Appendix B. High Reliability Organization Learning Network Operational Advice from the Exempla Healthcare Site Visit

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Overview

This document summarizes practical suggestions on how to move toward high reliability using "Lean" concepts. These concepts have been adapted from Toyota Motor Company's practices and culture that it developed over the second half of the past century. Lean concepts have been applied by a number of innovative healthcare systems. Both Exempla Healthcare (who hosted the site visit) and Denver Health are using the Lean approaches and have learned a great deal about the challenges and opportunities that they present. Most of the examples in this document were drawn from Exempla Lutheran Hospital, a 400-bed facility in Denver, Colorado.

Ideas are organized into three general categories to make locating information of most value to you easier:

- What is Lean thinking (in a nutshell)?
- What are the preconditions for using Lean concepts and tools effectively?
- What examples exist for improvements that can be achieved using these concepts and tools?

Slides from Exempla's presentations as well as other materials related to the use of Lean thinking in healthcare are available on the HRO Learning Network extranet and from AHRQ and Delmarva staff.

What Is Lean Thinking?

Lean thinking is an interpretation of an organizational philosophy that evolved within the Toyota Motor Company over the last half of the 20th century. The motor company's application of its own Toyota Production System (TPS) has resulted in unparalleled success. In this document, the terms *Lean* and *TPS* are used interchangeably. Understanding the tools, leadership behaviors, and cultural underpinnings that led to Toyota's success have been elusive. A few scholars have recently contributed to our understanding of these elements. For example, Jeffrey Liker, in his book *The Toyota Way*, described 14 management principles.[1]

Although the term *lean* suggests that the core focus of this approach is increased efficiency, the true focus of "Lean" is on evolving to a state in which work processes relentlessly emphasize eliminating waste. *Waste* is defined as acts that do not add value to customers and includes wasted resources, time, and human spirit.

Like Alcoa (one the most successful adopters of the TPS), Exempla chose safety as the first area for application of Lean strategies for its hospitals. That is, Alcoa chose employee safety; Exempla chose patient safety. In both organizations, the leadership realized that the economic connotations of Lean as a cost-cutting strategy could lead employees to reject the approach out of hand. Instead, Exempla placed emphasis on standardizing work processes and minimizing

[1]Liker, J. (2004). The Toyota way: 14 management principles from the world's greatest manufacturer. New York: McGraw-Hill.

variation embedded in Lean tools would result in safer care. Further, by corralling employees around a morally unquestionable goal (safety), the essential culture and leadership principles are more likely to take hold. Thus, Lean principles were introduced as a tool for ensuring safer care rather than cheaper care.

Exempla shared its recognition of the many areas of overlap between Lean principles and hospital models to increase safety, quality, and reliability. As shown in Table 1, the four key concepts of the TCP correspond to hospital models for increased safety and quality.

Table 1. Four Key Concepts Between Lean Principles and Hospital Models

Lean Principles	Hospital Model
Continuous improvement driven by the frontline team	**Malcolm Baldrige Pursuit, Shared Governance**
All work focused on customer needs	**Patient-centered care**
Eliminating waste	**Waste of time, lives, materials**
Eliminating defects	**Eliminating medical errors**

Several key emphases of Lean principles are reflected in Table 1:

- Although leadership action, teaching, and support are essential, operational change is driven by the frontline staff who best understand the processes that need to be improved.
- Rather than organizing work processes to accommodate physicians, nurses, ancillary departments, or other hospital needs, Lean stresses the need to make the customer or patient the *starting point* for all process design, with all subsequent decisions guided by the notion of narrowing down all actions to only those that the patient deems valuable. Examples of occurrences that the patient does not perceive as valuable include waiting to be seen, getting a hospital-associated infection, not having a medication when needed, and so forth
- Lean stresses the need to continuously drive both waste and defects out of processes. This includes not only lost lives and resources, but also lost human potential that can be applied more usefully to providing better care if waste and defects are eliminated.

The remainder of this document discusses what Exempla and other systems have learned about how to succeed in applying Lean concepts to its efforts to become a safer organization. It starts with key success factors and then provides examples of how Exempla has applied Lean concepts and tools in the hospital.

What Are the Preconditions for Successful Applications of Lean?

Members of the Exempla team stressed that they found no magic checklist for applying Lean concepts or tools with certain success. Experience, persistence, and effective execution help, but using Lean is not easy. That said, there are some factors to consider before even starting a Lean-driven initiative. Many of these preconditions are applicable for a broad range of strategies and tools you may use to transform your system into one that is highly reliable.

Leadership

Although committed leadership is essential for success, Jeff Selberg, CEO at Exempla Healthcare, noted that in many cases, commitment still does not lead to the desired results. His assessment is divided into two sections:

- What leaders must understand.
- How to assess whether leadership is accomplishing its goals

What Leaders Must Understand

Creating a culture of safety requires that leaders understand three things:

- Why and how systems currently function
- A vision for how to arrive at the desired end state
- The resolve to carry out the transformation

Organizational leaders must fully understand what the organization is and why the organization is what it is in order to generate clarity about its current and desired state. Only with this clarity can transformation occur.

- Creating a high reliability organization that is safe requires that leaders recognize the following:
    - **Culture is the foundation for vision and strategy.** A culture characterized by fear and self-protection will not lend itself to openness, learning, and improvement.
    - **Transparency is the key to change the culture.** An unwillingness to face and share the hard facts is an indicator of denial, and denial is not compatible with a safe environment.
    - **Safety must be the overarching strategy.** Safety should be the root cause of achieving efficiency and effectiveness. If the inverse of this relationship exists, the likelihood of having unsafe, yet highly efficient processes increases. Only if safety is the starting point can the correlation among safety, efficiency, and effectiveness remain positive.
    - **Leaders must take ownership for setting the climate and focusing the work.** Generating clarity, setting the example, and demonstrating confidence will help to transform organizational culture. However, without an outright acceptance of ultimate accountability for setting organizational direction, a leader's vision will not be legitimized in the eyes of his or her followers.

How Leadership Should Be Assessed

- Leadership actions must clearly support the vision laid out for the desired state of the organization. Priority setting and adoption of a learning organization mentality are only valuable if both are truly used to guide the decision-making process.
- One way to assess whether leadership decisions are aligned with stated priorities is to track management-based sentinel events. As much as leaders promote evidence-based medicine, they must also promote evidence-based management practices. Decisions based on environmental pressures and fear of market retribution do not illustrate a leader's commitment to the priorities he or she outlined and do not illustrate alignment.
- In gauging success as a leader, the following key questions can be used as a guide:

    - **Are you committed to your own growth as you grow your organization?** Your organization's ability to transform and improve is directly correlated to your ability as a leader to transform and improve.
    - **Are you creating the environment so that the right and, most of the time, the wicked questions are asked?** It is not your role to have an answer for all of the questions but, rather, to create an environment where the right questions are asked and greater personal and organizational awareness are achieved. Asking these types of questions may feel risky, but the result will be a greater organizational tolerance for diversity of thought.
    - **Are you engaging in patient-centered versus ego-centered conversations?** You must take yourself out of the center of your strategy and replace yourself with the patient to ensure that you are protecting your patients first and foremost. A great deal of self-awareness is required to know where you are in every conversation.
    - **Are you embracing challenges that stretch your capacity as a leader?** Your approach must be that every situation, no matter how challenging, is the perfect opportunity to learn, grow, and meet long-term objectives.

Just Culture

A just culture is one where people can report mistakes, errors, or waste without reprisal or personal risk. This does not mean that individuals are not held accountable for their actions, but it does mean that people are not held responsible for flawed systems in which dedicated and trained people can still make mistakes. A just culture that promotes sharing and disclosure is a precondition for using Lean because it depends heavily on frontline staff to drive improvements. All staff must feel empowered to identify errors, defects, and system failures that could lead to an unsafe environment for patients.

Alignment of Lean With Organization Goals, Performance Reviews, and Organization Resources

- **Lean applications must be aligned with the organization's core values and mission.** This is why Exempla's first applications of Lean were to strengthen patient safety rather than to save money.
- **Lean should be aligned with performance reviews for both people and units.** Exempla is just starting this process but has already seen the value of this alignment. Currently, some training in Lean is required of certain staff, and completion of this training is a component of the performance review. A substantial pay-for-performance component exists in the physician contracts.

Avoiding Overcommitment of Resources and Staff

Exempla has recognized the importance of understanding its capacity for quality improvement efforts at the organizational and microsystem level.

- **Too many initiatives can overwhelm frontline staff who are working diligently to provide safe care.** Exempla has coined the phrase, "Get it right for every patient, every time," and encourages frontline staff to consider patient safety one patient at a time.
- **At the organizational level, there is only so much capacity for change.** Exempla has realized that the threshold for change depends on many things, including staff, facilities, timing, funds, and so forth. When staff members are recruited to participate in intensive system redesign activities, Exempla finds replacement staff for them during that period. Without this, it is unrealistic to expect that efforts will succeed.
- **Extensive research on Lean should occur before implementation and the initial focus kept small.** Exempla's capacity to do Lean was expanded to other areas as efficiencies were gained.

Extensive Communication at the Organization and Microsystem Levels

- **Communication is key throughout the organization.** Exempla has struggled with explaining the term *Lean* to staff, as it may be misconstrued with reducing the workforce or changing of a job or job description. This can prove problematic when getting frontline staff to be actively involved in Lean because people are hesitant to participate in efforts that may lead to the loss of their job or rework of their job description. The pharmacy department currently is coping with low morale from technicians whose physical location and job description have been changed due to recent efforts using Lean.
- **Including only some frontline staff in quality improvement efforts may be a struggle.** Exempla's pharmacy department has found that some frontline staff feel left out when one individual is representing the team in a Lean initiative. This has led to a need for improved communication.

Change Management

- **Change management training is important to leaders in Lean.** Many frontline staff are placed in difficult positions as change agents, often feeling the brunt of negativity from other colleagues who are not as involved.
- **One key to successful change management is avoiding taking on tasks that are too large.** One of Exempla's first applications of Lean was to redesign patient flow. However, it quickly found that this process was too complex, and the effort bogged down. To succeed, changes needed to be limited to manageable chunks, particularly when just starting to use Lean tools.

How Can Lean Be Used?

This section captures ideas about how Exempla applied its overall Lean strategy and summarizes, through examples, how it used the strategy.

Overall Strategy

Healthcare organizations have used several approaches to implementing Lean principles. Exempla has elected to use "Kaizen Events," which involve selecting a specific process for improvement and identifying a team to spend one week studying, redesigning, and deploying a new Lean-inspired process with the guidance of a corporate facilitator. These Kaizen Events involve three key components:

- A planning phase.
- Change processes.
- Appropriate tools.

Planning

During this phase, a multidisciplinary team is first formed to work on the quality improvement initiative. Exempla found that these teams should include 8 to 10 people.

- About one third of the team should be directly affected by the outcomes of the change because they are most knowledgeable and motivated.
- One third should be leaders in their units, whose opinions and choices will be respected by their peers.
- The remaining third should include individuals from multiple disciplines involved in the process. Exempla also has found value in including one to two outsiders, called "spotters," who have no familiarity with the process. The role of spotters is to:

    - Be an advocate for team members.
    - Help others to ask the question behind the question.
    - Help to mitigate unintended consequences.
    - Challenge assumptions and assist others to voice concerns.

Second, before a Kaizen Events team is convened, the Exempla facilitation team spends several weeks preparing. An example preparation checklist is found in the Appendix.

Third, a Value Stream Analysis, which is the flow of steps that result in a specific output, is conducted. Multidisciplinary teams at Exempla use Post-it notes to outline the flow on a conference room wall to allow for ease in structuring the analysis. The Value Stream Analysis has two components:

- **Current state analysis.** This analysis outlines which steps in the process are value added and which are not needed to achieve the desired objective from the patient's perspective.
- **Future state design.** This component lays the groundwork for next steps. It identifies the quality improvement initiatives, including the very small (do-its), the medium (events), and the large (projects). This component also considers the upstream and downstream impacts of the initiatives as well as the proper sequencing and prioritizing of these initiatives.

Change Processes

Following the planning component, the quality improvement initiative is implemented. The Lean quality improvement initiative is called a Kaizen (Kai = change, zen = good) Event. These rapid improvement events involve multidisciplinary and interdepartmental teams, including frontline staff.

A Kaizen Event comprises the following steps:

1. Three weeks of preparation: topic, team, targets.
2. Five days of rapid, focused team action.
    - Day 1: Study current state.
    - Day 2: Redesign to a future state.
    - Day 3: Test and implement changes.
    - Day 4: Develop standard work and plan for implementation.
    - Day 5: Present and communicate.
3. Three weeks of follow-up: mentoring, monitoring, measuring.
4. Ongoing monitoring. Exempla has found that changes need to be studied 30, 60, 90, and 120 days out from implementation. Longer periods are needed to understand the true impact of the change. Exempla also has found that this process rarely leads to the ideal future state. Instead, it may take several iterations to get gradually closer to the final goal.

Appropriate Tools

A range of tools and concepts are considered when developing and implementing a change. Potential concepts and tools are summarized in the next section and described in much greater detail in other sources. Failure to select the right tools is one reason change processes fail.

Examples of Implementing Lean Concepts and Tools

Lean Concepts and Tools

For a glossary of lean tools, visit one of the following Web sites:

- www.teamresearch.com/lean_glossary.asp
- www.tpslean.com/leanglossaryall.htm

Applications of Lean at Exempla

The following are examples of using Lean. Many relate to the pharmacy department because it has had supportive leadership to drive the redesign process. Exempla has attempted 16 Kaizen Events, with 60% achieving positive results. As the examples show, further progress often is still needed.

Specimen Processing Improvement

Challenge. The laboratory at Exempla receives 127 specimens per hour. Each specimen is matched with orders, recorded into the computer system, and prepared for distribution to testing sites. The laboratory found that 35% of specimens arrived without orders, causing these to be reworked and the patient and specimen to wait.

Objectives.

- Redesign the Specimen Processing workstation.
- Create process flow, standard work, and an organized and improved work area.

The Laboratory team used the following tools and concepts to meet the objectives:

- *Six S to organize and redesign the space*.
  1. Sort out: Get rid of what is not needed.
  2. Straighten: Organize what is needed (visual management).
  3. Scrub: Clean up (see and solve).
  4. Safety: Address unsafe acts, conditions, and motions.
  5. Standardize: Establish who, what, and when for upkeep.
  6. Sustain: Be self-disciplined and care.
- *Standard work*, or process, for all procedures.
- *Work flow* for processing specimens.
- *Eight wastes*.
  1. Overproduction: rainbows on ED patients
  2. Overprocessing: retesting
  3. Excess inventory: batching lab samples

4. Defects: redraws
5. Unused employee creativity: grassroots improvement
6. Excess movement: too many hand-offs
7. Excess transport: delivering specimens
8. Waiting: ED for test results

Metrics and results.

- Redesigned Specimen Processing workstation using six S.
- Created more workspace (increased counter space by at least 33%), an organized area, and flow of work in L-type shape, the HIGHWAY.
- Created visual workspace and reduced inventory.
- Moved equipment to aid in flow for specimen processing, phlebotomy, and hematology.
- Wrote standard work for specimen processing for all procedures.
- Learned one important lesson about the need to involve all shifts in the redesign. Night shift staff members were not included initially, and they did not like or understand the changes, which they promptly undid. Further discussions with the night shift were needed to obtain agreement and understanding.

Chemotherapy Process Improvement

Challenge. Problems were identified with providing chemotherapy treatment to adult patients in the oncology unit. This improvement was prioritized as very important due to the high risk of chemotherapy. Problems existed in the following areas:

- *Storage and procurement*. Drug not available or limited strengths, look-alike–sound-alike drugs stored together
- *Prescribing*. Lack of standardization, abbreviations causing errors, illegible handwriting, look-alike, sound-alike prescribing, no weight, poor fax quality
- *Transcribing*. Errors on medication administration record
- *Pharmacy review and order entry*. Labs not available; references not current; errors in order entry; height, weight, and body surface area not available; no alerts to prevent errors
- *Preparation and dispensing*. Mislabels, such as wrong drug, diluents, and volume; check process inconsistent; nurse cannot find where the drug was delivered
- *Administration*. Inconsistent check process
- *Monitoring*. Missed vitals and monitoring parameters

Objectives.

- Map out details of current process.
- Label steps as value added or waste.
- Review concepts of error proofing.

- Create ideal state.
- Create future state.

The Chemotherapy team used the following tools and concepts to meet the objectives:

- *Identification of waste*. Reduced interruptions (change location of chemo preparation).
- *Error proofing*. Standardized chemo orders, up-to-date references, competency, standardized checklist for pharmacist and nurses
- *Standard work*. Medication locations, chemo medication administration record in same sequence as administration, improved pharmacy–nurse communication

Metrics and Results.

Table 2. Safety Metrics

Metric	Baseline March 2006	Follow-Up September 2006
Abbreviations (avg. #)	3	2
Standardize order sets (%)	0	80
Illegible orders (%)	56	28
With diagnosis (%)	78	91
Protocol (%)	9	81
Weight/body surface area available (%)	16	47

- While early results are promising, Exempla commented that the results are still not at their target.
- More than one cycle of Lean will be performed and additional tools may have to be applied in order to improve the process and decrease abbreviations and improve order legibility.

Table 3. Staff Satisfaction Metrics: Nursing

Metric	Baseline March 2006[a]	Follow-Up September 2006[a]
Overall satisfaction	2	4
Comfort with chemo process	4	4
Safety of process	4	3
Orders clear and understandable	2	4

[a]Pharmacy survey: 1 = worst/never, 5 = best/always.

- The drop in the nurses perception of safety may be due to the fact that the nurses were not completely aware of all the potential for error at the time of the baseline measurement and their awareness was thus heightened through the Lean process.

Medication Dispensing Machine

Challenges. The following problems were identified with the use of medication dispensing machines on the floors:

- Three separate medication dispensing machines existed on each floor.
- Each medication dispensing machine had different inventory, and there was no way of knowing which machine had the medication the nurse was looking for.
- All three medication dispensing machines were located away from the patient care areas.
- Some medications that looked alike or sounded alike were placed next to one another within the machines.
- Inventory within the medication dispensing machines was difficult to manage.

Objectives.

- Reevaluate standard medications.
- Determine inventory needs based on usage.
- Redesign medication dispensing machine locations to improve nursing efficiency.
- Establish a process for separating high-risk medications.

The medication dispensing machine team used the following tools and concepts to meet the objectives:

- *Gemba walk*: moved the medication dispensing machine to its own room so that it was easy to locate
- *Create standard work for medication dispensing machine maintenance*: consolidated the three medication dispensing machines down to one
- *Reduce wastes*: decreased number of stock-outs
- *Reduce wait or delay of care*: standardized medication delivery times to the medication dispensing machines and decreased the time until the medication was available for administration
- *Waste in motion (nurse)*: reduced the distance that nurses had to travel to access the medication dispensing machines
- *Overprocessing*: inventory changed to meet the needs of the patients instead of stocking excess medications that did not get used.

Metrics and results.

Table 4. Medication Dispensing Machine Team Results

Metric	Baseline	Result	Comments
Inventory reduction	3 machines: $16,163.59	1 machine: $8,276.26	$7,887.33 reduction
Number of medications sent to ICU (3 days)	255	184	28% decrease
Number of medications in medication dispensing machine not used	362	136	62% decrease

- Consolidated medication dispensing machines from 3 to 1

- Decreased the distance traveled by nurses to access medication dispensing machine
- Decreased stock-outs
- Changed inventory to meet the needs of the patients
- Decreased the time until the medication is available for administration
- Still working to ensure that only one medication at a time is being removed from the medication dispensing machine

Patient Transfer Process

Challenges. The following problems were identified with the patient transfer process between floors and to testing areas:

- Communication was lacking about patient ready for transport status; patients not ready for transport resulted in delays.
- Patient transportation log did not exist.
- Patients were not placed on monitors when returned to room.
- Isolation precautions were not followed during transport and testing.
- Transport equipment storage was lacking on units.

Objectives. The Transfer Process team outlined the following objectives to address the problems with the transfer process:

- Improve the handoff of patients between transporter and requester.
- Review the communication process between transporters and requestors.
- Evaluate the transport process.
- Develop script for transport team members.
- Determine how to add in-house transfers to current workload.

The Transfer Process team used the following tools and concepts to meet the objectives:

- *Visual workplace*. Use transport safety checklist sticker to identify patients ready for transport
- *Standard work*.
- *Gemba*: Create central dispatch station to control all in-house transfers

Metrics and Results. The Transfer Process team expects to achieve the following results:

- Improved flow from more efficient communication
- Decreased wait times pre- and post-test

Overall Process Redesign Lessons Learned

- Even a seemingly simple process can be very complex.

- Mapping out the discrete steps in any process can highlight additional challenges and problems not previously identified.
- The team needs to dig deeper (collect more information on all aspects of event) before the event and consider increasing the planning time.
- The team has to have reason to buy in for change.
- All team members need to be unified about the purpose before the event starts.
- There never is too much communication among team members.
- The scope of work must be kept manageable.
- Frontline staff should be responsible for deciding what changes need to be made.
- Required engagement of various physician groups and physician availability are a challenge for the dedicated time needed to complete an event.
- Patient-centered solutions can help to keep team on track.
- Solutions can be reached more quickly by pulling together a multidisciplinary team.
- Staff members must remember to listen to others before speaking

Rapid Improvement Checklist

Table 5. Rapid Improvement Checklist

Team: Date of Event:		
6 Weeks Before Event Due Date	**2 Weeks Before Event Due Date**	**1 Week Before Event Due Date**
Project Planning 1. ❑ Select area and topic 2. ❑ Determine coleader and the team members. 3. ❑ Complete Team Charter. 4. ❑ Ask a few hard questions, e.g.: — Will this team improve your value stream? — Will this team improve the area's key measurements? 5. ❑ Prepare the business case for this improvement event. 6. ❑ Define the objectives and deliverables expected from the event team. 7. ❑ Define the measurements and targets for the team. Make sure there are only three or fewer key measurements. 8. ❑ Review action deliverables, measurements, and targets with the external or internal consultant. Revise if needed. **Details** 9. ❑ Schedule event team meetings for next 2 weeks. 10. ❑ Schedule meeting to educate stakeholders (ssc/ managers/ directors of involved departments). 11. ❑ Send invitations to join to team members. **Schedule Team Meetings**	**Project Planning—Develop Plan To Gather Current State Data** 1. ❑ Determine actual customer demand. 2. ❑ Determine backlog or wait times. 3. ❑ Determine actual output. 4. ❑ Determine total hours worked to create this output. 5. ❑ Calculate productivity: output/total hours worked. 6. ❑ Calculate relevant cycle times. 7. ❑ Determine top 5–10 problems. 8. ❑ Review occurrences/complaints in the past 12 months, if applicable. 9. ❑ Review customer and patient satisfaction comments. List top five issues from complaints, rework, and delays. **Communication** 10. ❑ Post announcement about rapid improvement event date, time, and focus. 11. ❑ Put up a blank flipchart to get suggestions/feedback. Ask questions, clarify, and put these ideas on a list. 12. ❑ Discuss rapid improvement event in staff meetings. Explain objectives, measurements, and targets. 13. ❑ Review and confirm team members. Confirm entire week commitment. **Team Meeting** 14. ❑ Team introductions 15. ❑ Why are we here? What is the scope? 16. ❑ Lean orientation 17. ❑ Event schedule, measurements, targets, and action deliverables 18. ❑ Business case and Team Charter 19. ❑ Tasks to team for data preparation	1. ❑ Resolve open items. 2. ❑ Define clearly the boundaries of the event: —Who are the customers? What are the outputs? What triggers the area to do something for a customer? —Who are the suppliers? What are the inputs? —Prepare additional flowcharts, spaghetti diagrams, layouts, and time studies, as needed. 3. ❑ Brief the consultant. 4. ❑ Prepare supplies and logistics for the team: —Locations and schedules —Food, supplies **Team Meeting** 5. ❑ Review measurements, targets, and objectives. 6. ❑ Review data collected to date. 7. ❑ Ask for feedback, try to address concerns. 8. ❑ Reinforce what's in it for them. 9. ❑ Establish group norms. 10. ❑ Discuss roles of team members during week. 11. ❑ Reconfirm scheduled commitments with each team member, supervisor, etc.