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ONLINE SUPPLEMENT

Reducing Door-to-Needle Times using Toyota's Lean Manufacturing Principles and Value Stream Analysis

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Supplemental Expanded Methods:

Lean Improvement Process, Value Stream Analysis, and Streamlined Acute Stroke Protocol

In 2006, the hospital's leadership made a hospital-wide commitment to improving processes by way of lean manufacturing principles, employing lean experts and taking advantage of several lean tools. Lean performance engineers analyzed numerous processes across several departments, of which neurology was one. The VSA directed at our acute stroke protocol represents one aspect of a much larger lean process improvement within the hospital and specifically within the hospital's neuroscience division. Several rapid improvement events (known as Kaizen) and other lean tools such as 5S (sort, straighten, shine, standardize, sustain) were implemented to help develop the standard work for other processes besides tPA delivery, such as: expediting patient discharge, improving flow within the outpatient neurology clinics, and facilitating outside hospital transfers/drip and ships, amongst other projects.

With regard to expediting tPA delivery for patients arriving in the ED, a VSA was performed. Over two days, a multi-disciplinary team met which included: a lean performance management engineer, ED and neurology physicians, ED nurses, patient care and radiology technicians, and an ED pharmacist. The VSA involved four steps outlined below:

1) **"Current-State Analysis" -** The current acute stroke protocol was mapped out step by step from patient arrival to tPA bolus. A critical review of each step revealed sources of productivity that "added value" or sources of lost productivity, i.e. "waste". Input was obtained from all team members who were directly involved with each step of the process, and team members were asked to build the current tPA protocol, step-by-step. Additional notes were added to the flow-chart to identify steps as "wasteful" or those that "added value".

   As a brief description of our pre-VSA protocol, since 2004, we have utilized a resident-based stroke protocol placing post-graduate-year-4 ("chief") neurology residents in decision-making roles for tPA administration[1]. The protocol was initiated by the ED triage nurse upon activation of the acute stroke pager. On arrival, the patient was placed

in the trauma bay where the junior neurology resident evaluated the patient by obtaining the history, time-of-onset, and NIHSS; the patient care technician obtained the ECG; the nurse place an IV and sent labs; the patient was taken to head CT; and the patient was returned to the room where the neurology resident called the chief resident to discuss the tPA decision.

2) **"Future-State Analysis" -** The second step of the VSA was to focus on the primary barriers preventing rapid tPA treatment (steps that were wasteful) and eliminate them from the protocol. A root-cause analysis was performed with a goal of identifying the root cause of tPA-treatment delays beyond 30 minutes. Several tPA cases which had DNT's > 30 minutes were discussed. We compared "what actually occurred" to what "should have occurred". Then supporting causes were discussed until one or more root-causes were identified. In the end, a few root causes for a delay in tPA treatment were identified, from which several potential solutions were identified and Standard Work for this process was defined. Wasteful steps included: 1) inefficient patient flow, requiring a patient to be routed by EMS to the trauma bay, then to CT, then back to the room; such inefficient flow led to redundant procedures whereby a patient was placed on a cardiac monitor, then removed, and then re-attached after imaging; 2) serial processing of multiple tasks and inefficient use of available staff, such as reliance on the neurology resident for obtaining the history, exam, and tracking down witnesses for time-of-onset; and 3) delays in laboratory processing in patients suspected of being on oral anticoagulation.

3) **"Action Plan" –** Next, a "lean" process was formulated to retain the steps that were crucial to efficient and safe tPA delivery, while excluding those that only caused delay. The action plan described the implementation of a streamlined protocol which addressed the inefficiencies identified in the root-cause analysis: 1) patients were routed directly to the CT scanner by EMS, and then brought to the trauma bay; 2) the ED residents were given a shared responsibility such that the neurology and ED residents divided the tasks of obtaining the brief history and performing the NIHSS. During the daytime hours, (7am-7pm) the ED residents obtain the history while the Neurology residents perform the NIHSS. During the evening hours (7pm-7am) the neurology residents obtain the history while the ED residents performed the NIHSS. In this way the residents would become skilled in acquiring the relevant history/time of onset as well as learning how to perform the NIHSS; the pharmacists and social worker were assigned tasks such as calculating the tPA dose / preparing tPA and bringing witnesses to the bedside (or getting them on the phone) so physicians could quickly determine time of onset, respectively; and 3) point of care (POC) testing for INR was implemented so that patients suspected of being on oral anticoagulation could be tested rapidly. POC INR completion times were not tracked post-VSA (INR results were immediately available at the bedside) and thus could not be compared before and after the protocol change.

While not all inefficiencies could be remedied due to budget or logistical constraints, each was discussed and a solution was provided to the greatest extent possible. The streamlined protocol was initiated on March 1, 2011. Flow-charts of the old and new stroke protocols are shown for comparison of major differences (Figure). There were no differences between the two protocols with respect to how the residents were trained to obtain the onset time, perform the NIHSS, or manage blood pressure prior to tPA treatment. Moreover, both pre- and post-VSA, the protocol did not require waiting

for laboratory results of INR, PTT, or platelet count, unless patients were suspected of having a bleeding abnormality, low platelets, or being on anticoagulation.

4) **"Feedback Loop for Continued Improvement"-** As an important component of lean methodology, a two-step plan for continued improvement in order to continually identify sources of waste, was created and implemented: (1) when tPA is administered, the case is reviewed by a stroke neurologist and ED attending with stroke fellowship training within 24 hours of tPA administration. For any case that has a DNT outside of the expected range (< 25 minutes or >35 minutes), immediate feedback is requested from the junior ED and neurology residents involved in the tPA case. Details and metrics are reviewed and the potential causes for each delay are identified and addressed through nursing, pharmacy, resident education, attending education, etc. If the DNT is faster than expected, the case is also reviewed in detail to identify ways to continue the process that led to an expedited tPA delivery. The process is modified accordingly and the results of the modification are re-evaluated within monthly quality control meetings. (2) Monthly meetings occur on the 4th Thursday of each month. All team members (similar representation as in the VSA with neurology / ED residents and attendings, ED nurses, and pharmacists) meet to review every tPA case in detail with particular attention to cases with DNT's > 30 minutes, stroke mimics, and cases of sICH / in-hospital mortality. In this forum we continually monitor standard work. We identify sources of waste and determine how to eliminate them.

Supplemental Results

S1: Quarterly comparison of DNT in post-VSA

	Median NIHSS	Median DNT *
1st Quarter: 3/1/11-5/31/11 (N = 23)	12.0	36
2nd Quarter: 6/1/11-8/30/11 (N = 22)	7.5	40
3rd Quarter: 9/1/11-11/30/11 (N = 18)	6.0	40
4th Quarter: 12/1/11-3/1/12 (N = 24)	5.0	39

* ANOVA, p=0.88.

S2: Volume and proportion of tPA-treated patients pre- and post-VSA

	Pre-VSA 1/1/2009-2/28/2011	Post-VSA 3/1/2011-3/1/2012	P-value
tPA-treated patients per month, n	5	7	0.08
tPA-treated patients / total ischemic stroke patients admitted from ED, %	13%	18%	**0.03**

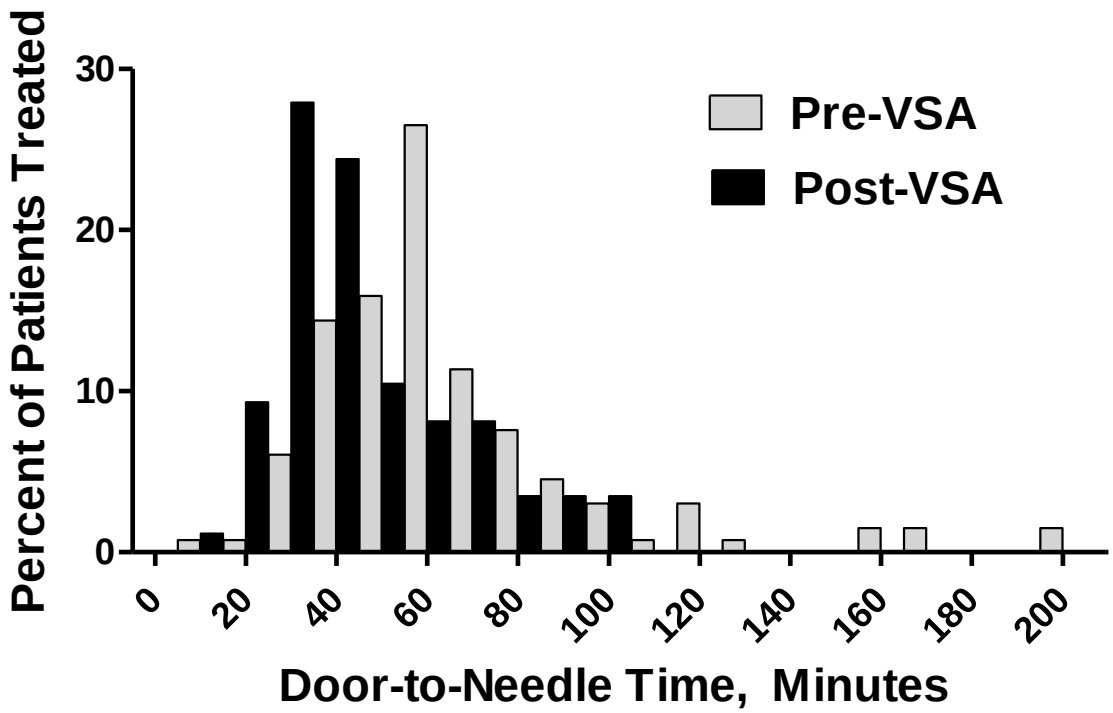
S3: Discharge Diagnoses for Pre-VSA and Post-VSA Stroke Mimics

Stroke Mimic Diagnosis	Pre-VSA (N=9)	Post-VSA (N=10)
Seizure	2	2
Migraine	4	2
Conversion Disorder	1	4
Other	2 (HIV encephalopathy, alcohol intoxication)	2 (transient global amnesia, stroke recrudescence)

S4. Clinical Outcomes after removal of patients with a final discharge diagnosis other than ischemic stroke.

	Pre-VSA 1/1/2009-2/28/2011 N=123 Excluding 9 Stroke Mimics	Post-VSA 3/1/2011-3/1/2012 N=77 Excluding 10 Stroke Mimics	P-value
Door-to-Needle Time, min*	59 [45, 70]	39 [28, 56]	**P<0.0001**
Symptomatic ICH	3.3%	3.9%	P=1.0
Favorable Discharge Location[+]	74%	80%	P=0.31
90 day mRS 0-2[++]	50%	41%	P=0.32
Length of Hospital Stay, days*	4 [3, 7]	3 [2, 7]	P=0.071

*Reported as median [interquartile ratio].
ICH=intracerebral hemorrhage
[+] Favorable discharge location=discharge to home or inpatient rehabilitation; unfavorable discharge location=discharge to nursing home or in-hospital death
[++] 90 day mRS=Modified Rankin Score of 0-2 at 90 day telephone follow-up.



S5. Relative Frequency of Door-to-Needle Times Pre- (gray bars) and Post- (black bars) VSA

Supplemental References:

1. Ford AL, Connor LT, Tan DK, Williams JA, Lee JM, Nassief AM. Resident-based acute stroke protocol is expeditious and safe. *Stroke*. 2009;40:1512-1514.