Clinical Pathways

A User's Guide

2015

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INTRODUCTION

Senior leadership and staff at the Children's Hospital & Medical Center (CHMC) are committed to delivering the highest quality of care to children. In order to ensure that our patients receive the safest, most effective care, it is imperative that we maintain a clinical quality improvement program that:

1. Defines best practices in the care of patients at CHMC;
2. Educates providers and families about best practices;
3. Delivers decision support around best practices at the point of care;
4. Continually monitors variation from best practices and the resulting clinical outcomes; and,
5. Continually improves our care processes in response to monitoring activities and new innovations in healthcare.

Safety and effectiveness increase when staff has a common mental model for how care should be delivered and when the workflow of patient care incorporates tools that facilitate care according to this model. A clinical pathway is frequently used as a tool in quality programs to provide the model for care delivery. Clinical pathways will be a key tool in our quality improvement program to ensure that CHMC is a highly reliable and accountable healthcare organization.

The purpose of this user's guide is to outline the steps involved in developing and utilizing clinical pathways at CHMC. The audience for the user's guide includes members of the pathway development teams, individuals who will help to disseminate and implement the pathways, as well as those responsible for monitoring the uptake and impact of the pathways.

DEFINING CLINICAL PATHWAYS

A clinical pathway (CP) is a "task-oriented care plan that details steps in the care of patients with a specific clinical problem and describes the patient's expected clinical course." The term "clinical pathway" is often used interchangeably with clinical guideline and clinical protocol. While the differences between pathways, guidelines and protocols are subtle, the distinction is important. Five characteristics

of clinical pathways have been agreed upon that differentiate them from guidelines and protocols:

1. A clinical pathway is a structured *multidisciplinary* plan of care;
2. A clinical pathway details the steps in a course of treatment or care in a decision tree or other inventory of actions;
3. Clinical pathways have timeframes or criteria-based progression (i.e. steps are taken if designated criteria are met), and
4. Clinical pathways are intended to standardize care for a specific clinical problem, procedure or episode of healthcare in a specific population.

Additionally, adherence to a clinical pathway should limit unwanted or unintended variation in practice, but is not meant to be proscriptive. The clinician retains the responsibility to select the appropriate pathway for a particular patient and to use the pathway to the extent that it serves the individual patient. Clinical pathways are intended to be tools to increase clinician control over patient care, not to constrain clinical judgment. To emphasize this point, each pathway will carry the following disclaimer: "The guidance provided in this clinical pathway does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate."

GOVERNANCE OF CLINICAL PATHWAYS AT CHMC

Overarching

Central to the development and implementation of robust clinical pathways is leadership and participation from clinicians. Therefore, the governance model for the clinical pathways program at CHMC will facilitate clinician leadership of the process.

Governance will be composed of three constituents:

1. Pathway Steering Committee (PSC)
2. Pathway Development Teams (PDT)
3. Performance Improvement Team

Clinical Pathways Steering Committee

A steering committee will oversee the process of clinical pathway development as well as serve as advisors to hospital administration regarding institutional needs for support of clinical pathway development and use.

The Steering Committee will champion quality improvement through pathway development and use by:

- Identifying opportunities to enhance care through pathway development or enhancement;
- Prioritizing the use of institutional resources made available to support pathway development and use;
- Serving as advisors to pathway development teams and stewards of CHMC resources by providing oversight and guidance to pathway development teams,
- Ensuring that the numbers of clinical pathways are limited to the minimum necessary to achieve clinical improvement and standardization goals, and that the program will avoid inconsistencies, contradictions, and lack of clarity in clinical pathways,
- Establishing a familiar, consistent, reliable system of notification of stakeholders when a new pathway is developed and implemented, and
- Advising hospital administration regarding opportunities to enhance care through pathway use and infrastructure or other system changes that would support pathway use.

Steering Committee membership will include clinical leaders and key stakeholders from functional groups within CHMC who are critical to building and sustaining the infrastructure required for ongoing pathway development, implementation, evaluation and maintenance. Functional areas that will have representation on the Steering Committee include clinical decision support/informatics, web development, education, communication, and data warehousing. The Chief Medical Officer will be the Executive Sponsor for the Steering Committee.

Clinical Pathways Development Teams

The Steering Committee will facilitate the assembly of Pathway Development Teams.

Each team will have a team leader, usually a staff physician or nurse. The team leader will be the primary champion and driver of the pathway development effort. He/she will lead the team in the definition of the goals of the pathway with input

from the Steering Committee. The team leader will also direct the work of the team to ensure that these goals are met. The leader will facilitate consensus building among team members and the stakeholder groups that they represent. The team leader will brief the steering committee on the team's progress on a regular basis so that any barriers to the team's progress can be addressed.

Other members of the team will be selected by the team leader in conjunction with the Steering Committee to represent various stakeholder groups that will be using the pathway. They may include residents, fellows, nurses, general and subspecialty physicians, and representatives from radiology, pharmacy, laboratory services, or facilities management. Whenever possible, local content experts will be included in the group. If appropriate, family advisors may also be invited to participate. Team members will be responsible to provide content expertise in the development of the pathway and to help implement it within the stakeholder group they represent.
Teams also will be supported on an ad hoc basis by experts in critical appraisal and systematic review of the literature, reporting analytics, decision support, and finance.

Performance Improvement Department

Operational leadership will be provided by the Performance Improvement Department (PI) under the direction of the Chief Medical Officer or Chief Medical Quality Officer.

A PI staff member will ensure that improvement science is the foundation for all pathway development activities, and will facilitate change management, project management, and team facilitation.

Analytic and clinical abstraction support will also be provided by PI staff.

PRIORITIZATION AND SELECTION OF TOPICS

Clinical pathways will be developed to provide guidance on the management of conditions throughout the entire continuum of care (i.e., diagnosis, treatment, follow-up, and referral in ED, outpatient, and inpatient settings) as well as specific processes of care that cut across multiple conditions and care settings (i.e., diagnostic or therapeutic procedures). Given the limited resources available to

develop clinical pathways, the Steering Committee will use the following criteria for prioritizing and selecting conditions and processes for improvement:

1. Documented variation in practice
2. Adverse impact of variation on safety, clinical outcome, cost
3. Will to change – presence of a clinical champion and consensus among providers that a pathway for standardization of practice is needed
4. Clear direction for change – good evidence base or local expert consensus about best practices that should be adopted at CHMC
5. Feasibility of implementing change at CHMC
6. Likelihood that implementation of a pathway will result in improvement

The prioritization process will make use of a variety of data gathering tools, including queries of CHMC and peer data (using the CHA Pediatric Health Information System (PHIS) comparative database), limited chart review, structured brainstorming with flowcharting, provider and administrator interviews and surveys re: current challenges and opportunities, cost analysis, and review of pertinent safety reports.

METHODOLOGY

Pathways are developed and implemented to achieve specific clinical outcomes by establishing and facilitating specific approaches to care. The process of development, implementation, and monitoring will follow the Model for Improvement and the CHMC Improvement Framework.

The Model for Improvement uses three key questions to guide the improvement project:

1. What are we trying to improve (what about care delivery will improve)?
2. How will we know if a change is an improvement (what are the measures of success)?
3. What changes can we make that will result in an improvement (what are the elements to standardize and tools to introduce)?

Small tests of change are used to develop and test specific improvements prior to large scale introduction.

The CHMC Improvement Framework is intended to guide a project to a successful completion by segmenting the work into components to be reviewed and approved sequentially. The components include:

1. Plan/Define – identify the aims (outcomes) and timelines for the pathway development
2. Do/Diagnose – identify the sources of variation and the gap between current and ideal state
3. Check/Test and Implement – develop, introduce, and test the change package intended to achieve the project aims
4. Act/Sustain and Spread – disseminate the change package, monitor conformance and outcomes

Define

The Steering Committee will identify a Pathway Development Team (PDT) leader, and together they will identify other members of the team (as described above in the description of PDT composition).

The team will work with key stakeholders to understand the causes of variation, system characteristics that contribute to variation, and key areas of clinical decision making.

The input of key stakeholders and data review will be considered in the synthesis of specific aims for the project and the scope of the pathway. Three to five measures of success will be identified that will typically reflect a clinical outcome, reliability of care process, and resource utilization/cost. The measures should be linked to the specific aims for the pathway. Additionally, the scope will define the clinical settings in which the pathway will operate (i.e., inpatient, outpatient, ED, ICU, surgery, etc.) and the various phases of disease management that it will cover (i.e., evaluation and initial management, escalation therapy and long term follow-up).

A charter drafted by the team leader reflecting the agreement on the aims, scope, and measurement concept between the PDT and the Steering Committee will represent the culmination of the Define phase.

Diagnose

In-depth data analysis will be conducted to confirm the sources of variation in the care process that were identified as potential drivers in the Define phase. Local as well as national data about current management of the condition/process under consideration, including variation in care and clinical and cost outcomes, and existing guidelines and published systematic reviews on the topic will be identified and reviewed. Evidence review will be conducted for key decision points, and consensus building with key stakeholders (clinicians, nurses, and administrators) will be used when the evidence is not clear.

These data will be used to develop a proposed pathway and practice recommendations that will be tested. The pathway should be produced in a form that is best suited for the care setting (i.e. flow chart, checklist, etc.) Delivery mechanisms for the toll must also be determined based on the care setting (i.e. paper, web, and mobile application).
Key elements of the care process will be depicted in the pathway which may include:

- Main elements of initial patient assessment (i.e. history and physical exam, initial laboratory or imaging studies)
- Important decision points in management
- Anticipated care that could be routinely implemented at various points in management (i.e. medications, testing, and consultations)
- Admission criteria
- Discharge criteria
- Discharge planning (i.e. home care/equipment, follow-up appointments, pending labs, repeat studies, prescriptions)

Decision support mechanisms (i.e. order sets, alerts, etc.) to support the implementation of the pathway should be identified in this phase and the team should begin plans for collecting data for pilot testing the performance measures identified in the Define phase.

An executive summary created by the PDT will discuss the pathway objectives, recommendations, rationale, metrics, and evidence.

Agreement on the pathway proposal between the PDT and the Steering Committee, as well as the decision support tools and data collection and analysis plan will represent the culmination of the Diagnose phase.

Test and Implement

Prior to large scale implementation, the proposed pathway and decision support tools will be tested for feasibility and usability and iteratively enhanced through small tests of change as appropriate. This may require that the pathway may be tested in a single practice or care site with manual data collection and frequent feedback cycles from frontline caregivers. Measures of conformance as well as outcome will be developed and tested. Pathways, tools, and measures will be iteratively enhanced through small cycles of change (PDCA approach) until the PDT is satisfied that broad implementation is appropriate.

Once initial feasibility and usability is established, the PDT should work within the standardized notification and education process established by the Steering Committee to develop an implementation plan that will identify resources needed for staff education, support of use, and monitoring specific to each pathway.

Examples of resources that may be needed for dissemination, implementation, and monitoring of the pathway include:

- Posting of the clinical pathway and supporting materials (i.e. links to research articles, systematic reviews, and national practice guidelines) on the Clinical Pathways web site. This will be done for all pathways.
- Decision support tools such as orders sets to help clinicians follow recommendations related to ordering of diagnostic studies, therapeutic interventions, monitoring, infection control, consultations, restrictions in diet or activity, etc.
- Standardized documentation tools.
- Educational materials that will be disseminated to providers, including a set of reference articles on the topic, a systematic review for key decision points, and any other materials that can be used for education.

The PDT will ensure membership from appropriate sub-committees of the Medical Staff and Hospital, will provide ongoing updates to those committees, and will obtain any necessary approvals for the pathway implementation from subcommittees of the Medical Staff and Hospital, according to the PI Plan flow of Utilization and Quality Information.

Prior to large scale implementation, the PDT will present a full implementation change package to the Medical Executive Committee. This will represent the culmination of the Test and Implement Phase.

Sustain and Spread

PI staff, in cooperation with IT, will perform ongoing monitoring of the clinical pathway. Together they will:

1. Identify data streams and/or chart review processes for populating the metrics selected by the pathway development team.
2. Obtain historical data for the metrics. This exercise involves writing database queries, validation of the feasibility of the measures, validation of the data fields (through chart review), determination of baseline results, and establishment of data feeds for subsequent measurements.
3. Plot data points for the relevant metrics in statistical process control charts or other dashboards that are publically available, in order to determine whether pathway implementation is resulting in a change, and also to determine whether there is assignable variation in steady state processes that needs to be addressed.
4. Produce customized reports for clinicians (as appropriate) to compare their practice patterns and results to others in the hospital network.

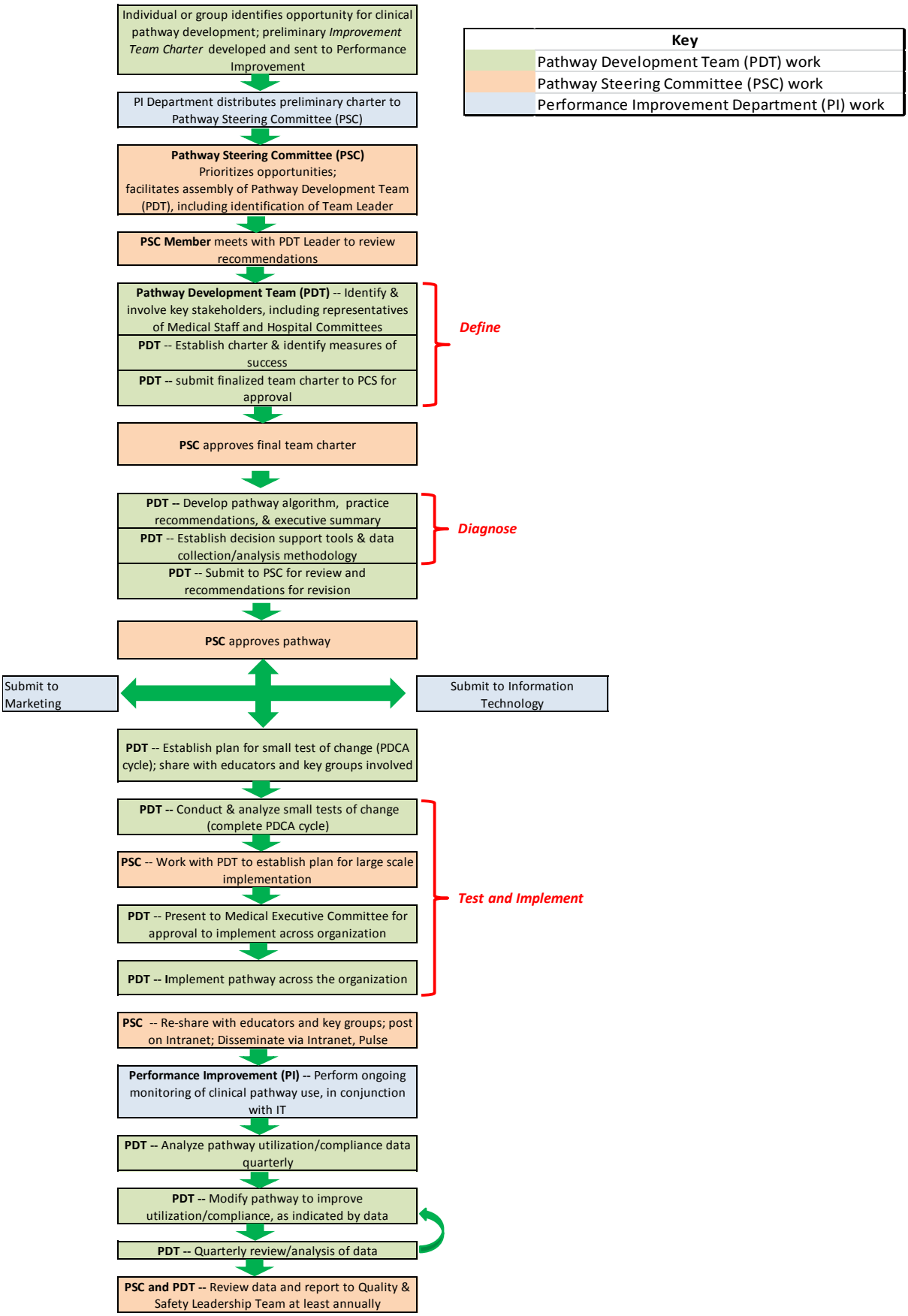
The PDT will meet at least quarterly to review the monitoring data, develop strategies for improving adherence to the pathway, and modify pathway recommendations given the results and/or new findings in the scientific literature. The PDT may also decide to expand the scope of the pathway and/or add additional metrics to focus improvement efforts on additional aspects of care.

The PDT leader and the Steering Committee will meet quarterly to review the monitoring data. Additionally, data will be presented to the Quality & Safety Leadership Team on a quarterly basis for each pathway by the Pathway Steering Committee.

REFERENCES

1. Campbell H, Hotchkiss R, Bradshaw N, Porteous M. Integrated care pathways. *BMJ* 1998, 316:133-7.
2. Kinsman L, Rotter T, James E, Snow, Willis J. What is a clinical pathway? Development of a definition to inform the debate. *BMC Medicine* 2010; 8:31.
3. Childrens' Hospital of Philadelphia. Clinical Pathways: A User's Guide.

Clinical Pathway Work Flow



GLOSSARY

Algorithm: a step-by-step procedure for a solution to a problem using specific mathematical or logical operations; term often used interchangeably with protocol.

Clinical Guideline: a systematically developed evidence-based consensus statement to assist practitioners in making patient management decisions related to specific clinical circumstances. Multidisciplinary participation in the development of guidelines is encouraged when appropriate.

Clinical Decision Support: a clinical system application or process that helps health professionals make clinical decisions to enhance patient care. Clinical knowledge of interest could range from simple facts and relationships to best practices for managing patients with specific disease states, new medical knowledge from clinical research and other types of information.

Clinical Pathway: multidisciplinary task-oriented and time-sequenced care plan which details steps in the care of patients with a specific clinical problem and describes the patient's expected clinical course. Pathways are used as a means of structured translation for implementation of guidelines and are also based on common practice where evidence may be lacking. Use of a pathway is not mandatory.

Dashboard: dashboards monitor and measure processes. A dashboard is operational and reports information typically more frequently than scorecards and usually with measures. Each dashboard measure is reported with little regard to its relationship to other dashboard measures. Dashboard measures do not directly reflect the context of strategic objectives. This information can be more real-time in nature, like an automobile dashboard that lets drivers check their current speed, ideally be linked directly to systems that capture events as they happen, and it should warn users through alerts or exception notifications when performance against any number of metrics deviates from the norm or what is expected.

Decision Tree: a visual and analytical decision support tool of the task-time, criteria-based plan of care for the evaluation and management of a patient with a specific condition.

Order Sets: a tool designed to assist ordering clinicians to write orders either on paper electronically. The format is similar to a menu from which the practitioner

makes selections to be applied to a particular patient. Order sets must be signed by an ordering clinician, dated and timed.

Policy: the formal guidance needed to coordinate and execute activity throughout an institution. Policies are broad statements that provide the operational framework within which the institution functions.

Procedure: the operational processes required to implement institutional policy. Operating practices can be formal or informal, specific to a department or applicable across the entire institution. If policy is "what" the institution does operationally then its procedures is "how" it intends to carry out those operating policy expressions. Compliance is expected.

Protocol: a set of orders constrained by rules and algorithms that define the care of a patient with a specific condition and requires an order by a prescriber to be initiated. Requires approval by Clinical Practice Council; if medication is included, approval of Pharmacy & Therapeutic Committee is required.

Scorecard: scorecards chart progress toward strategic objectives. A scorecard displays periodic snapshots of performance associated with an organization's strategic objectives and plans. It measures organizational activity at a summary level against pre-defined targets to see if performance is within acceptable ranges. Its selected key performance indicators help executives communicate strategy to employees and focuses users on the highest priority projects, initiatives, actions and tasks required to execute plans.

Standing Orders: an approved set of orders constrained by rules and algorithms that define the care of a patient with a specific condition which can be initiated and carried out by a licensed professional and signed by a prescriber after care has been initiated. The order must be signed as soon as possible after care is initiated. Requires approval by Clinical Practice Council; if medication is included, approval of Pharmacy & Therapeutics Committee is required.

Systematic Review: a literature review focused on a single question that tries to identify, appraise, select and synthesize all high quality research evidence relevant to that question.

APPENDIX A: Sample Charter

Improvement Team Charter

Project Name:_____
Department/Area:_____ Project Start Date: _____

If you would like the PI Department to help you complete this form, please contact extension 8476.

Select project type:

- ☐ **Process Efficiency Improvement Project**
- ☐ **Performance/Quality/Safety Improvement Project**
- ☐ **Order Set, Protocol or Clinical Pathway Development Project***

Problem Statement (what problem have you identified?):

Business Case (why is this project important to the organization? Include some estimate of the volume of patients that will be impacted):

Project Scope (who/what areas or phases of care will this project affect?):

Are there existing tools (order sets, protocols, guidelines, algorithms, etc.) that should be modified or referenced based on this project? And who are their owners?

Team Goals (what are you intending to achieve, write in SMART format):

Metrics (what metrics will you use and how will you track them to show your change resulted in improvement? 3 metrics are recommended):

Milestones (estimated completion dates for project phases – see User's Guide "Methodology" section for expected phases for pathway development)**:**

Project Champion(s):

Key Stakeholders (anyone affected by the change – List by department or job title)**:**

Team Members (who are the right people to accomplish the goals – list by name and position):

*For development of an order set, IT will request you complete a "Decision Tracker Flowsheet" at the start of the build process.

Team Charter Guide

Problem Statement:	• Identifies where the problem is occurring • Includes a short description of the problem • Includes quantitative data that demonstrates the extent of the problem ***For example:*** *The CLABSI rate in the hospital is too high. It is currently at 2.58 per 1000 device days. That rate is significantly higher than the CLABSI rate at comparable hospitals in our CHA peer group.*
Business Case:	• Is short and to the point • Is linked to the strategic plan Explains why the project is worth doing • Explains the consequences of not doing the project • Includes financial and/or non-financial benefits ***For example:*** *Central line infections cause harm to patients and increase LOS. Twenty five children were harmed in our hospital last year as a result of central line infections.*
Project Scope:	• Sets the project boundaries • Identifies what areas are inside and/or outside of the project • Helps prevent scope creep ***For example:*** *The project will include all patients with a central line on the 4th, 5th and 6th floor of the hospital. The project will not include Home Health or the Infusion Center*
Team Goal(s) – should meet the SMART criteria:	• **S**pecific – target a specific area for improvement • **M**easurable – accurate data collection is possible • **A**ctionable – trends indicate when action is needed • **R**ealistic – the needed time and resources are available • **T**ime bound – a deadline should be set for achieving the goal ***For example:*** *The goal is to reduce the CLABSI rate on the Medical/Surgical floors to 2.0 per 1000 device days by December 31, 2015.*
Metrics	Outcome data used to demonstrate your change resulted in improvement
Milestones – clear time bound events in the life of the project	• Identify important deliverables and the date they will be finished • Document how you plan to reach the goal
Physician Champion	The physician who will lead the team and/or is responsible for helping overcome the barriers encountered by the team
Nurse Champion	the nurse who will lead the team and/or is responsible for helping overcome the barriers encountered by the team
Key Stakeholders	the people or areas that will be affected by the changes you plan to implement
Team Members	the people who are responsible for resolving the identified problem
Order Set	a tool designed to assist ordering clinicians to write orders either on paper electronically
Protocol	a set of orders constrained by rules and algorithms that define the care of a patient with a specific condition and requires an order by a prescriber to be initiated
Clinical Pathway	A multidisciplinary task-oriented and time-sequenced care plan which details steps in the care of patients with a specific clinical problem and describes the patient's expected clinical course. See User's Guide for more details.

Clinical Pathway
Executive Summary

Physician Owner:

Primary Objective

Recommendations

Rationale (Safety, Quality, Cost, Delivery, Engagement, & Satisfaction)

- Safety
- Quality:
- Cost:
- Delivery:
- Engagement:
- Patient/Family Satisfaction:

Implementation Items

Metrics Plan

Evidence

Supporting Documents (Pathway, inclusion/exclusion criteria, definitions, algorithm)

Disclaimer: Pathways are intended as a guide for practitioners and do not indicate an exclusive course of treatment nor serve as a standard of medical care. These pathways should be adapted by medical providers, when indicated, based on their professional judgment and taking into account individual patient and family circumstances.

Date Last Reviewed: 12/2015

Executive Summary Guide

Primary Objective:	• Identifies what the pathway's intended outcome is • Includes which patients and/or what areas the pathway will be used ***For example:*** *Develop a pathway for treating asthma that directs patient care from the Emergency Department through inpatient management to discharge.*
Recommendations:	• Explains the clinical guidelines that are being recommended as a result of this pathway ***For example:*** 1. *Provide standardized dosing for Short Acting Beta Agonists, Anticholinergic Bronchodilators, and Steroids.* 2. *Provide guidelines for when and how patients should be assessed during an asthma exacerbation.* 3. *Establish classes of severity and therapeutic interventions based on those classes.* 4. *Establish admission and discharge criteria.* 5. *Reduce unnecessary testing not routinely recommended for evaluation of an asthma exacerbation.*
Rationale (Safety, Quality, Cost, Delivery, Engagement, & Satisfaction):	• **Safety**: How will this pathway impact patient safety? ***For example:*** *Will be maintained by close communication between the ED providers, RNs, and Inpatient providers, especially when a patient is categorized as severe.* • **Quality**: How will this pathway improve the quality of care patients receive? ***For example:*** *Will be improved by instituting consistent terminology, dosing, and care between providers.* • **Cost**: Will this pathway have an impact on cost? ***For example:*** *Will be improved by instituting consistent terminology, dosing, and care between providers.* • **Delivery**: How will the delivery of care be improved? ***For example:*** *Will be improved by expediting patient flow through the Emergency Department to the Inpatient unit for providers, RNs, and RTs* o *RN administration of oral steroids after triage and use of double dosing of Ipratropium Bromide with triple dosing of albuterol has been shown to reduce hospitalization rates and length of time spent in the ED.* o *Provider assessment within one hour after initial inhaled treatment is also anticipated to reduce length of time spent in the ED.* o *Developing discharge criteria may reduce length of stay in the hospital.* • **Engagement:** How will implementing this pathway impact engagement? ***For example:*** *Is created and supported by the involvement of a multidisciplinary team in the development and maintenance of the pathway.* **Patient/Family Satisfaction**: How will the pathway impact patient satisfaction? ***For example:*** *Shall be improved by providing the highest quality care based on established guidelines and the latest evidence available in the literature.*
Implementation Items:	• List any algorithms, order sets, tools, or surveys that are related to the pathway ***For example:*** *ED and Inpatient Algorithms, ED and Inpatient Order sets, Asthma History Tool for Admission, M-PACT Screening Tool for the ED.*
Metrics Plan:	• Outcome data used to demonstrate your change resulted in improvement. Same as written on Team Charter.

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Date Last Reviewed: 12/2015