Clinical Initiative Review Process

V3.1 – 8.13.2018

The City of Austin / Travis County EMS System

Table of Contents

Process Overview

The clinical practice serves as the foundation for any emergency medical services system. Our clinical practice is designed to guide the safe and effective delivery of clinical services in a manner that places the patient at the center, uses an evidence-based approach to defining care, minimizes the risk of harm to patients and providers, and seeks to provide a positive patient experience. The Clinical Initiative Review Process is intended to proactively plan for the successful implementation of clinical initiatives, identify potential challenges and unintended consequences, and evaluate the financial and operational impacts of the proposed clinical initiatives.

This process does not specifically identify the person or organization responsible for each phase. Instead, the process focuses on ensuring any new or revised clinical initiative is clinically effective, safe, feasible, appropriately prioritized, and implemented with minimal impact on the delivery of services to patients. It serves as a project planning tool for use by the applicable stakeholders involved in any new or revised clinical initiative. This process is most valuable when the initial focus is placed on prioritization of clinical effectiveness and patient safety. Once these key elements are addressed, the focus shifts to the initiative's feasibility and financial impact. When stakeholders reach consensus on these elements implementation may then occur in a manner that minimizes risk of harm to patients and providers, ensures continued delivery of clinical services to the community, and maximizes the likelihood of meeting the intended objectives.

Definitions

- Clinical – pertaining to the EMS medical practice as defined under TAC 22 Chapter 197.
- Drug/Medication – a finished dosage form containing a drug substance intended to furnish pharmacological activity or other direct effect in the diagnosis, mitigation, treatment or prevention of disease, or to affect the structure or any function of the human body.
- Initiative / Project – a proposed new or revised action, guideline, strategy, proposal, method, or device intended for the diagnosis, prevention, and/or treatment of disease or injury. For the purposes of this process, initiative and project are used synonymously.
- Medical Device – an instrument, tool, machine, software, or other similar or related article or equipment which is intended for use in the diagnosis, treatment and/or prevention of disease or injury.
- Medical Intervention – an action taken with the intent of modifying a clinical outcome (e.g. treatment) typically performed to treat or cure a condition. In some cases, an intervention is used to prevent disease or a specific condition.

Boundaries

Clinical evidence reviews and clinical priorities for all proposed clinical initiatives are collated and prioritized by the Office of the Medical Director. Evidence reviews and priorities for all proposals are then submitted to the Committee for further review and implementation. Consistent with Texas law, the ultimate approval of any new or revised clinical initiative, medical device or medical intervention lies solely with the EMS System Medical Director (Texas Occupations Code, Chapter 164.052(17)). While the ultimate approval rests with the System Medical Director, a collaborative approach with EMS System stakeholders ensures that the implementation of initiatives are vetted to address implementation concerns.

Although the expectation is for all initiatives to be subjected to the review process, there may be circumstances that require emergent implementation of a clinical change by the System Medical Director (e.g., regulatory requirements, Identified patient harm, Identified provider harm, etc.). Committee review of such items will be discussed and reviewed at the next scheduled committee meeting.

Excluded from this process are changes related to credentialing processes, minor edits to clinical guidelines and changes to patient receiving center capabilities. The operational aspects and impacts of credentialing processes remain within the scope of the Clinical Initiative Review Process.

Initiative Submission

In this phase, a new or revised clinical initiative proposal is first created. This may take the form of a new or replacement medication, equipment, clinical guideline, policy or procedure, process or function that impacts the clinical practice for the System. The proposal must directly relate to a defined clinical gap or improvement need. In some cases, the proposal may be based on a financial or operational improvement. Proposed changes intending to direct the clinical care or delivery of care to patients, capable of altering clinical care to include transportation, and those with the potential to harm patients or providers utilize this process to achieve the objectives outlined in the above Overview.

Individual providers and/or organizations that determine a problem, need, or desire for a new or revised clinical initiative are responsible to champion the specific initiative. An initiative can be introduced by agencies, providers, and others within the medical community through the submission of a new clinical proposal. Such proposals will be tendered using the appropriate submission mechanisms.

The proposal should address the following:

1. Define the identified clinical gap, patient safety concern, or clinical improvement that if left unchanged is likely to increase the risk of patient or provider harm; result in less desirable clinical outcomes; lower effectiveness of clinical care; or reduce system capabilities to provide efficient clinical services.
2. Discuss how the proposed initiative will result in decreased likelihood of harm, improved outcome, improved effectiveness, or more efficient delivery of clinical services.
3. Identify, cite and summarize the clinical literature and other scientifically credible evidence supporting the presence of the gap, patient or provider safety concern, or improvement need as well as the clinical literature and other credible evidence supporting the proposed initiative.
4. With regard to implementation of the proposed initiative, identify and discuss the:
    - Potential harm resulting from the initiative
    - Challenges associated with implementation
    - Disadvantages to implementation
    - Other alternative solutions including a rationale for the proposed initiative over these alternatives
    - System Clinical Operating Guideline and educational requirements

Initiative submissions should be based on, but not limited to the following priorities. Other low impact and easily implemented proposals may be prioritized ahead of more complex proposals or those requiring lengthy implementation.

1. Patient Harm (is occurring and this new initiative is needed to address this harm)
2. Patient & Provider Safety (current clinical practices are exposing patients or providers to unnecessary risks; the proposal seeks to reduce the risk of injury or illness to a patient or provider)
3. Errors (performance data indicates clinical errors have resulted and this proposal seeks to reduce or eliminate the errors)
4. Evidence Base (new or updated clinical evidence indicates the need for a new/revised clinical practice)
5. Cost/Waste (the proposal provides equal or superior clinical care but is intended to provide a less costly solution or reduce waste)
6. Research/Innovation (the proposal is for clinical research at the patient's side or the proposal is based on some other innovative approach to clinical care)

Roles & Responsibilities

Proposal Submitter

1. Utilizing the provided proposal submission mechanism(s), create a complete and detailed proposal for a new or revised clinical initiative
2. Address all required proposal elements
3. Submit the proposal using the defined submission mechanism(s)
4. Respond to requests for proposal refinement, reevaluation or additional information

OMD

1. Create and oversee proposal submission mechanisms
2. Define required proposal elements
3. Receive and acknowledge submitted proposals

Deliverables

A written proposal in electronic format delivered to the OMD for the next phase in the process. The proposal should include cited references and address the elements defined above and as defined in the submission tool.

OMD Clinical Evidence & Safety Review

Purpose

The initial review within the OMD will include but is not limited to identifying the clinical suitability, appropriateness, and clinical significance of the initiative based on the submitted proposal. The OMD will undertake the initial review to assess the potential of harm to patients, providers and others, clinical implementation challenges, conceivable negative effects on patients, and unintended consequences impacting the clinical practice.

Further, the review will encompass any potential overlaps, redundancies, or conflicts from other committees or processes that could impact the submitted proposal.

Should the initiative be incomplete, devoid of supporting documentation, or leave questions unanswered, the OMD will return the proposal to the submitter for fine-tuning and re-submittal. Subsequent re-evaluation will be conducted applying the previous initial review process.

Roles & Responsibilities

OMD

1. Review each submitted proposal
2. Evaluate submitted proposals to determine:
    a. Risk of harm to patients, providers or others
    b. Clinical effectiveness
    c. Published supporting or opposing clinical evidence
    d. Risk of negative clinical effects
    e. Unintended consequences
    f. Implementation challenges
    g. Benefit over superior or alternative solutions
3. Prioritize the submitted proposal
4. Forward each submitted proposal and the OMD proposal review to the Clinical Initiative Review Committee (CIRC)

Deliverables

Perform a clinical literature review as needed to evaluate the proposal's clinical effectiveness, clinical safety, potential harm to patients or providers, published reports of harm, and regulatory requirements associated with the proposal.

The initial OMD review will be documented with sufficient clinical rationale for consideration by the Clinical Initiative Review Committee (CIRC). The OMD will prioritize the proposal and forward to the CIRC. No initiatives shall be submitted to the CIRC without the initial clinical effectiveness, quality and patient safety review by the OMD.

Clinical Initiative Review Committee (CIRC) – Stakeholder Review

Purpose

The CIRC will receive the proposed initiative using the designated priority level as assigned by the OMD.

The CIRC will undertake a comprehensive review of the proposal to determine the impact on individual stakeholder agencies and the EMS System overall. First Responder service delivery impact is an important consideration for any new field delivered clinical initiative and consequently the committee will consider this impact in its review.

Such a review shall include assessing the feasibility of the initiative, the challenges of implementation, potential barriers, impacts on budgets, and associated supporting operational and clinical elements such as:

Policy/COG changes
Training/Education needs
Infection Prevention implications
Credentialing criteria
Documentation requirements
Data capture
QI/PI review

The structure of the CIRC employs the diversity of the stakeholders within the system and requires a willingness of the committee participants to grasp the impact any and all such initiatives can have on individual agencies. Such an appreciation dictates the need for a comprehensive review that should utilize decision management tools that can effectively and efficiently scrutinize the proposal to uncover the actual implementation concerns, costs, and needs of each stakeholder organization and the overall system.

Stakeholders should approach the evaluation process anticipating the long-term impact and the potential for unintended consequences to the system and their individual entities. Attention should be given to the timetable for such initiatives. There can be concomitant and competing priorities that should be considered and accounted for in the review process.

The ultimate review focus should be on the feasibility of implementation with emphasis on the benefit (or harm) the proposal provides to future patients. Rejection of proposals should not be driven by personal preference or bias. Proposals should not be outright rejected for a lack of funding, but should be reviewed with the desire to seek appropriate financial support through the customary budgetary process. Essentially, the committee identifies potential barriers to implementation and seeks to find solutions to overcome these barriers.

Roles and Responsibilities

Committee members

1. Actively participate in scheduled Committee meetings
2. Review new or revised clinical proposals
3. Review summary documents on clinical effectiveness, evidence base, supporting documents, alternatives and potential impact on patient safety and provider safety.
4. Provide feasibility feedback with specific focus on how the proposal impacts:
    a. New/existing policies, procedures and clinical operating guidelines
    b. Training and education requirements, initial and ongoing
    c. Evaluation or testing of individual providers
    d. New/revised credentialing requirements
    e. Infection prevention and control measures
    f. Clinical documentation requirements & capabilities
    g. Data capture requirements
    h. Quality/Performance Improvement review needs
    i. Timing with other System or Organization initiatives or activities
    j. Time required to implement
    k. Need for further study, testing, field evaluation or research
    l. Long term impact on operations and budget
    m. Unintended consequences
5. Seek input from respective System Organizations and committees or councils within the member's respective organization
6. Participate in proposal discussions to determine feasibility and/or alternative solutions

7. Provide cost estimates and financial impact for initial implementation, ongoing use and other associated costs (e.g., training, monitoring, etc)
8. Provide input on operational feasibility
9. Identify and discuss potential implementation barriers and solutions for overcoming barriers
10. Define additional steps, if needed, for further review, testing or evaluation
11. Develop a high level implementation plan to include implementation goals, target milestones, timeline based on priority, and responsible staff for key implementation steps (define implementation team)
12. Communicate Committee discussions and action items with Organization leadership not represented on the Committee
13. Publish Committee meeting minutes

Deliverables

The committee will meet monthly unless no proposals are in need of review or continued discussion. In circumstances of risk of patient/provider harm or patient/provider safety, additional meetings or conference calls may be convened.

The review by the CIRC can offer one of four decisions:

1. Indicate that further study is required to determine the viability or appropriateness of the initiative. The need for additional investigation may reside with the CIRC, the OMD or returned to the initiative submitter. In general, this should only occur for low priority proposals or when a clear clinical need/gap is not identified.

2. The current initiative in its proposed form cannot be implemented however an alternative solution will be sought for high priority items.

3. Proceed with implementation and develop an action plan and timeline.

4. No clinical impact is evident.

CIRC - Define Implementation, Communicate Target Objectives, Timelines and Constraints

Purpose

Upon agreement for implementation, the CIRC will define the specifics for the proposed initiative and re-affirm or adjust the prioritization of the initiative with regards to existing initiatives and the constraints identified through the review process. The CIRC will utilize the concepts of the original submission coupled with the identified operational and clinical impact to articulate the final desired state. All reviewed clinical initiatives with estimated timelines and action items will be summarized in the meeting minutes for communication back to all Organizations within the System.

Deliverables

Develop an initiative charter which clearly states what will be the final product, identify targeted progress points of the initiative, implementation goals, and identify key human resources necessary for project implementation.

Designate personnel assignments that are multi-agency, demonstrate knowledge and appreciation for robust project management, are grounded in having the proper skill set(s) necessary for the successful implementation of the initiative.

Additionally, timelines and sequencing for critical task completion should be expressed to ensure adherence to the identified priority and impress the need for project discipline. Tools that may assist in the timeline focus include, but not limited to GANTT Charts, Critical Path Chart, and milestone benchmarks.

Implementation Team – Implement and Rollout

Purpose

The specific responsibilities of each team member should be clearly defined in the context of the initiative charter. As with any multi-functioning team, there can be overlaps in responsibilities and task assignments, and members can undertake several tasks, it is imperative that the project team be clear as to the expectations of the final product and which team member is responsible for each specific task.

While it is understood that not all initiatives will have the same depth, complexity, or range of impacts, the implementation team should avail the use of a checklist of the key clinical and operational areas to ensure that all initiatives address the potential impact in each area. If there is no impact, the checklist should note the query was expressed and the degree of the response.

Roles and Responsibilities

Implementation Team

1. Receive and review proposals and timelines accepted by the OMD and CIRC for implementation
2. Create specific implementation plans and timelines
3. Create and share a communication plan for both internal and external stakeholders
4. Refer requests for additional information or potential changes to the accepted proposals/timelines to the OMD and CIRC Chair and Vice-Chair for review and evaluation

Deliverables

Implementation for the purposes of this document is the thorough and complete execution of all that is necessary for the development, initial procurement, ongoing procurement, identifying the life cycle for replacement or enhancement, response access, required stocking levels, ensuring continuity of product availability, placement into and onto apparatus, understanding of product information from the manufacturer regarding use (IFU) which should include, storage, cleaning, disinfection, and compatibility with other ancillary devices or medications. Additionally, a communication plan that indicates what is to be communicated to both internal and external stakeholders shall be developed.
Should there be information, decisions, or organizational re-prioritizations by an agency that may result in a significant change to the initiative charter, it is imperative that any such alteration affecting the

implementation be communicated to all components of the Clinical Review Process so an informed decision can be made regarding the need to review the status of the initiative. The CIRC Chair or Vice Chair receives this information and is responsible for communicating it to the CIRC members and the OMD.

QI PI Group(s) Monitor and Measure

Purpose

In order to properly assess the impact of all initiatives, a process should be developed that monitors and measures the anticipated final product. Such a process should determine a monitoring period that captures reliable information on the execution of desired project outcome(s) and permits appropriate modification if necessary.

Roles and Responsibilities

Quality & Performance Improvement Groups

1. Define expected performance criteria (if applicable)
2. Identify required changes/additions to existing data collection tools and determine feasibility of changes/additions
3. Define quality and/or performance measures
4. Define measurement intervals to include short term and long term measurement
5. Define queries and reports as well as the distribution of reports
6. Define required surveillance to monitor for harm or other adverse events
7. Assign responsible persons and timelines for all defined quality and performance monitoring

Deliverables

The monitoring and measurement plan should include, but not limited to:

- Detailed measures and appropriate data elements
- Defined quality improvement and public information parameters
- How and who will be responsible for the Data collection process
- Required changes or additions to existing data collection tools or adjuncts.
- The frequency of measurements, timeliness of reporting, and desired in-depth analysis to determine trends which may trigger adjustments, modifications, or cancellation of the initiative.
- The ability of system components to develop specific queries and reports.
- Identification of harm or adverse effects experienced by patients and/or providers
- Determination and review of patient outcomes associated with the new/revised initiative as applicable

Additionally, the QI PI groups will evaluate this process to identify potential improvements. This effort will include descriptive data regarding the number of initiatives, committee decisions, causes for these decisions and similar data necessary to evaluate the process' performance and need for improvement.

Resources

Proposal Submission Tool/Template (TBD)

Operations / Clinical Impact Check List (TBD)

Initiative Tracking Tool (TBD)