2021 ASEU
Section 6 – Clinical

Learning Objectives:

After reading this section the learner will be able to:

1. State the difference between palliative care and hospice care.
2. State when to notify One Legacy.
3. List common sources of medication errors and how they can be prevented.
4. Identify where to locate information about the organization's High Risk/High Alert drugs, Look Alike-Sound Alike drugs, and drugs with Black Box Warnings.
5. Discuss what resources are available to assist and advise the patient, the patient's family, significant others or healthcare team when ethical issues in patient care arise.
6. State the reporting procedure for faulty medical devices.
7. State the benefit of the Baby Friendly Initiative.

A. Palliative Care

What is Palliative Care?

- Specialized medical care for any hospitalized patient in need of education, support and advance care planning.
- Addresses the physical, the psychological, the social and the spiritual needs of the patient and family.

Difference between Palliative Care and Hospice

Palliative Care	Hospice Care
• Focus on quality of life, regardless of life expectancy • Addresses physical, psychological, social and spiritual needs • Facilitates autonomy and choice • Provides information and education aiding the ability of make well informed decisions regarding one's health care	• Care for those with a life expectancy of 6 months or less • Focus on quality at the end of life • Provides medical, psychosocial and spiritual support • Facilitates choices at the end of life

• Service offered regardless of Medicare or insurance • Service offered at ANY stage of one's condition • Service offered while in the hospital, regardless of life expectancy • Serviced offered while in the hospital, regardless of diagnosis	• Provides support and bereavement services to family members • Medicare benefit • Requires 2 physicians stating patient has a terminal condition • Service offered at END of life

Palliative Care Program at Emanate Health

Palliative Care Services are offered at our Inter-Community Hospital, Queen of the Valley Hospital and Foothill Presbyterian Hospital.

The Palliative Care Team at Emanate Health is a decentralized interdisciplinary program with the goal of helping patients and their families cope with the patient's current hospitalization.

The Palliative Care core interdisciplinary team includes:

- Palliative Care Certified Physicians
- Certified Palliative Care Registered Nurses
- Chaplaincy
- Social Workers

Scope of Service

A Palliative Care Consult requires a physician's order. Services include but are not limited to:

- Assessing patient and families' needs regarding physical, psychological, social and spiritual
- Provide education to patients and families regarding the disease process, medical condition, course of the illness, treatment options
- Address advance care planning and goals of care
- Discuss and educate on Advance Directives
- Assist with identifying decision maker
- Work collaboratively to promote quality of life for the patient and family
- Collaborate with discharge planning, social services and care coordination Provide support to patients and their families in preparing for and addressing end of life when appropriate
- Serve as educators and mentors for staff
- Participation in Interdisciplinary Rounds, Length of Stay and/or In-patient Rounds as appropriate
- Perform ongoing patient assessment and follow up utilizing reliable and valid Palliative Assessment Tools and report significant findings to the Interdisciplinary Team and Health Care Professionals who are involved in the patient's care

Indications/Potential Triggers for Palliative Care Services (include but not limited to)

- Frequent readmissions
- Chronic, serious or potential life-limiting condition, such as CHF, COPD, ESRD, Dementia, Cancer
- Uncontrolled symptoms such as unmanaged pain, shortness of breath, anxiety
- Emotional, psychosocial or spiritual distress experienced by patient or family
- Technology or Care Dependent, such as Dialysis and Mechanical Ventilation
- Lack of Advance Directive/POLST
- Unclear/unknown Goals of Care
- Lack of Medical Proxy/Decision Maker

Referral Process:

A Palliative Care Consult order is required to obtain services. A Palliative Care Consult order is generated when ordered by a Physician.

Once the order is generated:

- The Palliative Care Team to provide an initial assessment, plan for interventions and formulate goals of care
- Patients receive regular follow up, monitoring and ongoing communication with the Palliative Care Interdisciplinary team involved in patient's care

Physician Order for Life-Sustaining Treatment (POLST)

POLST was developed in response to seriously ill patients receiving medical treatments that were not consistent with their wishes. The goal of POLST is to provide a framework for healthcare professionals so they can provide the treatments patients DO want, and avoid those treatments that a patient DOES NOT want.

- POLST is a physician order that helps give patients with **chronic or serious illness** more control over their care during serious illness.
- Produced on a distinctive **bright pink form** and **signed by both the doctor and/or nurse practitioner or physician's assistant and patient and/or designated medical proxy**
- Specifies the types of medical treatment that a patient wishes to receive towards the **end of life**.
- Can prevent unwanted or medically ineffective treatment, reduce patient and family suffering, and **help ensure that patients' wishes are honored.**

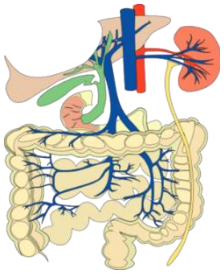
Filling out a POLST form is entirely voluntary. However, if a patient does have a valid POLST, California law requires that the POLST be followed by health care providers, and provides immunity to those who comply in good faith with a patient's POLST requests. If

there any questions regarding a patient's current POLST form, please obtain a Palliative Care order for assistance.

The **POLST** form complements an Advance Health Care Directive and is not intended to replace the Advance Health Care Directive document. An **Advance Health Care Directive** is still necessary to appoint a legal health care decision maker, and is recommended for all adults, regardless of their health status.

These are the primary differences between an Advance Directive and a POLST form:

Advance Directive	POLST
• For anyone 18 and older	• For persons with serious illness — at any age
• Provides instructions for **future** treatment	• Provides medical orders for **current** treatment
• Appoints a Health Care Representative	• Guides actions by Emergency Medical Personnel when made available
• Does not guide Emergency Medical Personnel	• Guides inpatient treatment decisions when made available
• Guides inpatient treatment decisions when made available	



B. Organ and Tissue Procurement

Who is OneLegacy?

OneLegacy is the organ procurement organization (OPO) that collaborates with Emanate Health facilities and the county coroner's office to provide organ and tissue donation-related services, including:

- Supporting potential donor families in their time of loss
- Coordinating the recovery of all medically suitable organs and tissues for transplant
- Ensure organs are effectively placed regional and national transplant centers
- Additionally, OneLegacy provides after care support to donor families and educates the diverse communities of Southern California about organ and tissue donation and transplantation.

Identifying the Potential Donor

Criteria for Organ and Tissue Donor Selection

Brain Death Criteria:

- Maintained on a ventilator
- Heart continues to beat

Donation After Cardiac Death Criteria:

- Maintained on a ventilator
- Not brain dead
- Family and physician have decided to discontinue ventilator support

Patients who meet the criteria for brain death or donation after cardiac death (DACD), are potential donors for the following organs and tissue:

- Organs: heart, heart/lung, lungs, liver, kidneys, pancreas, small intestine
- Tissue: corneas/eyes, heart valves, skin, bone, tendons, cartilage, veins

Patients who reach cardiac death - no cardiac or respiratory activity - are potential tissue donors only.

Each donor is evaluated on a case-by-case basis due to variable transplant center criteria.

Signs of Imminent Brain Death

The following are signs of imminent brain death:

- Ventilator dependent
- GCS of 5 or less
- Plans to discontinue pharmacological support
- One or more clinical signs:
- Pupils fixed and dilated
- No cough
- No gag reflex
- No spontaneous respiration
- No purposeful movement in response to noxious stimuli

Early Referral

The hospital takes ownership of the donation process by early identification and referral of potential donors. The early referral is not "giving up on a patient;" rather, it is an opportunity to provide families a chance to donate. An early referral also attunes us to the potential donor's medical and family needs in case treatment cannot prevent a decline in the patient's condition. Early referral (Glasgow Coma Scale of <5, per CMS guidelines) allow OneLegacy coordinators to assist the hospital team in preparing the family for the variety of outcomes.

Early Referral is Critical - and Required

The Center for Medicare and Medicaid Service (CMS) requires hospitals to refer all deaths and imminent deaths to the local OPO in a timely manner. These include:

Imminent brain death: Report as soon as patient shows one or more clinical signs of

cessation of brain and brain stem functions.

Cardiac death: Report death as soon as possible, preferably within one hour.

Organs can become non-viable during the time the family considers the donation option. It is essential that the potential donor be properly managed at all times so as to enable adequate hydration, ocular care, etc.

Referral to OneLegacy

Once a potential donor has been identified, the hospital calls OneLegacy's 24-hour Donor Referral Line, (800) 338-6112. Upon receiving the call, a OneLegacy Coordinator will arrive at the hospital to:

- Review the patient chart for donor suitability. It is not necessary to approach a family about donation if their loved one is not a candidate.
- Answer any questions or concerns from the hospital staff.
- Be available at the earliest possible time when intervention becomes appropriate.

The Nurse's Role

The nurse plays an essential role in the organ and tissue donation process. Without the nurse's referral to OneLegacy, the hospital and the family will not have access to the essential services that we provide.

There are a number of proactive steps the nurse can take to ensure the family's right to consider the opportunity to donate. They include:

- **Patient Care**
  - Maintain vital signs, including blood pressure, heart rate and normal temperature
  - Maintain pulmonary care as if the patient were expected to recover (pO2 > 100), even if a DNR or brain death
  - Obtain requested/necessary organ-specific labs
  - Ensure adequate urine output and fluid resuscitation
  - Notify OneLegacy of any changes in the patient's status
- **Donor Management Goals:**
  - SBP>100
  - PaO2>100
  - UO=100
  - Core temp=normothermic
  - Maximize function of donor organs for benefit of recipient

- **Family Care**
  - Do not mention organ donation to the patient's family. (Premature notification has been shown to reduce family trust in the hospital and caregivers.)
  - Identify the family's native/nurturing language

- Notify OneLegacy of any visits by family members

Declaration of Brain Death
The hospital that takes ownership seeks to ensure that treatment is not "decelerated" on patients for who continued treatment is deemed to be futile until OneLegacy has evaluated the patient as a potential candidate to donate and the family has been given the opportunity to choose donation.

The Physician's Role
The primary role of the physician is to determine and declare brain death.
Confirmatory tests are at the discretion of the physician. Tests to determine brain death include:

- A clinical exam, which is required in the State of California
- EEG or CBF, although these are not mandatory
- Any other tests required by Hospital Policy and Procedure

Once brain death has been determined, it must be documented by two licensed physicians. The notes should state "Patient is Brain Dead" and should be signed with date and time of declaration. Test(s) performed to determine brain death should also be documented.

California Uniform Determination of Death Act (1982)
California Health and Safety Code, Section 7180 et seq.
A person shall be pronounced brain dead if it is determined by a physician that the person has suffered a total and irreversible cessation of all functions of the entire brain, including the brain stem. There shall be independent confirmation of the death by another physician.

Family Support and the Opportunity to Donate
Recognizing that families who have the opportunity to donate find tremendous value in the act of donation, the hospital that takes ownership utilizes OneLegacy coordinators and family support staff to provide the explanation, counsel and grief support that the hospital simply does not have the time and current clinical information to offer.

OneLegacy believes that a critical point of our service is to offer families time, attention, information and care. We do this by helping hospital staff answer clinical questions, discuss issues the family will face, share the family's concerns with their physicians and hospital staff, clarify the diagnosis (as appropriate) and, when we are certain the family is ready, offer them the opportunity to give ever greater meaning to their loved one's life through donation of organs and tissues to help save lives.

The Approach Process
Formal steps that have been demonstrated to allow families to make informed choices include:

- **Physician informs the family of the death of their loved one.**
    - The concept of "brain death" is not an easy one to understand, especially for a family facing the sudden and overwhelming loss of a loved one. It is critical that the family understand "brain death" and have time to acknowledge the death of their loved one prior to approaching them with the opportunity to donate. This "separation of events" is such an important factor that it has a special name: decoupling.

    - After explaining brain death and the tests that were used to confirm the diagnosis, the physician may use a bridging statement to introduce the OneLegacy representative; i.e. "Someone will be coming in to speak with you regarding some of the end-of-life decisions that you will need to make. He/she works closely with our hospital in assisting families in times like these. He/she can provide you with information and answer any questions you may have. If you need any more information from me, they know how to get in touch with me."

- **Decoupling**
  Once the family is informed of the death of their loved one, they are given time alone or with grief support staff to process this information. It is essential to allow the family to ask questions of hospital staff and OPO staff in order to clarify their understanding of the diagnosis and decision that they must address.

Discuss End-of-Life Decisions and the Opportunity to Donate

A collaborative approach by the OneLegacy coordinator and the hospital health care team has the highest probability of obtaining consent. OneLegacy staff are specially trained to support and speak with families about the medical and personal issues of brain death and, of course, donation. Research has shown that families choose to donate more often when approached by OPO staff rather than hospital caregivers. Families and case research have identified that this variance is due to three reasons:

- OPO staff have more time to talk through the family's concerns;
- OPO staff can speak to specific information about the donation process; and
- OPOs have specially trained staff who can provide culturally sensitive support to families from our diverse communities

A number of factors create a heightened need for sensitivity when approaching the family. Family dynamics, language barriers, cultural traditions and religious beliefs, not to mention the emotional nature of the situation, all contribute to a challenging environment for all involved. With their day-to-day experience and extensive training, OneLegacy staff is well prepared to collaborate with hospital staff to approach the family with care and respect and to spend as much time with the family as necessary.

- **Support the Family Regardless of Their Decision to Donate**
  Families of potential donors are people in need. Many of them have never experienced the loss of a loved one. Whether a family consents to donation or not, OneLegacy provides information that helps the family to begin the recovery process. This includes a checklist of things to be done to prepare for the funeral, lists of mortuaries, grief resources and support groups, and information from the coroner, if appropriate. OneLegacy also provides continued support to each donor family for a year after the loss of their loved one through our Family Services Care Program.

Managing the Donor

OneLegacy Coordinator's Role

After brain death is declared and consent is given, management of the patient is assumed by the OneLegacy coordinator, whose key responsibilities include the following:

- Determine potential donor medical suitability
- Provide personal care and support to families
- Assist families in understanding clinical issues and end of life decisions
- Offer the family the opportunity to donate
- Seek coroner approval, when necessary
- Medical management of donor patient
- Clinical tests for organ suitability
- Organ placement (12-20 hours)
- Schedule O.R. time with multiple recovery teams
- Post-donation support and recognition of donor family
- Follow-up with hospital

Management of the Brain Dead Patient

Time is a critical factor as the coordinator maintains the patient's hydration, blood pressure (>90) and urinary output. Other key factors include:

- Fluid resuscitation
- Maintain normothermia
- Electrolyte normalization
- Cardiovascular support
- Ventilator management
- Hormone replacement
- ACLS

Family After Care

Whether or not a family chooses to donate, OneLegacy's Family Services Program believes that families who have faced the loss of a loved one are deserving of our best care, support and encouragement.

Grief Support and Resources

From our initial contact with the family in the hospital and continuing on during the weeks

and months after the death of their loved one, our specially trained staff focus on providing resources, practical information, and emotional support and guidance. The Family Services Program includes:

- Bereavement literature
- Grief support referral
- Follow-up letters and phone calls
- Gatherings and events to honor and remember donors
- Opportunities to OneLegacy as a volunteer

Donor Recognition Ceremonies

Each March, OneLegacy hosts invitation-only donor recognition ceremonies to celebrate those who have given the gift of life. Donor family members, transplant recipients and healthcare professionals are invited to share the program of remembrance and inspiration.

Correspondence between Donors and Recipients

OneLegacy encourages communication between donor families and organ transplant recipients. Donor families and recipients may correspond anonymously with each other whenever they so choose according to specified guidelines. If a donor family and recipient express mutual interest in direct contact or a meeting, the OneLegacy family coordinator and a representative from the recipient's transplant center will facilitate such a gathering.

C. Medication Safety

What are Medication Errors?

Medication errors are mishaps involving medications that cause, or could cause, harm to a patient. They may be errors in prescribing, dispensing, administering, or monitoring and they include both errors that reach the patient as well as errors that do not reach the patient. They can occur in any patient care area or in the Pharmacy.

What are Common Sources of Medication Errors?

- Lack of knowledge about drugs: Many new drugs are being developed each year. It has never been more important to understand what each drug can do and how to use it properly.
- Lack of patient information: It is important to know key information about each patient, including his/her age, weight, sex, clinical status, known drug allergies, and current list of medications, including herbs, supplements, vitamins, other holistic remedies. This is the “minimum information” needed before administering medication.

- Poor communication: Problems can result from things such as:
    - Not using standardized abbreviations.
    - Handwriting that is hard to read.
    - Verbal miscues (for example, mispronouncing a drug's name).
    - Unclear decimal points.
    - Poor verbal or telephone communication.
    - Storage and stocking of drugs: For example, the risk of someone picking up the wrong drug is higher when two different drugs are similarly packaged.
    - Equipment used to administer drugs: Variations in the design of IVs and infusion pumps can cause confusion. Poor maintenance and not understanding how to program automated equipment also increases the risk of medication errors.
    - Patient identification: Failure to use two identifiers before administering any medications.
    - Failure to use 7 rights during medication administration.
    - Distractions: Ringing telephones, too much conversation, and interruptions can cause even the most careful healthcare worker to lose concentration.

How Can Medication Errors be Prevented?
Most medication errors are not due to a careless individual act but are related more directly to some type of system failure or inefficiency. Medication errors can be prevented! Everyone in the organization must:

- Work together across departments, including physicians, pharmacists, nurses, support staff and administrators.
- Focus on systems and processes. This means improving procedures to help prevent mistakes and following procedures that are in place to decrease errors.
- Help patients understand their medications, follow their treatment plans, and take an active role in their care at every step along the way.
- Use benchmarks to compare challenges and successes of other health care organizations with our own.
- Report errors voluntarily so that a root cause analysis can be done when necessary. A Root cause analysis is a step-by-step method to understand what went wrong and why. It allows us to make improvements in a system and monitor changes to see how well they are working.

What are some of our Organizational Medication Error Prevention Strategies?
Numerous regulatory agencies want to examine what health care organizations are doing to help prevent medication errors. Although things can get confusing because the various agencies may use different terminology, we have broken down some of our **Error Prevention Strategies** into 3 lists.

These lists meet the requirements of the regulatory agencies AND identify specific drugs in our organization that may be more likely to be involved in errors.

High Risk/High Alert Medications

High Risk/High Alert medications have a high potential for causing patient harm. The High Risk/High Alert Medication designation comes from the National Patient Safety Goals set forth by The Joint Commission.

A few examples are:

- Heparin
- Insulin
- Chemotherapy drugs

Black Box Warning Drugs

These are drugs that have been designated by the FDA to have special risks associated with them that do not require the drug be pulled from the market, but do require special considerations when the drug is being used.

Some examples are:

- Fentanyl patches (All Facilities)
- Epogen (All Facilities)
- Droperidol (ICH and QVH)
- Methotrexate PO (ICH and QVH)

Look-Alike, Sound-Alike Drugs

These are drugs whose names have been often confused with the names of other drugs. This is also a National Patient Safety Goal.

Some examples are:

- predniSONE vs predniSOLONE (ICH and QVH)
- vinCRINSTINE vs vinBLASTINE (All facilities)
- METRONIDazole vs FLUCONazole (ICH and QVH)
- OxyCONTIN vs oxyCODONE (ICH and QVH)

****You can find a complete list of QVH/ICH's High Risk/High Alert, Black Box Warnings and LA/SA drugs and a review of the processes we use to prevent errors around these medications on the EMANATE HEALTH Intranet under Pharmacy Department Information.**

You can find a complete list of FPH's High Risk/High Alert, Black Box Warnings and LA/SA drugs we use to prevent errors on the EMANATE HEALTH Intranet under Policies and Procedures tab>FPH Hospital Policies.

****Additionally, you may also find comments about these drugs on the eMAR****

Why do Medication Errors Have to be Reported?

Reporting medication errors is a crucial part of preventing future mistakes. We need to be able to identify where a system has failed so that we can work on changing and improving it. It is only in this way that the organization can effectively address the issue of medication errors. Reporting is not for the purpose of blaming individuals.

How do We Report Medication Errors?
Any drug error that harms, or could harm, a patient should be reported as soon as possible. Timely reporting makes it easier to determine what went wrong because the event is still fresh in people's minds. Medication errors are to be reported through RL Datix, set up by Risk Management.

Every employee should know how to use this new system. Pharmacy uses reported errors to track and trend problems in order to identify areas that need improvement.
Remember: Medication error of all types can be reduced or eliminated.
While no one is perfect, steps can be put in place to help everyone learn from past mistakes and improve patient safety.

D. Ethical Issues

Complex moral, social, and economic factors in health care, force upon the healthcare provider, a host of ethical issues and potential dilemmas.

The way we, as individuals, see ourselves is determined by our beliefs and principles. These principles guide our choices about how we relate to each other individually, as a community, and spiritually.

Sometimes these principles conflict with each other. Ethical concerns in medical care arise from differing goals, beliefs, values and perspectives.

The Ethics Committee is available to assist and advise the patient, the patient's family or significant others and the healthcare team when patient care situations present complex medical/ethical issues that warrant further discussion and/or clarification.

The patient, family member, hospital staff or anyone who has an ethical concern can request an Ethics Committee meeting. Requests for a meeting of the Ethics Committee can be made twenty-four (24) hours per day. During regular working hours, requests can be made through the Medical Staff Office. During off-hours and weekends, requests can be made by contacting the Administrative Nursing Supervisor.

The Ethics Committee is comprised of a multi-disciplinary team including, but not limited to the following individuals:

- Physicians
- Nurses
- Social Workers

- Chaplains
- Risk Managers
- Community Members

All patient information that is shared in an Ethics Committee meeting is kept completely confidential.

E. Safe Medical Device Act

Federal law requires that information concerning events involving medical devices which may have caused or have contributed to the death, serious injury, or illness of a patient/staff member be reported to the FDA and/or the manufacturer of the device. This includes events occurring as a result of use error. It is also important to report events involving a medical device which do not cause serious injury/illness or death so that defects in the device can be addressed. This reporting is voluntarily.

Serious injury is defined as an illness or injury that is life threatening, or results in permanent impairment of a body function or permanent damage to the body structure, or necessitates medical or surgical intervention to preclude impairment of a body function or permanent damage to the body structure.

Risk Management submits the mandatory and voluntarily reports to the FDA.

Examples of medical devices are:

- Beds / Gurneys
- Heart valves
- Ventilators
- Patient Restraints
- X-ray Machines
- Defibrillators
- Patient monitors
- IV pumps
- Bandages

Generally, any item used in medical practice other than a drug is considered a device. Investigation devices (diagnostic testing equipment) are exempt from the reporting requirements.

If any equipment or device is suspected to not be functioning properly:

- The equipment or device must be immediately tagged by staff, noting the problem.
- Notify Bio-Med Services, Department Director, Nursing Supervisor, and the Risk Manager of the issue.
- To protect others from inadvertently using it, remove the device from service and sequester it for investigation until it is inspected by Bio-Med.
- Complete a Patient Safety Event Report.
- If the device has electronic memory, keep it plugged in so it maintains its memory.
- Keep any packaging, tubing or other accessories that may help investigators reconstruct the event. The manufacturer may need to inspect the device.

All employees are responsible for promptly reporting these events on the day of discovery. This ensures any reports to the FDA are done in time so reports to the FDA/manufacturer can be made, as required, within 10 workdays.

The appropriate means of notifying Risk Management is by telephone call if patient harm has occurred and followed by completing a Patient Safety Event Report. At the time of notification of a suspected medical device event, the Risk Management Staff, in conjunction with the Director of Bio-Medical Services, will conduct the investigation.

If you have any questions, contact the Bio-Medical Services Department or the Risk Management Department

Safe Medical Device Flow Chart