SURVEY READINESS – TALES FROM THE CRYPT

Transplant Quality Institute

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Disclosures

I do not have any disclosures
Learning Objectives

• Review FQAPI Survey

• Review Re-Approval Survey

• Discuss preparation strategies using worksheets

• Discuss 7 elements of compliance related to survey readiness

Jeopardy Question

• What occurred on June 28, 2007?
Answer

• What is the date the Transplant Program Conditions of Participation became effective.

http://www.superteachertools.us/jeopardyx/brandnewgame.php

CMS Survey Preparation at it’s finest
How do you know if you are ready?

**What does readiness look like?**
- Data are aggregated and analyzed
- Results of data analysis are communicated and acted on
- Committee structure is conducive to communication from leaders to program staff and back up the ladder
- Staff members are able to talk about patient safety and quality goals – and what the center/program is doing about them
- Workers are aware of the program as a whole, not only their niche
- Your staff members are familiar with the regulations and standards

**You're not ready if…**
- Your hospital isn't analyzing data, or staff isn't knowledgeable of results
- Your team isn't familiar with the quality and safety goals, or the hospital's efforts
- Workers see only their own department's function; they're not aware of the program as a whole
- They don't know the CMS language
- Staff members aren't cognizant of changes in regulations
- Staff do not understand why procedures change

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**Process for Maintaining Continuous Readiness**

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Survey Summary

FQAPI
(first 19 programs surveyed)

- Standard Re-Approval
  - 5 of 9 surveys demonstrated condition level deficiencies for QAPI
- Outcomes Non-compliance
  - 4 of 8 surveys demonstrated condition level QAPI deficiencies
- SIA
  - 1 of 2 re-survey subsequent to SIA demonstrated a condition level QAPI deficiency

Re-Approval

- ABO Verification
  - prior to incision time (for living donor)
  - prior to anastomosis (for recipient)
- Informed Consent
  - notification to patient about most recent transplant center outcomes
- Patient Selection
  - documentation of criteria used
  - psychosocial evaluation prior to listing
- Patient and Living Donor Care
  - Provided by Multidisciplinary Care Team
  - Coordinated by a physician
  - Throughout the inpatient & discharge phases
  - Process for wait list management
  - Written notification to patients about waiting list status
- Quality & Performance Improvement
  - Comprehensive & integrated into hospital plan
  - Process for adverse events

Getting ready for survey

Create a survey prep team that includes:

- Transplant administration
- QAPI
- Risk management
- Compliance
- Nursing
- Clerical
We know what to expect

- Review of transplant program policies vs CMS policy requirements
- Interview of transplant program team members
  - Transplant Physician/Transplant Surgeon
  - Transplant Coordinator
  - Staff Nurse
  - Social Worker
  - Living Donor Advocate
  - Nutrition
  - Pharmacist
  - Transplant Recipient
  - Living Donor
- Review of transplant program personnel files
- Review of patient records
- Observations in patient care areas (clinic, inpatient units, OR)
- Review of QAPI Program
Focused QAPI Requirements

- Comprehensive Plan
- Transplant Specific
- Incorporated into the Hospital/Institutional Plan
- Objective Measures
- Performance Improvement Projects
- Follow-Up to Recommendations
- Adverse Events (thorough analysis, intervention, implementation of change)
FQAPI worksheet

- Use in the development and ongoing assessment of transplant comprehensive quality program to
- To support multidisciplinary team communication
- As a process to facilitate issue discovery
- To recognize high risk, high volume or problem prone themes
- To provide direction for initiating QAPI
- Supports management of Adverse Events

Survey Preparation – Document Prep

FQAPI

- Copies of transplant specific quality plan
- Copies of hospital quality plan
- Organization chart – identify individuals responsible for QAPI
- Patient Complaint log for past 24 months
- Log of reported adverse events for past 24 months and all documentation related to these events
- Indicators, measures, monitored items under surveillance for all phases of transplant for the past 3 years.
- Quality reports (dashboards, scorecards, benchmarks, comparative national reports, data)
- Policies: complaints, adverse events and other reportable occurrences
- Copies of any contracts with external parties

Re-Approval

- Lists of Transplant Candidates, Recipients and Living Donors
  - List of Organ Recovery and Organ Offers
  - Program Administration: Policies, Procedures, Personnel, and QAPI

- Remember these survey teams have transplant experience

BE PREPARED
Keep it organized

• Keep Licensure, certifications and continuing education records current
• Be familiar with the CMS process requirements and program polices
• Policies should be consistent with CMS requirements
• Practice must be consistent with your policies

How to Be Prepared

• Documentation must be complete for all phases of care and must provide evidence of compliance to the CMS standards
• Be familiar with your program’s QAPI initiatives (performance measures, PI projects, process for addressing adverse events)
• Review “thorough analysis” of adverse events
  • Analysis Depends upon severity, risk and other factors
Adverse Event Thorough Analysis

A typical investigative process includes:
- Adverse event awareness (notification / discovery / identification)
- Form team or assign responsible staff to gather facts
- Gather facts (what happened, when, where, why, how, who was involved: patient, staff, family)
- Document any equipment involved or care environment concerns
- Develop a timeline as far back as possible to capture all relevant facts
- Conduct interviews with relevant internal staff
- Conduct interviews with relevant external groups
- Identify the process(es) that may be involved
- Identify policy / procedures that may be involved
- Report facts and details to Analysis team

How must the transplant analysis differ from the hospital analysis?

- **Hospital Examples**
  - **Falls:** investigate, analyze, take systemic action to reduce harm throughout the organization
  - **Near Miss:** investigate, analyze and take systemic action to prevent harm throughout the organization

- **Transplant Program Examples**
  - **Falls:** identify involved transplant patients or living donors, report to hospital system, analyze to determine if any transplant practices were involved, take action toward transplant policies and work with hospital on hospital policies.
  - **Near Misses:** identify, report to hospital system, analyze transplant practices involved, work through transplant pharmacist and with the hospital to improve processes (immunosuppression is normally unique to transplant programs).
How must the transplant analysis differ from the hospital’s analysis?

**Hospital Examples**

- **Harm/Death**: investigate, analyze and take immediate action to address cause or contributing factors throughout the organization

**Transplant Program Examples**

- **No Harm**: identify, report to hospital system, analyze, take action by working with hospital to improve the process involving transplant patients and living donors, (delayed labs related to immunosuppression increases the risk of harm to the patient / graft survival).
- **Harm / Death**: may follow the hospital processes with a root cause investigative process followed to determine cause or contributing factors – transplant should take action in transplant practices and policies. Ensure appropriate external reporting is performed.

Worksheet Methodology

- “Tracer” methodology
  - To provide an accurate assessment of the systems and processes for the delivery of care, treatment and services
  - Learn from individuals directly involved in the providing receiving services about how the process works
  - Retrospective-learn more about why a process didn’t work or was successful
  - Prospective-evaluate process identified as problematic, determine current practice around new regulatory standards, evaluate high risk population or processes with poor outcomes
Survey Day

Team Preparation

- Where will you house the surveyors?
- Who will scribe?
- How will you notify your team and institution?
- Do you have a plan for end of day and end of survey communication?
- Do you have survey team escorts identified?
- Have you prepared team members that may be interviewed?
- What is your plan if critical team members are absent?

Do you have an effective Compliance program?

• What is it?
  • Effective program that prevents and detects issues/violations
  • Defines expectations
  • Demonstrates program commitment to compliance
  • Encourages issue reporting
  • Provides a mechanism for constant monitoring
  • Recommended by government

• Who needs one?
  • Transplant programs!!!!!!
Role of Effective Compliance in Survey Readiness

1. Implementing written policies, procedures and standards of conduct.
2. Designating oversight
3. Conducting effective training and education.
4. Developing effective lines of communication.
5. Conducting internal monitoring and auditing.
6. Reporting and Investigation.
7. Responding promptly to detected offenses and undertaking corrective action.

Implementing written policies, procedures and standards of conduct.

- Policies and Procedures
- Senior leadership endorsed/approved
- Follow institutional template
- Periodically reviewed and revised
- Responsible party is defined
- Education is provided to all affected staff
- Ongoing evaluation/revision
- Do not duplicate what might be already in place
Designating oversight

- Executive Committee/Individual Role
- Audit and Compliance Committee
- Compliance Officer/Coordinator
- Compliance Committee/other similar committee
- Other Committees (quality committees/subcommittees)
- Distributed Compliance Documents
- Subject Matter Experts

Conducting effective training and education

- Role of Compliance Officer/Coordinator in developing
- Specific to roles and responsibilities
- Use training to focus on key risk areas
- Education is essential to reinforcing importance of compliance program
  - Everyone – 1 hour
  - High risk areas – 3 hours or more
- Other required by role
Conducting internal monitoring and auditing

- Leverage existing resources on auditing and monitoring activities
- Define for your program the difference between auditing and monitoring
- Annual Plan is developed from a risk assessment and includes reviewing previous audits, monitors and other pertinent internal and external information
- Addition of ad hoc projects
- Concurrent vs. Retrospective
- Sharing results across the organization

Reporting and Investigation

- Much of this is more related to compliance within the institution/hospital
  - Mechanism to report matters anonymously, ie: hotline
  - Internal vs. external
  - Caller knows how to receive updates and information related to their matter
  - Electronic tracking of investigations and results
  - Non-retaliation policy
  - Confidentiality and Anonymity
  - Process for triaging investigations
  - Considerations for attorney client privilege should be given to high risk and/or sensitive matters
  - Team/committee to conduct/review investigations
  - Investigators should be trained in procedures related to interview~objective methodologies, where applicable
  - Investigations are confidential
Responding promptly to detected offenses and undertaking corrective action

- Plan for non-compliant behaviors
- Fair and Consistent
- Reportable to outside agency (UNOS)
- Internal Investigation
  - Is it really a problem?
  - How serious is it?
  - Are there enough facts to investigate?
- Consult Audit/Risk Management
- Contact Legal Counsel
- Interviews and Discovery
- Assess Findings
- Revise/Create Policy/Procedure
- Follow up review

Survey Readiness

It makes sense, doesn’t it? Hospitals should be ready for examination without notice. After all, every patient deserves our best. No one in your organization would disagree with that. But it’s not just a matter of doing your best to deliver quality care. The snag is ever-changing regulations. Whether you’re accredited by UNOS, FACT, the Joint Commission or subject to a review against the CMS Conditions of Participation, you face a huge challenge in assuring your organization is always ready for unannounced survey.

A QHR White Paper: Maintaining Readiness for Unannounced Surveys
– Kaye Nance, Linda Almond Director Patient Services QHR Consulting
References

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- Joint Commission Resources on Continuous Service Readiness
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- October 24, 2008 CMS Memorandum on Organ Transplant Program State Operations Manual