



College of American Pathologists

Laboratory Accreditation Program

Patient Safety Goals (PSG)

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1. The PowerPoint handout, with lines for taking notes
2. Various Attachments that follow immediately behind the PowerPoint handout pages.

For Speaker info only...

Attachment A	PSG Indicator Audit
Attachment B	Q-PROBES
Attachment C	PSG related Checklist question compliance tool
Attachment D	Assessment tool: policies, procedures, indicators for the 4 PSG
Attachment E	CAP Lab Safety Plan

Objectives

- **After today's session, you will be able to**
 - 1. Explain the rationale for the Patient Safety movement and its impact on labs**
 - 2. Discuss how to comply with the CAP inspection checklist questions that address the Patient Safety Goals**
 - 3. Assess the compliance of your QM plan with the Patient Safety Goals**



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2

Slide 2 contains the objectives of this audioconference. After today's session, you will be able to:

1. Explain the rationale for the Patient Safety movement and its impact on the laboratory.
2. Discuss how to comply with the CAP inspection checklist questions that address the patient safety goals
3. Assess the compliance of your QM plan with the Patient Safety Goals.

Patient Safety

- When you hear the term “patient safety”, what do you think about?
- What is the role of patient safety in laboratory medicine?



Significance of PSGs

- **Rationale for Patient Safety Movement**
 - Public face of quality
 - Result accuracy and patient safety
- **Impact on Laboratory**
 - Is this something new?
 - Is this the trend of the week?
 - New terms, new emphasis



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4

Patients and the public expect high quality and safe care. Patient safety is an expectation of care, supported by initiatives of payers, providers, accreditation organizations and government regulators.

The practice of pathology and laboratory medicine is integral to safe and effective medical care.

As a profession, we have a long history of patient safety considerations.

The roots of the patient safety movement are so deeply entwined in pathology and laboratory medicine that we and most of medicine simply take it for granted.

In fact, patient safety is the public face of quality.

Why are we so fundamentally concerned about “quality”, accuracy, precision, reliability, validity, etc.?

It is because we know our product has always driven and continues to drive healthcare. Inside our world, the term “quality” resonates deeply.

Outside our world, quality is largely assumed by patients, providers, and payers.

To communicate with them, we must use their terminology and paint our picture of quality in images of patient safety.

Key Trigger – Institute of Medicine Report 1999

- *To Err Is Human: Building a Safer Health Care System* - Kohn et al
 - IOM report on Medical Error in America
 - Written by 38 people in two subcommittees
 - Published December 1, 1999



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5

So, how did our traditional concern become a national issue?

Medical Error Statistics

- **UT & CO study on adverse events**
 - Occur in 2.9% of hospitalizations
 - 8.8% of adverse events led to death
 - Extrapolates to 44,000 deaths annually
- **NY study on adverse events**
 - Occur in 3.7% of hospitalizations
 - 13.6% of adverse events led to death
 - Extrapolates to 98,000 deaths annually
- **Eighth leading cause of death in USA**



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6

In that report, which was largely based in studies from the early-to-mid 1980s, two referenced articles provided the data and now well-known quote of 44,000 - 90,000 deaths per year associated with medical errors.

No correlation or adjustment of those data were made to reflect technological and procedural improvements in the intervening years.

Solid arguments can be made to suggest the true figure for 2006 as being either higher or lower than these figures.

Regardless, this publication created a stir that continues to fill today.

Recommended Strategies

- **Establish a national focus to create leadership, research tools and protocols to enhance the knowledge base about safety**
- **Identify and learn from errors through mandatory and voluntary reporting systems**



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7

The Institute of Medicine committee believes that a basic level of safety should be assured for all who use the health system and a strong regulatory component is critical to accomplishing this goal.

Regulatory authority generally defines minimum levels of capability or expected performance. Recommended strategies include...

1. Establish a national focus to create leadership, research tools and protocols to enhance the knowledge base about safety
2. Identify and learn from errors through mandatory and voluntary reporting systems

AND...

Recommended Strategies

- **Create accountability throughout the healthcare system**
 - **Raise standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers and professional groups**
 - **Regulatory bodies**
 - **Professional groups**
 - **Consumer groups**
 - **Group purchasers**



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8

3. Create accountability throughout the healthcare system

Patient Safety Initiatives after the IOM Report

- **Patient Safety and Performance Measures Committee**
 - Laboratory Patient Safety Goals
 - Laboratory Patient Safety Plan
- **Incorporation into Inspection Checklists of the LAP program**



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9

The PSPMC (Patient Safety and Performance Measures Committee)

- part of the Council on Government and Professional Affairs (CGPA)
- decided to specifically address the needs of pathologists and the laboratory.

They devised Patient Safety Goals and the patient safety plan, which has since been incorporated into the LAP program.

Objectives of Laboratory Patient Safety Goals

- **Improve patient safety and reduce errors throughout the testing cycle**
 - **Focus on the pre-analytic and post-analytic phases of testing**
 - Analytic areas already heavily covered through the QC/QM process
- **Explicitly integrate patient safety activities in the LAP process**



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10

The objectives of the Patient Safety Goals are

- to improve patient safety and reduce errors throughout the testing cycle,
 - focusing on the pre-analytic and post-analytic phases of testing as analytic areas already heavily covered through the QC/QM process, and
 - explicitly integrate patient safety activities in the accreditation process.

It is the Laboratory Director's responsibility to ensure that the Patient Safety Goals are appropriately addressed.

During the laboratory inspection, when meeting with the chief or other active member of the medical staff, the team leader should ask

- questions about the scope, quality and timeliness of laboratory services
- the medical staff representative for input on pathologist participation in institutional quality management (performance improvement) and patient safety activities.

The discussion should include all laboratories being inspected, including special function and satellite laboratories.

Impact on Laboratory

- **Goals help organize what many labs are already doing**
 - Many QM plans already address PSGs
- **Allows for identification of gaps**
 - Labs may be monitoring many indicators, but all may pertain to the same PS goal
 - See Attachment A PSG Indicator audit



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11

These goals help organize what many labs are already doing in the area of patient safety, and encourage the identification of gaps.

Many QM plans already address PSGs.

All labs are monitoring quality indicators, some MANY indicators, but all these indicators may pertain to the same PS goal.

Attachment A, which is an example QM Plan PSG Indicator Audit tool.

- This example lists, by lab section, the indicators one lab is monitoring.
- The lab has identified which PSG is being addressed by each indicator.
- This example clearly shows that quality indicators are present for all 4 goals.

You could do such an assessment of your own quality indicators and processes.

Patient Safety and LAP Checklists

- Checklist questions related to patient safety are found throughout LAP checklists
- Definition of “Safety”
 - Broad term - all QC measures can be claimed to be in the name of patient safety
 - Safety typically thought of in terms of the possibility of direct harm to the patient
 - Clearly, accuracy of testing is a patient safety issue; an incorrect result could lead to harm



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12

Checklist questions related to patient safety are found throughout LAP checklists.

Definition of “Safety”

Broad term - all QC measures can be claimed to be in the name of patient safety

Safety typically thought of in terms of the possibility of direct harm to the patient

Clearly, accuracy of testing is a patient safety issue in that an incorrect result could lead to harm

The idea of putting patient safety checklist questions in the Laboratory General Checklist is to have labs

- take a second look at their processes that are involved with the CAP Patient Safety Goals,
- to determine if any improvements are needed, and
- which aspects of the processes should be monitored.

The lab must have written documentation that it has reviewed its processes related to the Patient Safety Goals.

If the lab doesn't have such a document, a deficiency should be cited.

Patient Safety and LAP Checklists

- “Safety” depends on how harm can result to the patient:
 - Safety (classic): If not performed properly can result in direct harm to the patient
 - Inadequate skin cleansing prior to phlebotomy
 - Accuracy: If not performed properly can result in indirect harm to the patient
 - Specimen identification errors



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13

But “safety” extends beyond the **direct** impact upon a patient.

Errors in “accuracy” can also harm the patient **indirectly**.

Patient Safety and LAP Checklists

- **Accuracy as a safety issue (indirect harm)**
 - **Preanalytic issues**
 - Patient identification & preparation
 - Specimen collection, handling, & processing
 - **Analytic issues**
 - Quality control process & personnel competency
 - **Postanalytic issues**
 - Result delivery & interpretation



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14

For example, here is a list of additional situations where errors in accuracy can lead to indirect harm.

Patient Safety and LAP Checklists

- **188 Checklist Questions related to patient safety**
 - **Classic Safety** **106**
 - **Pre-analytic Accuracy** **63**
 - **Intra-analytic Accuracy** **106**
 - **Post-analytic Accuracy** **75**



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15

A quick overview of the LAP checklists noted 188 questions related to patient safety.

These were well-distributed across classic safety as well as accuracy concerns throughout the

- pre-analytic
- Analytic and
- post analytic testing process.

Overarching Checklist Requirement

GEN.20365 Does the laboratory address the current CAP Laboratory Patient Safety Goals?

- **Inside the Laboratory General (GEN) Checklist**



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16

CAP has developed a core set of laboratory Patient Safety Goals for pre- and post-analytic laboratory processes. These goals are listed in the next slides.

What the lab must do is, on an annual basis,

1. review its processes related to the safety goals,
2. determine if any improvements need to be made, and
3. make a determination as to which safety goal-related activities should be monitored.

The requirement for *annual* review is new in the October, 2007 edition of the Lab General Checklist.

The laboratory must document how it addresses these goals.

Inspectors should pay particular attention to checklist questions that address the Patient Safety Goals and communicate any findings to the inspection team leader, who will address these issues with the laboratory director.

Patient Safety Goal #1

- **Improve patient & sample identification**
 - **At the time of specimen collection**
 - **At the time of analysis**
 - **At the time of results delivery**



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17

Of the 4 goals, the lab is most likely to be currently working to improve patient and sample identification, and perhaps has for quite some time.

Patient and sample identification is a problem for many laboratories since frequently other individuals in the organization procure samples.

There should be an organization-wide determination of what constitutes acceptable labeling at the time of collection.

At the time of analysis, there must be adequate labeling of aliquots, blocks, and slides.

Improve Patient Identification

- **Is there a documented procedure consistent with good laboratory practice describing methods for:**
 - Patient/client identification
 - Patient/client preparation
 - Specimen collection and labeling
 - Specimen preservation
 - Conditions for transportation and storage before testing?
- **In multiple discipline-specific checklists**



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18

Questions to consider include:...

The relevant checklist questions are found in multiple discipline-specific checklists.

Improve Patient Identification

- Does the specimen collector positively identify the patient before collecting a specimen?

NOTE: ... In the hospital, personnel must confirm the patient's identity by checking at least two identifiers before collection a specimen. ... The patient's room number may not be used...



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19

Another checklist question asks:

Improve Patient Identification

- Is there a system to positively identify all:
 - Patient specimens
 - Specimen types
 - Aliquots at all times?
 - Lab General



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20

This one is from the Lab General Checklist

Improve Patient Identification

- Is there a system to verify and maintain the identity of the specimen throughout
 - Receipt
 - Storage
 - Processing
 - Disposition?
 - Multiple checklists



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21

This one is found on the multiple checklists.

Improve Patient Identification

Before transfusion

- **Is the recipient always identified conclusively at the bedside**
 - i.e., by checking the wristband for name and hospital number
- **Is this information matched to the unit of blood**
 - Transfusion Medicine checklist



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22

The Transfusion Medicine checklist asks:

Benchmarks Available

- **Q-PROBES™ and Q-TRACKS**
- **In public domain**
- **Attachment B contains:**
 - **A listing of past Q-PROBES**
 - **Navigation steps to find them at CAP Web site**



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23

You may wonder where benchmark can be found to help monitor and assess compliance with the Patient Safety Goals.

Patient Safety Goal #2

- **Improve the verification and communication of life threatening or life altering information regarding**
 - Malignancies
 - HIV and other infections
 - Cytogenetic abnormalities
 - Critical values



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24

The laboratory director, with input from the clinicians, should determine which results in both Anatomic Pathology and the laboratory are critical and must be reported in a way to ensure that the clinician is aware of the information.

Some laboratories utilize two methods of communication for critical anatomic pathology and cytology results. In addition to the hard copy of the results, this process includes either faxing the results to the clinician's office or calling the clinician with the results. A note may be put into the computer-generated final report stating "results called (or faxed) to Drs. X and Y" to document that this occurred.

For laboratory results, the lab director should develop a critical results list with input from the medical staff, and a policy for contacting the ordering physician and who to contact for each coverage group when the ordering physician is not on call.

What CAP inspectors will look for is documentation that the lab has taken a look at its procedures involved in reporting these tests, made improvements as it deems necessary, and, if deemed necessary by the lab director, implemented monitors of key indicators related to these procedures. The director also must decide when it might be feasible to discontinue the monitoring of key indicators.

The lab should actively consider how it conveys information regarding new or unexpected malignancies. Numerous lawsuits have resulted from a failure to timely report a life-altering diagnosis.

Many of you may need to think carefully about communicating information regarding HIV and other infections. State laws vary and you must consider how to communicate information that may not be part of the traditional paper or electronic medical record. Other considerations include state reportable diseases, certain STDs, MRSA, VRE, etc.

Improve Effectiveness of Communication

- Does the laboratory have a policy:
 - That personnel receiving verbal or phone orders must read back the entire order to verify accuracy of transcription
 - With respect to a verification “read-back” of critical values that are communicated verbally or by phone?
 - Laboratory General checklist



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25

These checklist questions address in part Patient Safety Goal #2.

Patient Safety Goal #3

- **Improve identification, communication, and correction of errors**
 - All inaccuracies documented and communicated as soon as inaccuracy becomes known
 - Amended report
 - Errors that cause material injury must be disclosed to the patient
 - If a pathologist is directly involved, the pathologist should discuss the matter with the physician who ordered the consultation to determine how best to communicate the result to the patient



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26

It is important to foster a culture that stresses the goal of identifying errors and preventing them in the future rather than punishing the people involved. Many studies have shown that the majority of errors are due to system problems. So, the laboratory director must demonstrate when errors are discovered, how they have been corrected, and what steps have been put in place to reduce or eliminate future errors.

The lab needs to consider carefully how errors are communicated, and specifically address issues of timeliness and disclosure. The time to determine what degree of patient harm requires direct pathologist- to-provider or even pathologist-to-patient communication is before a disturbing event occurs.

An ongoing QA monitor is a good consideration. What is your plan to identify discrepancies? How will they be addressed? When do they rise to the level of direct communication?

QI plans may include group discussion of different cases, a defined percentage of cases reviewed by a second pathologist, daily review of difficult cases, outside pathology diagnosis reviewed before surgery, etc. In our practice, we believe that if a discrepancy is identified on an outside pathology diagnosis, we should call the pathologist involved as a professional courtesy, tell the surgeon of the updated diagnosis, and request that the surgeon tell the patient.

Since many errors detected in the laboratory are due to problems in other departments, it is important to demonstrate that the lab is working together with others in the institution.

In short, labs must think through how to handle mistakes/errors when times are calm.

Patient Safety Goal # 4

- **Improve coordination of the laboratory patient safety role within healthcare organizations**
 - **Nursing**
 - **Administration**
 - **POCT testing personnel**
 - **Providers**
 - **Exchange of information & review by relevant parties**



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27

Since many errors detected in the laboratory are due to problems in other departments, it is important to demonstrate that the lab is working together with others in the institution.

It is recommended that the Laboratory Director attempt to place a member of the laboratory staff on institutional patient safety committees.

Assessment Activity

- See Attachment C
- Tool for assessing your lab's compliance with checklist questions related to PSGs



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28

Attachment C is a tool you can use to assess your lab's compliance with checklist questions related to PSGs. Inspectors may ask how you specifically address an individual checklist item.

What Will Inspectors Look For?

- Does QM plan address PSGs?
- Is lab monitoring QI indicators that relate to PSGs?
- How is lab incorporating PSGs into policies, procedures, monitors and processes?
 - Is patient safety improving?



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29

This slide lists some of the questions inspectors will be asking themselves and may ask you during an interview session regarding compliance with patient safety goals.

- Does the QM plan address patient safety goals?
- Is the lab monitoring QI indicators that relate to patient safety goals?
- How is the lab incorporating patient safety goals into policies, procedures, monitors and processes?
- Most importantly... Is patient safety improving? What is the lab doing to improve its processes?

Assessment Activity

- See Attachment D
- Tool for assessing the incorporation of PSGs into own QM plan, policies, procedures, processes



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30

Attachment D is another audit worksheet you can use to evaluate how your lab addresses each PSG. This tool will help you assess which processes, policies and procedures might require revision to optimize your compliance with each Patient Safety Goal.

The Patient Safety Plan

Wrapping it All Together

(Attachment E)

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31

See attachment E provides you with information on the CAP Laboratory Patient Safety Plan.

You can find these plans at the CAP Web site by typing “safety plan” in the search box at the home page.

The Patient Safety Plan is really just a place to wrap together your patient safety activities is another way to document how you are addressing these goals.

Summary: Key Points

1. Explained the Patient Safety movement and its impact on labs
2. Discussed how to comply with the CAP inspection checklist questions that address the Patient Safety Goals
3. Discussed methods of how to assess the compliance of your QM plan with the Patient Safety Goals



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32

So, what we discussed today. Let us summarize the key points of today's audioconference:

We have:

1. Explained the patient Safety movement and its impact on labs
2. Discussed how to comply with the CAP inspection checklist questions that address the patient Safety goals.
3. Discussed methods of how to assess the compliance of your QM plan with the Patient Safety Goals.

Resources

- **Q-PROBES and Q-TRACKS**
 - Attachment B
- **CAP Laboratory Safety Plan**
 - Attachment E
- ***Archives of Pathology* article “Patient Safety in the Clinical Laboratory”**
- **CLSI “A Key to Quality” document available January 2007**



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33

Slide 33 lists some resources to help you learn more about patient safety and safety plans.

Resources

- **College of American Pathologists**
 - Quality Management in Anatomic Pathology (2005)
 - Quality Management in Clinical Laboratories (2005)
- **Clinical and Laboratory Standards Institute**
 - HS1-A2 A Quality Management System Model for Health Care (2004)
 - GP26-A3 Application of a Quality System Model for Laboratory Services (2004)
 - GP22-A2 Continuous Quality Improvement (2004)
 - “A Key to Quality” document available January 2007



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34

STATE:

- These are additional resources to help you learn more about Quality Management.



Technical Assistance

<http://www.cap.org>

e-mail: accred@cap.org

800-323-4040, ext. 6065

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35

Slide 35 provides information about how to access the technical specialists at the College, who can assist you in interpreting the intent of a checklist question.

<http://www.cap.org> home page – “Contact Us”

e-mail: accred@cap.org and your question will go directly to the Laboratory Accreditation Program area.

Or you may call 800-323-4040, ext. 6065 8:30 – 5:00 CENTRAL time Monday through Friday, except national holidays.

You will be connected to a medical technologist in the accreditation department.

Call

- while preparing for your inspection,
- while preparing to inspect, and
- even during the inspection.

Thank You

Questions?



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36

Thank you. Are there any questions?