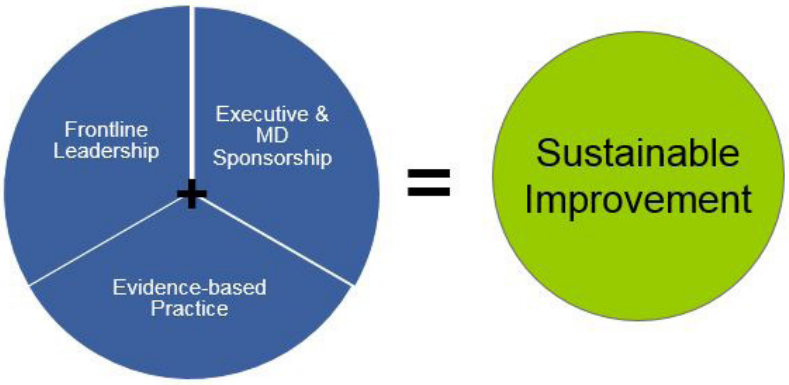
Implementation

Implementing Change



"Every system is perfectly designed to get the results that it gets."

"Inadequate systems produce inadequate results."

The INLP formula for change relies on three primary components to support a sustainable improvement: sponsorship and support from the executive level and doctors; developing frontline leadership; and implementing evidence-based practices.

Executive & MD Sponsorship

- Expertise & Clinical Knowledge
- Keepers of protocols & procedures
- Heads of departments
- Encouragement & Support
- Advocacy for positive change
- Collaboration

Frontline Leadership:

Process Redesign

- Identifying successful innovations, Making process changes, Developing tools, Identifying work flow changes needed, Identifying tests of change, Rapid cycle testing

Data Management

- Proper coding for data collection, Data collection processes, Statistical analysis, Data reporting, Using data to validate tests of change

Communications

- Goal-based communications, Branding, Promotion & Awareness, Communications Program, Development, Presentation training, Stakeholder analysis

Change Management

- Organizational influence, Executive engagement, Policies & procedures, Team building, Peer sharing and adoption of innovation, Implementing work flow changes

Evidence-based Practice

- The best available clinical practice
- Supported by research
- Proven effective
- Systematic & rigorous
- Standardized protocols
- NOT ad hoc
- Measurable

"Unpacking" the Components of "Change"

1. **How we did it/ How you can do it**
   - Focus on reliable systems & processes
   - Medication errors
   - Sepsis
   - Followed evidence-based practice
   - Decisions based on hard data

Errors come from bad teamwork and a toxic hospital culture, something that is endemic to the entire health care system…Checklists are useful, but they're not Harry Potter's wand.

2. **Why it works**
   - Goal-directed with specific aims
   - Institution-wide approach
   - Identifies sub-optimal systems (cross departmental)
   - Real-world tests (PDSA cycles) identify viable fixes (small steps, measured and validated)
   - Iterative process enables constant refinement

3. **What it looks like in practice**
   - Teamwork (Core Resource Teams / Unit-based Deployment Teams)
   - Front-line leadership
   - Executive & MD Sponsorship

We focus on process improvement and reliability across the entire system...

Focus on Reliable Systems & Processes

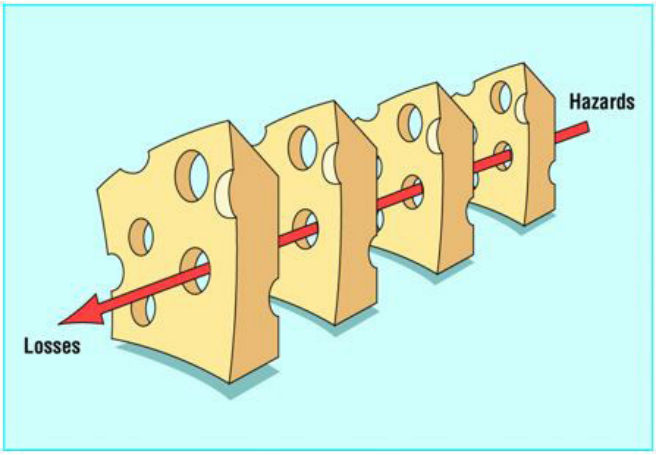
because you can't get better results without putting a better system in place.

While it may seem like the long-route, focusing on process instead of just the end result is important. When there are multiple steps within a certain process, the probability of successful implementation is reduced significantly. As you can see from the chart below, mistakes add up with increasingly complex processes.

	Probability of Success with Increasing Complexity				
		95%	99%	99.9%	99.99%
# of steps in a process	1	0.95	0.99	0.999	0.9999
	25	0.28	0.78	0.975	0.997
	40	0.12	0.66	0.96	0.995
	100	0.006	0.37	0.90	0.99

The Swiss Cheese Model of Harm

A model of systems analysis was developed by British psychologist James Reason to understand the nature of preventable adverse events. By studying industrial accidents across diverse fields, Reason determined that adverse events are almost never caused by individual errors in isolation. Conversely, he recognized that the majority of serious errors were caused by embedded flaws in a system or environment. The "Swiss Cheese" Model of Harm describes this, depicting flaws in the environment as holes in the cheese, which when lined up with human error, can lead to disastrous consequences. As seen in the image of the model below, in poorly designed systems, inadequacies line up and build on each other, with the end result being harm or loss.



A Systematic Process for Reducing Medication Errors

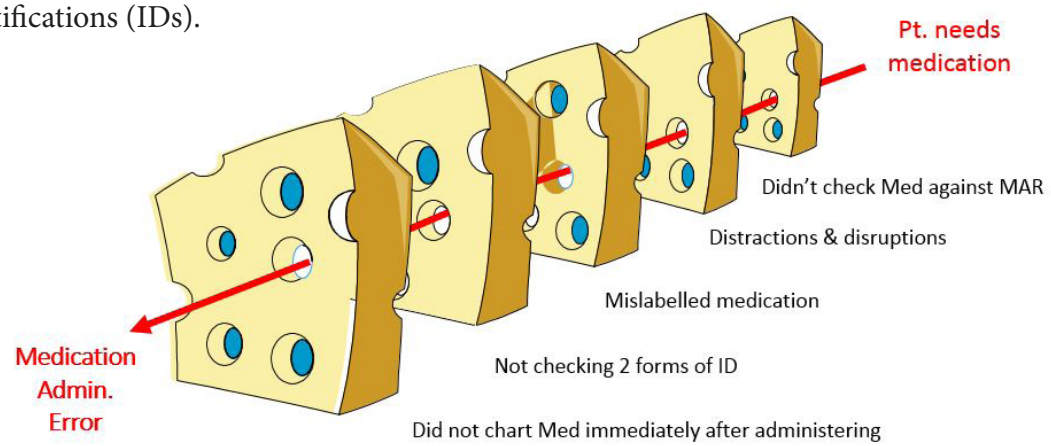
The Medication Administration project goals included:

- Improve Administrative Medication Errors by 50% from baseline
- Improve process measures by 80%
- Improve outcome measures by 50% (harm measures)

Project teams each worked on six safety processes to improve the accuracy of medication administration. These processes were chosen based on their endorsement by the California Nurse Outcome Coalition (CalNOC), a collaborative alliance for nursing outcomes. Each of the processes were derived from evidence-based literature.

The six safety processes included:

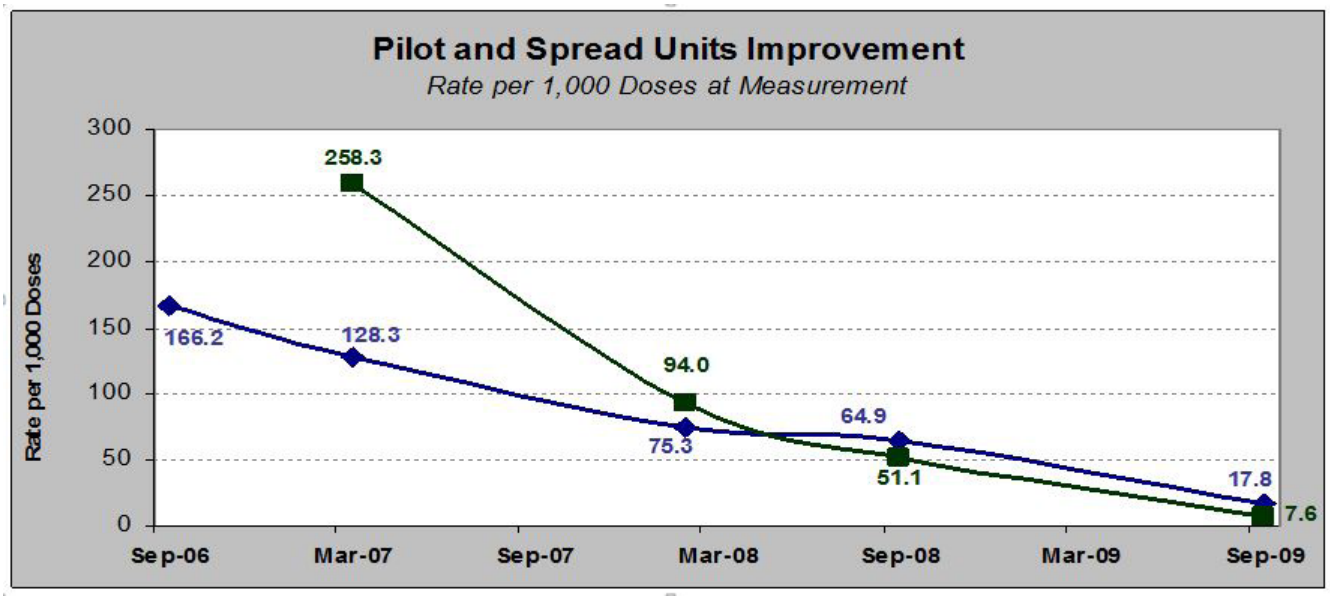
- Compare medication to the medication administration record (MAR).
- Keep medication labeled throughout.
- Check two patient identifications (IDs).
- Explain drug to patient (if applicable).
- Chart immediately after administration.
- Protect process from distractions and interruptions.



James Reason; CalNOC

Impact

By improving the quality and reliability at each step in the process we were able to see dramatically improved results. The chart to the right shows the steady decrease in rates of medication errors on both the pilot unit, as well as the spread units from 2006 through 2009.



A Systematic Process for Managing Sepsis

Based on our success with reducing medication errors, we asked, "Can the Same Approach Be Applied to Sepsis?" Clinical Evidence suggested that it could, and that sepsis diagnosis & treatment could be managed as a repeatable, standardized process. Over the following 2 years we learned that creating reliable processes could dramatically improve results, and Early Goal-Directed Therapy (EGDT) works.

Using the Swiss Cheese Model of Harm, we were able to map out the different processes that, when lined up, could result in potentially avoidable patient harm (in this case, sepsis mortality).

The INLP Sepsis project goals included:

- 15% reduction in the mortality rate from severe sepsis through improved early recognition and treatment within 18 months
- Use of screening tool 95% of the time
- Use of "mini" bundle section of SSB/EGDT 85% of the time

An interdisciplinary steering committee of nurses, pharmacists, administrators, physicians, and laboratory directors was chosen from each hospital. This committee was responsible for oversight of the work done at the unit level, and driving the program hospital-wide.

Four core strategies were used to **reduce sepsis mortality**:

1. Each hospital attended a series of **leadership training seminars**.
2. Each unit was trained on the importance of **identifying severe sepsis and septic shock. Sepsis screening of all patients was implemented**, along with diagnostic testing according to protocol.
3. Teams implemented the "sepsis bundle" on appropriate patients. Timely treatment was based on key elements of **Early Goal-Directed Therapy (EGDT)**, including:
   - Obtaining a lactic acid level, and if elevated, or if the patient is hypotensive (or believed by the medical staff to be severely septic), then obtaining blood cultures.
   - Obtaining a lactic acid level, and if elevated, or if the patient is hypotensive (or believed by the medical staff to be severely septic), then obtaining blood cultures
   - Administering fluids and antibiotics
   - Inserting a central line to measure patient response to therapies. (optional measure for this grant)
4. **Ongoing data review:** coded data was captured and submitted by each participating unit.

Final program measurement: April 2011

A critical piece of the INLP Sepsis improvement process was that it involved ALL Departments, including:

- Nursing
- RRT
- MDs
- Units(ED, MICU, MedSurg, etc.)
- Senior Leaders
- Pharmacy
- Labs

Only by working cross-departmentally were we able to identify each step of the process, and create a standardized, and reliable system for sustained, improved care for severely septic patient care.

Barriers to Improved Sepsis Process*

Perception Barrier:
- Need to upgrade sepsis to critical event (e.g., AMI, trauma, stroke)

Institutional barriers:
- Interdepartmental communication (MD, RN)
- Department collaboration (Lab, Pharm)
- Silo mentality between the ED, ICU and other floors

Professional barriers:
- Variation in expertise with HCPs
- Lack of expertise acknowledgment
- Cross coordination between disciplines
- Professional role challenged

Time lag:
- Between care elements & between departments

Data:
- Real-time and useful information not available

*Amended from Rivers & Ahrens

Frontline Leadership

While INLP deployed interprofessional leadership across departments, the primary profession focused on for leading quality improvement efforts and change were RNs. INLP identified RNs as a valuable and underutilized resource as organizational change agents.

Nurses typically:

- Work closest to the patients' bedside
- Are charged with implementing most processes
- Have valuable insight into what's working... and what's not
- Know how and why "work arounds" happen

Implementing the Improvement Infrastructure

As discussed in detail in the Core Curriculum section, INLP projects were implemented through a variety of modes, including on-site engagement, off-site trainings, and through embedded improvement projects in the hospital environment. Four areas that INLP focused on to develop the leadership skills of frontline nurses engaged in the program included: Process redesign, data management, communication strategies, and change management.

Process Redesign

Process redesign was an integral part of the INLP change process. In order to address system inadequacies, new tools and workflows were developed to support and lead to the desired outcomes (improved medication administration accuracy, and a reduction in sepsis mortalities). This included:

- Identifying successful innovations
- Making process changes
- Developing tools
- Identifying work flow changes needed
- Identifying tests of change
- Rapid cycle testing

Check out some of the process innovations developed by INLP participants below...

NICU nurses now check 3 forms of ID.

This bright yellow vest was worn by nurses during med pass time, as a visual cue to other staff to minimize disruptions.

This poster was another communication method used to educate, and remind staff about a new tool being used on the unit - a red light was used as a tool to remind staff that medication administration was happening.

Process Innovation: UCSF's Sepsis Screening Tool

①Are there 2 new signs of SIRS below? ☐yes ☐ no (acute changes over baseline, use most recent assessment)	② Is there 1 new sign of Organ Failure below? ☐yes ☐ no (acute changes that are persistent for > 1 hour)	
☐ Temp > 38°C < 36°C	☐	SBP < 90 or > 40 below baseline
☐ HR > 90	☐	Mental Status Change
☐ RR > 20	☐	SpO2 < 90% on room air
☐ WBC > 12K or < 4 K (most recent lab)	☐	↑ need for O2 to maintain SpO2
③Does the patient have a suspected or confirmed infection? ☐yes ☐ no	☐	Mottled Skin
	☐	Capillary Refill > 3 seconds
① + ③ or ② + ③ = + screen → call for further evaluation		

Process Innovation: Sepsis Screening Tool

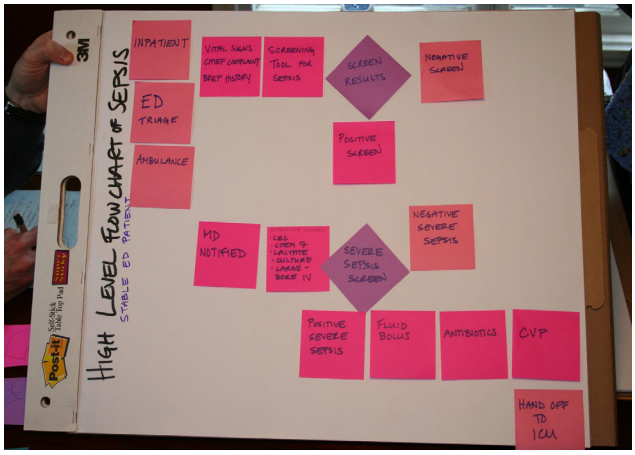
1. ❑ Y ❑ N SBP < 90 or > 40 below baseline
2. ❑ Y ❑ N ≥ 2 new signs of SIRS:
   - ☐ T>38°C or<36°C ☐ HR>90
   - ☐RR>20
   - ☐ WBC > 12K or < 4K
3. ❑ Y ❑ N ≥ 1 new signs of organ failure
   - ☐ Unexplained acute ▲in Mental Status
   - ☐ New or ↑ need for oxygen
4. ❑ Y ❑ N Suspected or confirmed infection

RN Initial: _____ Time: _____

Call MD if any of 1,or 2,or 3 are checked and 4 is checked

Two examples of sepsis screening tools developed by participating hospitals.

This poster was used by one participating hospital as a visual aid to walk clinicians through necessary EGDT bundle requirements.



Developing a high-level flowchart of sepsis during an off-site session.

Warning tape used to mark off med admin zone.

Data Management

Data management was an integral part of the change process, as it allowed team members to continually make sure that they were headed in the right direction. Details about the types of data collected, and processes for collection can be found in the Data Collection section of Section II. However, key topics included in the leadership curriculum included:

- Proper coding for data collection
- Data collection processes (i.e., bundle elements)
- Statistical analysis (e.g., run charts)
- Data reporting
- Using data to validate tests of change

Communications

Particularly during the spread portion of INLP projects, gaining buy-in for new workflows throughout participating hospitals was critical to each project's success. This required gaining support interprofessionally, and across departments. Due to the challenge of implementing unified improve processes, INLP developed a formal communication strategy, and incorporated training on goal-based communication strategies into the off-site trainings. To guide participating hospitals in developing a comprehensive communication plan, INLP provided the following **four-step process:**

"**Step 1.** Identify all key audiences and stakeholders, including individuals, committees, and departments.

Step 2. Brainstorm all potential objections to and reasons for noncompliance with the medication administration project. For example, one frequent objection concerned the failure to appreciate the problems posed by interrupting the nurse who was attempting to administer the medication. Because the first medication administration project had already proven effective on two units within each hospital, the potential reasons for not wanting to implement the project tended to focus less on the approach's efficacy and more on why the approach might not work in a specific unit or with specific patients.

Step 3. Group stakeholders on the basis of their expected objections and potential reasons for noncompliance. In some cases, the grouping of stakeholders was obvious. For example, at one hospital, during the first project the team had already en- countered resistance from intensive care unit (ICU) nurses who did not think that they needed to implement the intervention because (1) the unit is smaller and requires less travel distance be- tween activities, allowing the nurses to focus more on work at hand, and (2) each nurse is assigned only to one or two patients at a time, obviating the need for checking two forms of identification for their patients.

Step 4. Identify potential communication strategies (for example, one-on-one conversations, poster boards) to overcome the objections." [1]

Based on these four steps, a communication plan was developed by each team, with hospital-specific strategies created for specific stakeholder groups. A sample strategic communications message map can be found at the top right of this page. Lastly, the topic of "branding" was addressed, and each hospital create a tagline to facilitate consistent messaging, and promote program awareness. Program taglines were translated into logos, and incorporated across message mediums.

For the Medication Administration program, examples taglines included:

"Pass it Right", and ***"Your Safety is Our Priority."***

Additional example of communications strategies are below.

Educational "roadshow" to raise issue and project awareness.

T-shirt designed to raise awareness about the sepsis improvement project.

Integrated Nurse Leadership Program

Pass it Right

Our commitment to medication safety

"Pass It Right" Logo.

Additional strategic communication topics included in the Core Curriculum included:

- Goal-based communications
- Promotion & Awareness
- Communications Program Development
- Presentation training
- Stakeholder analysis

Change Management

Change management can be described as "an approach to transitioning individuals, teams, and organizations to a desired future state." [2] Whether on a singular hospital unit, or attempting to produce change organization-wide, there are many challenges to bringing about change. In order to address this topic, multiple aspects of managing change were addressed in the INLP core curriculum, including:

- Organizational influence
- Executive engagement
- Policies & procedures
- Team building
- Peer sharing and adoption of innovation
- Implementing workflow changes

Example of Work Flow Changes:

Problem: Timing of resident rounding was leading to unacceptable interruptions of nurses during medication administration.

Response: Members from Unit Team worked with physicians to adjust rounding schedules. Unit Team members met with chiefs of staff to explain purpose and approach to reducing medication errors.

Problem: Patients who are identified as septic require a lactate lab drawn as soon as possible. However, turn-around times for results can take up to an hour.

Solution: Unit Team and Steering Committee members lobbied Laboratory Services to place point-of-care testing machinery to run lab on unit, thus reducing time to results significantly (usually under 20 minutes).

References

Kliger, Julie. "Https://innovations.ahrq.gov/perspectives/sustaining-and-spreading-quality-improvement." AHRQ Healthcare Innovations Exchange. AHRQ, 01 Aug. 2012.

Kotter, J. (July 12, 2011). "Change Management vs. Change Leadership -- What's the Difference?". Forbes online.

Executive & MD Sponsorship

A core element of INLP was the active involvement of senior leadership. In recognition of the finding that senior leader support contributes to the sustainability of quality improvement changes, INLP required a designated senior leader at each partner hospital to sponsor the program.

This senior leader was responsible for building strategic alliances with other influential leaders, developing and deploying a message campaign, engaging clinical leaders, providing organizational resources, and providing access to resources as needed. Throughout the process, INLP provided coaching and peer support to these senior leaders to help them move the quality initiative forward. The senior leader appointed the members of the Core Resource Team, personally played an active role on the Core Resource Team, and completed specific duties throughout the life of the program.

INLP firmly believed that change could not happen without executive and MD champions. Each hospital team relied on their senior leadership for:

Expertise & Clinical Knowledge

Keepers of protocols & procedures

Encouragement & Support

Advocacy for positive change

Collaboration

Data Collection

In God we trust; All others must bring data.
- W. Edwards Deming

Nothing kills confidence like data.

Medication Administration Data Management

Overview

During the spread phase of the INLP Medication Administration project, each hospital conducted three 100 dose naive observation data collections with medical record chart review for each eligible unit. Each hospital also conducted 20 dose naive observation data collections. The scheduled 100 dose collections took place annually from September 2008 - September 2010. Additionally, hospitals provided INLP and the Gordon and Betty Moore Foundation bi-weekly project updates including roster of team participants.

Data Tracking & Management

A hospital-wide dashboard was used by each participating hospital to track data at the unit level, and determine hospital-wide averages. This dashboard, which was updated monthly and trended data over time, was used by the Core Resource Team (CRT) to assess improvement or performance lags. Additionally, it was used to update hospital leadership, and inform project communications hospital-wide.

An excel data tracking worksheet was developed by INLP, and used by each participating hospital to capture:

- Meeting attendance
- Completed tests of change
- Performance on the six safety processes for improving medication administration accuracy [1]

Data Collection Team/Resource Requirements

- Core Resource Teams spent at least 4 hours a month conducting tests of change on unit.
- A Data Analyst/Quality Improvement (QI) person on each Core Resource Team (CRT) spent at least 8 hours a month collating and reviewing unit data.
- Staff conducting naive medication administration observations and review allowed for 96 hours (32 hours each) for three (3) 100 dose observation measurements per qualified unit (all adult medical, surgical, intensive care and telemetry units).
- Participation in CalNOC medication administration safety measurement initiative.

The CalNOC (Collaborative Alliance for Nursing Outcomes) method of direct observation was used for the medication administration project. This method was combined with the review of patient records, in order to deem medication dose administration accuracy. Between 2-8 staff nurse observers were chosen by each hospital, who were then trained by CalNOC personnel in using the naive-observer methodology for observing medication administration.

The naive-observer methodology includes the following stages:

1. Random observation of nurses (who have consented to observation) during each stage of medication administration:
   - Medication preparation
   - Administration to the patient
   - Documentation
2. Patients chart review (by the observer); notes medications ordered. The patient's medication orders are not shared with the observer until after the observation and chart review is completed to avoid confirmation bias.
3. Observed doses compared with ordered doses

Medication administration accuracy rate

Two primary measures were derived from the data in order to evaluate the impact of the INLP QI projects.

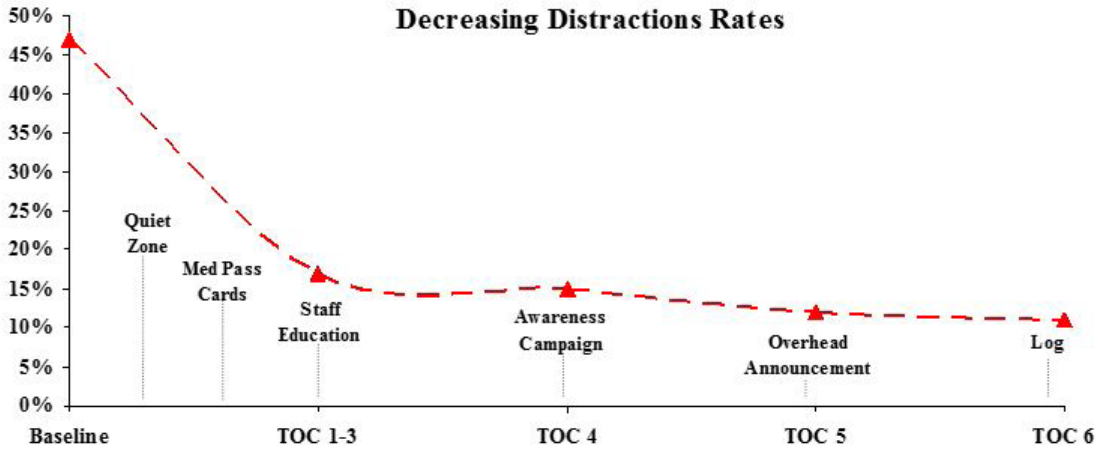
1. **Data was recorded** (and subsequently available) **regarding the accuracy of each dose administered**. Doses were classified as either correct or incorrect. Errors were classified as one or more of the following:
   - Unauthorized drug (not ordered)
   - Wrong dose
   - Wrong form
   - Wrong route
   - Wrong technique (use of an inappropriate procedure or improper technique in the administration of a drug)
   - Extra dose
   - Omission
   - Wrong time (greater than 60 minutes before or after the scheduled time for the drug)
   - Drug not available

Correct doses/Total # of doses = Accuracy Rate

2. Accuracy of the safety processes used by the staff nurse to improve medication administration included:

- Checking two patient IDs
- Checking the medication against the medication administration record
- Explaining the drug to the patient
- Keeping the medication labeled throughout the process
- Charting the medication immediately after administration
- Interruption/distraction of the nurse during the preparation and administration of the medication [2]

Overall safety process score: The sum of the six safety processes (valued at 0-6)
(Captured through 20 naive random observations monthly per unit)



Results based on data observed from 10 medication passes after each small test of change.

Sample Hospital	Hospitalwide	Unit 1	Unit 2	Unit 3
EGDT Measures	Percentage (%)	Percentage (%)	Percentage (%)	Percentage (%)
Overall Mortality	21.0			
Screening Tool Compliance	97.5	99.3	98.5	100.0
Lactate ordered w pos screen	65.2	57.3	45.9	83.7
Bld Cultures ordered prior to Abx	56.1	77.2	69.3	59.3
Abx given within hour	32.3	26.0	19.3	36.5
Fluid bolus within hour	49.0	13.9	47.8	35.2
CVP placed within 6 hours	16.0	26.9	13.7	32.5
Rating (Color)		G	Y	Y
Complete 2 tests of change (Y/N)		Y	Y	N
Meet at least twice (Y/N)		Y	Y	Y
Attendance 50% (Y/N)		Y	Y	Y
Conduct 2 mini-CalNOC obs w/ 10 doses per set (Y/N)		Y	Y	Y
Data measures are improving or at least stable (Y/N)		Y	NA	NA
Submit Complete Activity Sheets (Y/N)		Y	Y	Y

Data Tracking & Management

For the sepsis project, INLP kept a **monthly dashboard**, which tracked the following information:

- Percent attendance rate attending expanded Core Resource Team (CRT) meeting
- Number of Tests of Change (TOC) completed/unit
- Number of meetings held/unit
- Percent compliance with screening tool
- Percent compliance with EGDT
- Other data as requested "ad hoc" such as strategic communications map, process map

Each unit regularly collected and presented their process-level data on each element of the bundle to both the Steering Committee and unit-based teams. **Process-level data** included:

- Percent of time the screening tool was used
- Percent of time a lactate was ordered when a sepsis screen was positive

Additionally, over the course of the project, four types of measures were tracked by participating hospitals, which were reported on quarterly. The once exception was the mortality measure, which was reported every six months. Consistency in methods, measurements and definitions were assured throughout the duration of the program.

The two **screening compliance measures** used included:

- Percent of patients screened for sepsis from a random sample of 60 Emergency Department patients per month (30 patients per month in some of the smaller hospitals), and 30 patients per month from all other departments (e.g., ICU, medical/surgical)
- Percent of patients with a positive sepsis screen who received a lactic acid blood test

If a clinician assessed that a patient required the remaining EGDT bundle, the following additional data were collected:

- Timeliness of antibiotics and blood cultures
- Amount of fluid given (and over what period of time)

Remaining elements of the EGDT bundle were measured separately and reported as a group, including the portion of patients who had:

- Blood cultures obtained prior to administration of antibiotics
- Broad spectrum antibiotics administered within one hour of diagnosis of severe sepsis or septic shock
- Required amount of fluids administered within one hour
- Central line placed (for eligible patients only)

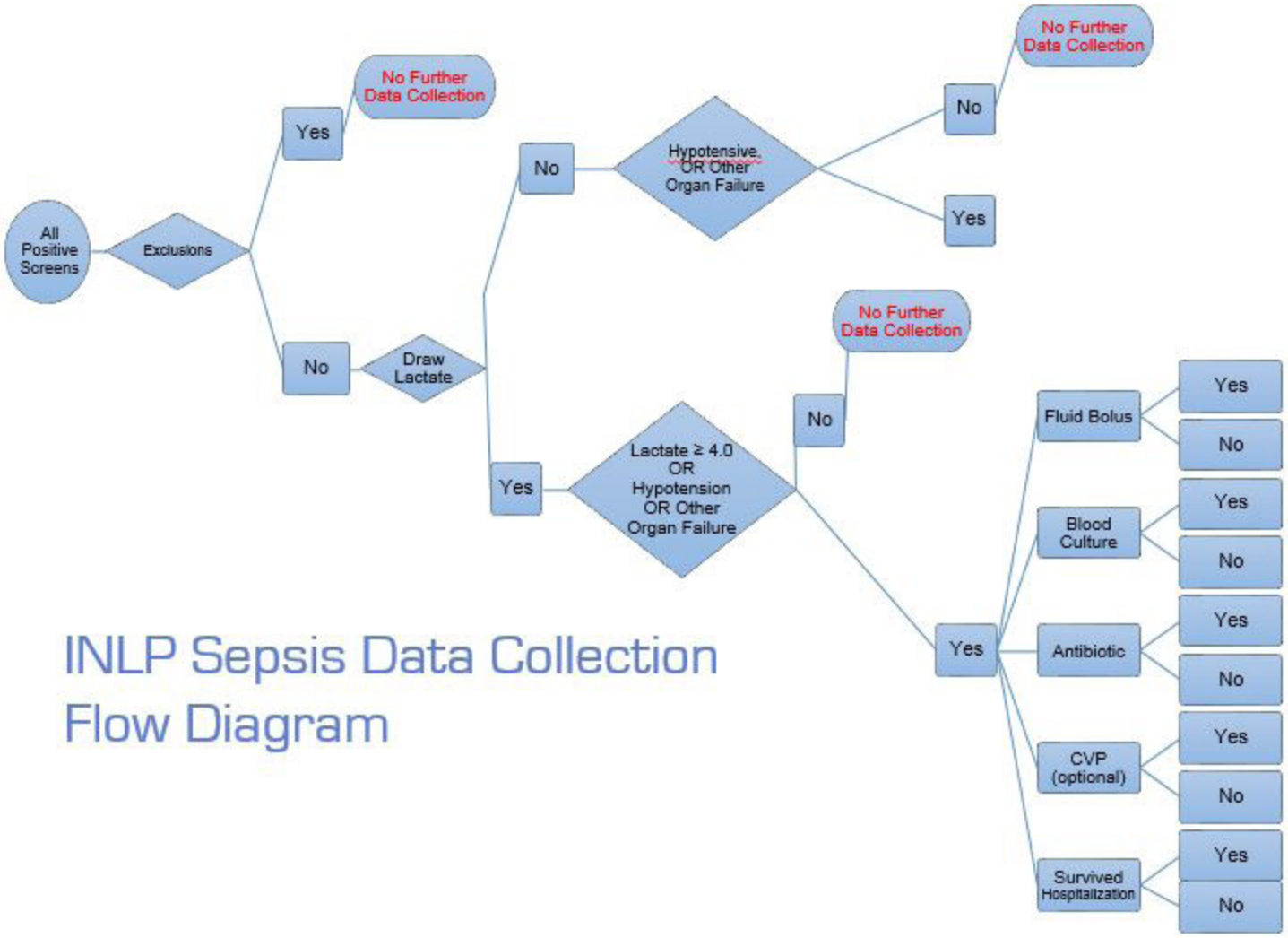
Sepsis Mortality Measure

A list of ICD-9 classifications were used to identify patients with severe sepsis or septic shock. Every six months, incidences of severe sepsis/septic shock patients were reported, along with mortalities among these patients per

month. Data was aggregated each six months to establish one mortality number for that time period in order to minimize fluctuations in mortality and smooth mortality rates for hospitals with very small numbers of septic patients.

Timeline

- Mortality data began being collected by participating hospitals: 2008
- Improvement work started: 2009
- Data reporting initiated: January 2010
- Quarterly reporting began: January 2011



The above diagram was created to guide staff through proper sepsis project data collection.

References

Kliger J, Singer S, Hoffman F, O'neil E. Spreading a medication administration intervention organizationwide in six hospitals. Jt Comm J Qual Patient Saf. 2012;38(2):51-60.

Kliger J, Blegen MA, Gootee D, O'neil E. Empowering frontline nurses: a structured intervention enables nurses to improve medication administration accuracy. Jt Comm J Qual Patient Saf. 2009;35(12):604-12.

Impact Survey

Another important measure that was developed to assess program effectiveness was the INLP Impact Survey. This survey was designed for use during the INLP Sepsis project, in order to help understanding the impact of the change model on developing clinical leaders, and improving clinical outcomes. The survey assessed changes in "individual and hospital capacity for improvement and incorporates elements from existing instruments measuring psychological safety, organizational learning, teamwork, implementation and hospital culture." Questions were developed for each factor of the INLP model of change, and a five-point Likert scale (strongly disagree to strongly agree) was used for each item.

Individual:

- Personal belief in leadership ability
- Self-efficacy
- Influence
- Process management

Team:

- Shared values among team members
- Ability to work together
- Effective decision-making
- Accomplishment of team goals
- Achieved buy-in as a result of teamwork

Culture:

- Assessment of hospital's history of innovation
- Support for change
- Evidence-based practice
- Cross-disciplinary / organizational coordination capabilities
- Learning orientation

Process:

- Improvement process skills
- Ability to replicate processes independently

Survey Administration

The INLP Impact Survey was issued to all team members from each hospital three times over the course of the Sepsis program:

- Within 3 months of the program's beginning (December 2009)
- February 2010
- Program conclusion (April 2011)