



Student Manual

Lesson 8: Patient Assessment and Discharge


Learning Objectives

At the conclusion of this lesson, you will be able to:

- Identify the various types of pre- and post-operative patient assessments an ASC must conduct.
- Understand the differences among them.
- Assess whether an ASC has conducted all required assessments.
- Understand and assess compliance with discharge requirements.



Patient Assessment & Discharge

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 - Assess whether an ASC has conducted all required assessments
 - Understand & assess compliance with discharge requirements





Overview

- ASCs are expected to assess patients
 - *Before surgery, to assure it is reasonably safe for the patient to undergo the procedure*
 - *After surgery, to assure the patient is ready for discharge or in need of additional care/transfer*



Assessment is Fundamental



- Poor patient selection/little or no patient assessment has been found in some of the more serious ASC problem cases
- ASCs cannot shift all responsibility for patient assessment to physicians
 - *They can & must partner with their physicians, but the ASC retains responsibility under the CfCs*



4

Types of Required Assessments

- 2 types of pre- & post-op ASC assessments:
 - History and Physical (H&P), general pre- & post-assessment (§416.52(a) & (b))
 - Anesthetic/procedure risk & recovery (§416.42(a)(1) & (2))



5

Requirements



- **All types must be performed for each patient!**
- Reasonable consolidation permissible, so long as all requirements are met



6

Differences



- **Who may perform the assessment**
 - *Anesthetic risk*: physician
 - *Anesthetic recovery*: physician or anesthetist
 - *H&P & pre-surgical assessment*: physician or other qualified practitioner (generally NP or PA)
 - *Post-surgical assessment*: physician, other qualified practitioner, or RN with specialized experience



7

Differences (cont.)



- **Timing:**
 1. H&P: ≤ 30 days prior to surgery
 2. Pre-surgical assessment: upon admission
 3. Anesthetic/procedure risk: immediately before surgery
 - 2&3 may be combined, if a physician is performing
 4. Anesthesia recovery: before discharge
 5. Post-surgical assessment: before discharge
 - 4&5 may be combined, if a physician is performing



8

Pre-op Assessments

- §416.52(a)(1)&(2) – comprehensive H&P and pre-surgical assessment (update H&P)
- §416.42(a)(1) – anesthesia & procedure risk





9

Pre-op Assessments (cont.)

§416.52(a)(1)



- Each patient must have a comprehensive H&P no more than 30 days prior to the date surgery is scheduled
- Must be performed by a physician or other qualified practitioner



10

H&P



- Purpose: to determine whether anything in patient's condition would affect the planned surgery
- Must be comprehensive, i.e., collect & assess pertinent data to minimize risks to the patient
- Should specify patient is cleared for surgery in ambulatory setting



11

H&P (cont.)



- Must be performed by:
 - Physician (MD, DO, DDS, podiatrist, optometrist, or chiropractor – for no MDs/DOs, must be practicing within their permitted State scope)
 - Other qualified practitioners – authorized IAW State scope of practice law & in ASC P&P



12

H&P Questions (cont.)



- How is the time period calculated?
 - H&P may not take place >30 calendar dates prior to date of surgery
 - Example:
 - Date of surgery = September 30th
 - H&P must be dated August 31st or later



13

H&P Questions (cont.)



- Is an H&P required for every surgery when multiple surgeries are scheduled at different times?
 - One H&P may be used for multiple surgeries, so long as for each surgery it is not > 30 days prior



14

H&P Questions (cont.)



- Is the comprehensive H&P still required when surgery is scheduled on the same date a patient is referred to the ASC?
 - Yes



15

H&P Questions (cont.)

- Can the H&P be completed by a physician who is not a member of the ASC's medical staff?
 - Yes, this is often the case. ASC P&P's should address whether it accepts H&Ps by qualified physicians or practitioners who are not medical staff members



16



Assessments on the Surgery Date

§416.52(a)(2)

- Pre-surgical assessment required upon admission

§416.42(a)



- Assessment of anesthetic & procedure risk required immediately before surgery



17

Pre-surgical Assessment



- After admission but before surgery, each patient must be assessed for significant changes since the H&P
 - May be performed by physician or other practitioner qualified under State law, standards of practice and ASC policy
 - Update assessment entry must be made in medical record



18

Pre-surgical Assessment



- May be combined with the anesthetic/procedure assessment, or performed separately
 - If combined, physician must conduct the assessment
 - If separate, e.g., a PA could perform update, & then a physician perform the anesthetic/procedure assessment



19

Anesthesia/Procedure Assessment



- **Physician** must perform, immediately before surgery
 - Ideally, the physician also assesses patient's risk for the anesthesia and procedure prior to admission, e.g., through review of H&P
 - But may not cite an ASC for failure to conduct anesthesia assessment pre-admission



20

Anesthesia/Procedure Assessment (cont.)



- Purpose of assessment: evaluate, based on patient's current condition, if the risks of the type of anesthesia/analgesia & the procedure are within an acceptable range
 - Must take ASC setting into account



21

Anesthesia/Procedure Assessment (cont.)



- Must assess each patient individually; physician expected to review results of comprehensive H&P, as well as update on admission, unless the physician is also performing the update



22

Anesthesia/Procedure Assessment (cont.)



- Cannot assume coverage of the procedure in an ASC means it's safe for any patient to have that procedure and anesthesia in an ASC setting
- E.g., an acceptable risk for a 50-year old with no significant co-morbidities might be unacceptable for a 77-year old with significant cardiovascular disease, diabetes, etc.



23

Anesthesia/Procedure Assessment (cont.)



- ASC P&Ps must address:
 - Assessment criteria used in the ASC, e.g., ASA classifications, other criteria, etc.
 - Consistency in assessments, e.g., through QA/PI



24

Assessing Compliance



- Observe during case tracer(s) whether the required assessments are made and who is performing them
- Observe whether the comprehensive H&P is reviewed as part of the assessment process



25

Assessing Compliance (cont.)



- Ask ASC how its patient selection and evaluation criteria assure there is an acceptable level of risk for each patient scheduled for surgery
- Review P&Ps and criteria the ASC refers to & assess if practices observed were consistent with them



26

Assessing Compliance (cont.)



- When constructing survey sample, inquire whether any patients were transferred out/died (timeframe should be at least the last 12 months); include those records



27

Assessing Compliance (cont.)



- Review the assessments of those patients with the ASC – preferably with the physician who conducted the anesthetic/procedure assessment – to explore basis for clearance
- Focus is on ASC systems & criteria for sound assessment, not on the physician's practice



28

Assessing Compliance (cont.)

- All sample medical records must contain:
 - Comprehensive H&P completed ≤ 30 days before the surgery
 - Update assessment upon admission & before surgery
 - Anesthetic/procedure risk assessment by a physician immediately before surgery
 - If a physician performs both the update and anesthetic/procedure risk, it is not necessary to have 2 separate entries in the medical record, so long as the required assessments are performed





29

Post-operative Assessments

Must take place after surgery & prior to discharge:



- §416.52(b) – post-surgical assessment
- §416.42(a)(2) – anesthesia recovery assessment



30

Post-surgical Assessment



- Purpose: assess patient's overall condition to determine:
 - How recovery is proceeding; whether/when patient is ready for discharge
 - What needs to be done to facilitate the patient's post-surgical recovery; must be addressed in discharge notes



31

Post-surgical Assessment (cont.)



- May be performed by:
 - Physician
 - Other qualified practitioner
 - RN with post-operative care experience, per State law, standards of practice & ASC policy



32

Anesthesia Recovery



- Patient must also be assessed for recovery from anesthesia
 - Technically conscious sedation is not anesthesia, and not covered by this requirement; deficiency citation unlikely to hold
 - But standard of practice calls for monitoring & evaluation before, during & after procedure



33

Anesthesia Recovery (cont.)



- Who can perform:
 - Physician
 - CRNA
 - Anesthesiologist's assistant (NOTE: must be supervised by an anesthesiologist)



34

Anesthesia Recovery (cont.)



- Standard of practice typically calls for evaluating things like:
 - Respiratory function, including airway patency, O2 saturation
 - Cardiovascular function, e.g., pulse, BP
 - Mental status
 - Temperature
 - Pain
 - Nausea/vomiting



35

Assessing Compliance



- During the tracer(s) observe whether the required assessments are being made, and who is performing them
 - Are the personnel properly qualified?
- Are the assessments reasonably designed to evaluate the patient's recovery & readiness for discharge?
 - There is no regulatory checklist of things to assess



36

Assessing Compliance (cont.)



- In the sample of medical records, look for evidence of general post-surgical assessment & anesthesia assessment
 - Are assessments completed by qualified personnel?
- Are post-surgical needs identified and addressed in the discharge notes?



37

Discharge



- §416.52(c) - Each patient must have:
 - Discharge order
 - Written discharge instructions
 - Overnight supplies
 - Follow-up physician appointment, if applicable
 - Adult accompaniment, unless exempted



38

Discharge Order



- Order discharging the patient must be signed by the physician who performed the surgery
- Order must comply with State law, standards of practice & ASC policy



39

Discharge Order (cont.)



- OK for physician to sign order to “discharge when stable”
- If the patient assessment indicates transfer to a hospital is required, a transfer order signed by a physician meets the regulatory requirement for a discharge order



40

Discharge Order (cont.)



- Patient expected to leave ASC within 15 – 30 minutes of discharge order being signed **or** assessment of anesthesia recovery being completed, **whichever occurs later**
 - OK for patient to wait (e.g., for ride) briefly in waiting room, as a courtesy
 - Not OK for patient to be “discharged” but remaining in patient care areas



41

Discharge Instructions

- §416.52(c)(1):
 - Prescriptions to be filled
 - Written instructions on:
 - Actions to take in immediate post-operative, post-discharge period;
 - Warning signs to be alert for & steps to take/contacts
 - How to contact the physician providing follow-up care
 - When a follow-up appointment is standard, the ASC must arrange the follow-up appointment



42

Overnight Supplies



- Gauze, bandages sufficient to get the patient through the first night after surgery
 - Assumes patient or family may not be able to purchase appropriate supplies before the next day



43

Adult Accompaniment



- Unless the physician providing the patient's care authorizes an exemption, no patient may be discharged from the ASC unless accompanied by a responsible adult
- Although it's a good idea for ASCs to have policies addressing exemption criteria, they are not required to do so



44

Assessing Compliance



- During the tracer case(s) observe:
 - Whether the physician signs a discharge order
 - Whether written discharge instructions are provided & are complete
 - Whether overnight supplies are provided
 - Whether a follow-up appointment is made
 - When the patient leaves the ASC (or the ASC's patient care areas, in the case of patients who briefly use the waiting room)



45

Assessing Compliance (cont.)



- Ask to see an example of written discharge instructions
- Ask staff how follow-up appointments are scheduled
- Ask staff how they check whether there is a responsible adult to accompany the patient, or if there is an exemption



46

Assessing Compliance (cont.)



- For every record in the sample, look for evidence of:
 - Discharge order signed by physician
 - Issuance of written discharge instructions & overnight supplies
 - Follow-up appointment
 - Discharge in the company of an adult, or exemption



47

Summary



- ASCs are expected to assess patients
 - Before surgery, to assure it is reasonably safe for the patient to undergo the procedure
 - After surgery, to assure the patient is ready for discharge or in need of additional care/transfer



48

Summary (cont.)



- 2 types of pre- & post-op ASC assessments:
 - H&P, general pre- & post-assessment (§416.52(a) & (b))
 - Anesthetic/procedure risk & recovery (§416.42(a)(1) & (2))



49

Summary (cont.)



- §416.52(c) - Each patient must have:
 - Discharge order
 - Written discharge instructions
 - Overnight supplies
 - Follow-up physician appointment, if applicable
 - Adult accompaniment, unless exempted



50

Questions?

Thank You!



51



Student Manual

Lesson 9: Quality Assessment/ Performance Improvement

Learning Objectives

At the conclusion of this lesson, you will be able to:

- Understand the essential components of a QAPI program.
- Understand the type of information used to assess a QAPI program.
- Determine whether the QAPI program is in compliance with the regulation.





Quality Assessment Performance Improvement



Learning Objectives

At the conclusion of this lesson, you will be able to:



- Understand the essential components of a QAPI program
- Understand the type of information used to assess a QAPI program
- Determine whether the QAPI program is in compliance with the regulation



2

QAPI regulation



- **§416.43 Condition for Coverage: Quality Assessment and Performance Improvement**
- The ASC *must develop, implement and maintain an **ongoing, data-driven** quality assessment and performance improvement (QAPI) program.*



3

QAPI



- Information used to assess a QAPI program
 - Is there an effective & ongoing system in place to
 - Identify problem events, policies, procedures
 - Take action to remedy problem events, policies, procedures
 - Follow up to see the effect of the actions taken
 - Not used to assess deficient practices



4

QAPI

- 4 main components
 - What needs to be measured and how do you measure it?
 - How do you monitor and act upon what you collected?
 - Specific performance improvement projects
 - Who will oversee it?





5

What Needs to be Measured and How Do You Measure It?

§416.43(a)
Standard: Program Scope

(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.

(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.





6

What Needs to be Measured and How Do You Measure It? (cont.)

§416.43(c)
Standard: Program Activities

(1) The ASC must set priorities for its performance improvement activities that –



- (i) Focus on high risk, high volume, and problem-prone areas.
- (ii) Consider incidence, prevalence and severity of problems in those areas.
- (iii) Affect health outcomes, patient safety and quality of care.

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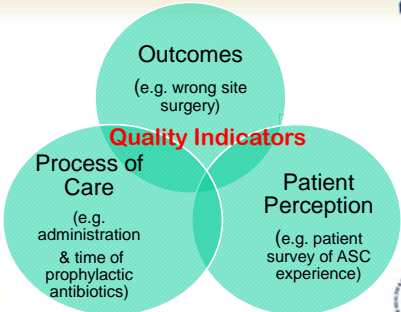


What needs to be measured and how do you measure it? (cont.)

High Risk	<ul style="list-style-type: none"> • Incidence • New cases over a specific period of time
High Volume	<ul style="list-style-type: none"> • Prevalence • Number of cases at a given point in time
Problem Prone Areas	<ul style="list-style-type: none"> • Unplanned outcomes of surgery • Transfer to the hospital

8

Potential Domains of Measures







9

Examples of QAPI Measures

- National Quality Forum consensus standards for ASCs includes patient safety/quality indicators:
 - Patient Burns
 - Patient Falls
 - Hospital Transfer

http://www.qualityforum.org/Publications/2007/01/National_Voluntary_Consensus_Standards_for_Ambulatory_Care_Specialty_Clinician_Performance_Measures.aspx





10

What Needs to be Measured and How Do You Measure It? (cont.)

Summary

Standards:
416.43(a) & 416.43(c)(1)

- Must be related to health outcomes
- Health outcomes data should be high impact areas for the ASC
 - Incidence
 - Prevalence
 - Problem Prone
- Examples of Quality Indicators
 - National Quality Forum
 - Agency for Health Care and Quality Research



11



How Do You Monitor and Act Upon What You Collected?

§416.43(b)
Standard: Program Data

(1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.

(2) The ASC must use the data collected to –

- (i) Monitor the effectiveness and safety of its services, and quality of its care.
- (ii) Identify opportunities that could lead to improvements and changes in its patient care.



12

**How Do You Monitor and Act Upon
What You Collected? (cont.)**

§416.43(c)

Standard: Program Activities

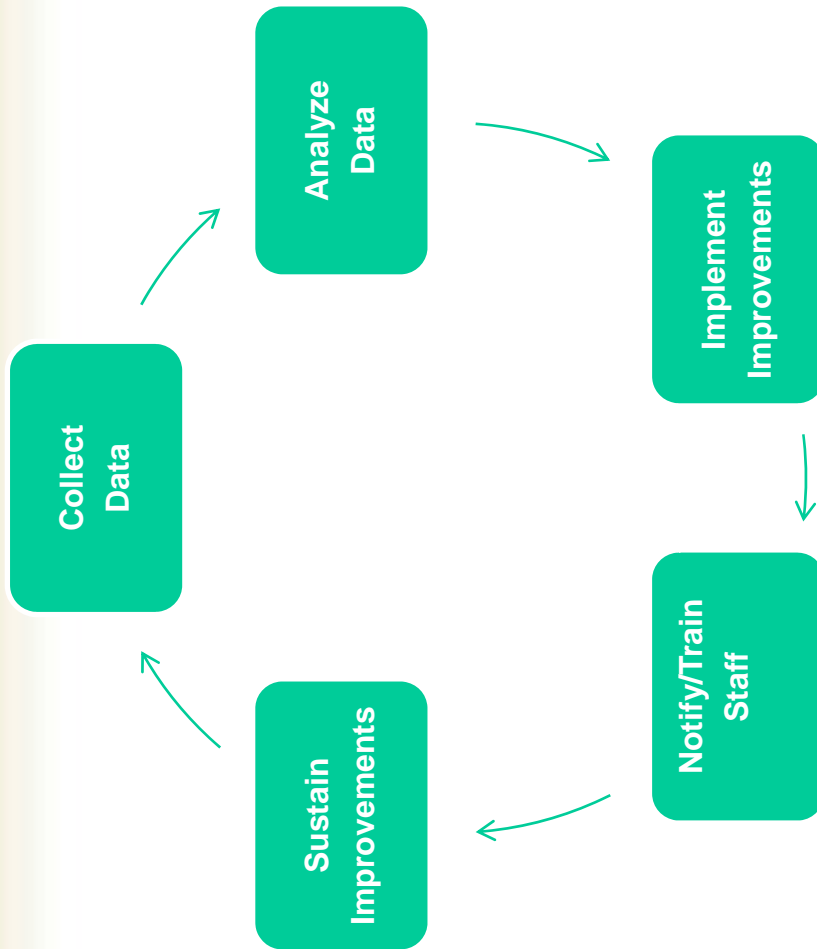
(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.

(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.

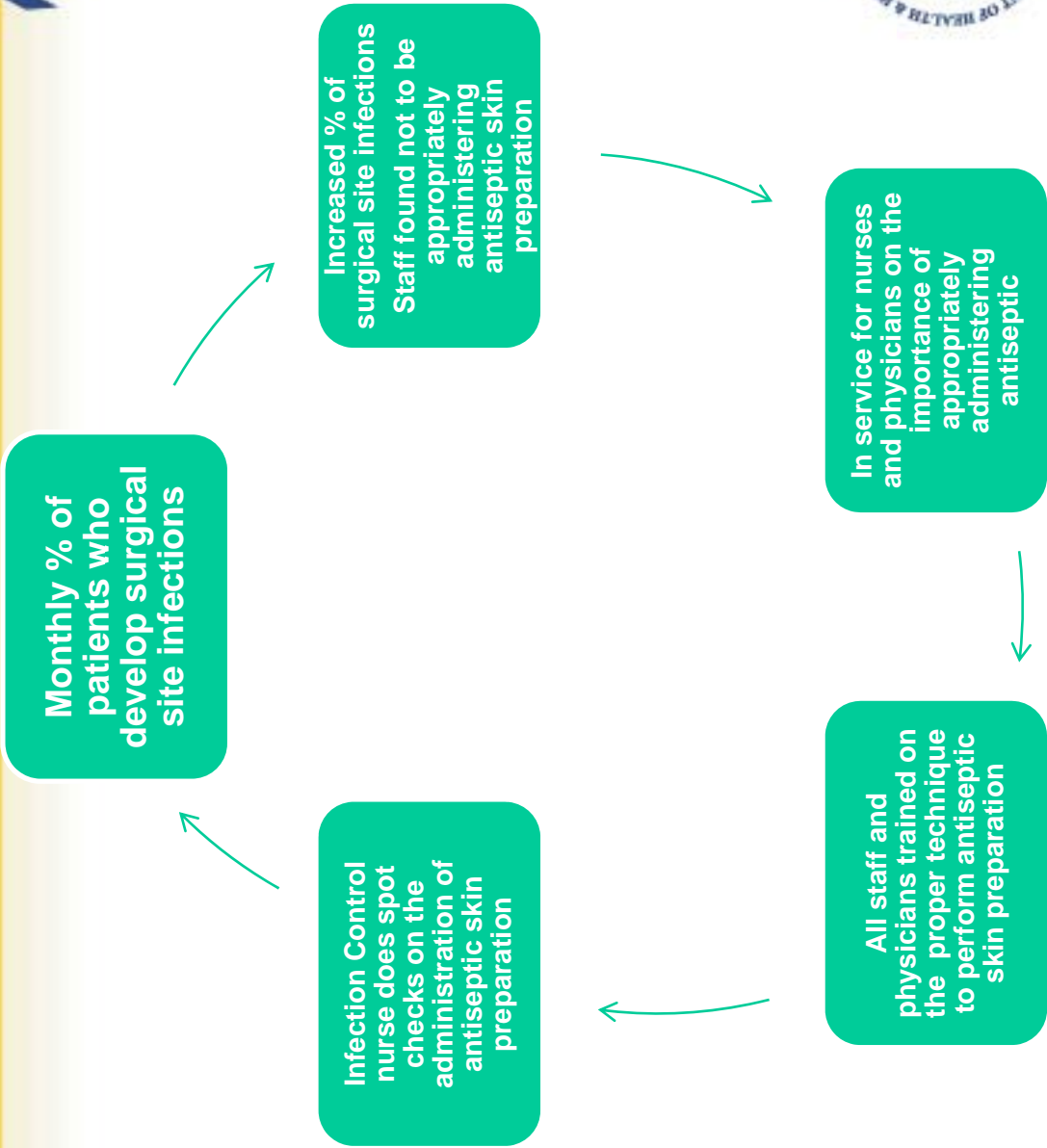


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How Do You Monitor and Act Upon What You Collected? (cont.)



How Do You Monitor and Act Upon What You Collected? (cont.)





Specific Performance Improvement Projects

§ 416.43(d)

Standard: Performance Improvement Projects



- 1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations
- 2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results



16

Specific Performance Improvement Projects (cont.)

- Performance improvement projects
 - ASC must perform ≥ 1 quality improvement project a year
 - Must have documentation showing the following:
 - Why the project was chosen?
 - What data was collected and why?
 - What evidence do they have that their project will lead to improvement (e.g. national standards)
 - Current status of project (findings/actions taken as a result of the project)





17

Program Accountability

§416.43(e) Governing Body responsibilities:



- (1) Is defined, implemented, and maintained by the ASC.
- (2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness.
- (3) Specifies data collection methods, frequency, and details.
- (4) Clearly establishes its expectations for safety.
- (5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.



18

QAPI



- Example
 - You are reviewing the monthly QAPI minutes that were sent to the governing board of the ASC and find that the rate of surgical site infections in patients over the last 3 months is increased from baseline.
 - The minutes indicate a quality study which showed it may be related to failure by newly hired staff to appropriately administer antiseptic skin preparation

19

QAPI (cont.)



- Example
 - The minutes indicate that an in-service on administration of skin antiseptics be held for all surgical staff
 - The following months minutes indicate the in-service was completed. The ASC implemented daily spot checks conducted by the infection control nurse at the start of each surgery

20

QAPI (cont.)



- Example
 - On your case tracer methodology of two different cases you note that the surgical skin preparation was appropriate
 - The next monthly QAPI meeting will occur in 2 weeks. On the agenda for the meeting is assessment of the change in infection rate since the implementation of the in-service and spot checks.

21

QAPI (cont.)



Do you cite the facility for not appropriately administering skin antiseptics due to the QAPI minutes?



22

QAPI (cont.)



- Example
 - No. You do not cite the facility based on previous QAPI minutes
 - The ASC identified the cause of their high infection rate
 - The ASC developed and implemented an action plan



23

QAPI (cont.)



- Example
 - The surveyors' observations of the staff's practices indicate that the action plan has been implemented
 - They are collecting the data but not enough time has passed for the next assessment of infection rate since the implementation of the action plan



24

Summary: QAPI



- A. What needs to be measured and how does the ASC measure it?
 - 1. Health outcomes data - high risk/volume
 - 2. Quality indicators
- B. How does the ASC monitor and act upon what data collected?
 - 1. How frequently are data reviewed
 - 2. Policies and Procedures in place to act on analysis
- C. Specific performance improvement projects
 - 1. What area was chosen and why?
 - 2. Follow through on analysis
- D. Who will supervise it?
 - 1. Governing Body



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Questions?

Thank you!



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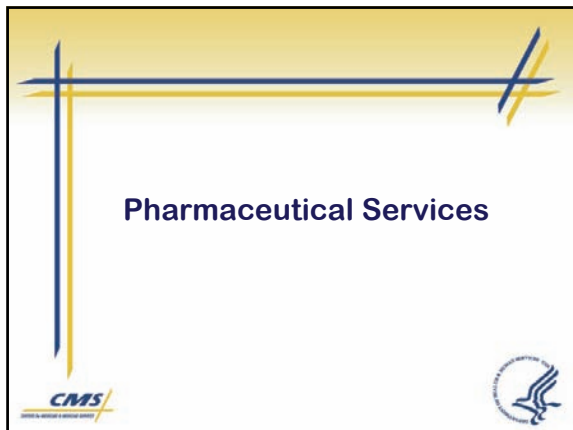
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Lesson 10: Pharmaceutical Services



Learning Objectives

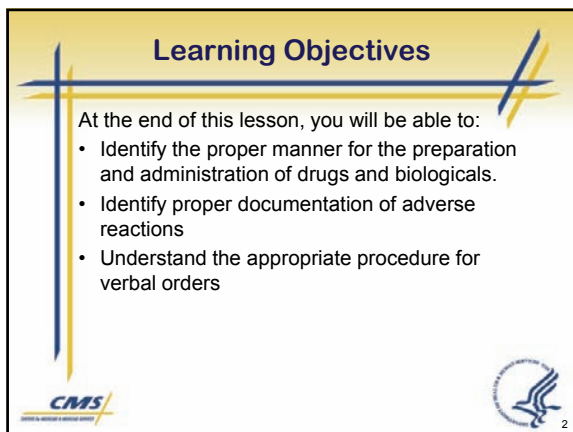
At the conclusion of this lesson, you will be able to:

- Identify the proper manner for the preparation and administration of drugs and biologicals.
- Identify proper documentation of adverse reactions.
- Understand the appropriate procedure for verbal orders.



Pharmaceutical Services







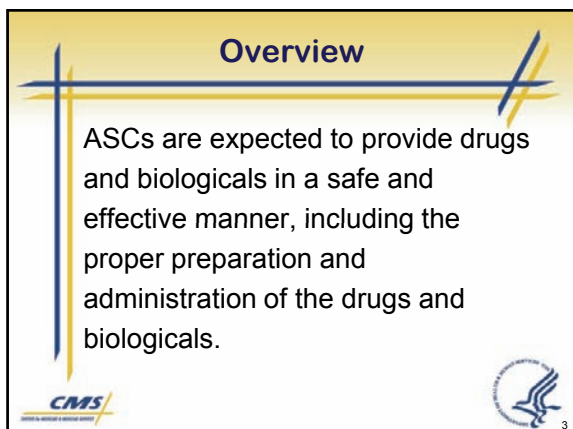
Learning Objectives

At the end of this lesson, you will be able to:

- Identify the proper manner for the preparation and administration of drugs and biologicals.
- Identify proper documentation of adverse reactions
- Understand the appropriate procedure for verbal orders





2



Overview

ASCs are expected to provide drugs and biologicals in a safe and effective manner, including the proper preparation and administration of the drugs and biologicals.




3

Safe and Effective Manner

Drugs and Biologicals must be provided:

- Safe
- Effective
- According to accepted professional practices
- Under direction of an individual designated responsible for pharmaceutical services



4

Healthcare Professional



- Specific individual
- Licensed healthcare professional
- Routinely present, but continuous presence is not required



5

“Routinely Present” Question



- What is the definition of routinely present? If an ASC has a contract with a Pharmacy consultant for quarterly review and based upon outcomes, will that suffice?
 - We have not provided a definition of the term “routinely present” as individual situations may vary among ASCs. However, the individual’s time at the ASC must permit the individual to provide direction to the facility’s pharmaceutical service



6

Licensed Healthcare Professional Question



- Can the Medical Director provide direction to the ASC's pharmaceutical services if a Pharmacy Consultant is available for consultation as needed?
 - The interpretive guidelines do not specify the type of licensed healthcare professional. Thus, a medical director could be designated to provide direction to the ASC's pharmaceutical service



7

Assessing Compliance – Licensed Healthcare Professional



- Ask the ASC leadership for evidence that a qualified individual has been designated to direct pharmaceutical services
- Ask how often and how long the individual is on-site at the facility
- Look for documentation that indicates that the individual is providing active direction and program oversight



8

Administration of Drugs



§416.48(a)
Drugs must be prepared and administered according to established policies and acceptable standards of practice



9

Administration of Drugs (cont.)



- Administered in accordance with formal policies adopted by the ASC
- Such policies and the ASC's actual practices must conform to acceptable standards of practice for drug administration



10

Standards of Practice

- Acceptable Standards of Practice
 - Drugs and biologicals are handled and provided in the ASC in accordance with applicable State and Federal laws as well as with standards established by organizations with nationally recognized expertise in the clinical use of drugs and biologicals
 - National Association. of Boards of Pharmacy
 - Institute for Safe Medication Practices
 - American Society of Health-System Pharmacists



11

Policies and Procedures

Must promote medical administration consistent with acceptable standards of practice

Should address:

- Appropriate personnel acting within their scope of practice must issue order for administered drugs
- Adherence to the manufacturer's label
 - Storage and discarding of drugs; single-use vials





12

Policies and Procedures (cont.)

Issues:



- Proper preparation of medication
 - Timing
 - Labeling
- Standard infection control practices



13

Records of Receipt and Disposition

- There must be records of receipt of drugs and disposition of all drugs, if the ASC uses any scheduled drugs
 - Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970
 - Federal law that requires physical security and strict record keeping for certain types of drugs
 - Schedules or classes are based on the potential for abuse, accepted medical use, and accepted safety under medical supervision





14

Administration of Drugs – Scheduled Drugs

Policies and Procedures should address:

- Accountability to ensure control of the distribution, use, and disposition of scheduled drugs
- Records of receipt, disposition, and movement
 - Current
 - accurate
- Drug records must be in order and an account maintained and reconciled
 - Responsibility of licensed healthcare professional





15

Administration of Drugs – Scheduled Drugs (cont.)

Polices and Procedures:



- Record system and documentation
 - System should provide information in a readily retrievable manner
 - Facilitate reconciliation of receipt and disposition
 - Records must be in order and account for all scheduled drugs; discrepancies reconciled promptly
 - Capable of readily identifying loss or diversion of all controlled substances
 - Minimize time between actual loss or diversion to time of detection and determination of extent

16

Assessing Compliance – Administration of Drugs



- Review medical records
 - Evidence that there is a order for every drug administered
 - Signed order
 - By physician or other qualified practitioner
- Review the ASC's policies to determine if there are formal policies regarding the administration of drugs
 - Only nurses or other qualified individuals administered drugs?

17

Assessing Compliance – Administration of Drugs (cont.)



- Interview staff
 - Are drugs administered only by nurses or other qualified individuals? Or under the supervision of nurses or other qualified individuals as permitted under Federal or State law and the ASC's policy?
- Observe staff
 - Do actual practices conform to the ASC's policies?
 - To acceptable standards of practice?

18

Assessing Compliance – Administration of Drugs (cont.)



- Observe medications to see if they are properly labeled, stored, and have not expired
 - Spot check drugs for expiration dates
- Utilize the infection control tool
 - Determine if facility employs safe infection practices
 - Refer to the lesson on infection control for more detailed information



19

Assessing Compliance – Administration of Drugs (cont.)

- Determine if the ASC uses scheduled (controlled) drugs
- If so:
 - Is there a record system that readily provides information?
 - Review records to trace the movement of the drugs throughout the facility; documentation of movement





20

Assessing Compliance – Administration of Drugs (cont.)

Use of scheduled drugs:

- Determine if the professional in charge of the pharmaceutical services is responsible for ensuring drug records are in order
 - Account maintained of all scheduled drugs
 - Account is periodically reconciled
- Surveyor: select medications
 - Have staff person count medication
 - Compare count to inventory sheet





21

Assessing Compliance – Administration of Drugs (cont.)

Use of scheduled drugs:

- Determine if record system identifies loss or diversion
 - Minimize time between loss or diversion and detection





22

Adverse Drug Reactions

§416.48(a)(1)



Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.



23

Adverse Drug Reaction



- More than one accepted definition of adverse drug reaction
- *Example definition from WHO: Harmful, unintended reactions to medicines that occur at doses normally used for treatment*



24

Adverse Reactions

- Must be reported to the physician responsible for the patient
 - Every occurrence
 - Promptly
- Must be documented in the medical record





25

Adverse Reactions (cont.)

Documentation:



- Permits assessment of patient in a timely manner
- Enables physician to determine if additional treatment is required



26

Adverse Reactions (cont.)



- The ASC's policies and procedures must incorporate requirements regarding adverse drug reactions
- Staff must be aware of and comply with policies and procedures



27

Assessing Compliance – Adverse Drug Reactions


- Interview clinical staff
 - Understand ASC's policies and procedures regarding adverse drug reactions
 - Steps to take if patient experiences adverse drug reaction
 - Must promptly report to physician on the ASC's medical staff responsible for the patient's care



28

Assessing Compliance – Policies and Procedures



- Review ASC's policies and procedures
 - Address adverse drug reactions
 - Consistent with regulatory requirements
 - Documentation
 - Prompt reporting



29

Assessing Compliance – Documentation

- Pull a sample of medical records
 - Documentation of adverse drug reactions
 - If no notation:
 - Ask staff if they remember any patients with adverse drug reactions
 - Pull a medical record with documentation of this patient and the adverse drug reaction




30

Administration of Drugs – Blood and Blood Products



§416.48(a)(2)
Blood and blood products must be administered only by physicians or registered nurses



  31



Blood and Blood Products

- Administration
 - Only a physician on the ASC's medical staff OR
 - An RN working in the ASC
- Policies and procedures must **specifically** address
 - Unless ASC does not keep blood or blood products on hand and
 - Never administers such products

  32

Assessing Compliance – Blood and Blood Products



- Review policies and procedures
- Interview staff
 - Does ASC administer blood or blood products?
 - Review medical records to determine who administered
 - Someone other than ASC physician or RN
 - Does ASC's policies specifically restrict administration to physician or RN?

  33

Administration of Drugs

§416.48(a)(3)



Orders given orally for drugs and biologicals must be followed by a written order and signed by the prescribing physician



34

Administration of Drugs (cont.)




- Verbal Orders
 - Oral, spoken communications between the prescribing physician and the ASC's nursing staff
 - Delivered either face-to-face or via telephone



35

Administration of Drugs (cont.)



- Verbal orders must be followed by a signed written order
 - Signed by the prescribing physician



36

Verbal Orders



- ASC's policies and procedures should include:
 - Read-back and verification process
 - Nurse receiving the order writes it down, reads the order back to the prescribing physician
 - Prescribing physician will verify if the order is correct
- If administering a drug per a verbal order:
 - Nurse should include in medical record a note that drug was prescribed orally; indicate name of the prescribing physician



37

Verbal Orders (cont.)



- Regarding the written order, the prescribing physician must:
 - Sign
 - Date
 - Indicate time
- This must be done as soon as possible after the verbal order is issued



38

Verbal Orders – Recovery Room



- Area of vulnerability
 - Prescribing medications for patients in the recovery room
 - Potential failure to follow-up verbal order with a written order signed by the prescribing physician
- Attention must be given to ensure compliance with the regulatory requirements for meds administered in the recovery room



39

Assessing Compliance – Verbal Orders



- Review ASC policies and procedures
 - Is verbal orders addressed?
 - Is the prescribing physician required to sign, date, and time a written order as soon as possible after the issuance of the verbal order?
 - Is there a “read back and verify” policy?



40

Assessing Compliance – Verbal Orders (cont.)




- Review the medical records:
 - Determine if each verbal order was followed by a written order
 - Determine if written orders are signed and dated by prescribing physician
 - How soon after verbal orders are issued is the written order signed, dated, and time stamped?
 - Verify that there is not a great lapse of time



41

Assessing Compliance – Verbal Orders (cont.)



- Interview nursing staff
 - How are verbal orders handled?
 - Is a “read-back and verify” process used?



42

Summary



- Drugs must be delivered in a safe and effective manner
 - Accepted professional practice
 - Direction of a designated individual
- Drugs must be prepared and administered according to established policies and acceptable standards of practice



43

Summary (cont.)



- Policies and procedures for the administration of drugs must:
 - Follow manufacturer's label for storage and disposing of drugs; use of single-dose vials for one patient only
 - Employ standards of infection control
 - Include accountability procedures and documentation



44

Summary (cont.)



- Adverse reactions must be reported to physician in a timely manner
- Must be documented in the medical record
- Only ASC physicians or registered nurses may administer blood and blood products



45

Summary (cont.)



- Verbal orders for drugs must be followed by a written order
- Policy should include read-back and verify procedure
- Written order must be signed, dated, and timed by prescribing physician
 - As soon as possible after verbal order is issued



46

Questions?

Thank you!



47
