K, et al. Falls among hospitalized patients. *Journal of Frailty, Sarcopenia & Falls*. 2017 Sep;2(3):53–57. https://doi.org/10.22540/JFSF-02-053.
World Health Organization. Falls. Jan 16, 2018. Accessed Jan 3, 2020. https://www.who.int/news-room/fact-sheets/detail/falls.

Zubcoff L, et al. Virtual Breakthrough Series, part 2: Improving fall prevention practices in the Veterans Health Administration. *Jt Comm J Qual Patient Saf*. 2016 Nov;42(11):497–AP12. https://doi.org/10.1016/S1553-7250(16)42092-1.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

# Care of Patients (COP)

## Overview

The most important responsibility of a health care organization and its staff is to provide safe and effective care and services to all patients. This requires effective communication, collaboration, and standardized processes to ensure that the planning, coordination, and implementation of care supports and responds to each patient's unique needs and goals.

Care may be preventive, palliative, curative, or rehabilitative and may include anesthesia, surgery, medication, supportive therapies, or a combination of these and is based on the assessment and reassessment of each patient. High-risk areas of care (including resuscitation, blood administration, organ and tissue transplantation) and care for high-risk or special needs populations require additional attention. Part of care delivery also includes identifying and reducing risk factors that could impact patient care such as risks associated with use of clinical alarms and lasers.

Care for patients is provided by many disciplines and support staff. All individuals involved in patient care must have a clear role determined by licensure; credentials; certification; laws and regulations; an individual's particular skills, knowledge, and experience; and organization policies or job descriptions. Some care may be carried out by the patient, his or her family, or other trained caregivers. Additional support may also be provided by an appointed individual(s), such as a living donor advocate, who has knowledge about the care process and can independently inform patients on all considerations that could affect decision making.

The delivery of care and services must be coordinated and integrated by all individuals caring for the patient. Working together with the patient and family, these individuals ensure that

- based on assessment, care is planned to meet each patient's unique needs;
- the planned care is delivered to each patient;
- the patient's response to care is monitored; and
- planned care is modified when necessary based on the patient's response.

## Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

### Care Delivery for All Patients

COP.1 There is a uniform process for prescribing and completing treatment orders.

COP.1.2 An individualized plan of care is developed and documented for each patient.

COP.2 The provision of high-risk services is guided by professional practice guidelines, laws, and regulations.

### Clinical Alarm System Management

COP.3 The hospital implements policies and procedures for safety of clinical alarm systems.

### Recognition of Changes to Patient Condition

COP.4 Clinical staff are trained to recognize and respond to changes in a patient's condition.

### Resuscitation Services

COP.5 Resucitation services are available throughout the hospital.

### Administration of Blood and Blood Products

COP.6 Clinical guidelines and procedures are implemented for the handling and administration of blood and blood products.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

## Management of Patients at Risk of Suicide or Self-Harm

COP.7 The hospital has a process to identify and protect patients at risk for suicide and self-harm.

## Food and Nutrition Therapy

COP.8 Food, nutrition products, and nutrition therapy are available to patients.

## Pain Management

COP.9 Pain is managed effectively.

## End-of-Life Care

COP.10 The hospital has a process to provide end-of-life care that addresses the needs of the patient and family and optimizes the patient's comfort and dignity.

## Hospitals Providing Transplant Services

COP.11 The hospital informs patients and families about how to donate organs and other tissues.

COP.11.1 The hospital provides oversight for the process of organ and tissue procurement.

COP.11.2 The hospital's leadership provides resources to support the organ, tissue, and/or cell transplant program.

COP.11.3 The hospital identifies a qualified transplant program leader(s) and includes an interdisciplinary team that consists of clinical staff with expertise in the relevant transplant programs.

COP.11.4 There is a designated coordination mechanism for all transplant activities.

COP.11.5 The hospital complies with organ, tissue, and cell transplant responsibilities.

COP.11.6 The transplant program obtains informed consent specific to organ, tissue, and/or cell transplant from the transplant recipient candidate.

COP.11.7 The transplant program has documented protocols, clinical practice guidelines, or procedures for organ recovery and organ receipt to ensure the compatibility, safety, efficacy, and quality of human cells, tissues, and organs for transplantation.

COP.11.8 Clinical practice guidelines and clinical criteria guide the selection and care of organ, tissue, and cell transplant patients.

## Transplant Programs Using Living Donor Organs

COP.12 Transplant programs that perform living donor transplantation adhere to local and regional laws and regulations and protect the rights of prospective or actual living donors.

- COP.12.1 Transplant programs performing living donor transplants obtain informed consent specific to organ donation from the prospective living donor.
- COP.12.2 Transplant programs that perform living donor transplants use clinical and psychological selection criteria to determine the suitability of potential living donors.
- COP.12.3 Individualized patient care plans guide the care of living donors.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

# Standards, Intents, Guidance, and Measurable Elements

## *Care Delivery for All Patients*

## Standard COP.1

There is a uniform process for prescribing and completing treatment orders.

### Intent of COP.1

A uniform process for the prescription, completion, and documentation of patient orders contributes to the integration and coordination of patient care activities, more effective use of human and other resources, and the increased likelihood of better patient outcomes.

### Guidance for COP.1

Each member of the health care team records observations and treatments in the patient's health record. Many patient care activities require a qualified individual to prescribe an order for that activity, **for example**,

1. orders for laboratory testing
2. administration of medications
3. specific nursing care
4. nutrition therapy
5. rehabilitative therapy.

These orders are documented in the patient health record and must be easily accessible.

Effective communication, which is timely, accurate, complete, unambiguous, and understood by the recipient, reduces errors and results in improved patient safety. Communication can be electronic, verbal, or written. Patient care circumstances that can be critically affected by poor communication include verbal and telephone patient care orders, verbal and telephone communication of critical test results, and handover communications.

Patient care orders given verbally in person and over the telephone, if permitted under local laws and regulations, are some of the most error-prone communications. Different accents, dialects, and pronunciations can make it difficult for the receiver to understand the order being given. **For example,** drug names and numbers that sound alike, such as erythromycin and azithromycin or fifteen and fifty, can affect the accuracy of the order. Background noise, interruptions, and unfamiliar drug names and terminology often compound the problem. When received, a verbal order must be transcribed as a written order, which adds complexity and risk to the ordering process.

Clinical and diagnostic procedures and treatments performed are documented in the patient's health record. The outcomes or results of any treatment or procedure are documented in the patient's health record. Information about who requested the procedure or treatment and the indication for the procedure or treatment are included in the documentation.

The hospital decides

- which orders must be documented, including which orders may be received by telephone, verbal, or text messaging (if permitted by the hospital); **for example**, telephone orders may be limited to emergency situations when a physician is not

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

present, verbal orders may be limited to situations in which the ordering physician is performing a sterile procedure, and texting orders may be limited to diagnostic tests only;

1. which staff is authorized to receive and record verbal orders, including documentation of the verbal orders
2. what information must be included in patient orders
3. which diagnostic imaging and clinical laboratory test orders include providing a clinical indication/rationale for interpretation;

- any exceptions in specialized settings, such as emergency departments and intensive care units;
- who is permitted to prescribe orders; *and*
- where orders are to be located in the patient medical record; orders are located in a designated section of the health record. **For example,** an orders requisition form in a hard copy health record or order entry section of an electronic health record. They should not be interspersed throughout various sections of the health record, **for example,** the order requisition form and progress notes, as this increases the likelihood of a missed order

Safe practices for communicating orders and test results include the following:

- Limiting verbal communication of prescription or medication orders to urgent situations in which immediate written or electronic communication is not feasible. **For example**, verbal orders can be disallowed when the prescriber is present and the patient's chart is available. Verbal orders can be restricted to situations in which it is difficult or impossible for hard-copy or electronic order transmission, such as during a sterile procedure.
- The development of guidelines for requesting and receiving test results on an emergency or STAT basis, the identification and definitions of critical tests and critical values, to whom and by whom critical test results are reported, and monitoring compliance
- Writing down, or entering into a computer, the complete order or test result by the receiver of the information; the receiver reading back the order or test result; and the sender confirming that what has been written down and read back is accurate. Permissible alternatives for when the read-back process may not always be possible may be identified, such as in the operating theatre and in emergent situations in the emergency department or intensive care unit.

## Measurable Elements of COP.1

- ❑ 1. The hospital develops and implements a uniform process for prescribing patient orders that includes
  - a) the information required in the order
  - b) identifying orders that may be received verbally, via telephone, and via text.
  - c) Who is qualified and permitted to prescribe patient orders
  - d) How and where orders are documented uniformly in patient health records
  - e) Which staff are authorized to receive and record verbal, telephone, and text orders, in accordance with law and regulation
  - f) The timeframe in which verbal, telephone, and text orders must be signed by prescriber.
- ❑ 2. Diagnostic imaging and clinical laboratory test orders include a clinical indication/rationale when required for interpretation.
- ❑ 3. Complete verbal orders, including telephone orders, are documented and read back by the receiver and confirmed by the individual given the order.
- ❑ 4. Procedures and treatments are carried out as ordered and are documented in the patient's medical record.
- ❑ 5. The results of procedures and treatments performed are documented in the patient's medical record.
- ❑ 6. Complete test results are documented and read by the receiver and confirmed by the individual giving the result.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

# Standard COP.1.2

An individualized plan of care is developed and documented for each patient.

## Intent of COP.1.2

The plan of care outlines care, treatment, and services to be provided to an individual patient. The overall goal of a plan of care is to achieve optimal clinical outcomes.

## Guidance for COP.1.2

The planning process is collaborative and uses the data from the initial assessment and reassessments performed by members of the health care team to identify and to prioritize the care and treatments, and services required to meet the patient's needs. The patient and family are involved in the planning process with the health care team.

The plan of care is developed within 24 hours of admission as an inpatient and is updated as appropriate to reflect the evolving condition of the patient. The plan of care is documented in the patient's health record.

The plan of care for a patient must be related to their identified needs. Patient needs may change as the result of clinical improvement or new information from a routine reassessment (**for example**, abnormal laboratory or radiography results), or they may be evident from a change in the patient's condition (**for example**, loss of consciousness). The plan of care is revised based on these changes and is documented in the health record as notes to the initial plan or as a new plan of care.

One method of developing care plans is to identify and establish measurable goals. Measurable goals can be selected by the *responsible practitioner* in collaboration with the nurse and other members of the health care team. Measurable goals are observable, achievable targets related to patient care and expected clinical outcomes.

Goals must be realistic, specific to the patient, and time-based to provide a means for measuring progress and outcomes related to the plan of care. **Examples** of measurable, realistic goals include:

- The patient will resume and maintain an adequate cardiac output as indicated by a heart rate, rhythm, and blood pressure that are within normal limits.
- The patient will demonstrate proper self-administration of insulin injections prior to hospital discharge.
- The patient will be able to walk from his bed to the visitor lounge with a standard walker, bearing weight as tolerated on the affected leg.

Note: A single, integrated plan of care that identifies measurable goals expected by each health care practitioner is preferable. It is good practice for the plan of care to reflect individualized, objective, and measurable goals to facilitate reassessment and revision of the plan of care.

Some departments may conduct multidisciplinary patient care conferences for patients receiving complex care from multiple services; **for example**,

1. patients receiving rehabilitative services
2. patients with multiple diagnoses in intensive care units
3. patients with complex discharge planning needs

Any results or conclusions from collaborative patient care team meetings or similar patient discussions are written in the patient's health record.

## Measurable Elements of COP.1.2

- ❑ 1. The care for each patient is planned by the responsible practitioner, nurse, and other members of the health care team within 24 hours of admission as an inpatient.
- ❑ 2. The plan of care is individualized based on the patient's initial assessment data and identified needs and is documented in the patient's health record.
- ❑ 3. The plan of care is updated or revised based on any changes in the patient's condition and is documented in the patient's health record.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

❑ 4. The results or conclusions of any patient care team meetings or other collaborative discussions are documented in the patient's health record.

---

# *Provision of High-Risk Services*

---

## Standard COP.2

The provision of high-risk services is guided by professional practice guidelines, laws, and regulations.

### Intent of COP.2

Providing high-risk services involves unique risks to patients and staff; the hospital establishes and implements guidelines and procedures to identify and decrease risks associated with these services.

### Guidance for COP.2

Some services are considered high risk because of the complex medical equipment, the nature of the treatment, the potential for harm to the patient, or toxic effects of certain high-risk medications.

High-risk care is supported by the use of tools such as

1. clinical practice guidelines
2. hospital procedures
3. clinical pathways

These tools are important for staff to understand and implement in a uniform manner. Hospital leadership is responsible for

- identifying services considered high risk in the hospital;
- using a collaborative process to develop written tools for guiding the uniform care; and
- training staff in implementing these tools.

Written tools for care must be tailored to the high-risk service to be effective in reducing risk. When providing high-risk service, the hospital establishes and implements guidelines and procedures that address the following:

- how care planning will occur, including special considerations related to the high-risk service;
- the documentation required for effective communication among the care team;
- special consent considerations, if appropriate;
- patient-monitoring requirements, including the proper use of alarms;
- special qualifications or skills of staff involved in the care process; and
- the availability and use of specialized medical equipment.

Hospital leadership identifies additional risk for hospital-acquired conditions as the result of any procedures or plan of care. **Examples** of hospital-acquired conditions include

1. deep vein thrombosis, pressure ulcers, and ventilator-associated infections in patients on life support;
2. neurological and circulatory injury in restrained patients;
3. bloodborne pathogen exposure in dialysis patients;
4. central line infections;
5. and falls).

When these risks are present, they must be prevented by educating staff and developing appropriate policies, guidelines, and procedures. The hospital uses measurement information to evaluate the services provided and integrates that information into the hospital's overall quality improvement program.

Hospital leadership identifies high-risk services provided by the hospital. When providing high-risk services, the hospital establishes and implements guidelines and procedures that address the following:

- how care planning will occur, including special considerations related to the high-risk patient population or service;
- the documentation required for effective communication among the care team;
- special consent considerations, if appropriate;

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

- patient-monitoring requirements, including the proper use of alarms;
- special qualifications or skills of staff involved in the care process; and
- the availability and use of specialized medical equipment.

### Measurable Elements of COP.2

❑ 1. Hospital leadership identifies the high-risk services, including at least the following when provided by the hospital.

1. emergency services;
2. life support, including ventilators and Extracorporeal Membranous Oxygenation;
3. infectious disease services;
4. dialysis;
5. restraints;
6. chemotherapy;
7. critical care services

❑ 2. Hospital leadership establish and implement policies, procedures, and/or principles of care for high-risk services provided by the hospital.

❑ 3. Staff are trained to use the written tools for high-risk services.

❑ 4. Hospital leadership identifies additional risks that may affect high-risk services and implements measures to reduce and/or prevent these risks.

❑ 5. Hospital-acquired conditions are tracked and included in the hospital's quality improvement program.

---

## *Clinical Alarm System Management*

---

## Standard COP.3

The hospital implements policies and procedures for safety of clinical alarm systems.

### Intent of COP.3

Clinical alarm systems are intended to alert caregivers of potential patient problems or equipment malfunction. However, improperly managed clinical alarm systems compromise patient safety.

### Guidance for COP.3

Risk factors associated with alarm management include too many devices with alarms, default settings that are not at an actionable level, and alarm limits that are too narrow or not appropriate for the patient's condition. Patient care areas have multiple alarm signals, and the noise from improperly managed alarms desensitizes staff and causes them to miss, ignore, or disable alarms. These issues vary greatly among hospitals and within different clinical areas in a single hospital. Hospital leaders must develop a systematic, coordinated approach minimize risks associated with clinical alarm management.

Standardization contributes to safe alarm system management, but alarm management solutions may have to be designed for specific clinical units, groups of patients, or individual patients. In designing customized solutions for proper alarm management, leaders begin by identifying the most important alarm signals to manage. **For example**, the most common alarms to address in an adult cardiac population would be cardiac monitoring, and in labor and delivery fetal monitoring alarms may be the most common.

Consideration of the following can be helpful in determining alarm signals that may pose a risk to patient safety:

- Input from clinical staff
- Data from medical devices, including false or nonactionable alarms
- Risk to patients if the alarm signal is not attended to or if it malfunctions
- Whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

- Potential for patient harm based on internal incident history
- Published best practices and guidelines

### Measurable Elements of COP.3

- ❑ 1. Hospital leaders implement an alarm system management program for alarm signals that pose a risk to patient safety.
- ❑ 2. The program identifies the most important alarm signals to be managed based on the risk to patient safety.
- ❑ 3. Hospital leaders develop strategies for managing alarms that include
  - a) Clinically appropriate settings for alarm signals
  - b) Situations in which alarm signals can be disabled
  - c) Circumstances under which alarm parameters must be reviewed and/or be changed (**for example,** with significant changes in patient condition, when patients are transferred to different levels of care)
  - d) Identification of those who have the authority to set alarm parameters
  - e) Designation of those who have the authority to change alarm parameters
  - f) Reducing unnecessary alarm noise and improving alarm fatigue among the clinical staff
- ❑ 4. Clinical staff are educated on the purpose and operation of alarm systems for which they are responsible.
- ❑ 5. Staff responsible for the management of clinical alarms are trained and competent to do so.
- ❑ 6. Alarm systems, policies and procedures, and staff training procedures are reviewed annually to identify and implement improvements.

---

## *Recognition of Changes to Patient Condition*

---

## Standard COP.4

Clinical staff are trained to recognize and respond to changes in a patient's condition.

### Intent of COP.4

Hospitals that implement a systematic approach to early recognition and response to changes in a patient's condition reduce cardiopulmonary arrests and patient mortality.

### Guidance for COP.4

It is essential to recognize the signs indicating a change or deterioration in patient condition. Often, a patient will exhibit early warning signs (**for example**, a worsening of vital signs or a subtle change in neurological status) shortly before experiencing significant clinical decline, resulting in a major event. Clinical staff use physiological criteria to assist in early detection of deteriorating patients. Most patients who experience cardiopulmonary or respiratory arrest experience clinical deterioration prior to arrest. Clinical outcomes improve when staff can identify these patients early and request additional assistance from specially trained individuals.

All clinical staff receive education and training to recognize and intervene when a patient exhibits physiological signs that are outside of the normal range, indicating a potential for patient deterioration. Early response to changes in a patient's condition is critical to potentially preventing further deterioration.

Failure to rescue is a delay in recognizing or acting upon changes in a patient's conditions or complications of medical or surgical interventions or underlying conditions, resulting in death. Failure to rescue measures have been developed for various specialties, including

1. Adult and pediatric surgical services
2. Adult cardiac care
3. Trauma surgery

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

4. Gastrointestinal surgery

Failure to rescue measures are selected based on the populations treated and services provided; data from these measures are used to identify opportunities for process improvement.

Early warning criteria, also known as early warning scores, are used to quickly determine patient condition or changes in patient condition. These criteria are evidence-based and age-specific. The hospital implements early warning criteria for all age groups it cares for. **Examples** of early warning criteria include

1. Early Warning Score (EWS)
2. Modified Early Warning Score (MEWS)
3. Pediatric Early Warning Score (PEWS)
4. Revised Trauma Score (RTS)
5. 10 Signs of Vitality Score
6. Pasero Opioid-Induced Sedation Scale (POSS)

The hospital collects and analyzes data on failure to rescue measures applicable to the populations it services. These include clinical and operational measures to improve recognition and response times to ultimately increase patient survival rates.

### Measurable Elements of COP.4

- ❑ 1. The hospital implements a systematic process to recognize and respond to changes or deterioration of patient condition.
- ❑ 2. The hospital implements documented age-specific early warning criteria describing early signs of a change or deterioration in a patient's condition.
- ❑ 3. The hospital has a process for staff to seek additional assistance when they have concerns about a patient's condition based on the hospital's early warning criteria.
- ❑ 4. The hospital informs the patient and family how to seek assistance when they have concerns about a patient's condition.
- ❑ 5. The hospital collects and analyzes data on failure to rescue measures applicable to the patients served and services provided.
- ❑ 6. The hospital makes improvements to its early recognition process based on failure to rescue data analysis.

---

## *Resuscitation Services*

---

## Standard COP.5

Resuscitation services are available throughout the hospital.

### Intent of COP.5

The immediate initiation of chest compressions, respiratory support, and defibrillation when indicated impact patient outcomes including preventing permanent injury, disability, or death. Therefore, resuscitation services must be available throughout the hospital to decrease response time and improve patient outcomes.

### Guidance for COP.5

Successful resuscitation of patients in cardiopulmonary arrest is dependent on critical interventions, such as early defibrillation and initiation of advanced life support. These services must be available to all patients, 24 hours a day, every day. Staff trained in resuscitation must have access to standardized medical equipment and medications for resuscitation.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

Basic life support must be initiated immediately upon recognition of cardiac or respiratory arrest, and a process must be in place for providing advanced life support in fewer than 5 minutes. While the requirement for COP.5. ME 3 is for a response under 5 minutes, the hospital should continually reevaluate its response times and make efforts to shorten the response time as much as possible. This may involve elements such as placement of emergency carts and equipment such as automated external defibrillators (AEDs), and assignment/location of staff who respond to resuscitation emergencies.

Resuscitation services, equipment, and staff training within the hospital must be based on clinical evidence and the population served (**for example**, if the hospital has a pediatric population, medical equipment for pediatric resuscitation must be available). The hospital reviews internal data from previous emergency situations to evaluate response times and availability of appropriate equipment, and identifies areas for improvement.

Note: *All areas of the hospital* includes all areas where treatment and services are provided, including treatment or diagnostic areas in separate buildings on the hospital campus.

The hospital determines what resuscitation services, equipment, and training are provided based on its patient populations. These resources must be immediately available in all areas where specific patient populations receive services. **For example**, hospitals that treat children must have clinical staff trained in pediatric advanced life support, have standardized pediatric equipment and medications, and be able to appropriately select the size or dose of medication based on the child's weight or size.

Resuscitation equipment and medications are standardized throughout the hospital. Hospital leaders and clinical staff determine how to store and standardize equipment depending on the patient populations served. **For example:**

1. Emergency departments that treat adults and children may have two separate resuscitation carts – one for adults and one for children – or one cart with designated drawers for adult and pediatric patients
2. Pediatric departments may have resuscitation carts that include weight-based equipment and medications appropriate for neonatal through young adult patients
3. Maternity wards may have resuscitation supplies for laboring patients in one resuscitation box and resuscitation supplies for newborns in a separate resuscitation box

Advanced life support is provided in fewer than five minutes. Patient outcomes depend on quality CPR and correct recognition of the causes and treatments for cardiopulmonary arrest. Therefore, at five minutes, an adequate mount of staff members trained in advanced life support must have arrived and initiated advanced life support protocols based on the patient's condition and clinical data. Adequate staff trained in advanced life support must remain present and available to support the resuscitation efforts until the event has concluded.

If the hospital has consistently initiated advanced life support in fewer than five minutes, quality data should be reviewed to determine how this time could be even shorter. An interdisciplinary committee can be formed to complete resuscitation services reviews. These reviews include resuscitation cases and data to identify and suggest practice and system improvements in resuscitation performance. Examples of the review could include the following:

1. How often early warning signs of clinical deterioration were present prior to in-hospital cardiac arrest in patients in non-monitored or non–critical care units
2. Timeliness of staff's response to a cardiac arrest
3. The quality of cardiopulmonary resuscitation (CPR)
4. Post–cardiac arrest care processes
5. Outcomes following cardiac arrest

## Measurable Elements of COP.5

- ❑ 1. Resuscitation services are available and provided to all patients 24 hours a day, every day, throughout all areas of the hospital.
- ❑ 2. Medical equipment for resuscitation and medications for basic and advanced life support are standardized and available for use based on the populations served.
- ❑ 3. In all areas of the hospital, basic life support is initiated immediately upon recognition of cardiac or respiratory arrest, and advanced life support is initiated in fewer than 5 minutes.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

- ❑ 4. The hospital reviews internal data from previous emergency situations and identifies areas for improvement, including at least the following:
    1. The number and location of cardiac arrests (for example, ambulatory area, telemetry unit, critical care unit)
    2. The outcomes of resuscitation (for example, return of spontaneous circulation [ROSC], survival to discharge)
    3. Transfer to a higher level of care

---

# *Administration of Blood and Blood Products*

---

## Standard COP.6

Clinical guidelines and procedures are implemented for the handling and administration of blood and blood products.

### Intent of COP.6

Blood must be administered in accordance with standards of practice and in a consistent manner to ensure the safety of the recipient.

### Guidance for COP.6

In addition to oversight of the blood bank and transfusion services, the hospital identifies who is permitted to administer blood and blood products according to local laws and regulations and uniformly implements clinical guidelines and procedures for the handling and administration of blood and blood products. The hospital provides and documents training of all clinical staff permitted to administer blood and blood products. This training is overseen by an individual with education, knowledge, and expertise related to blood and blood products administration. Uniform training ensures that processes, procedures, and clinical guidelines for transfusions are implemented throughout the hospital.

Training for clinical staff permitted to administer blood and blood products includes

1. How to obtain consent
2. How to obtain blood and blood products from the blood bank or blood storage areas
3. How to verify patient identification
4. Administration procedures, including special considerations for special patient populations (**for example,** neonates, trauma patients)
5. Documentation requirements
6. How to monitor for and respond to transfusion reactions

The hospital has a process to monitor and investigate any adverse events and near miss events involving the administration of blood and blood products. This process includes

1. Clinical staff involved in the event
2. The individual(s) who oversee blood and blood product administration training
3. The individual(s) who oversee the blood bank and transfusion services
4. Individual(s) from the quality and risk management program
5. Others as identified

Adverse events and near miss events are reported to local and regional authorities as required.

### Measurable Elements of COP.6

- ❑ 1. The hospital identifies who is permitted to administer blood and blood products in accordance with laws and regulations.
- ❑ 2. Individuals permitted to administer blood and blood products must have the education, knowledge, and clinical expertise to do so safely.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

- ❑ 3. The hospital provides and documents training of practices associated with administering blood and blood products.
- ❑ 4. Clinical guidelines and procedures are uniformly implemented for the handling and administration of blood and blood products.
- ❑ 5. Clinical guidelines and procedures address the processes for

    1. patient consent for administration;
    2. procurement of blood from the blood bank or blood storage area;
    3. patient identification;
    4. blood administration;
    5. monitoring of the patient; and
    6. identification of and response to signs of potential transfusion reactions

- ❑ 6. The hospital monitors, investigates, and reports any adverse events and near miss events involving the administration of blood and blood products.

---

## *Management of Patients at Risk of Suicide or Self-Harm*

---

## Standard COP.7

The hospital has a process to identify and protect patients at risk for suicide and self-harm.

### Intent of COP.7

Suicide is considered a sentinel event. The hospital presents a unique combination of risk factors—acute illness or presentation of symptoms, environmental risk factors, and varied levels of staff experience with suicide and self-harm. Therefore, the hospital must implement screenings and assessments to identify patients at risk for suicide and self-harm to minimize the likelihood of a suicide or self-harm attempt.

### Guidance for COP.7

The hospital creates or selects screening criteria or tools to identify patients who may be at risk for suicide and self-harm. These criteria and tools are brief and are based on populations served by the hospital, current evidence, and common risk factors. Patients who are considered "at risk" based on a positive suicide or self-harm screening are then assessed for additional information about this risk.

Suicide and self-harm assessment tools are evidence-based and appropriate for the patient population. **For example,** pediatric, adolescent, and adult assessment tools are used.

The hospital implements processes to minimize the risk of suicide and self-harm in patients who are at risk for suicide and/or self-harm based on assessment findings. These processes may vary depending on the type of unit or ward, including the emergency department, and the patient population. **For example**, a general ward may implement a requirement for one-to-one monitoring for patients at risk of suicide, whereas psychiatric units may opt for hourly intentional rounding. The focus of these processes is to keep patients safe, regardless of where they are being cared for in the hospital. Department/service leaders conduct risk assessments and collaborate with clinical staff to identify and implement processes that are most applicable and appropriate to each clinical care area.

Hospitals that care for patients at risk for suicide and self-harm need to assess risks in the physical environment to identify areas and features that could be used to attempt suicide. Psychiatric hospitals and hospitals with psychiatric wards and units design, build, and maintain the environment in a manner that minimizes or eliminates risks identified in the environmental risk assessment. Nonpsychiatric units in hospitals assess clinical areas to identify objects that could be used for self-harm so they can be removed

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

when needed from the area around a patient who has been identified as high risk for suicide. **For example**, removal of anchor points, door hinges, and hooks that can be used for hanging.

Screening criteria or tools may include identifying specific populations that are at risk for suicide and self-harm. **For example,**

1. Trauma or emergency care patients
2. Psychiatric patients
3. Post-partum patients
4. Patients with terminal diagnoses

Screening criteria or tools may include asking patients brief yes or no questions.
**For example,** answering "yes" to any of the following questions may lead to further assessment:

1. Have you ever thought of hurting yourself or others?
2. Do you have any diagnosed psychiatric disorders?
3. Do you have a history of self-harm?

Suicide and self-harm assessment tools focus on at least the following:

1. suicidal ideation
2. intent and plan for suicide or self-harm
3. risk and protective factors
4. past suicidal or self-harm behaviors

Processes to minimize suicide and self-harm risk may vary based on factors in the care areas, including

5. physical environment of the care area
6. staffing ratios and training
7. equipment and supplies in patient care areas

The risk environmental risk assessment includes

1. Patient rooms
2. patient bathrooms
3. corridors
4. and other areas

The most common hazards for suicide risk are anchor points used for hanging; however, there are many other types of hazards, and it is important to do a thorough assessment of the environment. **For example**, the risk assessment includes

5. the accessibility of sharps
6. the accessibility of medications
7. the accessibility of cleaning chemicals
8. blind spots and entrances/exits from the care area

## Measurable Elements of COP.7

- ❑ 1. The hospital develops criteria or tools for suicide and self-harm screenings with consideration for the population served by the hospital, current evidence, and common risk factors.
- ❑ 2. Patients who screen positive are identified as "at risk" for suicide and/or self-harm and are assessed for suicidal ideation and/or self-harm using evidence-based tools.
- ❑ 3. Screenings and assessments are documented in the patient health record.
- ❑ 4. The hospital conducts an environmental risk assessment that identifies features in the physical environment that could be used to attempt suicide or self-harm; the hospital takes necessary action to minimize the risk(s).
- ❑ 5. The hospital implements processes to mitigate the risk of patient suicide and/or self-harm.
- ❑ 6. The hospital monitors implementation and effectiveness of processes for the prevention of patient suicide and/or self-harm by analyzing relevant data.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

- ❑ 7. Clinical staff are trained on screening criteria, assessments, and suicide and self-harm risk reduction processes.

---

# *Food and Nutrition Therapy*

---

## Standard COP.8

Food, nutrition products, and nutrition therapy are available to patients.

### Intent of COP.8

Appropriate food and nutrition contribute to improved patient outcomes, including wound healing, and management of complex diseases and disorders.

### Guidance for COP.8

Based on the patient's assessed needs, diagnoses, and plan of care, the patient's practitioner or other qualified caregiver orders food or other nutrients for the patient. The order may include special dietary requirements such as low cholesterol, diabetic diet, and clear liquids.

The patient participates in planning and selecting foods whenever possible. Patients are offered a variety of food choices consistent with their nutritional status when possible. The patient's family may participate in providing food, consistent with cultural, religious, and other traditions and practices and compatible with the patient's diagnosis when appropriate. When the patient's family or others provide food to the patient, they are educated about foods that are contraindicated to the patient's care needs and plans, including information about any medications associated with food interactions. Food provided by family or others is stored under proper conditions, following current food storage guidelines, to prevent contamination.

Patients are screened to identify those who may be at nutritional risk during the initial assessment. *These patients are referred to a nutritionist for further assessment. A plan for nutrition therapy is developed and carried out for patients at nutritional risk*. Nutrition therapy includes

1. Enteral feedings
2. Total parenteral nutrition
3. Fortification of breast milk
4. Other nutritional supplements

The patient's progress is monitored and recorded in their medical health. Physicians, nurses, the dietetics service, and, when appropriate, the patient's family, collaborate to plan and to provide nutrition therapy.

### Measurable Elements of COP.8

- ❑ 1. A variety of food choices or nutrition, consistent with the patient's condition, care, and needs, is regularly available.
- ❑ 2. There is an order for food in the patient's health record based on the patient's nutritional status and needs prior to inpatients being fed.
- ❑ 3. The distribution of food is timely, and special requests are met.
- ❑ 4. When families provide food, they are educated about the patients' diet limitations.
- ❑ 5. Food and nutrition products, including those provided by family, are stored under proper conditions, following current food storage guidelines, to prevent contamination.
- ❑ 6. Patients determined to be at nutrition risk receive nutrition therapy.
- ❑ 7. A collaborative process is used to plan, deliver, and monitor nutrition therapy.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

- ❑ 8. The patient's response to nutrition therapy is monitored and documented in the health record.

---

## *Pain Management*

---

# Standard COP.9

Pain is managed effectively.

### Intent of COP.9

Unrelieved pain has adverse physical and psychological effects. Patients in pain have the right to appropriate assessment and management of pain.

### Guidance for COP.9

Pain may be part of the patient experience and may be associated with the patient's condition or illness. Pain may also be an expected part of certain treatments, procedures, or examinations. Patients are informed about the likelihood of pain when it is an anticipated effect from treatments, procedures, or examinations and what options for pain management are available.

Based on the scope of services provided, the hospital has processes to manage pain appropriately, including

- identifying patients with pain during initial assessment and reassessments;
- providing information to patients about pain that may be an expected result of treatments, procedures, or examinations;
- providing management of pain, regardless of the origin of pain, according to guidelines or protocols and in alignment with patient goals for pain management;
- communicating with and educating patients and families about pain and symptom management in the context of their personal, cultural, and religious beliefs; and
- educating clinical staff about pain assessment and management.

### Measurable Elements of COP.9

- ❑ 1. Patients are informed about the likelihood of pain and options for pain management when pain is an expected result of planned treatments, procedures, or examinations.
- ❑ 2. Patients in pain receive care according to pain management guidelines and in alignment with patient goals for pain management.
- ❑ 3. The hospital has processes to communicate with and to educate patients and families about pain.
- ❑ 4. The hospital provides education to clinical staff about pain assessment and management.

---

## *End-of-Life Care*

---

# Standard COP.10

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

The hospital has a process to provide end-of-life care that addresses the needs of the patient and family and optimizes the patient's comfort and dignity.

## Intent of COP.10

End-of-life or dying patients have unique needs; the hospital implements processes to address these needs and to incorporate the patient's and family's preferences into the care processes.

## Guidance for COP.10

End-of-life care may be influenced by cultural and religious traditions. Concern for the patient's comfort and dignity guides all aspects of care during the final stages of life. All staff members are made aware of patients' needs at the end of life. These needs include

1. treatment of primary and secondary symptoms;
2. pain and discomfort management;
3. response to the patient's and family's psychological, social, emotional, religious, and cultural concerns;
4. and involvement in care decisions.

The patient assessment may identify symptoms that require management, such as nausea, respiratory distress, and pain; factors that alleviate or exacerbate physical symptoms; and the patient's response to symptom management. Identifying the patient's physical needs is just one aspect of determining the patient's end of life care. Patients and families may also have a need for spiritual, psychosocial, and support services, as appropriate to the patient's individual needs and cultural preferences.

End-of-life care provided by the hospital includes

- taking interventions to manage pain and discomfort;
- providing appropriate treatment for any symptoms according to the wishes of the patient and family;
- sensitively addressing such issues as autopsy and organ donation;
- respecting the patient's values, religion, and cultural preferences;
- involving the patient and family in all aspects of care; and
- responding to the psychological, emotional, spiritual, and cultural concerns of the patient and family.

To accomplish these goals, all staff are educated and trained to assess and manage the needs of patients and their families at the end of life.

The hospital's goal for providing care at the end of life considers the settings in which care or service is provided (such as a hospice or palliative care unit), the type of services provided, and the patient population served. The hospital develops processes to manage end-of-life care. These processes include

1. assessment and management of symptoms;
2. defining the frequency of assessments
3. treating terminally ill patients with dignity and respect;
4. planning preventive and therapeutic approaches to manage symptoms; and
5. educating patients, family, and staff about managing symptoms
6. providing support to the patient's family and/or caregivers
7. providing support to staff members caring for the terminal patient

## Measurable Elements of COP.10

❑ 1. The hospital has a process to assess and manage the needs of patients receiving end-of-life care.

❑ 2. Staff are educated and trained about assessing and managing needs of patients and their families at the end of life.

❑ 3. The hospital provides patient care and support services that accommodate the patient and their family with consideration of their personal, spiritual/religious, and cultural preferences.

❑ 4. End-of-life care addresses the symptoms, conditions, and health care needs of the dying patient as indicated by their assessment, including pain and comfort needs.

❑ 5. The patient and family are involved in end-of-life care decisions.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

❑ 6. The hospital provides support to the patient's family, caregivers, and staff members caring for the terminal patient.

---

## *Hospitals Providing Transplant Services*

---

Note: The following standards are intended to be used in situations in which organ or tissue transplantation will not occur but during those times when patients request information about organ and tissue donation and/or when organ or tissue donation may occur. When organ or tissue donation and transplantation are performed, the standards for organ and tissue transplant programs apply.

The following are considered *tissue* and *cell products* for below standards:
Examples of Tissue and Cell Products
- Amnion/Amniotic Membrane
- Arteries
- Autologous Cells
- Autologous Tissue
- Bone
- Bone Marrow
- Bone Paste
- Bone Powder
- Bone Putty
- Cancellous Chips
- Cardiac (Heart) Valves (Aortic, Pulmonary)
- Cartilage
- Chondrocytes
- Cornea
- Demineralized Bone Matrix
- Dendritic Cells
- Dermal Matrix
- Dermis
- Dura Mater
- Embryo
- Fascia/Fascia Lata
- Hematopoietic Stem Cells
- Leukocytes
- Ligaments
- Limbal Graft
- Limbal Stem Cells
- Lymphocytes
- Marrow
- Membrane
- Meniscus
- Nerves
- Non-valved Conduits
- Oocyte/Ovarian Cells
- Ovarian Tissue
- Pancreatic Islet Cells
- Parathyroid
- Pericardium
- Peripheral Blood Stem Cells
- Progenitor Cells
- Sclera
- Semen, Sperm
- Skin
- Somatic Cells

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

- Tendons
- Testicular Tissue
- Therapeutic Cells (T-Cell Pheresis)/T-Cells
- Tissue (also Synthetic Tissue)
- Trachea
- Umbilical Cord Blood Stem Cells
- Vascular Graft
- Veins (Saphenous, Femoral, Iliac)
- Other cellular- and tissue-based transplant or implant products whether classified by the FDA as a tissue or a medical device
- Other tissues that are classified as tissues by state law and regulation

Transplantation of organs is often a lifesaving procedure, and organ and tissue transplants are sometimes the only options for treatment of a wide range of diseases. Recent advances in transplantation have led to a greater success rate for transplanted organs and tissues. However, transplantation is not free from risk. Transmission of infections from the donor to the recipient is a well-documented safety concern. Diseases with documented transmission from infected donors subsequent to transplant include, to name a few, HIV, hepatitis B and C, and Creutzfeldt-Jakob disease (CJD). Recipients may also contract bacterial or fungal infections through contamination during transportation, storage, or handling.

Leadership's commitment to creating a culture conducive to organ and tissue donation can have significant impact on the overall success of the hospital's organ and tissue procurement efforts. These standards address the hospital's responsibilities for organ and tissue donation and procurement. This includes any individual who has been determined medically suitable for donation by the organ-procurement organization. If the hospital has the necessary resources to support the recovery of organs and tissues after cardiac death, non–heart-beating donors are included in the organ procurement effort.

# Standard COP.11

The hospital informs patients and families about how to donate organs and other tissues.

## Intent of COP.11

Patients and families receive information about the donation process and the way organ procurement is organized for the community, region, or nation (such as a national or regional organ procurement agency or network) to ensure organ donor and recipient safety.

## Guidance for COP.11

Many countries have developed procedures and systems to increase the supply of organs available for transplant. In some countries, laws determine that everyone is a donor unless specified otherwise. This is considered presumed consent. Other countries require explicit consent for organ donation.

The hospital is responsible for defining the process of obtaining and recording consent for cell, tissue, and organ donation in accordance with international ethical standards and the way organ procurement is organized in the hospital's country. The hospital has a responsibility to ensure that adequate controls are in place to prevent patients from feeling pressured to donate.
The hospital supports the choice of patients and families to donate organs and other tissues for research or transplantation.
Information is provided to patients and families on the donation process and the way organ procurement is organized for the community, region, or nation.

## Measurable Elements of COP.11

❑ 1. The hospital supports patient and family choices to donate organs and other tissues.
❑ 2. The hospital provides information to patients and families on the donation process.
❑ 3. The hospital provides information to the patient and family on the manner in which organ procurement is organized.
❑ 4. The hospital ensures that adequate controls are in place to prevent patients from feeling pressured to donate.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

# Standard COP.11.1

The hospital provides oversight for the process of organ and tissue procurement.

## Intent of COP.11.1

Oversight for the process of organ and tissue procurement is needed to ensure it is consistent with laws and regulations, respects the community's religious and cultural values, and is ethical.

## Guidance for COP.11.1

One of the primary goals for oversight of the process for organ and tissue procurement is establishing requirements for consent. Hospital staff are trained on the donation process and support patient and family choices about the donation of organs and tissues. Staff are also trained in contemporary concerns and issues related to organ donation and availability of transplants. The hospital cooperates with other hospitals and agencies in the community responsible for all or a portion of the procurement, banking, transportation, or transplantation process.

## Measurable Elements of COP.11.1

- ❑ 1. The hospital develops organ- and tissue- donation processes and consistency with the region's laws and regulations and its religious and cultural values.
- ❑ 2. The hospital identifies consent requirements for organ and tissue donation and develops a consent process consistent with those requirements.
- ❑ 3. Staff are trained on the issues and concerns related to organ donation and the availability of transplants.
- ❑ 4. The hospital cooperates with relevant hospitals and agencies in the community to respect and to implement choices to donate.

---

# Standard COP.11.2

The hospital's leadership provides resources to support the organ, tissue, and/or cell transplant program.

## Intent of COP.11.2

The transplant program requires staff with specialized education, training, and resources in order to provide safe, high-quality care.

## Guidance for COP.11.2

Staff education and training must be specific to the responsibilities and requirements of transplants provided by the hospital. Other essential resources include supplies, patient rooms with ventilation required for the type of transplant procedure (**for example**, positive pressure ventilation), required pharmaceuticals for the type of transplant procedure, laboratory testing to ensure that tissues, organs, and cells are not contaminated, and other resources as identified by the program service leader. Resources related to information management systems are necessary to assist with the collection of data associated with risks, outcomes, and other information that support the quality of the transplant program.

## Measurable Elements of COP.11.2

- ❑ 1. Staff education and training are specific to the types of organ, tissue, and/or cell transplants provided by the hospital.
- ❑ 2. The hospital's leadership allocates resources for the transplant program.
- ❑ 3. Information management systems are used to support the quality of the transplant program.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

# Standard COP.11.3

The hospital identifies a qualified transplant program leader(s) and includes an interdisciplinary team that consists of clinical staff with expertise in the relevant transplant programs.

## Intent of COP.11.3

Oversight by a qualified individual(s) and the inclusion of a interdisciplinary care team ensures the quality and safety of transplant services and improves the success of the transplant and associated patient outcomes.

## Guidance for COP.11.3

A qualified individual(s) is responsible for supporting and overseeing all transplant program activities. This individual(s) has support and oversight defined in a job description. This individual(s) is qualified to manage transplant services through education, training, experience, licensure, and/or certification. The required qualifications depend on the activities carried out.

Transplant recipients and a living donors have specific nursing, psychological, pharmacological, and nutritional needs. As related to the type of transplant, a interdisciplinary team consists of individuals from

- medicine;
- nursing;
- nutrition;
- pharmacology;
- infection prevention and control;
- social services;
  1. fertility services
- psychological services; and
- rehabilitative services.

This team should have the qualifications, training, and experience to provide care and services to transplant recipients and living donors.

Hospitals with transplant programs consider the types of organs and/or tissues harvested and/or transplanted when creating its interdisciplinary transplant teams. These teams are formed with consideration for the specific risks, challenges, needs, laws and regulations, and professional guidelines for each type of transplant.

## Measurable Elements of COP.11.3

- ❑ 1. The transplant program has an infrastructure capable of supporting all aspects of the transplant program.
- ❑ 2. A qualified individual(s) oversees and manages the transplant program.
- ❑ 3. The individual(s) fulfills the program's oversight responsibilities as defined by the transplant program.
- ❑ 4. The transplant program documents the composition of each transplant team(s).
- ❑ 5. The transplant program documents the team members' responsibilities.
- ❑ 6. Based on the services provided by the transplant team, the team includes individuals experienced in medicine, nursing, nutrition, pharmacology, infection prevention and control, social services, psychological services, rehabilitative services, and transplant coordination.
- ❑ 7. The transplant program evaluates team members for qualifications, training, and experience at the time each individual is being considered for the transplant team.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

## Standard COP.11.4

There is a designated coordination mechanism for all transplant activities.

### Intent of COP.11.4

An important component in ensuring safe, high-quality care through all phases of the donor/recipient process is ensuring the coordination and continuity of the live donor's and recipient's care.

### Guidance for COP.11.4

Transplant services carry unique and critical risks to organ, tissue, and cell recipients and, in the cases of living donors, to the donor. The complex care required by the donor and recipient necessitate a coordination mechanism, typically a qualified clinical staff member. This individual ensures continuity of care for the donor and/or the recipient throughout the transplant process. This individual is also responsible for communication with the care team about the donor's and/or recipient's care. This may occur through facilitated meetings and documentation.

The individual responsible for the coordination of all transplant activities may be a physician, registered nurse, or other qualified clinical staff member – this individual may be known as a "transplant coordinator."

### Measurable Elements of COP.11.4

- ❑ 1. The individual responsible for the coordination of the live donor's and transplant recipient's care is identified and available through all phases of transplant care.
- ❑ 2. The hospital ensures continuity of care for transplant patients (candidates and recipients) is facilitated through the pre-transplant, transplant, and discharge phases of transplantation.
- ❑ 3. Continuity of care is facilitated for living donors during the evaluation, donation, and discharge phases of donation.
- ❑ 4. The coordination of all transplant activities is communicated to all staff involved in the transplant program activities.

## Standard COP.11.5

The hospital complies with organ, tissue, and cell transplant responsibilities.

### Intent of COP.11.5

Organs, tissues, and cells are a limited resource. The hospital ensures that organs, tissues, and cells are managed in a way that protects these resources and ensures their integrity.

### Guidance for COP.11.5

Organ, tissue, and cell donation, procurement, and transplantation are highly regulated. The hospital complies with all rules and regulations set by the local, regional, or national procurement and transplantation network(s). These networks often require various data regarding transplant services to monitor the quality of these services and to allocate organs, tissues, and cells only to hospitals with successful, compliant programs.

The hospital implements procedures for the handling of all organs, tissues, and cells to ensure their safe handling and to ensure that patients receive the correct organ, tissue, or cells in a condition that increases the likelihood of a successful transplantation.

Organs, tissues, and cells have specific requirements for their transportation and storage until transplantation. The hospital fully implements these conditions to maintain the viability of the organ, tissue, and cells. Additionally, the hospital has a process to track transplanted organs, tissues, and cells for data collection purposes, including outcomes of the transplant and ability to recall any transplants.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

### Measurable Elements of COP.11.5

- ❑ 1. The hospital performing solid organ, tissue, and/or cell transplants complies with all rules set by the local, regional, or national procurement and transplantation network.
- ❑ 2. The hospital performing solid organ transplants shares all data related to transplant processes required by the local, regional, or national procurement and transplantation network.
- ❑ 3. The hospital develops and maintains standardized written procedures for the acquisition, receipt, storage, and issuance of organs, tissues, and/or cells.
- ❑ 4. The hospital verifies at the time of receipt of the organ that package integrity is met and transport temperature range was controlled and acceptable for the organ(s), tissues, and/or cells. This verification is documented.
- ❑ 5. The hospital follows the tissue suppliers' or manufacturers' written directions for transporting, handling, storing, and using tissue.
- ❑ 6. The hospital has implemented a process to track transplanted tissues.
- ❑ 7. Refrigerators, freezers, nitrogen tanks, and other storage equipment used to store organs, tissues, and cells at a controlled temperature have functional alarms and an emergency backup plan.

---

## Standard COP.11.6

The transplant program obtains informed consent specific to organ, tissue, and/or cell transplant from the transplant recipient candidate.

### Intent of COP.11.6

Organ, tissue, and cell transplant carries unique risks; to make an informed decision about whether to proceed with a transplant, the potential recipient must be informed of these risks and challenges.

### Guidance for COP.11.6

To consent, a patient must be informed of those factors related to the planned care required for an informed decision. Patients are informed about factors that could affect the success of the graft or the candidate's health as a recipient

In addition, there may be psychological, ethical, financial, and other factors that are unique to the transplant patient than for other patients, such as the need for immunosuppressive medications and the projected survival rate. *The patient needs to be informed of all special considerations as part of the consent process.* The transplant program also follows the hospital's policy for informed consent as well as local and regional laws and regulations.

### Measurable Elements of COP.11.6

- ❑ 1. The transplant program follows the hospital's policy when obtaining informed consent from solid organ, tissue, and/or cell transplant candidates.
- ❑ 2. The transplant program informs the prospective transplant candidate of organ donor risk factors that could affect the success of the graft or the candidate's health as a recipient, including, but not limited to
  - a) the donor's history, as appropriate to the laws and regulations of the country/region;
  - b) condition of the organ(s) used;
  - c) age of the organ(s); and
  - d) the potential risk of contracting infectious disease(s) if disease(s) cannot be detected in an infected donor
  - e) the potential psychosocial risks
- ❑ 3. The transplant program informs the prospective transplant candidate of the transplant center's observed and expected one-year survival rate following solid-organ transplant; or when the transplant program has been in operation less than 18 months, the one-year survival rate as documented in the literature.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

- ❑ 4. The transplant program informs the prospective solid organ, tissue, and cell transplant candidate about potential rejection rates, immunosuppressive drugs, and possible associated costs, as applicable to the type of transplant.
- ❑ 5. The transplant program informs the prospective organ, tissue, and/or cell transplant candidate of alternative treatments.

---

# Standard COP.11.7

The transplant program has documented protocols, clinical practice guidelines, or procedures for organ recovery and organ receipt to ensure the compatibility, safety, efficacy, and quality of human cells, tissues, and organs for transplantation.

## Intent of COP.11.7

To reduce the risk of organ, tissue, or cell rejection, the transplant surgeon must ensure the compatibility of the donor organ(s), tissue, and/or cells to the recipient.

## Guidance for COP.11.7

Transmission of infectious diseases and malignancies is a potential risk for recipients of donor cells, tissues, and organs. Therefore, the level of safety, efficacy, and quality of human cells, tissues, and organs for transplantation must be ensured. Evaluation of organ and tissue donors may identify those donors who have a higher risk for infection with a potentially harmful pathogen. Donor screening of clinical history and donor testing for communicable diseases can significantly reduce the incidence of donor transmission of disease. Donor screening should include evaluation of medical history, behavioral risk factors, and a physical examination. Donor testing should include tests for HIV, hepatitis B, hepatitis C, and other recommended tests.

The most frequently used tests for compatibility include blood typing and crossmatching and tissue typing. The transplant surgeon ensures that testing for compatibility occurs before organ recovery and organ transplantation takes place.

For any transplantation of human material, traceability should be ensured for the anticipated lifetime of the donor and the recipient. Internationally agreed-on means of coding to identify tissues and cells used in transplantation are essential for full traceability.

## Measurable Elements of COP.11.7

- ❑ 1. The transplant team follows written organ recovery protocols, clinical practice guidelines, or procedures, which include reviewing the essential donor data and recipient data to ensure compatibility before organ, tissue, or cell recovery takes place.
- ❑ 2. The transplant surgeon is responsible for confirming, in writing, the medical suitability of donor organs, tissues, and cells for transplantation into the recipient.
- ❑ 3. When an organ or tissue arrives at the transplant center, the transplanting surgeon and at least one other health care practitioner at the transplant center verify and document that the donor's blood type and other essential data are compatible with the recipient prior to transplantation.
- ❑ 4. The transplant surgeon is responsible for confirming that donor evaluation and donor testing for infectious diseases and malignancy have been completed, and are documented in the medical record, before organ, tissue, or cell recovery and transplant occur.
- ❑ 5. When an organ arrives at the transplant center, the transplanting surgeon and at least one other health care practitioner at the transplant center verify and document that evaluation and testing of the donor organ shows no evidence of disease and the condition of the organ is suitable for transplant.

---

# Standard COP.11.8

Clinical practice guidelines and clinical criteria guide the selection and care of organ, tissue, and cell transplant patients.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

### Intent of COP.11.8

Individualized care plans are developed and guide the care of transplant patients in conjunction with clinical practice guidelines, as the care of the patient donating or receiving a cell, organ, or tissue transplant is based on the type of transplant and individual needs.

### Guidance for COP.11.8

The patient's health history has an impact on his or her recovery. In addition, the patient's psychological status may have an impact on the success of the transplant. A psychological evaluation will be conducted by a psychiatrist, psychologist, social worker, or other qualified health care professional with experience in transplantation to determine the decision-making capacity of the patient and screen for any preexisting psychiatric illness.

### Measurable Elements of COP.11.8

- ❑ 1. The transplant program has documented cell-, tissue-, and/or organ-specific clinical practice guidelines for the pre-transplant, transplant, and discharge phases of transplantation.
- ❑ 2. Each transplant patient is under the care of a multidisciplinary patient care team coordinated by the patient's primary transplant physician throughout the pre-transplant, transplant, and discharge phases of transplantation.
- ❑ 3. Transplant recipient candidates are evaluated for the suitability of other medical and surgical therapies that may yield short- and long-term survival rates comparable to transplantation.
- ❑ 4. Transplant recipient candidates receive a psychological evaluation by a psychiatrist, psychologist, social worker, or other qualified health care professional with experience in transplantation to determine the decision-making capacity of the patient and screen for any preexisting psychiatric illness.
- ❑ 5. The transplant program updates clinical information in the transplant donor's and/or recipient's health record on an ongoing basis.
- ❑ 6. The transplant program documents organ compatibility confirmation in the living donor's medical record.

---

## *Transplant Programs Using Living Donor Organs*

---

## Standard COP.12

Transplant programs that perform living donor transplantation adhere to local and regional laws and regulations and protect the rights of prospective or actual living donors.

### Intent of COP.12

Living donors face difficult decisions and are at potential risk for lifelong complications and should not feel coerced or pressured into organ donation.

### Guidance for COP.12

The growing demand for and limited supply of organs from deceased donors have resulted in increased efforts to promote live organ donation. Living donor standards for the selection of suitable candidates for donation, informed consent, and care following the donation do not universally exist.

To help with decisions and to ensure that the living donor's rights are protected, an individual with knowledge of living organ donation, transplantation, medical ethics, and informed consent is identified and appointed to protect the patient's rights. This person is independent of the transplant team and if employed by the hospital does not report to any member of the transplant team. The goal of this person is to ensure that the living donor understands all aspects of the donation process and is autonomous in his or her decision-making abilities.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

### Measurable Elements of COP.12

- ❑ 1. Transplant programs that perform living donor transplantation adhere to local and regional laws and regulations.
- ❑ 2. The living organ donor has the right to make a decision about donation in a setting free of coercion and pressure.
- ❑ 3. An individual with knowledge of living organ donation, transplantation, medical ethics, and informed consent is identified and appointed as an advocate for the living donor.
- ❑ 4. The individual appointed as the living donor advocate is not involved in routine transplantation activities.
- ❑ 5. The individual appointed as the living donor advocate informs, supports, and respects the living donor in a culturally appropriate manner during decision making.

---

## Standard COP.12.1

Transplant programs performing living donor transplants obtain informed consent specific to organ donation from the prospective living donor.

### Intent of COP.12.1

The prospective donor needs to thoroughly understand all aspects of the donation process, particularly to understand the risks and benefits associated with being a living donor.

### Guidance for COP.12.1

Many living donors give their organ to a family member or acquaintance; however, some living donors do not influence the placement of their donated organ. A very important aspect of obtaining informed consent is to ensure that the prospective donor is willing to donate and has not been coerced or promised compensation, and understands that he or she may decline to donate at any time. The consent process includes the information provided to any patient undergoing anesthesia, sedation, or surgery, as well as information specific to transplant.

### Measurable Elements of COP.12.1

- ❑ 1. Informed consent for living donation is obtained by trained staff and is in a language the prospective living donor can understand.
- ❑ 2. The transplant program informs the prospective living donor of potential psychological risks of donation.
- ❑ 3. The transplant program informs the prospective living donor of potential complications and risks associated with living organ donation.
- ❑ 4. The transplant program informs the prospective living donor of potential future health problems.
- ❑ 5. The transplant program informs the prospective living donor of alternative treatments for the transplant candidate.
- ❑ 6. The transplant program informs the prospective living donor of the donor's right to opt out of donation at any time during the donation process.

---

## Standard COP.12.2

Transplant programs that perform living donor transplants use clinical and psychological selection criteria to determine the suitability of potential living donors.

### Intent of COP.12.2

Organ donors must be evaluated for suitability, both physical and psychological, as an organ donor.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

## Guidance for COP.12.2

The medical evaluation determines the donor's physical ability to donate and identifies any immediate health risks and possible future health risks. The psychological evaluation will be conducted by a psychiatrist, psychologist, or social worker with experience in transplantation to determine decision-making capacity, screen for any preexisting psychiatric illness, and evaluate any potential coercion. The donor must also be evaluated for his or her ability to comprehend the donation process and the potential outcomes, including possible adverse outcomes.

## Measurable Elements of COP.12.2

- ❑ 1. The transplant program documents defined organ-specific living donor selection criteria.
- ❑ 2. The transplant program's living donor selection criteria are consistent with laws and regulations and the principles of medical ethics.
- ❑ 3. The results of a medical evaluation related to the living donor's own physical health are included in the determination of suitability for donation.
- ❑ 4. The results of medical tests identifying infectious diseases or malignancies are included in the determination of suitability for donation.
- ❑ 5. The results of a psychological evaluation conducted by a psychiatrist, psychologist, or social worker with experience in transplantation are included in the determination of suitability for donation.
- ❑ 6. The transplant program documents organ compatibility confirmation in the living donor's medical record.

---

# Standard COP.12.3

Individualized patient care plans guide the care of living donors.

## Intent of COP.12.3

The living donor has unique treatment and health care needs that require specific consideration. Individualized care plans are developed and implemented for all living donors.

## Guidance for COP.12.3

Live donor transplants are guided by living donor guidelines. However, donors have individual needs that must be addressed through careful care planning. The care of the donor is coordinated by a physician and carried out by a multidisciplinary team to ensure that the donor's needs are met prior to, during, and following donation.

## Measurable Elements of COP.12.3

- ❑ 1. Transplant programs performing living donor transplants are guided by documented living donor guidelines for care in the evaluation, donation, and discharge phases of donation.
- ❑ 2. Transplant programs performing living donor transplants provide multidisciplinary care by a team coordinated by a physician to each donor throughout the donor evaluation, donation, and discharge phases of donation.
- ❑ 3. The living donor candidate receives ongoing psychological support following donation.

## References

### Care Delivery for All Patients

Adibi S, et al. Medical and dental electronic health record reporting discrepancies in integrated patient care. *JDR Clin Trans Res*. Epub 2019 Sep 27. https://doi.org/10.1177/2380084419879387.

Agency for Healthcare Research and Quality. Care Coordination. Jun 2014. (Updated: Aug 2018.) Accessed Jan 3, 2020. http://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/index.html.

Doctor K, et al. Practice pattern variation in test ordering for low-acuity pediatric emergency department patients. *Pediatr Emerg Care*. Epub 2018 Oct 17.

CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY
DO NOT COPY – DO NOT DISTRIBUTE

Doherty RF, Knab M, Cahn PS. Getting on the same page: An interprofessional common reading program as foundation for patient-centered care. *J Interprof Care*. 2018 Jul;32(4):444–451.

Duddy C, Wong G. Explaining variations in test ordering in primary care: Protocol for a realist review. *BMJ Open*. 2018 Sep 12;8(9):e023117.

ECRI Institute. *2019 Top 10 Health Technology Hazards: Executive Brief*. 2018. Accessed Jan 3, 2020. https://www.ecri.org/Resources/Whitepapers_and_reports/Haz_19.pdf.

The Joint Commission. Update: Texting orders. *Jt Comm Perspect*. 2016 May;36(5):15.

Mercer T, et al. The highest utilizers of care: Individualized care plans to coordinate care, improve healthcare service utilization, and reduce costs at an academic tertiary care center. *J Hosp Med*. 2015 Jul;10(7):419–424. https://doi.org/10.1002/jhm.2351.

Providence St. Joseph Health Digital Commons. Individualized Fall Prevention Care Plan to Decrease Fall Rates in an Adult Inpatient Psychiatric Unit. Accardi SR, Chamberlain C. Nursing Boot Camp Posters. Jun 20, 2019. Accessed Jan 3, 2020. https://digitalcommons.psjhealth.org/cgi/viewcontent.cgi?article=1012&context=stvincent-bootcamp.

Sidani S, et al. Exploring differences in patient-centered practices among healthcare professionals in acute care settings. *Health Commun*. 2018 Jun;33(6):716–723.

Turnbull AE, Sahetya SK, Needham DM. Aligning critical care interventions with patient goals: A modified Delphi study. *Heart Lung*. 2016 Nov–Dec;45(6):517–524.

World Health Organization. *Integrated Care for Older People: Realigning Primary Health Care to Respond to Population Ageing*. 2018. Accessed Jan 3, 2020. https://apps.who.int/iris/bitstream/handle/10665/326295/WHO-HIS-SDS-2018.44-eng.pdf.

## Care of High-Risk Patients and Provision of High-Risk Services

Agency for Healthcare Research and Quality. *A Toolkit to Engage High-Risk Patients in Safe Transitions Across Ambulatory Settings*. Davis K, et al. AHRQ Publication No. 18-0005-1-EF. Dec 2017. Accessed Jan 3, 2020. https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/hais/tools/ambulatory-surgery/safetransitions/safetrans_toolkit.pdf.

Chandrashekar P, Jain SH. Improving high-risk patient care through chronic disease prevention and management. *J Law Med Ethics*. 2018 Sep;46(3):773–775.

Ganguli I, et al. What do high-risk patients value? Perspectives on a care management program. *J Gen Intern* Med. 2018 Jan;33(1):26–33.

Hong CS, Siegel AL, Ferris TG. Caring for high-need, high-cost patients: What makes for a successful care management program? *Issue Brief (Commonw Fund)*. 2014 Aug;19:1–19.

Ingram B. Ambulatory care for haematology and oncology patients. *Br J Nurs*. 2017 Feb 23;26(4):S12–S14.

McDonald KM, et al. Implementation science for ambulatory care safety: A novel method to develop context-sensitive interventions to reduce quality gaps in monitoring high-risk patients. *Implement Sci*. 2017 Jun 24;12(1):79.

Meybohm P, et al. Patient blood management bundles to facilitate implementation. *Transfus Med Rev*. 2017 Jan;31(1):62–71.

Watanabe Y, et al. Japanese Society for Dialysis Therapy clinical guideline for "hemodialysis initiation for maintenance hemodialysis." *Ther Apher Dial*. 2015 Mar;19 Suppl 1:93–107.

World Bank Group. *Enhanced Care Management: Improving Health for High Need, High Risk Patients in Estonia: Evaluation Report of the 2017 Enhanced Care Management Pilot in Estonia*. Draft version. Oct 25, 2017. Accessed Jan 3, 2020. https://www.haigekassa.ee/sites/default/files/enhanced-care-management.pdf.

World Health Organization. WHO Definition of Palliative Care. Accessed Jan 3, 2020. http://www.who.int/cancer/palliative/definition/en/.

## Clinical Alarm System Management

AAMI Foundation. *Clinical Alarm Management Compendium*. 2015. Accessed Jan 3, 2020. http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/Foundation/Reports/Alarm_Compendium_2015.pdf.

Assis AP, et al. Individualized parameterization of multiparametric monitors alarms in infarcted patients. *Rev Bras Enferm*. 2019 Jun 27;72(3):609–616.

Cameron HL, Little B. Nurses' perceptions and practices related to alarm management: A quality improvement initiative. *J Contin Educ Nurs*. 2018 May 1;49(5):207–215. https://doi.org/10.3928/00220124-20180417-05.

Casey S, Avalos G, Dowling M. Critical care nurses' knowledge of alarm fatigue and practices towards alarms: A multicentre study. *Intensive Crit Care Nurs*. 2018 Oct;48:36–41. https://doi.org/10.1016/j.iccn.2018.05.004.

Edworthy JR, et al. Getting better hospital alarm sounds into a global standard. *Ergon Des*. 2018;26(4):4–13. https://doi.org/10.1177/1064804618763268.

Jeong YJ, Kim H. Evaluation of clinical alarms and alarm management in intensive care units. *Journal of Korean Biological Nursing Science*. 2018 Dec;20(4):228–235. https://doi.org/10.7586/jkbns.2018.20.4.228.

Johnson KR, Hagadorn JI, Sink DW. Reducing alarm fatigue in two neonatal intensive care units through a quality improvement collaboration. *Am J Perinatol*. 2018 Nov;35(13):1311–1318.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

Mirhafez SR, et al. Perceptions and practices related to clinical alarms. *Nurs Forum*. 2019 Jul;54(3):369–375. https://doi.org/10.1111/nuf.12338.

Short K, Chung YJ Jr. Solving alarm fatigue with smartphone technology. *Nursing*. 2019 Jan;49(1):52–57.

Simpson KR, Lyndon A. False alarms and overmonitoring: Major factors in alarm fatigue among labor nurses. *J Nurs Care Qual*. 2019 Jan–Mar;34(1):66–72.

Winters BD, et al. Technological distractions (part 2): A summary of approaches to manage clinical alarms with intent to reduce alarm fatigue. *Crit Care Med*. 2019 Jan;46(1):130–137.

## Recognition of Changes to Patient Condition

Massey D, Chaboyer W, Anderson V. What factors influence ward nurses' recognition of and response to patient deterioration? An integrative review of the literature. *Nurs Open*. 2016 Apr 26;4(1):6–23.

Miller PJ. Case study: Continuous monitoring of patient vital signs to reduce 'failure-to-rescue' events. *Biomed Instrum Technol*. 2017 Jan–Feb;51(1):41–45. https://doi.org/10.2345/0899-8205-51.1.41.

Petersen JA, Rasmussen LS, Rydahl-Hansen S. Barriers and facilitating factors related to use of early warning score among acute care nurses: A qualitative study. *BMC Emerg Med*. 2017 Dec 1;17(1):36.

## Resuscitation Services

Hasselqvist-Ax I, et al. Early cardiopulmonary resuscitation in out-of-hospital cardiac arrest. *N Engl J Med*. 2015 Jun 11;372(24):2307–2315.

Kleinman ME, et al. 2017 American Heart Association focused update on adult basic life support and cardiopulmonary resuscitation quality: An update to the American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2018 Jan 2;137(1):e7–e13.

UpToDate. Advanced Cardiac Life Support (ACLS) in Adults. Pozner CN. (Updated: Sep 18, 2019.) Accessed Jan 3, 2020. https://www.uptodate.com/contents/advanced-cardiac-life-support-acls-in-adults.

## Administration of Blood and Blood Products

Hensley NB, et al. Wrong-patient blood transfusion error: Leveraging technology to overcome human error in intraoperative blood component administration. *Jt Comm J Qual Patient Saf*. 2019 Mar;45(3):190–198.

Robinson S, et al. The administration of blood components: A British Society for Haematology guideline. *Transfus Med*. 2018 Feb;28(1):3–21.

Rygård SL, Holst LB, Perner A. Blood product administration in the critical care and perioperative settings. *Crit Care Clin*. 2018 Apr;34(2):299–311.

## Management of Patients at Risk for Suicide and Self-Harm

Abdelraheem M, McAloon J, Shand F. Mediating and moderating variables in the prediction of self-harm in young people: A systematic review of prospective longitudinal studies. *J Affect Disord*. 2019 Mar 1;246:14–28.

Borschmann R, Kinner SA. Responding to the rising prevalence of self-harm. *Lancet Psychiatry*. 2019 Jul;6(7):548–549.

Hogan MF, Grumet JG. Suicide prevention: An emerging priority for healthcare. *Health Aff (Millwood)*. 2016 Jun 1;35(6):1084–1090. https://doi.org/10.1377/hlthaff.2015.1672.

Jansson L, Graneheim UH. Nurses' experiences of assessing suicide risk in specialised mental health outpatient care in rural areas. *Issues Ment Health Nurs*. 2018 Jul;39(7):554–560.

The Joint Commission. Suicide Prevention Portal. Accessed Jan 3, 2020. https://www.jointcommission.org/topics/suicide_prevention_portal.aspx.

Kene P, Yee ET, Gimmestad KD. Suicide assessment and treatment: Gaps between theory, research, and practice. *Death Stud*. 2019;43(3):164–172.

McClatchey K, et al. Suicide risk assessment in the emergency department: An investigation of current practice in Scotland. *Int J Clin Pract*. 2019 Apr;73(4):e13342.

Roaten K, et al. Development and implementation of a universal suicide risk screening program in a safety-net hospital system. *Jt Comm J Qual Patient Saf*. 2018 Jan;44(1):4–11.

Sequeira L, et al. Factors influencing suicide risk assessment clinical practice: Protocol for a scoping review. *BMJ Open*. 2019 Feb 18;9(2):e026566.

Velupillai S, et al Risk assessment tools and data-driven approaches for predicting and preventing suicidal behavior. *Front Psychiatry*. 2019 Feb 13;10:36.

Whitehead M, et al. An empirical approach to assessing training needs for emergency department management of intentional self-harm and related behaviors in the United States. *J Educ Eval Health Prof*. 2017 Dec 14;14:30.

## Management of Lasers

Cressey BD, Keyes A, Alam M. Laser safety: Regulations, standards and practice guidelines. In Nouri K, editor: *Lasers in Dermatology and Medicine: Dermatologic Applications*, 2nd ed. Cham, Switzerland: Springer International, 2018, 37–47.

Gupta P. Laser safety: Recommendations for lasers in healthcare. *Professional Safety*. 2018 Feb:63(2):59–60.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

He JX, et al. [Investigation of non-ionizing radiation hazards from physiotherapy equipment in 16 medical institutions]. *Zhonghua Lao Dong Wei Sheng Zhi Ye Bing Za Zhi*. 2013 Dec;31(12):900–901.

Ilce A, et al. The examination of problems experienced by nurses and doctors associated with exposure to surgical smoke and the necessary precautions. *J Clin Nurs*. 2017 Jun;26(11–12):1555–1561.

Okoshi K, et al. Health risks associated with exposure to surgical smoke for surgeons and operation room personnel. *Surg Today*. 2015 Aug;45(8):957–965.

Parker PJ, Parker SPA. Laser safety. In Coluzzi DJ, Parker SPA, editors: *Lasers in Dentistry—Current Concepts*. Cham, Switzerland: Springer International, 2017, 87–106.

Pinto I, et al. Blue light and ultraviolet radiation exposure from infant phototherapy equipment. *J Occup Environ Hyg*. 2015;12(9):603–610.

## Food and Nutrition Therapy

Craven DL, et al. Barriers and enablers to malnutrition screening of community-living older adults: A content analysis of survey data by Australian dietitians. *Aust J Prim Health*. 2017 May;23(2):196–201.

Gjerlaug AK, et al. Screening of nutritional risk among older persons. *Norwegian Journal of Clinical Nursing*. 2016;11(2):148–156.

Huysentruyt K, Vandenplas Y, De Schepper J. Screening and assessment tools for pediatric malnutrition. *Curr Opin Clin Nutr Metab Care*. 2016 Sep;19(5):336–340.

Rub G, et al. Validation of a nutritional screening tool for ambulatory use in pediatrics. *J Pediatr Gastroenterol Nutr*. 2016 May;62(5):771–775.

## Pain Management

Al-Harthy M, et al. The effect of culture on pain sensitivity. *J Oral Rehabil*. 2016 Feb;43(2):81–88.

Corradi-Dell'Acqua C, et al. Pain management decisions in emergency hospitals are predicted by brain activity during empathy and error monitoring. *Br J Anaesth*. 2019 Aug;123(2):e284–e292.

Jungquist CR, et al. Assessing and managing acute pain: A call to action. *Am J Nurs*. 2017 Mar;117(3 Suppl 1):S4–S11.

Matula ST, Polomano RC, Irving SY. The state of the science in paediatric pain management practices in low-middle income countries: An integrative review. *Int J Nurs Pract*. 2018 Dec;24(6):e12695.

Rochmawati E, Wiechula R, Cameron K. Centrality of spirituality/religion in the culture of palliative care service in Indonesia: An ethnographic study. *Nurs Health Sci*. 2018 Jun;20(2):231–237.

Siddiqui TM, et al. Prevalence of orofacial pain perception in dental teaching hospital—Karachi. *International Dental & Medical Journal of Advanced Research*. 2015;1:1–6.

Upadhyay C, et al. Measuring pain in patients undergoing hemodialysis: A review of pain assessment tools. *Clin Kidney J*. 2014 Aug;7(4):367–372.

Xiao H, et al. Pain prevalence and pain management in a Chinese hospital. *Med Sci Monit*. 2018 Nov 1;24:7809–7819.

## End-of-Life Care

Hall A, Rowland C, Grande G. How should end-of-life advance care planning discussions be implemented according to patients and informal carers? A qualitative review of reviews. *J Pain Symptom Manage*. 2019 Aug;58(2):311–335.

Long AC, et al. Agreement with consensus statements on end-of-life care: A description of variability at the level of the provider, hospital, and country. *Crit Care Med*. 2019 Oct;47(10):1396–1401.

Mayland C, et al. Quality assurance for care of the dying: Engaging with clinical services to facilitate a regional cross-sectional survey of bereaved relatives' views. *BMC Health Serv Res*. 2018 Oct 10;18(1):761.

Park SY, et al. End-of-life care in ICUs in East Asia: A comparison among China, Korea, and Japan. *Crit Care Med*. 2018 Jul;46(7):1114–1124.

Partain DK, et al. End-of-life care for seriously ill international patients at a global destination medical center. *Mayo Clin Proc*. 2018 Dec;93(12):1720–1727.

Toevs CC. Transitioning to comfort-focused care at the end of life. *Surg Clin North Am*. 2019 Oct;99(5):1019–1027.

## Organ and Tissue Donation Information

Greenwald MA, Kuehnert, MJ, Fishman JA. Infectious disease transmission during organ and tissue transplantation. *Emerg Infect Dis*. 2012 Aug;18(8):e1. https://doi.org/10.3201/eid1808.120277.

Gunderson S. Donation starts with a decision: The role of the individual and family in organ donation. *Transplantation*. 2019 May;103(5):864–865. https://doi.org/10.1097/TP.0000000000002623.

Istrate M, et al. Seeding life: Cooperation for innovation and exchange of good practices in education in organ donation and transplantation. *Transplantation*. 2018 Jul;102:S817. https://doi.org/10.1097/01.tp.0000543858.03116.5a.

Oczkowski SJ, et al. A mixed-methods study of organ donation in the intensive care unit: 22 actionable practices to improve organ donation. *Can J Anaesth*. 2019 Jun;66(6):686–695. https://doi.org/10.1007/s12630-019-01332-9.

Park UJ, et al. Effects of phased education on attitudes toward organ donation and willingness to donate after brain death in an Asian country. *Asian J Surg*. 2019 Jan;42(1):256–266.https://doi.org/10.1016/j.asjsur.2018.04.007.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

Poppe C, et al. Evaluation of the quality of the communication and emotional support during the donation procedure: The use of the Donor Family Questionnaire (DFQ). *J Crit Care*. 2019 Oct;53:198–206. https://doi.org/10.1016/j.jcrc.2019.06.011.
Sarti AJ, et al. A multicentre investigation of organ and tissue donation education for critical care residents. *Can J Anaesth*. 2018 Oct;65(10):1120–1138. https://doi.org/10.1007/s12630-018-1176-1.
Shaw DM. The side effects of deemed consent: Changing defaults in organ donation. *J Med Ethics*. 2019 Jul;45(7):435–439.
Tollefsen, C. Family consent and organ donation. *J Med Philos*. 2019 Oct;44(5):588–602. https://doi.org/10.1093/jmp/jhz021.
World Health Organization. Transplantation: Outcomes of Organ Transplantation. Accessed Jan 3, 2020. http://www.who.int/transplantation/gkt/statistics/kidney_outcomes/en/index.html.

## Hospitals Providing Organ and/or Tissue Transplant Services

Arredondo E, et al. Council of Europe Black Sea Area Project: International cooperation for the development of activities related to donation and transplantation of organs in the region. *Transplant Proc*. 2018 Mar;50(2):374–381.

Brett KE, et al. Quality metrics in solid organ transplantation: A systematic review. *Transplantation*. 2018 Jul;102(7):e308–e330.

Courtwright AM, et al. An ethical framework for the care of patients with prolonged hospitalization following lung transplantation. *HEC Forum*. 2019 Mar;31(1):49–62.

Eguchi S, et al. The donor advocacy team: A risk management program for living organ, tissue, and cell transplant donors. *Surg Today*. 2017 Aug;47(8):980–985.

Gunnar W. The VA Transplant Program: A rebuttal to criticism and a look to the future. *Am J Transplant*. 2019 May;19(5):1288–1295.

McCall M, Wright LS. The regulatory and legal environment of a contemporary kidney transplant program. In Ramirez CGB, McCauley J, editors: *Contemporary Kidney Transplantation*. Cham, Switzerland: Springer International, 2018. https://doi.org/10.1007/978-3-319-14779-6_23-1.

Pasquini MC, et al. Worldwide Network for Blood and Marrow Transplantation recommendations for establishing a hematopoietic cell transplantation program, part I: Minimum requirements and beyond. *Biol Blood Marrow Transplant*. 2019 Dec;25(12):2322–2329.

Schaenman JM, et al. Transplant center support for infectious diseases. *Transpl Infect Dis*. 2017 Oct;19(5).

Schaffhausen CR, et al. The importance of transplant program measures: Surveys of three national patient advocacy groups. *Clin Transplant*. 2018 Dec;32(12):e13426.

Srinivas R, et al. Association between patient satisfaction and outcomes in kidney transplant. *Am J Med Qual*. 2015 Mar–Apr;30(2):180–185.

Welch R, Rowe-Nichols, K. Development and use of a competency based orientation (CBO) to improve and standardize transplant coordinator training. *Biol Blood Marrow Transplant*. 2018 Mar;24(3 Suppl):S445.

Wey A, et al. A five-tier system for improving the categorization of transplant program performance. *Health Serv Res*. 2018 Jun;53(3):1979–1991.

Wickline M, et al. Long-term follow up (LTFU) for blood and marrow transplant (BMT) survivors: Building collaborative practice between a comprehensive cancer center and community oncology nurses. *Biol Blood Marrow Transplant*. 2018 Mar;24(3 Suppl):S472–S473.

## Transplant Programs Using Living Donor Organs

Budiani-Saberi D, Mostafa A. Care for commercial living donors: The experience of an NGO's outreach in Egypt. *Transpl Int*. 2011 Apr;24(4):317–323.

Gruessner RWG, Gruessner AC. Solid-organ transplants from living donors: Cumulative United States experience on 140,156 living donor transplants over 28 years. *Transplant Proc*. 2018 Dec;50(10):3025–3035.

Habbous S, et al. Healthcare costs for the evaluation, surgery, and follow-up care of living kidney donors. *Transplantation*. 2018 Aug;102(8):1367–1374.

Hunt HF, et al. Strategies for increasing knowledge, communication, and access to living donor transplantation: An evidence review to inform patient education. *Curr Transpl Rep*. 2018 Mar;5(1):27–44. https://doi.org/10.1007/s40472-018-0181-1.

Joint Commission Resources. Tracer methodology 101: Transplant safety tracer: Standardized procedures to acquire, receive, store, and issue tissue. *Joint Commission: The Source*. 2013 Apr;11(4):10–12.

Kook YWA, et al. Multicenter investigation of the reliability and validity of the live donor assessment tool as an enhancement to the psychosocial evaluation of living donors. *Am J Transplant*. 2019 Apr;19(4):1119–1128.

Laprise C, et al. Sex and gender considerations in transplant research: A scoping review. *Transplantation*. 2019 Sep;103(9):e239–e247.

Lau A, et al. Living donors: Caring for the trailblazers of progress in transplantation. *Transplantation*. 2018 Nov;102(11):e461.

Lee L. The ethics of organ donation in patients who lack the capacity for decision making. *Creat Nurs*. 2018 Aug;24(3):186–190.

Patel NP, et al. Quality improvement project: Workflow, standardization and data validation of comorbidity index at a small to medium volume transplant center. *Biol Blood Marrow Transplant*. 2017;23(3 Suppl):S416–S417.

Tulla KA, Jeon H. Living donor liver transplantation: Technical innovations. *Gastroenterol Clin North Am*. 2018 Jun;47(2):253–265.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**

US Food and Drug Administration. Blood & Blood Products. (Updated: Mar 28, 2019.) Accessed Jan 3, 2020. https://www.fda.gov/vaccines-blood-biologics/blood-blood-products.

World Health Organization. Transplantation: Outcomes of Organ Transplantation. Accessed Jan 3, 2020. http://www.who.int/transplantation/gkt/statistics/kidney_outcomes/en/index.html.

Yoon YI, Lee SG. Living donor liver transplantation for hepatocellular carcinoma: An Asian perspective. *Dig Dis Sci.* 2019 Aug;64(4):993–1000.

**CONFIDENTIAL PROPOSED REQUIREMENTS FOR FIELD REVIEW PURPOSE ONLY**
**DO NOT COPY – DO NOT DISTRIBUTE**