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# **Applying Lessons from an Inaugural Clinical Pathway to Establish a Clinical Effectiveness Program**

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#### Abstract

Introduction: Clinical effectiveness (CE) programs promote standardization to reduce unnecessary variation and improve healthcare value. Best practices for successful and sustainable CE programs remain in question. We developed and implemented our inaugural clinical pathway with the aim of incorporating lessons learned in the build of a CE program at our academic children's hospital. Methods: The Lucile Packard Children's Hospital Stanford Heart Center and Center for Quality and Clinical Effectiveness partnered to develop and implement an inaugural clinical pathway. Project phases included team assembly, pathway development, implementation, monitoring and evaluation, and improvement. We ascertained Critical CE program elements by focus group discussion among a multidisciplinary panel of experts and key affected groups. Pre and postintervention compared outcomes included mechanical ventilation duration, cardiovascular intensive care unit, and total postoperative length of stay. Results: Twenty-seven of the 30 enrolled patients (90%) completed the pathway. There was a reduction in ventilator days (mean 1.0+0.5 versus 1.9+1.3 days; P < 0.001), cardiovascular intensive care unit (mean 2.3+1.1 versus 4.6+2.1 days; P < 0.001) and postoperative length of stay (mean 5.9+1.6 versus 7.9+2.7 days; P < 0.001) compared with the preintervention period. Elements deemed critical included (1) project prioritization for maximal return on investment; (2) multidisciplinary involvement; (3) pathway focus on best practices, critical outcomes, and rate-limiting steps; (4) active and flexible implementation; and (5) continuous data-driven and transparent pathway iteration. Conclusions: We identified multiple elements of successful pathway implementation, that we believe to be critical foundational elements of our CE program. (Pediatr Qual Saf 2018;3:e115; doi: 10.1097/ pq9.00000000000115; Published online October 31, 2018.)

# **INTRODUCTION**

Reducing unintended variation in clinical practice improves value in health care delivery.<sup>1,2</sup> Noting significant practice variation within our organization, we recognized the need to develop a Clinical Effectiveness (CE) program to identify and reduce unnecessary variation, improve quality and outcomes, and sustain a change in culture toward value-based healthcare. Turning to the literature for guidance, we came

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across several Quality Improvement (QI) and CE programs aimed at targeting variation. However, their impact was variable, with QUALITY particular challenges in reliability and sustainability.<sup>3-11</sup> Programs struggled with lack of transparency in clinical practice guidelines and clinical pathways, leading to mistrust among providers.<sup>12-16</sup> Inflexibility and inertness of guidelines limited relevance and applicability to dynamic

clinical practice.12-15,17 One program addressed

some of these challenges by involving a multidisciplinary clinical team in guideline development and creating a dynamic system focused on gathering and analyzing data after implementation to continually improve

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the guideline.<sup>8,9</sup> However, this approach involves extensive data management and analysis burden potentially limiting scalability and sustainability. Other clinical pathway programs employed different strategies with varying success. The heterogeneity of these programs coupled with a limited description of interventions and contexts, made it challenging to extrapolate best practices.<sup>3-10</sup>

Given this lack of literature-based best practices, we developed our first clinical pathway with the purpose of identifying critical elements to integrate into the build of a comprehensive CE program at our institution. This report describes (1) the phase-by-phase approach to development, implementation, evaluation, and follow-up of this clinical pathway; (2) our preliminary results; and (3) elements we identified through this process, which we believe to be critical foundational elements of our CE program.

# **METHODS**

Lucile Packard Children's Hospital Stanford (LPCH) is a 303-bed academic, freestanding, tertiary care children's hospital. The LPCH Heart Center offers comprehensive care for children with cardiac medical and surgical problems. The LPCH Center for Quality and Clinical Effectiveness oversees the implementation of hospital-wide initiatives supporting quality and safety strategy and goals. The Heart Center and Center for Quality and Clinical Effectiveness partnered to develop, implement, and learn from an initial clinical pathway. The Institutional Review Board at Stanford University Medical Center reviewed and approved a waiver of consent for this project.

### Development

During development (July 1, 2014, to October 31, 2014): (1) we selected the target population and analyzed baseline performance measures; (2) assembled a multidisciplinary team; (3) identified target processes, reviewed relevant literature, and constructed the first clinical pathway draft; (4) established a standard method of eligible patient identification; and (5) developed a monitoring and evaluation plan. Details of each of these stages are listed below.

# *Selecting the Target Population and Evaluating Current State*

Tetralogy of Fallot (TOF) is the most common cyanotic congenital heart defect and undergoes repair with openheart surgery.<sup>18</sup> The postoperative care of primary TOF repair was selected for clinical pathway development based on wide internal variation in care approach and length of stay (LOS). Additionally, national benchmarking data from the Society of Thoracic Surgeons and Pediatric Health Information Systems Databases, showed that mean LOS placed LPCH in the worst performing tertile.<sup>19,20</sup>

### Assembling a Multidisciplinary Team

First, we assembled a core team including a physician, an advanced practice provider (APP) and nursing leaders in cardiology and cardiac anesthesia and key members of the hospital QI team (Chief Patient Safety Officer, Director of Analytics and CE, Director of Improvement Science Research and a quality manager). Key members of the core team received formal improvement science training. This team participated in all aspects of the development, implementation, and adaptation of the clinical pathway. Second, champions (including nurses, physicians, and APPs) promoted engagement in pathway development and implementation. Finally, a partnership with Heart Center and LPCH executive and operational leadership was established to assure effective and efficient implementation.

# *Examining Current State and Developing the Clinical Pathway*

Because this was our first systematic clinical pathway initiative, there was no standardized process for developing and vetting pathways within our institution. The core team began by evaluating the current state for the postoperative management of TOF at LPCH using a key-driver diagram as a roadmap (Fig. 1). The project aim considered: (1) analysis of baseline internal performance between January 1, 2011, and July 1, 2014, which showed a mean overall LOS of 12 days for all patients undergoing primary TOF repair and (2) comparison with linked Society of Thoracic Surgeons and Pediatric Health Information Systems benchmark data showing a LOS of 9 days for best-performing hospitals.<sup>19</sup> Inclusion and exclusion criteria targeted a standard risk TOF population. We reviewed pathways from other institutions to compare their practices to ours and ultimately to develop our version. A comprehensive review of relevant literature and existing institutional policies, procedures, and standards was completed. We incorporated these best practices into a task-oriented clinical pathway structured by day and extending from the patient's arrival to the cardiovascular intensive care unit (CVICU) through hospital discharge. After obtaining feedback from expert stakeholders (pediatric cardiothoracic surgeons, cardiologists, intensivists, anesthesiologists, a clinical pharmacist, APPs, registered nurses, respiratory therapists, a registered dietician, and a case manager), we then further refined the clinical pathway.

The draft clinical pathway detailed essential steps in the postoperative management of patients undergoing primary TOF repair and described a patient's expected clinical course, with a focus on critical outcomes and milestones. A data collection form organized management goals and served both as a checklist and form to document goal achievement or deviation and the reason for the variance. The clinical pathway document and supporting data collection form were intentionally paperbased during the pilot period (Figs. 2, 3).

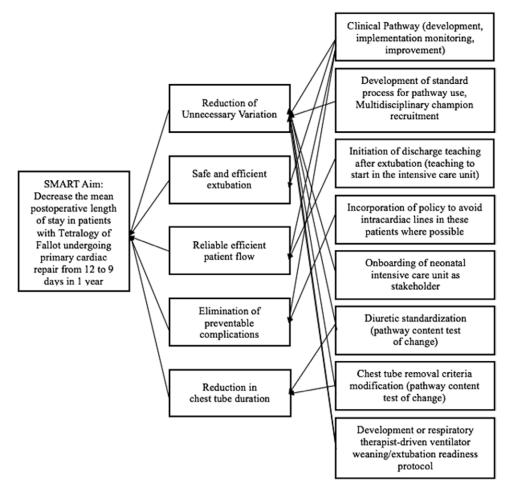


Fig. 1. Key driver diagram for the postoperative management of TOF. Key drivers for the postoperative care of TOF reflected patient and system factors. The multidisciplinary core development team generated potential interventions for these key drivers and updated both key drivers and interventions regularly during the iteration and improvement phase.

### Identifying Clinical Pathway Eligible Patients

We incorporated eligible patient identification into the existing workflow at a weekly multidisciplinary surgical conference. In this conference, patients presenting for TOF repair were identified in the surgical schedule and reviewed for pathway eligibility based on predetermined inclusion/exclusion criteria. Notification of upcoming TOF pathway eligible patients was circulated to the clinical care team by secure electronic mail. The core team reviewed the surgical schedule daily as back up to ensure identification of all patients undergoing primary TOF repair.

### Development of an Evaluation Plan

Monitoring included adherence, impact, and perceived usefulness to guide pathway adaptation. A multidisciplinary panel of experts and affected stakeholders reviewed each pathway patient's experience in detail within 1 week of pathway completion, and the core team applied the lessons learned from this review to each subsequent patient through rapid-cycle improvement. Process, outcome, and balancing measures included:

- Process measures:
  - · Count (percentage) of eligible patients who were enrolled
  - Count (percentage) of enrolled patients who completed the pathway through hospital discharge
- Outcome measures:
  - Mechanical ventilation duration
  - Postoperative CVICU LOS
  - Postoperative total LOS
  - Family satisfaction (Fig. 4)
- Balancing measures:
  - Reintubation
  - CVICU readmissions within 48 hours
  - Unplanned readmissions within 30 days of discharge
  - Mortality

Variance, defined as patient outcomes or staff actions that did not meet the expectancies of the clinical pathway, was closely tracked.

#### Implementation

Implementation (November 1, 2014, to March 31, 2015) involved provider education, pathway deployment, and prompt data collection to identify areas for improvement.

|                | Day of Surgery  | Post-op Day #1  | Post-op Day #2  |
|----------------|---|---|---|
| Unit           | CVICU   | CVICU   | CVICU   |
| Date           |   |   |   |
| Monitoring     | <ul> <li>Vital signs per routine</li> <li>CR monitor/telemetry</li> <li>CV line/RA line/Arterial line</li> <li>Pacing wires/rhythm</li> <li>Chest tube drainage</li> <li>Foley catheter</li> <li>Temperature Probe</li> </ul> | <ul> <li>Vital signs per routine</li> <li>CR monitor/telemetry</li> <li>CV line/RA line/Arterial line</li> <li>Pacing wires/rhythm</li> <li>Chest tube drainage</li> </ul> Discontinue if appropriate: <ul> <li>Temperature probe</li> <li>Foley catheter</li> <li>CV line/RA line</li> </ul> | <ul> <li>Vital signs per routine</li> <li>CR monitor/telemetry</li> <li><u>+</u> CV line/RA line/Arterial line</li> <li>Pacing wires/rhythm</li> <li>Chest tube drainage</li> <li>Discontinue if appropriate:</li> <li>CV line/RA line</li> <li>Arterial line</li> <li>Chest tube/s <sup>b</sup>- Keep mediastinal chest tube in place after RA line out to avoid echo after RA line removal</li> </ul> |
| Diagnostic     | <ul> <li>CVICU Arrival: EKG, CXR, CBC,<br/>CMP, coags</li> <li>ABG, lactate q2 hrs until &lt;2 + prn</li> </ul>   | <ul> <li>In morning: CXR, CBC, CMP,<br/><u>+</u> coags</li> <li>ABG, lactate q6 hrs, <u>+</u> pm</li> </ul>   | <ul> <li>In morning: CXR, CBC, Chem10</li> <li>Pm: ABG, lactate</li> </ul>  |
| Cardiovascular | Dopamine, Calcium <u>+</u> Epinephrine  | VS- Lasix IV q6 hrs (+/- Aldactone)     TP- Lasix IV q6 hrs (+/- Aldactone) Discontinue if appropriate:     Dopamine, Calcium + Epi   | <ul> <li>VS- Lasix IV q8 hours (+/- Aldactone)</li> <li>TP- Lasix IV q6 hours (+/- Aldactone)</li> <li>Discontinue if appropriate and not done:</li> <li>Dopamine, Calcium, Epinephrine</li> </ul>  |
| Respiratory    | Wean ventilator   | Extubate     + Oxygen/pulmonary toilet  | <u>+</u> Oxygen/pulmonary toilet  |
| Pain/Sedation  | Titrate pain/sedation drips     Acetaminophen IV/PR ATC <u>+</u> Morphine IV ATC/prn     + Versed IV prn  | Acetaminophen IV/PR ATC <u>+</u> Toradol IV ATC <u>+</u> Morphine IV ATC/pm <u>+</u> Versed IV prn  | Acetaminophen PO/IV/PR ATC <u>+</u> Toradol IV ATC or Ibuprofen PO ATC <u>+</u> Morphine/Oxycodone PO/IV ATC/pm   |
| Infectious     | <ul> <li>Cefazolin x3 doses (or<br/>Vancomycin if MRSA/MRSE<br/>suspected/confirmed or allergy)</li> </ul>  | Complete antibiotic     Check dressing  | Remove dressing/check incision <u>+</u> CT site occlusive dressing (48 hrs post removal)  |
| Nutrition      | • IVF   | IVF     Initiate diet when extubated and stable   | <ul> <li>Advance to regular diet</li> <li>Caloric Goal: <u>&gt;120 kcal/kg/day</u></li> <li>Check weight</li> </ul>   |
| Activity       | Bed rest  | <ul> <li>Bed rest/ ad lib after extubation</li> </ul>   | Ad lib  |
| Psychosocial   | Assess psychosocial status  | <ul> <li>Assess psychosocial status</li> </ul>  | Provide support   |

**Fig. 2.** Excerpt from the clinical pathway for the postoperative management of TOF. Formatting courtesy of Cincinnati Children's Hospital TOF clinical pathway.<sup>5,6</sup> ABG, arterial blood gas; ATC, around-the-clock; CBC, complete blood count; CMP, complete metabolic panel; CR, cardiorespiratory; CT, chest tube; CV: central venous; CXR: chest x-ray; EKG, electrocardiogram; IV, intravenous; IVF, intravenous fluids; MRSA: methicillin- resistant Staphylococcus aureus; MRSE: methicillin- resistant Staphylococcus epidermidis; PO: per os, "by mouth"; PR, per rectum; PRN, pro re nata, "as needed"; RA, right atrial; TP, transannular patch type of TOF repair; VS, valve-sparing type of TOF repair.

### Preimplementation: Socialization and Education

First, the core team conducted a series of presentations across the Heart Center to provide a general overview of clinical pathways, introduce the TOF clinical pathway and outline pilot implementation. Second, the team shared more granular details (criteria for pathway eligibility, pathway content, data collection instructions, and provider roles) with front-line staff, leveraging existing QI and PI resources including CVICU and acute care unit multidisciplinary microsystems improvement teams<sup>21</sup> and daily staff huddles to assist in education efforts.

### Implementation

We integrated clinical pathway implementation into the existing workflow. After undergoing surgery, the anesthesiologist presented appropriate patients as "pathway eligible" during the operating room-to CVICU handoff, and a member of the core team placed pathway and data collection forms visibly at the patient's bedside. A core team member attended daily rounds and handoffs to ensure placement of eligible patients on the clinical pathway, support adherence with pathway guidelines as appropriate, observe and guide documentation, and obtain firsthand feedback on potential facilitators and barriers.

### **Continuous** Improvement

Improvement (April 1, 2015, to July 31, 2017) involved quantitative and qualitative assessment in adapting the pathway process, content, and outcomes through rapid cycle improvement. Using REDCap<sup>22</sup> (Research Electronic Data Capture) for data management, core team members evaluated data captured from the data collection form and electronic health record. Core team members met every 2 weeks to discuss implementation progress. Adherence was assessed by frequency of eligible patient pathway enrollment and completion. Key "milestones" that signaled a patient was following the expected course defined by the pathway were tracked, including extubation within 24 hours of arrival in the CVICU, transfer to acute care by postoperative day 3, and discharge from the hospital by postoperative day 5. Failure to meet a milestone at the expected time indicated a significant variance, and we encouraged the medical

| ystem                    | Goals Post-operative day #                                      | 0                         | 1       | 2      | 3       | 4      | 5      | 6 | 7 | 8 |    |
|--------------------------|---|---------------------------|---------|--------|---------|--------|--------|---|---|---|----|
| Monitoring               | Discontinue foley catheter by POD #1                            |                           |         |        |         |        |        |   |   |   | Г  |
|                          | Removal of central/right atrial lines by POD #3                 |                           |         |        |         |        |        |   |   |   | 1  |
|                          | Removal of arterial line by POD #3                              |                           |         |        |         |        |        |   |   |   | L  |
|                          | Removal of chest tubes by POD #4                                |                           |         |        | _       |        |        | _ |   | _ | Ł  |
|                          | Removal of pacing wires by POD #4                               |                           |         |        |         |        |        |   |   |   | Ł  |
|                          | Discontinue telemetry by POD #4                                 |                           |         |        |         |        |        |   |   |   | 1  |
| Diagnostic               | Postoperative echocardiogram by POD #4                          |                           |         |        |         |        |        |   |   |   | Ł  |
| Cardiovascular           | Discontinue inotropes by POD #2                                 |                           |         |        |         | _      |        | _ | _ | _ | Ł  |
|                          | Start diuretics on POD #1                                       |                           |         |        |         |        |        |   |   | - | Ł  |
|                          | VS: transition to oral diuretic on POD#3                        |                           |         |        | _       |        |        | _ |   | _ | Ł  |
|                          | TP: transition to oral diuretic on POD #4                       |                           |         |        |         |        |        |   |   |   | L  |
| Respiratory              | Wean to extubation by POD #1* Time                              |                           |         |        |         |        |        |   |   |   | L  |
|                          | Discontinue supplemental oxygen by POD #4                       |                           |         |        |         | 1      |        |   |   |   | Г  |
| Pain/Sedation            | Transition to oral pain medications by POD #3                   |                           |         |        |         |        |        |   |   |   | 1  |
| Infectious               | Discontinue perioperative antibiotics on POD #1                 |                           |         |        |         |        |        |   |   |   | 1  |
|                          | Remove surgical site dressing on POD #2                         |                           |         |        |         |        |        |   |   | _ | 1  |
|                          | Start clears by POD #1  | -                         |         |        | -       |        |        |   |   | - | 1  |
| Nutrition                | Achieve regular diet/ goal feeds by POD #3                      |                           |         |        |         |        |        |   |   |   | ł. |
|                          | Daily weights after extubation                                  |                           | -       |        | _       | _      | _      | _ | _ | _ | 1  |
| Pychosocial              | Determine family barriers to care by POD #2                     |                           |         |        |         | -      |        | - |   | 1 | t  |
| Education                | Family to attend discharge class by POD #4                      |                           |         |        | _       | _      | _      | _ | _ | _ | Ł  |
| Education                | Family education complete by POD #4                             |                           |         |        | -       |        | -      | - |   | - | Ł  |
|                          | Determine transfer eligibility by POD #2                        |                           |         |        |         |        |        |   | _ |   | Ł  |
| Discharge Biagaing       | Transfer to 3W by POD #3*                                       |                           |         |        |         |        |        | _ | - | _ | Ł  |
|                          | CVICU update referring cardiologist by POD #2                   |                           | -       |        | _       |        | -      | - | _ | _ | ł  |
|                          |   |                           |         |        | _       |        | _      | _ |   | _ | Ł  |
| Discharge Planning       | Discharge prescriptions picked up by POD #4                     |                           |         |        |         |        |        |   | _ | - | Ł  |
|                          | Discharge appointments scheduled by POD #4                      |                           | -       |        | -       |        |        | - | - | _ | Ł  |
|                          | 3W update referring cardiologist by POD #5                      |                           |         |        | _       |        |        | _ | _ | _ | Ł  |
|                          | Discharge by POD #5   | - 0                       | -       | es cr  | itica   | 1.00   |        |   |   |   | L  |
| nclusion Criteria        | Exclusion Criteria  | 1                         | enou    | es cr  | nuca    | got    |        |   |   |   |    |
| OF Repair                | pulmonary atresia   |                           |         |        |         |        |        |   |   |   |    |
| 6 weeks                  | <36 weeks gestational age                                       |                           |         |        |         |        |        |   |   |   |    |
|                          | <1.5 kg   |                           |         |        |         |        |        |   |   |   |    |
|                          | significant comorbidities                                       |                           |         |        |         |        |        |   |   |   |    |
|                          | ion on Critical Measures. Circle all that apply and included de |                           | _       | _      | ow.     |        |        | _ |   |   |    |
| xtubation                | Transfer  | Disc                      | harge   |        |         |        |        |   |   |   |    |
| vrhythmia (any)          | Arrhythmia (any)  | Arrh                      | ythmi   | ia tam | y)      |        |        |   |   |   |    |
| ow cardiac output        | Low cardiac output  | Low                       | cardia  | ac out | put     |        |        |   |   |   |    |
| ulmonary hypertension    | Pulmonary hypertension  | Pulmonary hypertension    |         |        |         |        |        |   |   |   |    |
| espiratory insufficiency | Respiratory insufficiency                                       | Respiratory insufficiency |         |        |         |        |        |   |   |   |    |
| amily concerns           | Family concerns   | Family concerns           |         |        |         |        |        |   |   |   |    |
| edation issues           | Feeding intolerance   | Feed                      | ting in | tolera | ance    |        |        |   |   |   |    |
| Other:(specify)          | No bed available  | Teaching not complete     |         |        |         |        |        |   |   |   |    |
|                          | Other:(specify)   | Disc                      | harge   | suppl  | lies no | ot ava | ilable |   |   |   |    |
|                          |   |                           | ers(spe |        |         |        |        |   |   |   |    |

# Describe reason for pathway deviation/s here

| D | evia | tior | 1 |
|---|------|------|---|
|   |      |      |   |
|   |      |      |   |
|   |      |      |   |

Deviation

Details

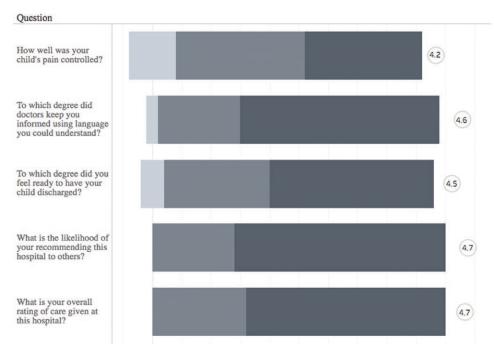
Details

Fig. 3. Data and variance collection form for TOF clinical pathway. Formatting courtesy of Cincinnati Children's Hospital TOF clinical pathway.<sup>5,6</sup> POD, postoperative day; TP, transannular patch type of TOF repair; VS, valve-sparing type of TOF repair.

team to document the reason for this variance (Figs. 2, 3). The core team summarized outcomes and observations for communication to all stakeholders and translated lessons into small tests of change (Plan-Do-Study-Act) for continuous improvement and adaptation.<sup>23</sup>

### Evaluation of the Intervention

We compared the performance of clinical pathway enrolled and completed patients from November 1, 2014, to July 31, 2017, to a similar historical cohort from January 1, 2010, to July 31, 2014, using a quasi-experimental study



**Fig. 4.** Family satisfaction after implementation of a TOF clinical pathway. Likert Scale Chart demonstrating respondent results to postintervention family satisfaction survey through 7-day post discharge standardized phone survey with the above 5 questions measured on a Likert scale (1 = very poor, 2 = poor, 3 = fair, 4 = good, 5 = very good). The encircled numbers indicate mean respondent scores. No participants responded 1 or 2. Light gray corresponds to response 3 (fair), medium gray to response 4 (good), and dark gray to response 5 (very good).

design. In the absence of a true comparator group, we compared our results to the baseline state conservatively to avoid biasing the preintervention group toward sicker patients. Two reviewers independently evaluated individual patients in the preintervention cohort to determine if the patient (1) would have been excluded from enrollment based inclusion/exclusion criteria; and (2) would have met criteria for coming off the pathway. Disagreements were resolved by discussion to achieve consensus. If either of the above responses was affirmative, we excluded the patient from the analysis. Process, outcome, and balancing measures were analyzed as described above. We summarized demographic variables with standard descriptive statistics. For continuous variables, we reported the means (SD) for normally distributed variables and median and interquartile range (IQR) for skewed variables. For categorical variables, we reported counts with percentages. Univariable analysis was done using Fisher's exact text for discrete variables, Student t test for normally distributed continuous variables, and Mann-Whitney U test for skewed variables. Statistical Process Control charts, for example, as shown in Figure 5, were used regularly to monitor primary outcomes as part of the rapid cycle improvement process. Statistical significance was

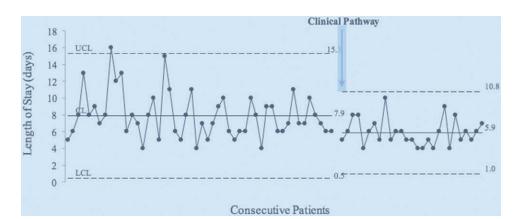


Fig. 5. Postoperative LOS after primary TOF repair before and after clinical pathway implementation. This individual-X statistical process control chart demonstrates improvement in mean LOS and outcome variability in the postintervention period. Each data point indicates consecutive individual patients. CL, control limit; LCL, lower control limit; UCL, upper control limit.

| Table 1. Demographics of Patients TO | OF Repair |
|--------------------------------------|-----------|
|--------------------------------------|-----------|

| Preintervention<br>N = 50 | Postintervention<br>N = 27                                   | Р  |  |
|---------------------------|--|--|--|
|                           |  |  |  |
| 3.2 (2.5–3.6)             | 3.3 (2.8–4.3)  | 0.11   |  |
| 5.1 (4.4–5.9)             | 5.7 (5.0-6.3)  | 0.11   |  |
|                           |  | 0.81   |  |
|                           |  | 0.42   |  |
| 5 (10)                    | 4 (15)   | 0.71   |  |
|                           | N = 50<br>3.2 (2.5–3.6)<br>5.1 (4.4–5.9)<br>5 (38)<br>5 (10) | N = 50         N = 27 $3.2 (2.5-3.6)$ $3.3 (2.8-4.3)$ $5.1 (4.4-5.9)$ $5.7 (5.0-6.3)$ $5 (38)$ 9 (33) $5 (10)$ 1 (4) |  |

determined a priori as a two-tailed *P* value of <0.05. We performed statistical analysis with STATA software (version 12, StataCorp., College Station, Tex.).

# RESULTS

There were 30/35 (86%) pathway eligible patients, and 27/30 (90%) remained on the pathway through hospital discharge. The remaining 3 patients exited the pathway for clinical reasons (ie, development of important postoperative complications). In comparison, during the preintervention period, there were 52/74 (70%) pathway eligible patients and 50/52 (96%) who would have likely met criteria for remaining on the pathway through hospital discharge. The most common reasons for noneligibility in both periods were young age, low weight, and prematurity. There were no significant demographic differences in the pre and postintervention periods (Table 1).

Postoperative outcomes and variability for all primary outcomes improved, including a reduction in ventilator days (mean 1.0+0.5 versus 1.9+1.3 days; P < 0.001), CVICU LOS (mean 2.3+1.1 versus 4.6+2.1 days; P <0.001) and total postoperative LOS (mean 5.9+1.6 versus 7.9+2.7 days; P < 0.001) compared with the preintervention period (Fig. 5). Twenty-three out of 25 (93%) response rate) families responded to the follow-up survey, with a mean 4.7 in overall rating and likelihood to recommend the hospital, mean 4.5 in perceived readiness for discharge, mean 4.6 in degree to which they felt informed, and mean 4.2 in degree to which their child's pain was controlled (Fig. 4). There was no significant difference in CVICU (pre: 2% versus post: 0%; P = 0.9) or hospital readmissions (pre: 6% versus post: 0%; P = 0.5), and no mortalities in either period.

# DISCUSSION

After implementation, there was a reduction in the duration of mechanical ventilation and postoperative CVICU and total LOS with no significant adverse change in mortality, reintubation, or readmission rates and high family satisfaction rating. Analysis of the build, implementation, and evaluation of the TOF prototype clinical pathway through multidisciplinary focus group review resulted in the identification of 5 principles to guide our CE program build.

### **Population Selection Is Critical**

By strategically prioritizing projects, a CE team can maximize return on investment, properly allocate resources, and ensure projects align with institutional goals. In our case, guiding principles included long LOS, high cost, and opportunity suggested by existing variation in clinical practice and deviation from national benchmark.<sup>19,20,24</sup>

# Multidisciplinary Stakeholder Involvement Is Required

CE programs require relevant stakeholder engagement and activation. The process of identifying potential stakeholders who may both affect a clinical pathway or be affected by it is a critical challenge of clinical pathway development.<sup>8,11,12,15,25-28</sup> Involvement of clinicians, nurses, and other allied professionals in pathway development lent credibility to the pathway and helped build a foundation of multidisciplinary support, teamwork, and communication. There are several examples of this. First, although the clinical pathway started at the patient's arrival to the CVICU, key representatives of the pretarget location (the Operating Room) including cardiac anesthesiologists and cardiac surgeons were critical in designing intraoperative care to support early extubation. Second, the inclusion of clinical nurse specialist and bedside registered nurse representatives in pathway design helped identify clinical and operational barriers and proactively incorporate countermeasures. Third, the involvement of a diverse and clinically focused team in clinical pathway development facilitated an innovative design in which we explored embedded research questions during implementation and variance analysis. Fourth, a partnership with QI and PI leaders provided ready access to tools, skills, and vision to affect sustained improvement and change. Selection of key champions proved equally important. Leveraging the position of leadership among multidisciplinary stakeholders facilitated successful implementation. Finally, support from top management and clinical leaders was crucial to the success and acceptance of this initial pathway initiative.

# Clinical Pathway Development Should be Evidence-based

Clinical pathway development is at the heart of a CE program but can be rate limiting. This limitation was approached by early planning with a key driver-diagram (Fig. 1), comprehensive literature review and critical

evaluation, structured cross-functional vetting to achieve content and process consensus especially when evidence of literature-based standards were lacking, and incorporation of existing institutional policies, standard procedures and best practices to promote overall standardization of care. Process mapping,<sup>29</sup> to consider all aspects of patient flow through the continuum of care identified important processes and key rate-limiting steps. This exercise, for example, uncovered discharge planning early after admission as an integral component of all inpatient clinical pathways. Finally, acknowledgement that clinical pathways can be too rigid with the potential to undermine providers' abilities to care for patients optimally,<sup>8,16,25,30,31</sup> led to the strategy of (1) avoiding too many prescriptive details to preserve some flexibility in practice and allow for variation reflecting patient circumstances; and (2) allowing deviation but requiring explanation to guide evaluation and adaptation of the clinical pathway.

### Active and Flexible Implementation Is Critical

Method of implementation is a decisive factor in the success or failure of clinical pathway deployment.<sup>16,23,27,28,30-33</sup> The CE core team learned that active implementation at the front line with prompt adjustment from feedback was most effective for continuous improvement at LPCH. The ubiquitous availability of the core team allowed for efficient monitoring, clarification of questions, and identification of facilitators and barriers.

## *Iteration and Adaptation Should be Continuous, Data-driven and Transparent*

An often overlooked element of clinical pathway work centers around continuously evaluating and adapting pathways to ensure that they remain dynamic and reflect evolving best practices.<sup>8,12,13,15-17,25,32</sup> In our case, there was continuous evaluation of the clinical pathway experience, which led to modifications of pathway content and process. Also, by being attentive to reasons for variation in practice, the core team uncovered unanticipated opportunities for the introduction and evaluation of standardized management approaches. A robust but parsimonious variance management system allowed for flexible and rapid iteration without overwhelming data collection and analysis efforts. Reporting outcomes and feedback transparently to the frontline and executive stakeholders encouraged collective efforts to drive iteration and innovation for greater impact. Use of a paper-based pathway and documentation tool allowed nimble and efficient changes. In the future, information technology supported pathways aligned to clinical workflow and including computerized physician order sets and decision support tools that "make it easy to do it right,"<sup>33,34</sup>are underway.

This study has several limitations. First, this evaluation is limited to a small population. However, it is encouraging that even in preliminary analysis with a small sample size, there was a statistically significant favorable difference in primary outcomes compared with the preintervention period, without unintended consequences. Second, given the quasi-experimental study design without randomization, our evaluation shows an association but cannot infer causality. Selection bias was mitigated by excluding preintervention patients who would not have met pathway eligibility criteria or remained on the pathway through hospital discharge, and demographic characteristics suggest no significant difference in the pre- and postintervention populations. Third, the approach used at LPCH Stanford may not be directly translatable to other organizations that have different healthcare environments, patient populations, and culture. By describing both our intervention and framework in detail, we believe other institutions can better adapt our process and approach to their setting.

## CONCLUSIONS

Development and implementation of an inaugural clinical pathway were associated with substantial improvements in early outcomes and revealed best practices we believe formed the basis of our successful CE program. Future research to determine if our approach is associated with safe and sustained outcome improvement is ongoing.

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### DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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