

Texas Department of State Health Services

Perinatal Quality Assessment Performance Improvement, Patient Safety Overview

Designation Unit EMS-Trauma Systems Section Consumer Protection Division

Goal

Establish a consistent structure and processes for the Maternal and Neonatal Quality Assessment, Performance Improvement, Patient Safety Plan.



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Objectives 1 Review the structure and processes for a successful QAPI, PS Plan 2 Review the elements of a QAPI Patient Safety Plan 3 Describe screening events, level of harm, and levels of review 4 Expectations of the QAPI PS Oversight Process / Committees 5 Examine what is needed to demonstrate event resolution 6 Examine how the QAPI, PS documents are integrated into the site survey planning process.



Maternal Rule Requirements

The written Maternal Program Plan must be reviewed and approved by Maternal Program Oversight and be submitted to the facility's governing body for review and approval. The governing body must ensure that the requirements of this section are implemented and enforced.

The facility must demonstrate that the maternal QAPI Plan consistently assesses the provision of maternal care provided. The assessment will identify variances in care, the impact to the patient or level of harm, and the appropriate levels of review.

This process will identify opportunities for improvement and develop a plan of correction to address the variances in care or the system response. An action plan will track and analyze data through resolution or correction of the identified variance.

Maternal facilities must review their incidence and management of placenta accreta spectrum disorder (PASD) through the QAPI Plan and report the incidence and outcomes through Maternal Program Oversight.

Neonatal Program Oversight

Neonatal Program Oversight--A multidisciplinary process responsible for the administrative oversight of the neonatal program and having the authority for approving the defined neonatal program's policies, procedures, and guidelines for all phases of neonatal care provided by the facility, to include:

- defining the necessary staff competencies,
- · monitoring to ensure neonatal designation requirements are met, and
- the aggregate review of the neonatal Quality Assessment and Performance Improvement (QAPI) Patient Safety (PS) initiatives and outcomes.

Neonatal Program Oversight may be performed through the neonatal program's performance improvement committee, multidisciplinary oversight committee, or other structured means.

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Neonatal Program Plan

The facility must demonstrate that the neonatal QAPI Plan consistently assesses the provision of neonatal care provided.

The assessment must identify variances in care, the impact to the patient or level of harm, and the appropriate levels of review.

This process must identify opportunities for improvement and develop a plan of correction to address the variances in care or the system response.

An action plan will track and analyze data through resolution or correction of the identified variance.





TEXAS

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What is Quality Care?



The Institute of Medicine defines health care quality as the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

Regulations are designed to maximize the quality and safety of health care services, maximize access to healthcare, and promote efficiency.

Quality assessment performance improvement relies on *data*.











	Culture of Safety			
	Change in	Change in Institutional Culture		
	Foster	Foster Environment for Safety and Reliability		
	Remove	Remove the "Culture of Blame"		
TEXAS Health and Human Services Texas Department of State Health Services	Promote	Promote "Safety" and the Culture of Reporting		

Culture of Safety

Resilience

- Team-Based Training
- Executive Safety Rounding
- Unit-Based Champion / Safety Teams 2 Pt. ID; Hand-off; Bed-side Report
- Defined Checklists
- SBAR
- Just Culture Accountability System Issues
- Engage All Levels of Staff
- Safety Briefings



Toolkit for Improving Perinatal Safety | Agency for Healthcare Research and Quality (ahrq.gov) Learn About the Comprehensive Unit-based Safety Program for Perinatal Safety | Agency for Healthcare Research and Quality (ahrq.gov)









Program Plan – Structure

EBP Standards of Care / Program Management Guidelines

Oversight and Authority

Data Management

Physician / APP Credentialing

Staff Education and Credentialing Requirements

Integration of Pharmacy, RT, Anesthesia, Surgery, Radiology Guidelines

Benchmarking / Collaboratives

Public Education / Outreach

Disaster Integration

Perinatal Care Regions Collaborative Practices

Maternal/Neonatal Program Oversight

Program Oversight

Establishes the Perinatal Culture

- Defines and Approves Program Plan and QAPI PS Plan
- Approves Management Guidelines
- Reviews Compliance to Designation Requirements
- Focuses on Hospital System Performance
- Reviews Identified "Perinatal Dashboard" of selected QAPI PS Elements monthly, quarterly, annually
 - Neonatal Events
 - Maternal Events



QAPI Roles and Responsibilities

QAPI PS Roles & Responsibilities

Administrator

Commitment

- Hospital Commitment
- Leadership
- Authority and Scope
- Hospital Integration
- Funding
- Resources
- Contract Metrics
- Transfer Agreements

Texas Department of State Health Services

QAPI PS Roles & Responsibilities

Medical Director Commitment

- Authority and Oversight
- Program Plan
 - Responsible for All Phases
 of Care
 - Responsible for Management Guidelines
 - Best Practice Guidelines

Responsible for QAPI

- Chairs Perinatal Secondary Level of Review, M&M, Referral to Peer Review & Program Oversight
- Defines Action Plans
- Ensures Event Resolution

epartment of State



QAPI PS Roles & Responsibilities

Program Manager / Director

Commitment

- Authority and Oversight
 - Primary Level Of Review
 - Minutes & Tracking of QAPI Activities
 - Operationalize Action Plans
 - Daily, Weekly, Monthly, Quarterly, Annual Reports
 - Data Management
 - Confidentiality
 - Reporting Action Plan Data

- Prepares for Committees
- Minutes / Attendance
- Monitors Program Designation Criteria Requirements
- PCR/RAC Participation
- PAC Meetings
- Disaster Management



Summary – Establishing the Structure

- Leadership
- Structure Organizational Chart, Job Descriptions
- Process Program Plan
- Written QAPI Plan
- Culture of Safety
- Equity







QAPI PS Plan

- Scope and Authority
- Links with Program Oversight Process
- Events or Variations from Standard of Care System or Clinical
 Standardized Event Reviews or "Triggers"
 - System Variations
 - Core Measures
 - Benchmarking Elements (Collaboratives)
- Designation Requirements
- Processes for Event Identification
- Validation, Documentation, Define Level of Harm
- Levels of Review
- Opportunities for Improvement
- Action Plan Development
- Tracking Action Plan and Analyzing Data
- Program Oversight Committee
- M&M / Program Peer Review
- Event Resolution

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(Child Health Corporation of America, Vermont Oxford Network and Institute for Healthcare Improvement)

(Maternal Quality Improvement Program)

Perinatal Progression of Care

QAPI Plan Continuum of Care

- Pre-Hospital / Transfers
- Emergency Care
- Labor and Delivery
- OR / Anesthesia
- OB ICU/Neonatal ICU
- Pharmacy
- RT
- Radiology
- Specialty Services / Psychosocial Support

- Nutrition Services
- Lactation Counselors
- General Unit / Support Services
- Discharge Planning
- Rehabilitation

Perinatal QAPI PS Plan

Structure of Event Review

- Event Impact on Patient = Level of Harm
- What Led to Event
- Validation and Documentation
- Levels of Review
- Identify Opportunities for Improvement
- Creating Action Plan (Desired Change)
- Tracking Action Plan's Outcomes
- Event Resolution



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Management Guidelines Institutional Specific Written Set of Evidence Based **Management Guidelines** Recommendations • Clinical Practice Guidelines (CPG) Assist with Clinical Decisions • Evidence-Based Guidelines (EBG) • Decrease Variances in Practice Best-Practice Guidelines (BPG) • Establish Performance Benchmarks • Grades for Supporting Evidence • Level I – Minimum of 1 **Randomized Controlled Trial** Level II – Observational Design Level III – Expert Consensus

Established Management Guidelines

- Evidence of Education and Training
- All Staff and All Areas Providing Care
- Resources Required Available
- What is Monitored to Validate Compliance?
- How is Non-compliance Managed?



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Required Maternal Management Guidelines

- Behavioral Health Disorders
- Discharge Planning and Follow-up
- Disaster Response Specific to Mothers and Babies
- Resuscitation
- Hypertensive Disorders
- Massive Transfusion Guidelines
- Obstetrical Hemorrhage
- Placenta Accreta Spectrum Disorder
- Sepsis or System Infection

- Shoulder Dystocia
- TOLAC Immediately Available Response Guidelines
- Level III Facilities MFM Consult and Response Guidelines
- VTE
- Telemedicine Utilization
- Transfer Guidelines
- Bereavement Guidelines
- Lactation Guidelines

Neonatal Required Management Guidelines

- Neonatal Resuscitation
- Transfusions
- Nutrition
- Transfers
- Psychosocial
- Telemedicine
- Retinopathy Prematurity Screening
- Lactation



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Maternal Screening Events

- Adherence to Policies / Procedures
- Maternal Deaths
- Transfers
- Resuscitation Events
- Breastfeeding / Lactation
- Emergency Cesarean
- Imaging Initial Read/Final Read Variances
- Lack of Pastoral/Spiritual Care
- Complications

- PASD Screening, Management, Outcomes
- Telehealth Response
- Level III MFM Response Guidelines
- TOLAC Physician Immediately Available Response
- Imaging Interpretation of CT, MRI, Echocardiography - Appropriate for Patient Condition
- Unplanned or Unexpected Admission to the ICU or OR

Maternal Screening Events

Texas Collaboratives of Health Mothers and Babies (TCHMB)

- Obstetrical Hemorrhage
- Perinatal Depression
- Reduction in Racial/Ethical Disparities
- Thermoregulation

Texas AIM

- Obstetrical Hemorrhage
- Severe Hypertension
- Obstetrical Care for Women with Opioid Use Disorder

ACOG Practice Bulletin (203) Chronic Hypertension in Pregnancy ACOG Practice Bulletin (222) Gestational Hypertension and Preeclampsia

Joint Commission

- Elective Delivery
- Cesarean Section
- Exclusive Breast Milk Feeding
- Unexpected Complications in Term Neonates
- Reduce Likelihood of Harm Related to Maternal Hemorrhage
- Reduce the Likelihood of Harm Related to Maternal Hypertension/Preeclampsia

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TexasAIM Hypertensive Dashboard (Example)

	1 st Quarter	2 nd Quarter	3 Quarter	4 th Quarter
Total Birthing Mothers	100			
Total with Hypertension	15/100			
Preeclampsia	5/15 hypertensive			
Eclampsia	5/15 hypertensive			
Antihypertensive within 30 minutes	11/15 hypertensive			
Antihypertensive within 60 minutes	4/15 hypertensive			
Serial BP checks	80/100 birthing			
Patient education	15/15 hypertensive			
Family education	12/15 hypertensive			

Neonatal Screening Events - All Facilities

- Accuracy of Medical Compounding
- Adherence to Policies / Procedures
- Blood Administration
- Neonatal Deaths
- Transfers
- Resuscitation Measures and Outcomes
- Changes in Initial Imaging Reads

- Pastoral/Spiritual Care Availability
- Urgent Response Request Response Times
- Speech, Occupational or Physical Therapy Consult Response
- Lactation Support Availability
- Telehealth / Telemedicine Services
- Retinopathy of Prematurity Evaluation and Referral

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Neonatal Screening Events

- TCHMB
 - Infant Mortality
 - Thermoregulation
 - Neonatal Transitions in Care
- Joint Commission
 - Breastfeeding / Human Milk
 - Endotracheal Intubation
 - Evidence-Based Guidelines
 - Exclusive Breastmilk Feeding
 - Feeding Techniques
 - Hospital Acquired Infection

- Joint Commission Cont'd
 - Infant Mortality / Morbidity
 - Medication and Oxygen Admin.
 - Newborn Safety
 - Readmission
 - Nosocomial Infections
 - Resuscitation Events
 - Skin-to-Skin
 - Social Services Availability
 - Thermoregulation
 - Umbilical Line Placement
 - Unexpected Complications

Vermont Oxford Network (VON)

- Brain Care
- Antibiotic Stewardship
- Chronic Lung Disease
- Cystic Periventricular Leukomalacia
- Golden Hour Interventions
- Human Milk
- Hypoxic Ischemic Encephalopathy (HIE)
- Infections
- Initial Resuscitations
- Length of Stay
- Meconium Aspiration
- Mortality and Morbidity

- Nosocomial Infections
- Necrotizing Enterocolitis (NEC)
- Patient Care Resources Limited Settings
- Pneumothorax
- Readmissions
- Retinopathy of Prematurity (ROP) Evaluation
- Seizures
- Severe Intraventricular Hemorrhage (SIVH)
- Surgery
- Therapeutic Hypothermia
- Transfers
- Transitions in Care

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Adverse Events

Events that produce unintended harm to the patient by an act of commission or omission rather than disease or condition of the patient. (National Quality Forum Definition)

Neonatal - An injury, large or small, caused by the use or non-use of a drug, test, or medical treatment.

Patient Safety 2024



https://www.jointcommission.org/-/media/tjc/documents/standards/nationalpatient-safety-goals/2024/npsg_chapter)

Incorporate Joint Commission Patient Safety Standards

Improve the accuracy of patient identification

Improve the effectiveness of communication among caregivers

Improve the safety of using medications

Reduce patient harm associated with clinical alarm systems

Reduce the risk of risk of health care – associated infections

Hospital identifies safety risks inherent in its patient population

Improve health care equity

Rural Perinatal Health

Alliance for Innovation on Maternal Health Program: HRSA in Collaboration with ACOG

Perinatal Quality Collaboratives - CDC

Maternal Mortality Review Committee – Standardized Data System to Support MMRC

Quality Reporting – 2019 Core Set – 12 Measures

Telehealth and Related Technology

Restoring Access to Maternity Care in Rural America | Commonwealth Fund

Rural Maternity and Obstetrics Management Strategies (RMOMS) Program | HRSA









Levels of Harm Definitions

No Harm – Standard of care provided with some deviations with no impact to the patient.

No Detectable Harm – Event occurred but did not reach or impact patient; no treatment necessary.

Minimal Harm – Impact to patient, is symptomatic, symptoms are mild, loss of function is minimal or intermediate but short term, and no or minimal intervention *necessary* (extra observation, investigation review, minor treatment) is required.

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Levels of Harm Definitions

Moderate Harm – Patient is symptomatic, requiring an intervention (e.g. operative intervention, therapeutic treatment), and increase in the length of stay, or causing long term loss of function; requires higher level of care; expected to resolve prior to discharge

Severe Harm – Patient is symptomatic, requiring *life-saving intervention* or major **surgical/medical critical care intervention**, shortening life expectancy or causing major permanent or long-term harm or loss of function; error in judgment, deviation from practice, system delays; impact quality of care; quality of life

Death – death was caused or brought forward by the event

VON Neonatal Level Of Harm Definitions

Category E	Category F	Category G	Category H	Category I
Contributed to or resulted in temporary harm to the patient and required intervention	Contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization	Contributed to or resulted in permanent patient harm	Required intervention to sustain life	Contributed to or resulted in patient's death







Perinatal QAPI PS Processes

- How and When Events are Identified; and Common Sources
- Move from Identified Event Validated Documented Event
- Impact to the Patient or Level of Harm
- Structure and Processes for Levels of Review
- Level of Harm Assists with Urgency of Review
- Define Processes for Appropriate Cases for
 - Primary Level of Review (Program Manager)
 - Secondary Level of Review (Medical Director)
 - Tertiary Level of Review (Medical Director Operations, M&M, Peer Review)

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Levels of Review

Primary Review

Event Validation / Documentation – Program Manager

- Evaluate Concurrent Processes
- Validation of Event, Impact to Patient or Level of Harm, Patient Status
- System Issue or Patient Impact
 - Level of Harm
 - Where did it occur? Who was involved? What were the surrounding circumstances?
- Management Process Written in QAPI PS Plan
 - System Issues with No Harm to Patient Program Manager
 - Patient Impact with Harm Medical Director Must Review
 - Physician Issues Medical Director Must Review / Address
 - Complications, Failure to Provide Standard of Care, Death Medical Director











Corrective Action Plan = Opportunity Identified Action Plan Selective Risk Reduction • Protocol, BPG Review / **Development / Procedure** Revision Education – Content, Targeted Participants, Subject Matter Expert QAPI Workgroup • Dashboard Review • Referral xas Department of State Health Services 72
QAPI PS Action Plan Follow-Through

Implementation of Action Plan

- Process to Measure Achievement
- Achievements Compared to Desired Goal
- Continual Monthly Data Analysis Shared at the Operations Committee
- Desired Goal Reached for Three Consecutive Months or Selected Time
- Re-visit in a Defined Timeframe
- If Continued Success Event Resolution Achieved
- Hardwire the Change







Successful Committee Meetings

- Defined by Program Oversight
- Scope of Work Plan
- Meeting Frequency Plan
- Defined Reporting Structure Plan
- Integration with Other Departments
- Established Quality and Safety Standards
- Data Driven Metrics

- Identifies Opportunities
 - Develops Targeted Interventions
 - Monitors and Analyzes Effectiveness
 - Integrates Change Management Theories
 - Integrates Transformational Principles
- Coordinates External Collaboratives
- Ensure Dissemination of Information
- Bi-Directional Flow of Information

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Multidisciplinary QAPI PS Review

- Led By Medical Director
- Program Manager Co Leads (Committee Organization)
- Multidisciplinary
- Physician Liaisons
- Nursing Leaders
- Support Clinical Services
- All Departments Providing Care

Morbidity & Mortality Review



Selected Cases

System Response Patient Pre-Existing Condition Processes of Care: Coordination of Care, Timeliness of Care Physician Nursing

Opportunities For Improvement

Coordination Through Phases of Care Medical Staff Nursing Staff Support Staff Processes of Care Regional System



Maternal/Neonatal Program Oversight

Agenda

- Welcome / Introduction
- Minutes / Attendance
- Statistical Report
 - Number of Perinatal Cases
 - Number of Admissions
 - Number of Transfers
 - Distribution of Admissions L&D, Unit, ICU, Other • Dashboard
- Perinatal Designation Requirements Compliance
- Quality Assessment Performance Improvement Initiatives Action Plans Defined Through QAPI Review Process
- Old Business
- New Business
- Open Discussion
- Action Items
- Priorities for Next Committee
- Next Committee Date
- Adjourn

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endal

1.

2.

3



QAPI: Change Agent Purpose of QAPI - Identify Variances in Care and Correct Processes of QAPI - Produce Change Change in Care Practices Changes in Continuum of Care Promotes Safety Culture Change in Organizational Processes IMPROVES CARE

Perinatal QAPI PS: Event Resolution



QAPI PS Processes Changed Outcomes

Desired Measurable Difference

Desired Outcome Reached

Rate of Occurrence Changed

Documented Compliance Achieved

Defined By Medical Director / Committee







Perinatal QAPI PS Plan

Data Management

- Confidentiality and Security
- Data Definitions
- Data Storage (Electronic)
- Who Has Access to Data
- Standardized Reports
 - Dashboards
 - Designation Requirement Reports
 - Follow-up Action Items



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Perinatal QAPI PS Plan Revisions

Minimum of Every Three Years

Change in Program Manager or Medical Director

Upgrading Level of Designation

Downgrading Level of Designation

Change in Hospital Ownership or Physical Location





Perinatal Care Regions

Aggregate Multicenter Data Collaboratives

Community of Interested Colleagues With Common Goal

Analyze Patient Selection, Processes of Care, and Outcomes

Cultural and Political Benefits of Relationship Building

Potential to Secure External Funding with Multi-Institutional Participation

Data

Leadership

Shared Vision

Multidisciplinary



Planning for Perinatal Site Survey

Prepare QAPI PS Documents

Meeting Minutes

- Complete, Signed by Medical Director, Dated, Attendance Requirements
- Minutes Reflect Discussion
- Meeting PowerPoint and Data Available

Case Reviews

- Timely, Complete, Action Plan Defined, Tracked, Analyzed to Event Resolution
- QAPI PS for Each Case in a Folder with All Relevant Documents
- Staff Serving as Navigators Can Explain all Processes
- Prepare for In-Person and Virtual Surveys



Thank you!

- Adrienne Kitchen
- Rebecca Wright
- Celia Cantu
- Debra Lightfoot
- Dorothy Courage
- Elizabeth Stevenson
- Jorie Klein

Special Recognition

- Jaime Martin
- Kate Drone
- Dara Langford
- Patrick Ramsey, MD
- Emily Briggs, MD
- Sadhana Chheda, MD
- Cynthia Blanco, MD



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