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Post-Webinar Discussion Document

Clear-cut Clinical Policies

January 5, 2024

The vast majority of survey citations start by quoting from an organization's policy and procedure and then listing the many ways this policy and procedure was violated.

Our monthly webinar for January 2024 stimulated many excellent questions from attendees as they struggle to develop meaningful documents that guide reliable, safe, and compliant practices. As we respond to some of the questions posted during and after the webinar, it will be helpful to review a few key points that have emerged from our decades of experience responding to adverse state, federal, and accreditation findings.

We define three different types of policy-related documents.

- **Policies:** broad expressions of the intent or desired outcome of a [typically multidisciplinary] process. They establish what is to be done but do not go into the steps necessary to implement the policy.
- **Procedures:** the **required** steps that must be taken to successfully complete a process. Omissions of or substitutions for steps in a procedure are not permitted. The following are examples of such inflexible "procedures:"
  - preventive maintenance instructions for equipment or utilities,
  - steps in the sterilization process required in the instrument manufacturer's instructions for use, and
  - steps necessary for a clinical laboratory test.
- **Guidelines:** the steps that are **normally or ideally taken** to complete a process. A "guideline" can be labeled a protocol, a procedure, a care path, or other things. However, <u>all</u> clinical processes prescribed in guidance documents should be considered guidelines no matter what the title. Deviations from a "guideline" are allowed only when justified by valid clinical or operational considerations. Just culture algorithms are typically used to determine the validity of deviations from a guideline. Most clinical "procedures" are actually "guidelines" due to the inherent variability of clinical processes based on the unique needs of the individual patient and the constantly changing operational environment. Here are a few examples of clinical guidelines.
  - Emergency departments typically have a "policy and procedure" that requires a prompt triage assessment when a patient presents for care. However, a triage assessment is not typically performed for patients arriving who require immediate intervention (e.g., patients undergoing resuscitation). A triage assessment can also be safely omitted if the patient is seen right away, instead relying on the nurse or Practitioner's prompt evaluation in lieu of a triage assessment. So, although 95% or so of ED patients should have a prompt triage assessment, triage can be skipped if justified by valid clinical (patient undergoing resuscitation) or operational (there is no wait for care) considerations.

- Most surgical patients are taken from the operating room directly to a post-anesthesia recovery unit. However, some patients are recovered in a critical care unit (e.g., post-CABG patients). A guidance document that specifies all patients are taken to the PACU would be considered a “guideline,” and taking the post-operative patient directly to critical care would be justified by valid clinical and operational considerations.

- **Reducing Confusion**: This nuanced approach to policies, procedures, and guidelines, although very important, is difficult to communicate and consistently implement. The term “Policy and Procedure” or “P&P” is commonly used by hospitals to describe all guidance documents regardless of their content. In practice a P&P may or may not contain a policy statement (a general indication of the intent or outcome of a process that has been approved by executive or governing leadership). Also the procedural steps in most clinical P&Ps should be considered guidelines. We communicate the difference between “procedures” and “guidelines” in the following ways:

  - We help the organization adopt a “policy on policies” indicating that, unless otherwise specified, “procedures” addressing clinical processes should be considered guidelines and the steps prescribed may be omitted or changed, but only if justified by valid clinical or operational considerations. Although we have developed a model for such a “policy on policies,” each organization’s version will vary based on its unique history, policy oversight structure, and progress on its Just Culture journey.

  - The term “procedure” should be reserved for required steps. Guidelines should be labeled as such.

  - We recommend that P&Ps use the term “should” for guidelines and reserve “shall” or “will” for required steps (procedures).

  - We also recommend that any P&P containing guidelines include a brief explanation that “*variations from guidelines in this document are allowed only if justified by valid clinical or operational considerations.”*

Why Guidelines?

- Policies and procedures grow exponentially when they try (unsuccessfully) to accommodate all possible clinical situations and operational conditions. The result is a confusing document that is 10 or 20 pages long filled with phrases like “we do *this* except when *that* happens,” “we don’t do *that* unless *this* exists,” and on and on and on …

- We find it virtually impossible to anticipate all situations when the steps in a clinical process may legitimately be skipped or modified. For example, we inevitably miss something when we try to address the many different situations were a post-operative patient may need to skip the PACU or a triage assessment is not necessary for individuals presenting to the ED.

- Guidelines are easier to enforce than required procedures. Progressive discipline is hampered when the involved associate can point to the many times a required procedural step has been omitted by colleagues, which is very common in the clinical setting. It is better to start with the Just Culture algorithm at the very beginning.

SPECIFIC QUESTIONS BY ATTENDEES:

QUESTION:

> “I find when you don't put the info in a policy (like how often an assessment should be done), then staff can't speak to it and these are the details that surveyors want to know.

So if we put all that in a ‘guidance document’ - surveyors won't cite us for not following our guidance documents?”

ANSWER:

We find significant variability in what a given surveyor will cite. There are thousands of surveyors across the country representing hundreds of state, federal, local, and accrediting agencies. Each surveyor has their own approach to citations. Trying to avoid a surveyor citation is futile: what one surveyor will accept will be rejected by the next. Instead we focus on comprehensive compliance with the underlying requirement by formulating, communicating, and reinforcing succinct and sustainable internal expectations.

Trying to accommodate the many valid clinical exceptions to ideally desired processes is impossible and leads to policy and procedure documents that are dense, difficult to understand, and very, very long; greatly decreasing the likelihood that they will be followed.

There are a number of ways surveyors can infer what is required by the institution. They can look at your training materials, staff meeting notes, informational flyers, elements of the medical record, written procedures, protocols, guidelines, or many other formats used for communicating expectations to associates at the point of care and service. We find that being clear about when exceptions to a guideline are allowed significantly enhances compliance. Some surveyors understand that. Others do not. Over decades of dealing with adverse survey findings we uniformly find that compliance with hospital expectations is profoundly enhanced by the concept of a guideline and the application of Just Culture principles.

QUESTION:

In the example shown during the webinar a simple statement is made that the “dress code policy will be followed.” But “where are those standards outlined with organizations that go this route?”

ANSWER:

Expectations for performance, including acceptable attire, should indeed be clear. However, the overarching policy statement should reflect only general principles (e.g., clothing should be clean, professional, etc.), leaving the details for other documents such as infection prevention policies, human resources procedures or job descriptions, and departmental guidelines.

The most important feature of these detailed guidelines is that they not contradict one another and duplication should be minimized. Although the “location” of these guidelines will vary, they would ideally be linked to the overall policy document in the hospital’s electronic document/policy management application.

QUESTIONS:

“Why use absolute terms, such as ‘will'? Why not just the expected action?”

“Our legal department does not like words like should, shall. They actually prefer us not to use passive verbs. How do you balance?”

ANSWER:

Modal auxiliary verbs (can, could, may, might, must, shall, should, will, would) are usually necessary to communicate an expectation. Rule one is always “follow the

guidance of your legal counsel," but in our experience we see the word "shall" used when transmitting an expectation that a step must always be taken (in our model, shall would be used in a required "procedure"). We see the word "should" be used for guidelines, suggesting that justified variations are acceptable.

Sometimes we see policies and procedures that omit expectations and read "remove cover," "draw up medication into a syringe," "apply ointment," etc. The modal auxiliary verb in such cases is implied since the intent of the document is to communicate expected practice.

So, not withstanding advice from council, we prefer to use "shall" for mandatory steps and "should" for guidelines. However, grammar is less important than clarity.

QUESTION:

"I am currently the chairperson for nursing practice & administration policies in my organization. I often find that we have the job duties of people who are not employed by the organization. For example we were reviewing the organ donation policy -- we have referred to what the 'coroner' will do and what the Organ procurement organization employees will do. Is this wise?"

ANSWER:

An organization's procedure or guideline should only cover those things under its control. In the case of the 'coroner,' practices are governed by state and local statutes and regulations and should not be in the hospital's procedure or guideline. However, it is possible to put performance expectations in contracts or written agreements. Such expectations would ideally be in only one place: the contract itself, which can be referenced by the procedure or guideline. Repeating expectations in more than one document (e.g., in a guideline and also in a contract) often become out of sync with each other, making compliance impossible.

QUESTION:

"What policies do you recommend approval by the Medical Staff? Board of Directors?"

ANSWER:

Some states have specific requirements. For example, in California, many "policies" require approval by the Medical Staff and Governing Body. ("Procedures" only require the approval of operational leadership.)

MEDICAL STAFF: Specific state requirements not withstanding, we recommend that the organized Medical Staff approve 1) procedures and guidelines related to Medical Staff functioning, as required by some accreditors, and 2) procedures and guidelines that impact medical practice. It is not necessary for the Medical Staff to be in the line of approval for procedures that have no impact on the provision of clinical care.

GOVERNING BODY: When direct approval by the Governing Body is required by regulation (e.g., some policies in California), we recommend being clear that the Board is only responsible for approving the overall policy statement: their approval is not required for the individual steps in the process that are contained in "procedures" or "guidelines."

In the absence of an external requirement to the contrary, we recommend that the Chief Executive Officer be empowered to adopt policies on behalf of the Governing Body and that departmental leadership be empowered to approved pertinent procedures and

guidelines that pertain only to their department. Executive leadership is usually responsible for approving guidelines that impact more than one discipline or department.

ALSO REMEMBER: The QAPI Program, the Emergency Management Plan, the Infection Prevention and Control and Antibiotic Stewardship Plan(s), and other specified documents must be approved by the Governing Body (additional information is available upon request). We recommend any such document also be approved by the Medical Staff prior to going to the Board.

QUESTION:

"Regarding references, is it ok to use an original article? How old should references be?"

ANSWER:

We recommend references primarily be used in risk assessments, for example if you're considering using standard precautions for MRSA patients. Any references should be the latest available, but in some cases the "latest" authoritative reference was published a decade or more ago.

When incorporating a guideline by reference avoid recapitulating the reference and just provide a link to the incorporated expectation (e.g., AORN or AMI/ANSI standard).

Original articles that have not been published in a peer-reviewed journal or other recognized expert or regulatory/accrediting body are generally not helpful. However, the hospital's experience with the issue through their QAPI, Infection, or similar program is very pertinent in a risk assessment.

We trust this document and the associated webinar have been useful as you struggle to meet the significant challenge of matching practice to policy and procedure expectations. And remember: we are here to help.