Combining Lean and Applied Research methods to improve rigor and efficiency in acute care outcomes research: A case study

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ABSTRACT

Hospital care is the single, largest contributor to health spending, yet evidence to guide value transformation is lacking. The large, real-world studies required to fill this void are challenging to conduct in the complex and fast-paced acute care environment. To address these challenges, we created a framework that combines Lean manufacturing methodology and Applied Research principles. We deployed this framework to design, pilot, and iteratively improve a study protocol testing the effectiveness of an innovative care pathway for patients hospitalized with acute exacerbations of Chronic Obstructive Pulmonary Disease. Over a three month period, the protocol was successfully piloted and refined at a single site, subsequently becoming the basis for a large system-wide randomized controlled trial. This framework combining Lean and Applied Research methods resulted in synergies that neither method could accomplish alone and may serve as a template for learning healthcare systems to efficiently generate real-world evidence in the acute care setting.

1. Background

As healthcare payments in the United States continue to shift towards value-based purchasing, healthcare delivery systems are increasingly interested in learning how to deliver high-quality care at decreased costs. While the single largest contributor to health spending is hospital care, evidence showing how to decrease costs and improve quality (i.e. value) in acute care settings is lacking [1]. To fill this void and drive sustainable improvements in value requires evidence that is rigorous, broadly applicable, and timely. Unfortunately, current quality improvement and research approaches fall short of delivering on these requirements, and thus new evaluation frameworks are needed.

Lean manufacturing methodology is a quality improvement framework that has been widely adopted by hospitals, particularly in very process-oriented settings like operating rooms. In general, Lean methods focus on improving 'customer value' and 'removing waste' through in-depth examination of processes that define activities as either 'value add' or 'non-value add' [2]. Lean's strengths include demonstrable success in understanding complex hospital processes, engaging diverse stakeholders to identify opportunities for improvement, modeling how care innovations fit within existing processes, and rapidly iterating to refine newly implemented processes [3]. Despite its

widespread integration into hospital quality improvement, a recognized short-coming of Lean is that very few studies demonstrate improved patient outcomes. This paucity of evidence is due in part to the lack of rigorous, prospective evaluations and a focus on process outcomes rather than patient-oriented outcomes [4].

As hospitals have increasingly adopted Lean, Applied Research has also evolved as a discipline that informs value-based decision making through the evaluation of healthcare innovations [5]. Applied Research generates broadly applicable evidence by conducting evaluations in real-world settings using rigorous study designs. However, for Applied Research to reach its potential, it must overcome challenges inherent to the acute care environment's complexity like integrating study protocols into fast-paced workflows and achieving buy-in across a labyrinth of provider and operational stakeholders.

We saw potential synergy in creating a new Lean/Applied Research evaluation framework that would harness the strengths unique to each of these approaches. This framework leverages Lean methodological strengths to guide a much deeper understanding of process, context, and stakeholder engagement for more efficient, relevant intervention development. It then relies on the rigor and pragmatism found in Applied Research methods to create a corresponding, robust study protocol focused on patient-oriented outcomes.

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Researchers and Lean experts at our health system had an opportunity to test the feasibility of this new Lean/Applied Research framework, when our leadership asked the question: "Can we implement an intervention to improve standardization of care delivery for patients with Acute Exacerbation of Chronic Obstructive Pulmonary Disease (AECOPD), while reducing drivers of cost?" As our system was preparing to enter into COPD value-based payment models, we needed to be able to answer this question rigorously, efficiently, and with results applicable to our broader healthcare system. The AECOPD population was specifically identified as a target for value-focused improvements because of its high prevalence in our healthcare system (over 10,000 COPD patient admissions annually), high costs, and the associated morbidity reflected in national statistics. For example, Medicare patients discharged after an AECOPD hospitalization are readmitted at rates approaching 20% at 30 days, and 7.3 million Emergency Department (ED) visits were for COPD in 2015, resulting in annualized costs of $32 billion in 2010 [6,7]. This case study describes how we deployed the Lean/Applied Research framework to guide the development of an intervention and study protocol designed to both improve value for the AECOPD population and inform health system decisions.

2. Methods

2.1. Setting

The planning and piloting activities for this case study, occurred at a 185 bed, urban hospital within Atrium Health –a large, integrated healthcare system in Charlotte, North Carolina. The pilot was reviewed by the Atrium Health Institutional Review Board (IRB) and deemed to be quality improvement.

2.2. Lean/Applied Research framework

The Lean/Applied Research framework is based on the following four steps: (Step 1) Define the current state of processes and care activities using historical patient data; (Step 2) Engage stakeholders from across the care continuum in intervention design; (Step 3) Pilot intervention implementation using Plan Do Study Act (PDSA) cycles and Lean huddles to guide iterative improvements; and (Step 4) Develop a research study protocol that incorporates patient-oriented outcomes (Fig. 1). Similar conceptually to the Lean "model cell", the planning and piloting activities within the framework ideally take place at a single site prior to more widespread implementation [8]. In this case, our Lean and research teams worked through each step at a pilot hospital with a patient mix that was generalizable to the rest of the organization.

2.3. Step 1 - define current state

A clinical member of the team performed chart reviews to define care activities for 21 patients hospitalized with AECOPD. The care activities that all patients experienced during their stays were categorized based on common themes into four phases: (i) diagnosis and treatment initiation; (ii) stabilization; (iii) recovery; and (iv) discharge readiness (Fig. 2). At the same time, the data analytics team prepared a summary of the AECOPD population's demographics and outcomes of interest like readmission rates.

2.4. Step 2 – engage stakeholders

The data describing the population and the phases of care abstracted from chart review were used as the basis for Lean Value Stream Mapping (VSM). We assembled a multidisciplinary team of clinical providers and hospital leaders for two in-person meetings to develop an intervention designed to change the selected value outcome − 30 day acute care utilization for the AECOPD population. The research team collated existing evidence and expert consensus to inform the group's work creating a future-state VSM. This VSM outlined activities that should occur for the majority of patients within the four phases (Fig. 2). Individual providers (e.g. the attending) or clinical groups (e.g. respiratory therapy department) were assigned responsibility and accountability for each activity. The final VSM included discrete, evidence-informed activities, the timing of the activities, and responsible parties, which formed the basis of a comprehensive AECOPD intervention bundle. The team recommended the intervention bundle also include: a renewed push to improve utilization of an existing, but inconsistently executed, AECOPD order set (orders for steroids, antibiotics, a short and long acting bronchodilator protocol, COPD education, smoking cessation, and pulmonary rehabilitation referral); a daily alert to proactively identify patients admitted with possible AECOPD; and a COPD coordinator to manage patients to this clinical pathway and address gaps in care.

2.5. Step 3 – pilot intervention

After presenting the AECOPD intervention bundle to clinical teams across the hospital, we launched the pilot in May 2017. Over the subsequent three month period, we used daily and weekly Lean huddles to evaluate improvement opportunities and drive iterative changes. Key performance indicators were tracked and analyzed.

2.6. Step 4 – develop study protocol

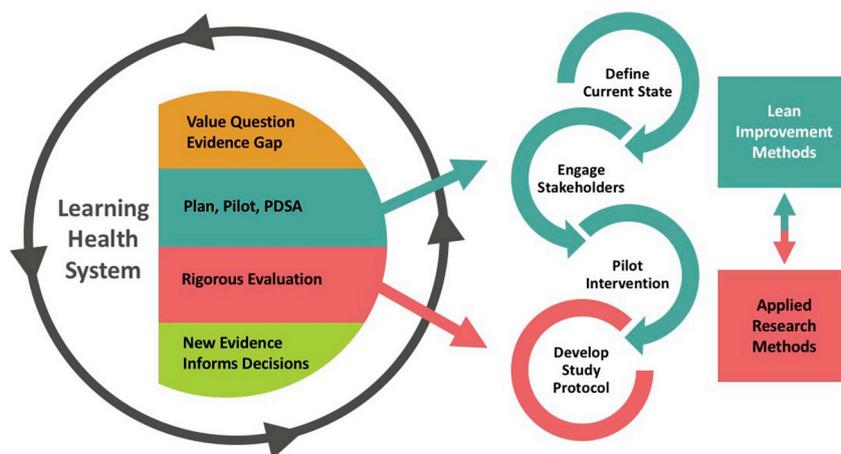As the pilot progressed in Step 3, the research team developed the

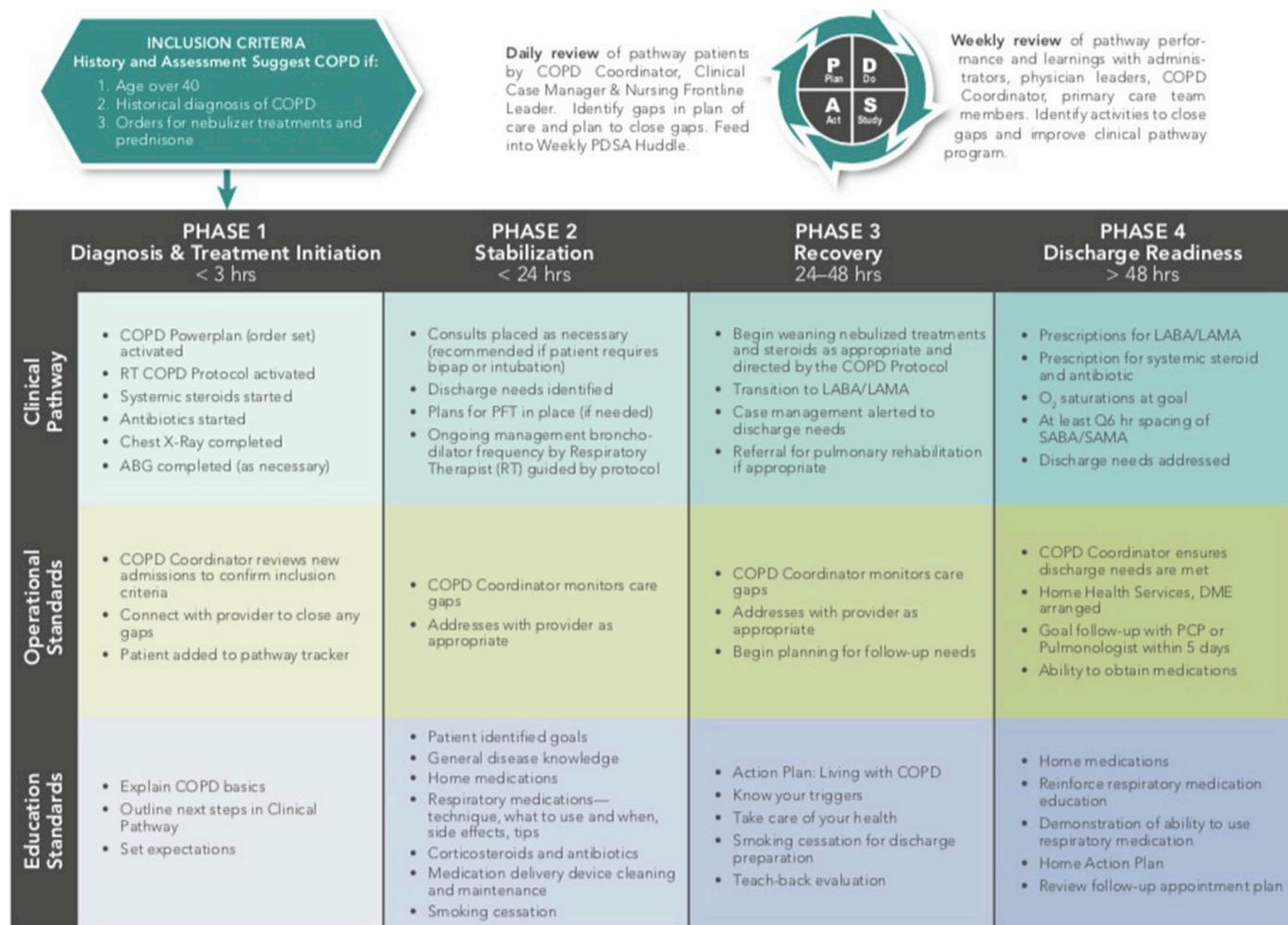**Fig. 1.** Lean/Applied Research evaluation framework.

Fig. 2. Lean Value Stream Map derived COPD clinical pathway.

study protocol in parallel. Based on stakeholder feedback and the pilot intervention findings, we chose a stepped-wedge randomized controlled trial design to be implemented across eight additional hospitals within the same healthcare system. The research team worked to have the protocol completed and IRB approval by the completion of the Step 3 pilot. This study, called the COPD Pathways Trial, and its results are presented elsewhere (clinicaltrials.gov/ct2/show/NCT03207776).

2.7. Eligibility

Patients included in the pilot analyses were over 40 years old with a discharge diagnosis of COPD exacerbation (ICD 10 code J44.1). Patients were excluded from the readmission analysis if they died during their index stay or left against medical advice.

2.8. Process metrics and outcomes

Process metrics and outcomes were collected retrospectively from clinical and administrative data over the three-month period of the pilot (May–July 2017) and for comparison from the same period one year earlier (May–July 2016). Because a central focus of the intervention bundle was use of the AECOPD order set, the rate of its utilization for patients with AECOPD was chosen as the pilot's primary process metric. We also examined length of stay (LOS) and orders for each of the individual medication components in the order set: antibiotics, steroids, short-acting bronchodilators, and long-acting bronchodilators. We collected outcome measures to demonstrate feasibility for the COPD Pathways Trial. These outcomes included 30-day readmissions and

acute care utilization, both of which are patient-oriented and significant drivers of costs. A readmission was defined as an unplanned, inpatient, or observation admission within 30-days of index discharge to any of 40 hospitals within the healthcare system. Acute care utilization included 30-day readmissions and ED utilization.

2.9. Analysis

All data are presented as means and proportions. Because of the pilot design, no power analysis or statistical analyses were planned.

3. Results

During the timeframe May 1, 2016 through July 31st, 2016, 82 patients met inclusion criteria compared to 147 from May 1, 2017 through July 31st, 2017. The 2017 cohort had higher percentages of Caucasian and male patients (Table 1). Of patients admitted with AE-COPD, 73% had the AECOPD order set initiated by providers in 2017 versus 54% in 2016. Additional process metrics are reported in Table 1. In the 2016 baseline and 2017 pilot periods respectively, LOS was 4.2 days versus 4.5 days; the 30-day readmission rates were 21.0% versus 19.3%; and 30-day acute care utilization was 31.7% versus 32.0%.

4. Discussion

This case study outlines the steps we took to implement a new Lean/ Applied Research framework. Many synergies resulted from combining Lean and Applied Research methods. First, Lean methodology

Table 1
Patient characteristics and outcomes.

	Baseline Cohort 5/1/16–7/31/16 (n = 82)	Usual Care 5/1/17–7/31/17 (n = 147)
Male, n (%)	31 (38)	67 (46)
Race, n (%)		
African American	59 (72)	75 (48)
Caucasian	23 (28)	71 (51)
Other	0 (0)	1 (1)
Age, mean (SD)	63 (8)	65 (11)
Process metrics, n (%)		
Patients with an AECOPD order set	44 (54)	107 (73)
Patients with an activated Bronchodilator Protocol	32 (39)	111 (76)
Antibiotic ordered during encounter[a]	64 (78)	124 (84)
Steroid ordered during the encounter[a]	80 (98)	142 (97)
Short acting bronchodilator ordered during the encounter[a]	82 (100)	146 (99)
Long acting bronchodilator ordered prior to discharge[a]	61 (74)	124 (84)
Average length of stay (days)	4.2	4.5
30-day readmission rate (observation and inpatient), %	21.0	19.3
30-day readmission rate (inpatient only), %	18.5	16.4
30-day acute care utilization[b], %	31.7	32.0

SD, Standard Deviation.

[a] At least 1 medication order during the encounter.

[b] Acute care utilization is defined as having at least one observation, inpatient, or emergency department encounter.

facilitated rapid understanding of granular care processes and opportunities for improvement, which led to a more clearly defined and informed AECOPD intervention. Second, piloting the intervention prior to the system-wide COPD Pathways Trial allowed the research team to iterate and adapt the care pathway, creating a more relevant intervention that integrated into workflows. The following are examples of iterations made possible through the pilot and the daily Lean huddles: (i) the group refined protocols for how the COPD coordinator should engage providers when care gaps were identified; (ii) the algorithm to identify potential AECOPD patients in real-time underwent six iterations and repeat testing before settling on the model to be used in the trial; and (iii) providers gave feedback that certain elements with the AECOPD order set (routine respiratory viral panels and initial arterial blood gases) should be removed from 'standard care', as disagreement existed over doing these for all patients. Third, informed by operational stakeholders, the pragmatic RCT design met the health system's need for timely information to inform decision-making, balanced by rigor and a focus on patient outcomes. Finally, the broad stakeholder engagement throughout the planning process set the stage for improved buy-in from providers at each new hospital onboarded during the COPD Pathways Trial.

As a single site case study, conclusions are limited to the feasibility

of implementing this new evaluation framework. Additionally, pre-post data do not control for confounders and should be interpreted cautiously. An example of one such potential confounding factor during this study was the health system's decision to increase outside ED transfers to the pilot hospital. This operational change is reflected in the increased AECOPD patient volumes, which may have had independent effects on process and outcome measures.

This Lean/Applied Research framework helped us effectively plan the intervention and study protocol for the COPD Pathways Trial. Because of the resultant efficiencies, the actual COPD Pathways Trial ultimately took only 12 months from planning to completion. Thus, we were able to inform health system decision-making by generating evidence that was rigorous (RCT), broadly applicable (pragmatic design), and timely (12 month cycle-time). The Lean/Applied Research framework may serve as a template for learning healthcare systems to better define the science of how costs and patient outcomes are improved in acute care settings.

Conflicts of interest

AM is cofounder of iEnroll, LLC. No other authors report any potential conflicts of interest.

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References

[1] National Health Expenditures 2016 Highlights https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf Accessed August 2018.

[2] J. Moraros, M. Lemstra, C. Nwankwo, Lean interventions in healthcare: do they actually work? A systematic literature review, Int. J. Qual. Health Care 28 (2) (2016) 150–165.

[3] T.P.C. Rotter, L. Adegboyega, M. Fiander, E.L. Harrison, R. Flynn, J.G. Chan, L. Kinsman, Lean management in health care: effects on patient outcomes, professional practice, and healthcare systems (Protocol), Cochrane Database Syst. Rev. 11 (2017).

[4] J.R. Vest, L.D. Gamm, A critical review of the research literature on Six Sigma, Lean and StuderGroup's Hardwiring Excellence in the United States: the need to demonstrate and communicate the effectiveness of transformation strategies in healthcare, Implement. Sci. 4 (2009) 35.

[5] T.A. Lieu, R. Platt, Applied research and development in health care - time for a frameshift, N. Engl. J. Med. 376 (8) (2017) 710–713.

[6] Chronic Obstructive Pulmonary Disease (COPD) Includes: Chronic Bronchitis and Emphysema. https://www.cdc.gov/nchs/fastats/copd.htm. Accessed November 2017.

[7] COPD Costs. https://www.cdc.gov/copd/infographics/copd-costs.html. Accessed December 2018.

[8] J. Toussaint, Transformation House, (2016) Accessed December 2018 https://createvalue.org/wp-content/uploads/ACN0116carter.pdf.