Critical Review Form
Therapy

PGY-2

Application of lean manufacturing techniques in the Emergency Department. *J Emerg Med*. 2009 Aug; 37(2):177-82.

Objectives: **"To evaluate whether the adoption of Lean principles by an Emergency Department (ED) improves the value of emergency care de- livered." (p. 177)**

Methods: **This observational study was conducted in the ED of a level one trauma center with an annual volume of 37,000 patients, at a tertiary referral center in the rural midwest associated with an Emergency Medicine Residency Program. Outcomes were measured in 2005, and again in 2006 after implementation of Lean strategies.**

ED managers, nurses, providers, and ancillary staff participated in a 5-day kaizen event about Lean principles and techniques. During this event, each member mapped a portion of the total patient flow process; a value stream map (VSM) was then created to identify areas within the process with the most waste. Process improvement ideas were then generated and the team worked on process redesign, and finally process implementation and refinement. Process improvements included many items such as 1) the immediate placement of patients in exam rooms with bedside registration when possible, 2) a team-based approach whereby history was obtained by nurses, residents, and attending physicians simultaneously when possible, and 3) earlier ordering and sending of lab tests and x-rays.

Outcome measures included percent of patients rating ED care as "Very Good," average monthly expenses per patient per month, ED length of stay (LOS), and average number of patient visits per month. As there was a 4.6% hourly rate increase in nursing personnel, the data from 2005 were normalized to the 2006 rate. There was no change in the number of ED physicians or treatment rooms.

Guide		Comments
I.	**Are the results valid?**	
A.	**Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?**	
1.	Were patients randomized?	No. This was a before and after study in which the "control" group was the ED prior to Lean process improvement. No randomization occurred.
2.	Was randomization concealed (blinded)?	No. The providers (physicians, nurses, patient care technicians) were aware of and involved in the institution of changes in patient flow. The potential impact of the Hawthorne Effect needs to be considered when interpreting the results.
3.	Were patients analyzed in the groups to which they were randomized?	Yes. The analysis was between the ED in the 3 months prior to and the 3 months following implementation of Lean process improvements.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	No. While there was no difference in the number of ED treatment rooms available and physician staffing, there was a 4.5% hourly rate increase in nursing personnel. There was also a 9.23% increase in patient visits per month (2818 vs. 3078; $p < 0.01$) and a 15% increase in admission rates. It is also possible that other interventions occurred in the ED or in the hospital during this study period that would have influenced the results.
B.	**Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?**	
1.	Were patients aware of group allocation?	Yes. There was no way to blind patients to triage processes and patient flow. It is unlikely that this would affect the outcomes described.
2.	Were clinicians aware of group allocation?	Yes. The providers (physicians, nurses, patient care technicians) were aware of and involved in the institution of changes in patient flow. The potential impact of the Hawthorne Effect needs to be considered when interpreting the results.
3.	Were outcome assessors aware of group allocation?	Uncertain. The authors do not mention whether or not the outcome assessors were blinded to the changes implemented. The outcomes were objective and would not likely be influenced by blinding.
4.	Was follow-up complete?	Yes. All patient visits were presumably included in the analysis, although the chart review and data collection methods were not provided.

II.	**What are the results (answer the questions posed below)?**	
1.	How large was the treatment effect?	• Average LOS was higher in the 3 months prior to Lean implementation compared to the 3 months following Lean implementation (161 min vs. 148 min). • Despite the reported 9.23% increase in annual patient visits, average LOS remained stable in the years prior to and following Lean implementation (160 vs. 157). • Using a continuous Press-Ganey survey, the percentage of patients ranking their overall ED experience "Very Good" was lower in the year prior to Lean implementation compared to the year following Lean implementation (54% vs. 59%, $p < 0.01$). • Inflation-adjusted direct expense per patient (including nursing care, nursing assistants, and medical supplies) was similar in the years prior to and following Lean implementation ($121 vs. $124).
2.	How precise was the estimate of the treatment effect?	95% confidence intervals were not provided. As standard deviations were also not provided, there is no way to calculate the 95% CIs.
III.	**How can I apply the results to patient care (answer the questions posed below)?**	
1.	Were the study patients similar to my patient?	No. While the study ED was a level 1 trauma center associated directly with an Emergency Medicine Residency Program, the volume was much lower than that seen in our institution (37,000 vs. ~100,000). This ED was also located in rural setting, which would result in very different logistics compared to our urban environment.
2.	Were all clinically important outcomes considered?	No. While patient satisfaction and average ED LOS were assessed, other outcomes such as time to triage, arrival to room time, and time to be seen by a physician were not considered. Additionally, patient safety outcomes such as mortality and sentinel event rates were not considered.
3.	Are the likely treatment benefits worth the potential harm and costs?	Yes. Value stream mapping and Lean process improvements are inexpensive to institute. It would be helpful to know if the benefits seen in this study persisted beyond the study period. A repeat assessment outcomes after a sufficient washout period would help in this regard.

Limitations:

1) **Before and after study with no true control. It is possible that other interventions occurred during the study period that would influence the results.**

2) **Failure to identify *a priori* a primary outcome (Pocock 1997).**

3) **Very few details are provided regarding the process changes implemented.**

4) **No attempt was made to control for confounders (such as hourly rate increase in nursing personnel).**

5) **Failure to include chart review and data collection methods Gilbert 1996, Worster 2004).**

6) **It is unclear if the ED staff was aware of the research being conducted. It is likely that the Hawthorne Effect had some influence on the outcomes.**

7) **Outcomes were provided over different time periods for the different outcomes (3 months for LOS, one year for patient satisfaction) with no explanation for this inconsistency provided.**

Bottom Line:

A series of Lean process improvements in this small, rural Emergency Department resulted in decreases in length of stay when measured 3 months before and after implementation, and increased patient satisfaction when measured the year prior to and after implementation. The study suffered from many methodological flaws that make interpretation difficult, including failure to identify a primary outcome, failure to account for other potential confounders, and inconsistencies in outcome reporting.