

Q241 & Q242: Infection Control

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As part of the Bureau of Facility Standards ASC Quality Improvement Initiative, ASC QAPI regulations (Q80 – Q84) were applied to statewide quality indicator data. The quality indicator data, which included complaints alleging non-compliance with ASC regulatory requirements, provider questions regarding regulatory requirements, and citation data from 2009 through 2014, were reviewed and analyzed. Based on that analysis, it was determined additional training regarding Infection Control, specifically the regulations at Q241 & Q242 would be beneficial in improving regulatory understanding and compliance. For additional information regarding the statewide quality indicator data and analysis, please refer to the Applied QAPI: Statewide ASC Quality Improvement Initiative Year 2 training on the BFS web site.

Learning Goals

- Identify the 9 areas Q241 and Q242 that have resulted in citations.
- Identify the 3 specific areas which represent 78% of all Q241 and Q242 citations.
- Describe how citation information can be incorporated into an ASC QAPI program.
- Describe the QAPI and Governing Body implications for repeat citations.

Appendix L

- Q241: “The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.”
- Q242: “The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.”

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The regulations at Q241 and Q242 are wide reaching and include multiple areas of infection control.

Performance Improvement Projects

Q241 & Q242	2009	2010	2011	2012	2013	2014	Totals
Number 9: Non-sterile implants used	0	1	0	0	0	0	1
Number 8: No infection control training	0	1	1	0	0	0	2
Number 7: Reuse of single use devices & supplies	0	1	0	1	0	0	2
Number 6: Inappropriate biohazard waste disposal	0	1	1	1	0	0	3
Number 5: No infection control program	1	2	2	0	0	0	5

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However, when quality indicator data was analyzed, it was determined that there were only 9 specific infection control areas which have been cited. Five of those areas have not been cited since 2012 (as indicated on the slide).

Performance Improvement Projects

Q241 & Q242	2009	2010	2011	2012	2013	2014	Totals
Number 4: No evidence of National Guidelines being adopted and implemented	0	1	1	0	2	2	6
Number 3: Lack of a comprehensive ongoing program (includes lack of biological and chemical indicators or sterilization logs)	0	4	2	7	2	3	18
Number 2: Lack of appropriate environmental cleaning (wrong chemicals, wrong contact time, expired chemicals, laundry not cleaned properly, unsanitary equipment and rooms)	1	1	2	6	2	7	23
Number 1: Lack of appropriate hand hygiene	2	5	3	9	2	4	25

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That leaves only 4 areas of Q241 & Q242 which continue to be problematic. Further, 3 specific areas (lack of a comprehensive ongoing program, lack of appropriate environmental cleaning and lack of appropriate hand hygiene) comprise 78% of all Q241 and Q242 citations.

Number 1: Lack of Hand Hygiene

CMS ASC Infection Control Surveyor Worksheet practices to be assessed:

- Availability of soap and water or alcohol-based hand rubs.
- Performance of hand hygiene:
 - After removing gloves
 - Before direct patient contact
 - After direct patient contact
 - Before performing invasive procedures (e.g. placing an IV)
 - After contact with blood, body fluids or contaminated surfaces
- Appropriate glove use:
 - Potential for contact with blood or body fluids
 - Handling potentially contaminated patient equipment
 - Removing gloves prior to moving to the next task and/or patient

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The number one reason for Q241 citations is a lack of appropriate hand hygiene during observations. Please be aware, during the survey process surveyors will conduct observations of care. During those times, surveyors assess hand hygiene practices in accordance with the direction provided on the CMS ASC Infection Control Surveyor Worksheet.

The infection control worksheet specifies hand hygiene practices surveyors must assess and the worksheet specifies when deficient must be cited.

Number 1: Lack of Hand Hygiene

Governing Body questions:

- How does your ASC monitor hand hygiene? Is the CMS ASC Infection Control Surveyor Worksheet utilized?
- Has quality indicator data related to hand hygiene been collected and analyzed as part of your ASC's QAPI program?

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For your ASC's hand hygiene practices, has the Governing Body considered and selected nationally recognized infection control guidelines related to hand hygiene (Q242)? How is the Governing Body monitoring to ensure the guidelines are being implemented appropriately? Are hand hygiene practices observed? Is the documentation of observations incorporated into the ASC's QAPI program as quality indicator data collection? Has the data been analyzed? After analysis, if a problem exists, what action did the Governing Body take to improve compliance with hand hygiene? Has there been continued data collection and analysis to ensure the problem was resolved and does not reoccur?

Number 2: Lack of Appropriate Environmental Cleaning

CMS ASC Infection Control Surveyor Worksheet practices to be assessed:

- Cleaning and disinfection of rooms and equipment (including laundry)
 - Cleaning is completed

 - EPA-registered disinfectants are used and
 - Tested for appropriate concentration
 - Replaced as recommended
 - Disinfected for the appropriate length of time
 - Disinfected at the appropriate temperature

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The number 2 reason for Q241 citations is a lack of appropriate environmental cleaning. Please be aware, during the survey process surveyors will conduct observations of the environment and observe cleaning of rooms and equipment. During those times, the manufacturer instructions' of the chemicals your ASC is using will be reviewed to ensure they are being used properly and that they have not expired in accordance with the direction provided on the CMS ASC Infection Control Surveyor Worksheet.

Number 2: Lack of Appropriate Environmental Cleaning

Governing Body questions:

- How does your ASC monitor cleaning and disinfection of rooms and equipment?
- Has quality indicator data for cleaning and disinfection been collected and analyzed as part of your ASC's QAPI program?

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For your ASC's environmental cleaning and disinfection practices, has the Governing Body developed policies and procedures to ensure cleaning and disinfection is being completed and that manufacturer instructions are being followed? If cleaning is being completed by a contracted service, how is the Governing Body monitoring the contract? Has environmental cleaning been included in your ASCs QAPI program as a quality indicator? Is data collection occurring? Has the data been analyzed? After analysis, if it was determined a problem exists, what action did the Governing Body take to improve the ASC's environmental cleaning practices? Has there been continued data collection and analysis to ensure the problem was resolved and does not reoccur?

Number 3: Lack of a Comprehensive Ongoing Program

CMS ASC Infection Control Surveyor Worksheet practices to be assessed:

- Does the ASC have an explicit infection control program?
 - Lack of infection control training
 - Lack of surveillance for adherence hand hygiene, cleaning standards, and post op. infection policies
 - Lack of biological and chemical indicators or sterilization logs, etc.)

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Q242 states “The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases...” Please note, the “ongoing” component of this regulation includes elements from multiple other regulations as stated in the Q242 interpretive guidance. The Q242 interpretive guidance states “an active surveillance component that covers both ASC patients and personnel working in the facility. Surveillance includes infection detection through ongoing data collection and analysis.” The guidance states, “The ASC should select one or more sets of guidelines that enable it to address the following key functions of an effective infection control program:

- Maintenance of a sanitary ASC environment (see requirements of §416.51(a));
- Development and implementation of infection control activities related to ASC personnel, which, for infection control purposes, includes all ASC medical staff, employees, and on-site contract workers (e.g., nursing staff employed by associated physician practice who also work in the ASC, housekeeping staff, etc.);
- Mitigation of risks associated healthcare-associated infections:
 - Identifying infections;
 - Monitoring compliance with all policies, procedures, protocols and other infection control program requirements;
 - Program evaluation and revision of the program, when indicated...”

Please be aware, during the survey process surveyors will review the ASC's complete infection control program. Deficient practices may result in both Q422 citations and citations at other infection control regulations as stated on the CMS ASC Infection Control Surveyor Worksheet.

Number 3: Lack of a Comprehensive Ongoing Program

Governing Body questions:

- How does your ASC monitor the total infection control program?
- Has quality indicator data been established to ensure all aspects of infection control are address? Has the data been analyzed as part of your ASC's QAPI program?

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For your ASC's total infection control program, has the Governing Body developed policies and procedures to ensure the total infection control program is being implemented? Is data collection occurring? Has the data been analyzed? After analysis, if it was determined a problem exists, what action did the Governing Body take to improve the ASC's infection control practices? Has there been continued data collection and analysis to ensure the problem was resolved and does not reoccur?

Number 4: No evidence of National Guidelines being adopted and implemented

CMS ASC Infection Control Surveyor Worksheet practices to be assessed:

- Does the ASC's infection control program follow nationally recognized infection control guidelines?
 - Nationally recognized guidelines considered & selected.
 - Nationally recognized guidelines implemented & monitored.

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Q242 requires the ASC to consider and select specific nationally recognized guidelines for its infection control program. Current citation data demonstrates, ASC's have considered and selected nationally recognized guidelines and specified those guidelines in policies and infection control plan. However, survey observations, interviews and record reviews do not always support the facility has implemented the guidelines which were selected.

Please be aware, during the survey process surveyors will review the nationally recognized guidelines selected by the ASC and ensure the guidelines are being implemented and monitored.

Number 4: No evidence of National Guidelines being adopted and implemented

Governing Body questions:

- Has your ASC considered & selected nationally recognized guidelines?
- Has quality indicator data been established to ensure the guidelines are being followed? Has the data been analyzed as part of your ASC's QAPI program?

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For your ASC's, has the Governing Body considered & selected nationally recognized guidelines? How is the Governing Body monitoring to ensure the guidelines are being followed? Is data collection occurring? Has the data been analyzed? After analysis, if it was determined a problem exists, what action did the Governing Body take to ensure guidelines are implemented? Has there been continued data collection and analysis to ensure the problem was resolved and does not reoccur?

CMS ASC INFECTION CONTROL SURVEYOR WORKSHEET

http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf

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Please remember, an exceptional tool for evaluating your ASC's infection control practices is the CMS ASC Infection Control Surveyor Worksheet which can be found on the CMS website.

Plans of Correction & QAPI

- Plans of Correction require ASCs to include information regarding how the deficient practice corrections will be monitored and tracked to ensure the PoC is effective in bringing the ASC into compliance, and that the ASC remains in compliance with the regulatory requirements.
- Repeat deficiencies.

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Whenever an ASC is cited for a deficient practice, the ASC is required to submit a Plan of Correction (PoC). For additional comprehensive information related to PoCs, please refer to the PowerPoint presentation Understanding the 2567 & Writing Acceptable Plans of Correction For Ambulatory Surgical Centers on the BFS website.

Part of the PoC requirements include monitoring and tracking to ensure the PoC is effective in bringing the ASC into compliance, and that the ASC remains in compliance with the regulatory requirements. Throughout this presentation, it has been demonstrated how each deficient practice should be assessed and monitored through the ASC's QAPI program.

Please be aware that surveyors review past survey reports and your PoC prior to conducting the next survey. When repeat deficiencies are identified (deficiencies which were cited during the last survey and are being cited again during the current survey) it calls into question your QAPI program and the Governing Body's ability to achieve and sustain compliance over time. Repeated deficiencies can result in Condition level findings at both QAPI (Q80) and Governing Body (Q40).

QAPI & Governing Body

- Survey results should not be a surprise. If the QAPI system is comprehensive in accordance with regulations Q80 – Q84, the facility will have identified areas in need of improvement (i.e. deficient practices) prior to a survey being conducted.

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While this presentation focused on how deficient practices with Q181 could be addressed within an ASC's QAPI program, it should be noted a comprehensive, well designed, implemented and monitored QAPI program allows the facility to identify areas in need of improvement prior to a survey occurring.

Ultimately this is the responsibility of the Governing Body. The regulation and interpretive guidance at Q84 states "The governing body must ensure that the QAPI program-

- (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.

An ongoing, successful QAPI program requires the support and direction of the ASC's leadership. This regulation makes clear CMS' expectations that the ASC's governing body must assume responsibility for all aspects of the design and and [sic] implementation of every phase of the QAPI program..."

Please ensure your QAPI program is implemented and maintained not only to meet the minimum regulatory requirements, but to ensure your patients are receiving the highest quality of care possible.

Questions

- Please submit your questions, comments or suggestions to fsb@dhw.idaho.gov

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Should you have questions, comments or suggestions regarding this or other aspects of the ASC survey process, please submit them to the Facility Standards email.