NEWS FROM TJC

Change in Decision Process for AFS and PDA

This month’s edition of Perspectives discusses a change in the flow of adverse accreditation reports. Previously an organization with a potential status of accreditation with follow up survey had the opportunity to appeal to the Joint Commission’s accreditation committee of the board before finalization of that decision. Staff made a recommendation and the board made the decision. That will now change to a staff decision based on the published decision rules. This will speed up the process and should not result in a worsening of outcomes as the success of appeals to the accreditation committee to prevent AFS were often of limited success. Potential preliminary denial of accreditation recommendations will still go to the accreditation committee for approval. The changes to the PDA process are more substantial and we find very much improved. Previously an organization with a PDA status had its entire outcome based on conditions at the time of the survey. This resulted in the PDA decision being upheld by the accreditation committee, and the next step being the need for a review hearing panel to prevent denial of accreditation. In the new process improvements that occur after the survey can be factored into the final outcome providing the reason for the PDA was too many requirements for improvement. Excluded from this new process will be PDA decisions based on an immediate threat to life, unlicensed activity, falsification and failure to clear findings during contingent accreditation.

The good news in this is that if an organization receives too many findings resulting in a staff recommendation of PDA, the good work done during the ESC phase can prevent an actual PDA final outcome. In this new process, if you have a PDA outcome based on too many findings, you will be required to submit both parts of your ESC in 45 days. This will include the ESC 45 and ESC 60 in 45 days. After TJC reviews the ESC, if acceptable they will schedule a follow up survey to verify that improvements have been made. If all findings are resolved the Joint Commission will create a decision status to reflect PDA only during that phase from the end of the survey until the last day of the follow up survey. This will be done without todays stepwise slide into a path toward denial of accreditation. There will be no need for a review hearing panel and trip to Chicago.

Fortunately only a very small subset of organizations ever experiences this process, but if you do there is light at the end of the tunnel in this new design. You just will need to work very quickly to bring things into compliance. As in the past there remains an opportunity for
clarification of some findings in that first 10-day period. To avoid misdirection or delay you are going to want any clarification submitted to be really solid and likely to result in removal of the finding.

There is also a change in the potential outcomes for initial organizations in this month’s Perspectives. In the future, initial organizations have only 2 potential outcomes, accredited or denial of accreditation. Previously they had the full range of outcomes similar to resurvey organizations. If the initial organization has RFI’s, and successfully submits an ESC, they will become accredited after evaluation of the ESC by TJC. If the organization fails to clear their ESC, they will be placed in denial of accreditation. For those organizations that are using their first survey for deemed status, if there are COP level findings, the outcome will also be denial of accreditation.

EC NEWS:
Great Q&A to Read and Share:

This month’s EC News has a very good article responding to EC questions. They answer questions about which bathrooms require call bells in public areas of a hospital. Their advice comes from FGI and they state public bathrooms in waiting areas are optional, while bathrooms in treatment or triage areas do require call bells. They also answer questions about storage of formalin and sterilization of instruments in a dental clinic. The response to the question about storage of items such as IV pumps in a clean storage area with sterile supplies is interesting. They advise basically a risk assessment to determine if the higher traffic in and out of the room to get IV pumps could in any way risk damage to the protective packaging of stored sterile items. They further advise that organizations should “pursue this option only if they are fully confident that they can mitigate any contamination risk”. This article should be shared with your EC staff and EC committee for their reference and analysis of compliance.

There is also a very detailed article on safe use of chemotherapy gloves and the specifications manufacturers must meet. There are two standards from the American Society for Testing and Materials, or ASTM for protection from permeation. The first test standard is FT39-12 for liquid and gas permeation. The second is D6978 for chemotherapy permeation where they test 9 different chemotherapy agents for permeation of the gloves. The advice provided in this article is to purchase gloves that pass the D6978 test and are labeled as such for safe handling of chemotherapy. NIOSH also recommends double gloving when handling hazardous drugs and changing gloves every 30 minutes. Again this is a useful article to share with your EC committee to verify that pharmacy and nursing staff who handle chemotherapy have the right level of protection from their gloves.

TJC Quick Safety Newsletter on Copy and Paste Forward Risks:

The Joint Commission has a newsletter entitled Quick Safety, with a new issue out this past month on the subject of copy and paste forward functionality in the EMR. The newsletter can be found through their Topics Header on the home page, then Patient Safety, then the Quick Safety Newsletter. Here is the direct link: http://www.jointcommission.org/issues/detail.aspx?Issue=BSvSdr9GJuWAo%2b6vGhxTYQK7jRZZJobZxAwwfumrmJQ%3d

You have probably all seen these extremely lengthy and redundant progress notes, notes that refer to the male patient as she, and the female patient as he, and other references to diagnoses that are totally unrelated to the specific patient
who’s chart is being reviewed. You may have also seen typographical errors that are not corrected and then carried forward in subsequent notes, or notes that begin with the words “post-OP day 1” day after day, instead of a note that includes the actual date the note is being entered. TJC reports in their newsletter that copy and paste forward has been reported as part of the root causes of sentinel events that have been reported, resulting in patient harm. TJC recommends healthcare organizations develop policies and procedures addressing the proper use of copy and paste functionality to assure compliance with governmental, regulatory and industry standards. In this edition they provide 7 references from the literature for consideration. TJC also recommends monitoring for compliance with the policies and procedures you develop. There is probably already a medical records committee of the medical staff looking at more historical issues and this copy forward function would be good to add. The Quick Safety article specifically suggests developing an FPPE/OPPE measurement process with specific triggers related to accuracy of the medical record. A similar audit process is appropriate for other disciplines also. We encourage our readers to remember that when TJC puts out new guidance like this for health care organizations to read, their own surveyors are also reading it. While content from a newsletter is not the same as standards, if the surveyor sees inaccuracy in the medical record, they are likely to follow that tracer to what leadership, medical staff and the medical records committee have been doing to develop policies and monitor practices.

CMS UPDATE:
Blood Glucose Meters — Another Change!

In November CMS issued Survey and Certification memo 15-11 describing the limitations on use of blood glucose meters (BGMS) in critically ill populations. Since that memorandum was first issued we have seen analysis and discussion but limited resolution of that issue in hospitals. Well, in this case procrastination won’t yet cause you a problem. You may have missed it because it was not issued as a new memorandum, but on March 13 CMS reissued this memo still as SC 15-11, but in the reissuance they made the memo a draft, and rescinded the earlier memo. When you go to the CMS website you will have to scroll back to last falls memo’s to find the new version. We would suggest that this version be shared with your laboratory staff and used just for preliminary planning purposes. At some point this will be finalized and reissued, but during this hiatus you will want to:

1. Define “critically ill population” for potential use of blood glucose meters. Continued use of the BGMS as a waived test would be considered “off label” use, but off label is not prohibited.
2. Evaluate the potential training and competency validation which would be required if you decided to perform this test off label at a high complexity level rather than as a waived test.

Most importantly remember this revised memo is only a draft and continuing what you are currently doing will not be a score-able issue for CMS. If your state has already taken action from a licensing perspective, it would remain score-able in your state however.

CDC INTERIM DUODENOSCOPE SURVEILLANCE PROTOCOL:

The CDC has published a guideline intended to address the recent concerns noted with CRE contamination on duodenoscopes or any other scopes with an elevator mechanism. Given the media attention that this issue has received it is essential that you print off this guideline and analyze potential actions with your infection control committee. This advisory provides
detailed advice about potential scope culturing and that advice is not as favorable as we would have assumed. CDC suggests that if you culture and find contamination the hospital should consider notification to patients who may have been exposed. They also suggest patients undergoing procedures with these scopes be advised of the risk of patient to patient bacterial transmission of a multidrug resistant organization during the consent process. Most hospitals are already documenting who each scope was used on in the reprocessing documentation but if you are not doing this, CDC has advised that you should be. CDC also brings up the subject of staff competencies, which we often see as a weak point on mock surveys. We often see documentation of education from the scope washer manufacturer, but not actually a validated competency. This is insufficient for a process with such complexity and risk. CDC advises and TJC has been looking for validation of competency when a new employee is assigned to process scopes. A competency validation process should involve observation and validation of each step in the process, including QC on the test strips, pre-cleaning, disassembly of a scope, proper use of brushes and each step in high level disinfection process and required documentation to proper transport and storage. In addition CDC establishes an annual competency expectation even though the standards would permit up to a 3 year cycle. CDC also advises a periodic revalidation of competency anytime a breach is identified or when new equipment or techniques are introduced.

SURVEY HOT TOPIC: ERCP Scope Cleaning & HLD Issues

We continue to see high level disinfection and sterilization activities as one of the most difficult issues on surveys conducted by TJC, CMS or state licensing. The issue that is not well understood is that the playing field has changed, these processes are no longer glossed over by inspection agencies. The surveyors have become very knowledgeable about the subject and they have access to references that we seldom see in hospitals. In addition to the AAMI ST-79 Recommended Practices for steam sterilization, an additional reference we are suggesting you obtain and study diligently is the AAMI ST-58 from 2013 for high level disinfection. This reference details the requirements for high level disinfection and specifically the logging of each disinfection cycle. We have seen an expectation for this same level of detail recently where TJC is also looking for these logs to contain all the AAMI required information. After you obtain this reference take a careful look at section 9.2.2 discussing cycle documentation and record keeping. They make specific reference to the patients name and medical record number, exposure time and temperature, and the disinfectant lot number documentation for each cycle. We seldom see this level of detail in the logs for ultrasound vaginal probe HLD, sleep apnea mask HLD, or other areas.

In addition make sure you know every location in your hospital where high level disinfection is being performed. When we conduct tracers on mock surveys we continue to find surprises for hospitals where the sleep lab or respiratory therapy or anesthesia is using a brand of OPA inappropriately, or not even using a high level disinfectant that is approved by the FDA for that purpose. There is a clear challenge to even finding a complete inventory of locations that are performing high level disinfection. If infection control asks department heads to report if they perform high level disinfection you are likely to get an incomplete response because very often people don’t know what HLD is. You may need to do an explanation and demonstration at a department head meeting so people even know when to report.

Readers might be wondering what high level
disinfection does the sleep lab or respiratory therapy perform. Well, the sleep lab often wants to clean and reuse sleep apnea masks and the package insert or manufacturers instructions for use that come with these masks are very confusing for hospitals. The IFU often discusses how the owner of the mask should clean their personal mask. You have to go to the manufacturer’s website to find the instructions for high level disinfection between patients. Further complicating this issue is that these masks are sold world wide, so the instructions provide multiple methods of cleaning, some of which involve chemicals or wipe systems not sold in the United States, or not approved by the FDA for high level disinfection. If this wasn't already difficult enough the manufacturers often provide limitations on how many high level disinfection cycles are permitted and this often varies by the model of the mask. We have not encountered a sleep lab or central sterile department anywhere that can track this completely. Once the hospital learns the complexity of this process they usually switch to single use only.

Respiratory therapy is sometimes involved in high level disinfection of cleaning a wire that goes into the ventilator to warm fluids for humidification. These wires sometimes require high level disinfection if actually in contact with the fluid. Much the same as in the sleep lab the device is sold world wide and again chemicals not approved for HLD are referenced.

One method you might want to try to get a handle on high level disinfection is to ask purchasing or central supply to provide a roster of all departments ordering a brand (e.g., Cidex, Metricide, Rapicide, etc.) of OPA, glutaraldehyde, peracetic acid, or high concentration hydrogen peroxide. In addition when the quality department, infection control or EOC teams conduct their inspections ask them to be on the lookout for equipment cleaning, equipment soaking to try and identify locations where they are performing HLD, or should be performing HLD. There may be more surprises waiting out there for you. Remember at a minimum these defects in HLD will be scored at a Medicare Condition of Participation level and you will expect a revisit in less than 45 days.

Best Regards,

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