

# **SUPPORTING STATEMENT**

## **Part A**

Reducing Waste and Inefficiency through Process Redesign: Lean/TPS  
Implementation

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Agency of Healthcare Research and Quality (AHRQ)

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## **A. Justification**

### **1. Circumstances that make the collection of information necessary**

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see Attachment A), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. Research that develops and presents scientific evidence regarding all aspects of health care; and
2. The synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and
3. Initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

To fulfill AHRQ's mission of health care quality improvement, this project seeks to develop a set of lessons learned and a business case about a specific redesign strategy that has shown great promise: the Lean/Toyota Production System (Lean/TPS). Lean/TPS is a process-redesign methodology adopted from Toyota Production Systems; it empowers front-line staff to apply continuous quality improvement methods to reduce waste and enhance value in workflows and operations (Spear, S. Fixing healthcare from the inside, today. *Harvard Business Rev.*, 2005 83(9), 78-91) (please see Purpose and Use of Data below for more background on Lean/TPS). Thus far, Lean/TPS has shown great promise to improve quality, efficiency, and safety in various health care settings.

The lessons learned and business case developed by this project will enable AHRQ to serve the needs of health care providers for unbiased information about how to improve quality and reduce errors. This study directly addresses AHRQ's legislative mandate to improve quality of care through conduct and synthesis of research and to undertake initiatives that advance private and public efforts to improve health care quality.

This project will use rigorous case study methods to tell the Lean/TPS stories of several different organizations. Our broad goals are to describe the implementation of Lean/TPS at the participating hospitals and to determine if the participating hospitals believe that Lean/TPS has had a positive effect on their operations. From this information, we will construct a business case that includes the individual case studies and our synthesis of common findings among the individual case studies.

Within these broad goals, the specific aims of our project are:

AIM 1: Assess whether Lean/TPS positively affects primary outcomes of interest to the participating hospitals. Health care organizations implement Lean/TPS because they expect Lean/TPS will have a positive affect on aspects of their operations that they deem to be important. From the organization's perspective, does Lean/TPS improve:

- Quality?
- Efficiency?
- Patient satisfaction?
- Employee satisfaction?
- Costs?
- Patient safety?

To achieve this aim, we need to understand:

- The implementation process (how Lean/TPS was implemented)
- How the hospital determined that implementation process affected the primary outcomes
- Variation in implementation processes and outcomes among the cases
- Elements of the redesign efforts that are essential to success or failure
- Characteristics of the environments, organizations, sites, departments, and projects that are more likely to result in successful adoption of Lean/TPS principles, and improvement in performance

AIM 2: Identify challenges and solutions (i.e., lessons) to implementing Lean/TPS.

To explore this aim, we must learn the following:

- How was Lean/TPS implemented at the organizational and/or departmental level?
- What were the barriers and facilitators to implementing Lean/TPS?

- How were these barriers overcome?

To achieve this aim, we need to understand:

- Detailed characteristics of the Lean/TPS implementation
- Capacity of the infrastructure (e.g., knowledge, staffing, equipment, etc.) to address the goals of redesign efforts
- Extent to which culture, support, and commitment of hospital and physician leadership is demonstrated such that it is clear that they are helping to facilitate the implementation of Lean/TPS and the redesign efforts

AIM 3: Present these lessons to prospective users in a way that will enable them to learn from the experiences of those who have gone before them. To explore this aim, we must learn the following:

- How does Lean/TPS implementation and success varies by hospital, departmental, staff, and environmental characteristics, so that other hospitals better understand the situation sin which the use of Lean/TPS might be successful and what they have to do to have a successful implementation.

To achieve this aim, we need to understand:

- The potential to spread the approach to other health systems (organized delivery systems, hospitals, medical groups, and/or hospitals with certain types of relationships with medical groups) and different types of settings (e.g., outpatient, transitions of care, etc.),
- The experience participating hospitals have had in implementing Lean/TPS principles

AIM 4: Develop a business case that describes the impact of Lean/TPS on participating hospitals, in financial and non-financial (e.g., reputation, morale) terms. Leatherman et. al. have described the successful business case as one that helps the entity contemplating investment in an intervention to understand how it can realize "...a financial return on its investment in a reasonable time frame, using a reasonable rate of discounting. This may be realized in 'bankable dollars' (profit), a reduction in losses for a given program or population, or avoided costs. In addition, a business case may exist if the investing entity believes that a positive indirect effect on organizational function and sustainability will accrue within a reasonable time frame." To explore this aim, we must learn the following:

- Are data relevant to the business case available?
- Is there a business case for Lean/TPS implementation?

To achieve this aim, we need to understand:

- What factors persuaded the managers at participating hospitals to use Lean/TPS for process redesign.
- What objectives financial and non-financial objectives were established for their Lean/TPS projects.
- What costs and benefits were experienced and how did they compare to the expected costs and benefits.
- How were these costs and benefits measured?
- Were the experienced improvements that resulted from Lean/TPS sustained and do they believe they will be sustainable in the future.

AIM 5: Identify community, market, and organizational factors that are associated with variations in the lessons and the business case, so that potential users can understand which experiences are relevant to their own situation. To explore this aim, we must learn the following:

- How does the organizational context impact Lean/TPS implementation and success?
- How does Lean/TPS implementation as an institutional policy differ from Lean/TPS implementation for a departmental level project?
- How does the external environment affect Lean/TPS implementation and success?

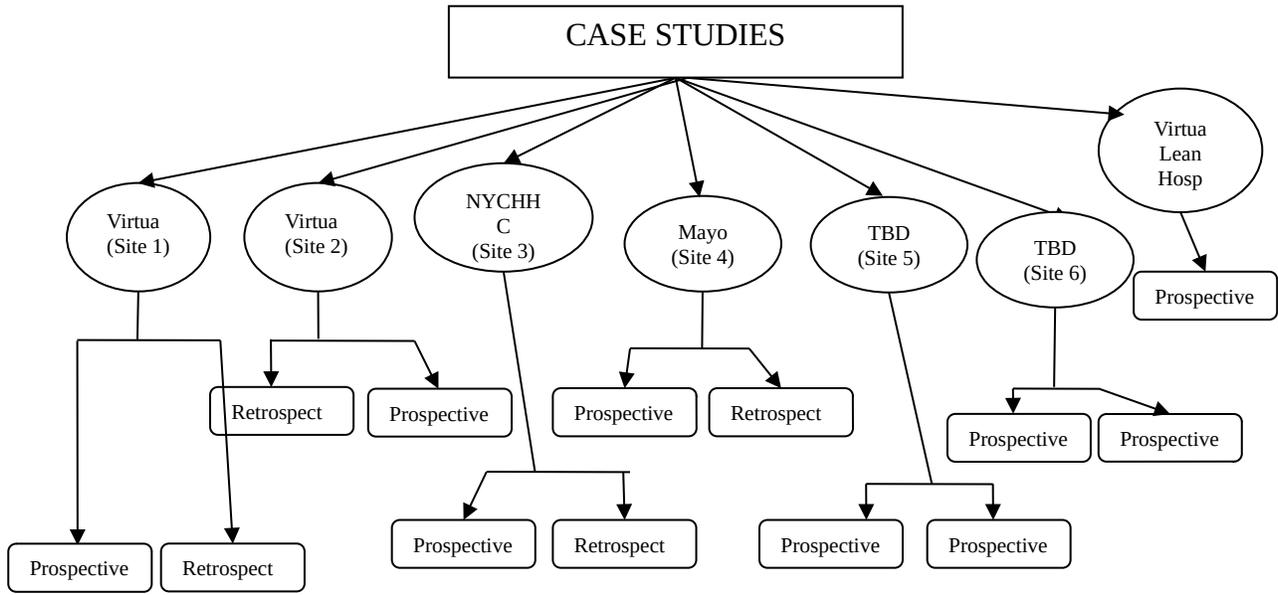
To achieve this aim, we need to understand:

- The characteristics of the community, market, institution, and department in which the Lean/TPS policy or project resides.
- How the favorable and unfavorable effects of the Lean/TPS implementation policy and project described in the case study vary by those characteristics, within the limited number of cases that can be studied under this contract.

To meet these aims, AHRQ and the American Institutes for Research (AIR) will conduct thirteen case studies. Due to a very recent contract modification, the project will increase the number of case studies from 9 (as originally proposed) to 13. We have adjusted the burden table in Exhibits 4 and 5 accordingly. We will select Lean/TPS projects from various departments in five health care organizations (see Exhibit 1 below for a description of the selection approach). Two of these organizations have yet to be selected, but we will notify OMB as soon as they are finalized. Twelve of these case studies will describe Lean/TPS implementation in a single department or operating unit of a health care organization, and the thirteenth will focus on the construction of an entire hospital using Lean/TPS principles. Four of the case studies at the department level will use a prospective analytic perspective, in that we will begin to collect data before the Lean/TPS project begins and continue collecting data throughout the process. The other four department-level studies will take a retrospective analytic perspective, in that the project will be complete by the time we begin data collection.

We will conduct one prospective and one retrospective case study at each of the sites. That is, two case studies will result from a single site. The only site from which only one case study will result is the construction of the hospital based on Lean/TPS principles. Please see Exhibit 1 for our case study design.

**Exhibit 1. Case Study Design**



Data collection for the hospital-level project will begin early in the construction phase and, thus, combine elements of the prospective and retrospective data collection. Exhibit 2 provides a brief description of the participating organization. We have noted the two organizations which are yet to be selected.

**Exhibit 2. Organizations participating as case study sites**

Organization	Description of Organization/Number of Case Study Sites
Mayo Clinic (Mayo)	<p>Mayo, which comprises the Mayo Clinic and the Mayo Health System (MHS), is an organized delivery system (ODS), with a significant number of hospitals (20) and clinics (64) operating in different areas of the country. Mayo Clinic became interested in possible applications of Lean principles in late 2003. Since mid-2006, Mayo has standardized process improvement training under the auspices of Quality Academy, which provides Lean Sigma training to teams and their project champions. Mayo has opted to merge several concepts and tools from Six Sigma™ with Lean, based upon issues uncovered with early Lean projects.</p> <p>One hospital – either Mayo Clinic in Phoenix, AZ or the Luther Hospital in Eau Claire, WI – from Mayo Health System will be selected for a prospective and a retrospective case study.</p>
New York City Health and Hospitals Corporation (NYCHHC)	<p>NYCHHC, the largest municipal hospital and health care system in the country, is a \$5.5 billion public benefit corporation. The Corporation provides medical, mental health and substance abuse</p>

	<p>services through its 11 acute care hospitals, four skilled nursing facilities, six large ambulatory diagnostic and treatment centers, and approximately 100 community and school-based health centers. NYCHHC is the single largest provider of health care to uninsured New Yorkers. One in every six New Yorkers receives health services at an HHC facility. HHC began its Lean journey formally in November 2007. Over a three year period, 22 sites (all municipal acute hospitals, large community health centers and skilled nursing facilities) will adopt Lean principles and process improvement tools. Over time, everyone at HHC will be involved in or affected by “Breakthrough Lean.” The hospitals in the NYCHHC offer our case studies with geographic and population diversity.</p> <p>One hospital from NYCHHC will be selected for a retrospective and prospective case study.</p>
Virtua Health (VH)	<p>VH is a multi-faceted, sophisticated and advanced regional healthcare organization. VH primary geographic market consists of the densely populated region of Burlington, Camden and Gloucester counties. This primary service area (PSA) incorporates 1.25 million diverse households. Virtua consists of four hospitals: Virtua Memorial Hospital Burlington County and Virtua West Jersey Hospitals in Berlin, Marlton and Voorhees. Virtua also provides services from a comprehensive outpatient health center in Camden; outpatient surgery centers in Mt. Holly and Voorhees; a home care service, rehabilitation and nursing centers in Mt. Holly and in Berlin, and the William G. Rohrer Center for Health Fitness in Voorhees. In early 2004, Virtua began implementing Lean/TPS principles, as part of a major strategic effort and initiative to redesign patient care. The hospitals from this system present diversity in adoption of Lean principles; additionally, Virtua has implemented Lean in their long term care and home healthcare facilities, as well as in their corporate office. Virtua Health has had several years to refine their use and implementation of Lean/TPS. Also interesting to note, in the next 5 years, Virtua is planning to build a new state-of-the-art hospital which will apply Lean/TPS principles from the very beginning.</p> <p>Two sites from VH will be selected for two prospective and two retrospective case studies. Additionally, the Virtua Hospital at Voorhees will serve as the single prospective case study of the construction of a hospital.</p>
TBD Organization 4	<p>This organization is being added due to a recently approved contract modification in which funds were allocated for additional case studies. Though we have not selected this organization, the burden tables (Exhibits 4 and 5) reflect the data collection at this organization. We anticipate this organization will be located in a rural area.</p>
TBD Organization 5	<p>This organization is being added due to a recently approved contract modification in which funds were allocated for additional case studies. Though we have not selected this organization, the burden tables (Exhibits 4 and 5) reflect the data collection at this organization.</p>

We will notify OMB once TBD Organizations 4 and 5 (noted above) are finalized.

The prospective case studies and the Lean/TPS hospital case study will include the following four kinds of data collection:

- 1 In-person interviews (see Attachment B) with the administrative and clinical personnel from each of the participating health care facilities. The purpose of these interviews is to determine the organizational culture surrounding Lean/TPS, assess the organizations' view of Lean/TPS and quality improvement, in general, and to gain a better understanding of the specific implementation strategies for each organization.
- 2 Telephone interviews (see Attachment C) with staff from each participating facility. The purpose of these interviews is to provide a complete understanding of Lean/TPS implementation at the prospective sites throughout Lean/TPS implementation. Interviewees in the telephone interviews may be the same personnel as those participating in the in-person interviews, but will differ from the staff completing the digital diaries. For both the telephone and in-person interviews, email invitations to participate are included in Attachment D.
- 3 Digital Diaries (see Attachment E) will be kept by two staff members from each participating establishment. The purpose of the diaries is to track the implementation of prospective Lean/TPS projects in real time. The digital diaries will be completed one time per week for approximately eight months.
- 4 Collection of documentation from each participating facility (see Attachment F). The purpose of this collection of documentation is to gather pre-collected data on the impact of Lean/TPS, and to gather documentation of the implementation of Lean/TPS. To the extent that it is available, we will gather the following types of documentation. Documentation may include:
  - Internal reports or memos on Lean/TPS implementation or decisions surrounding Lean/TPS implementation
  - Materials promoting the adoption of Lean/TPS in the organization
  - Tools used when implementing Lean/TPS (e.g. value stream maps, checklists, guides, etc.)
  - Press releases or other news media regarding the use of Lean/TPS in the organization
  - Data on the process evaluation for Lean/TPS (satisfaction surveys on Lean/TPS, use of Lean/TPS versus other methods)
  - Data on the outcomes or impacts of Lean/TPS (data files, surveys, reports, etc.)

- Materials disseminating information about Lean/TPS and its impacts to others outside of the organization (speeches, presentations, posters, etc.)
- Data on the business case for lean (e.g., cost information, return-on-investment data, etc.)

We anticipate this task will simply consist of forwarding emails and or photocopying and sending documents to the project team one time throughout the course of each case study.

Retrospective case studies will include only the in-person interviews (#1 above) and the collection of documentation (#4 above). The telephone interviews (#2 above) and the digital diaries (#3 above) are not appropriate for the retrospective case studies of completed projects because they are designed to obtain data while the project is in process.

Exhibit 3 on the next page shows how questions from the topic guides relate to each aim outline on pages 4-6 of this document.

### Exhibit 3. Crosswalk between Aims and Research Tools

Tool	Aim 1	Aim 2	Aim 3	Aim 4	Aim 5
<b>In-Person Interview Topic Guide Questions</b>					
<b>For all key informants</b>					
1.1.1 a) Please tell me about your current position.			•		
1.1.2 a) Please describe your department's and/or organization's quality improvement effort. Please give me an example of a quality improvement effort that your department and/or organization has implemented recently. What about this effort was typical for your department and/or organization? What was atypical? Please tell me about that.	•	•	•		•
2.1 a) How did you or your organization decide to implement Lean at the system or organizational level?	•	•	•		•
2.1 b) What were the overall department and/or organizational goals and time frame for the Lean implementation?			•		•
2.1 c) How did you or your organization decide in which unit or department to first implement Lean?	•	•			
3.1 a) Please describe the Lean/TPS projects currently underway in your organization. Are projects conducted simultaneously? How many?	•	•			
3.1 b) What projects have been completed? Please describe the completed projects.	•	•			
3.1 c) What projects are currently being planned? Please describe these expected projects.	•				
3.1 d) Please describe how Lean/TPS was implemented at the department level. Interviewer should have participant walk through how Lean/TPS was implemented at the department/unit level.	•		•		
3.1 e) Thinking back on the lean work you have done in your unit (including all Lean projects), what were the 2 or 3 greatest challenges?	•		•		
3.1 f) Thinking back on the Lean work you have done in your unit (including all Lean projects), what were the 2 or 3 greatest facilitators?	•		•		
3.1 g) Please describe any surprises or unintended consequences (positive or negative) of the intervention and its implementation (e.g., staff morale improved or got worse, found new ways to utilize advanced practice nurses) surfaced during the implementation process? If so, please describe.	•	•	•		
4.1 a) In your opinion, how is Lean/TPS progressing for each project, in each department, and within the organization? In general, has Lean/TPS been successful?	•	•	•		
4.1 b) Please describe the impacts or outcomes of Lean implementation. What has changed since Lean/TPS implementation? Have these changes been positive or negative? Please describe these impacts.	•	•		•	•
4.1 c) In your opinion, is there a business case for Lean implementation? Why or why not? By business case, we mean whether Lean/TPS works and results in enough benefits to the organization in a sufficient time frame for this organization and others to continue to pursue it.	•	•		•	
4.1 d) For all of these outcomes, what methods did you use to measure the impact? Are you still collecting data on these outcomes? How long do you anticipate collecting these data?	•	•		•	
4.1 e) Have any of these results undergone independent review? Have any of these results been published? If so, where?	•			•	
4.1 f) Please tell me how, if at all, these results have been validated.	•			•	

5.1 a) To date, is Lean still being implemented in your organization? Specifically, in what departments or units is Lean being implemented? How does your organization determine which departments should next implement Lean?	•				
5.1 b) Over what time period have improvements from projects been sustained? Have the successes or improvements decreased over time, remained the same, or continued to improve? Why do you say this?	•	•		•	
5.1 c) What do you think are the challenges to the sustainability of Lean in both the department and the organization? What about things that facilitate sustainability?	•	•		•	•
5.1 d) How, if at all, have you been involved in the sharing of information about Lean work and spread of Lean techniques? Please consider dissemination to other staff, other departments within your organization, other organizations, and/or the general public.			•		•
5.1 e) Based on what the project team has learned to date, what are the insights and/or lessons learned for your own system and practices as well as others? If you were advising others about Lean and its implementation, what would you most want them to know? What should they be aware of, what should they do, what should they NOT do?		•			
6.0 a) Do you have any additional thoughts you'd like to share with us about Lean/TPS in your department and/or organization? Decision to pursue, implementation, sustaining it?	•	•	•	•	•
<b>For all department level staff</b>					
1.2.1 a) Do you interact at least once or twice per month with senior and/or management staff in your organization? Specifically, with whom are these interactions? How much of these interactions involve or are about quality improvement activities and/or approach?		•			•
1.2.1 b) How often do you interact with other staff in your department? From your department, who do you interact with regularly? How much of these interactions involve or are about quality improvement activities and/or approach?		•			
1.2.1 c) To whom do you report? Who has primary responsibility for the department? To whom do they report?		•			
1.2.1 d) In your opinion, how much support do you receive from senior staff/organizational leadership to pursue or implement quality improvement activities at your level?		•			•
3.2.1 a) How, if at all, did staff react when they heard Lean would be implemented in their departments? Was there a specific staff person to champion this effort? How were they told of this decision? What types of questions did they ask?		•			
3.2.1 b) How did you first react when hearing of the organization's decision to implement Lean in your department? Why did you feel this way? Did you play a role in this decision? Please tell me about that.		•			
3.2.1 c) What type of support did you receive from the senior management/leadership when implementing Lean in your department? Support might include staff, training, additional staff, time assigned to Lean/TPS, IT support, or other resources. Please tell me about this/these.		•			•
<b>For all key system staff</b>					
1.2.2 a) How is your organization (hospital and/or system) structured?		•	•		•
1.2.2 b) Please describe the major payers in your area.		•	•		•
1.2.2 c) Do payers offer any financial incentives or rewards for improving quality, reducing waste, or making your care delivery more efficient?		•	•	•	•
1.2.2 d) Who are your major competitors?		•	•		•

1.2.2 e) Are there market, regulatory or other external pressures that encourage greater efficiency and increased quality of care?		•	•	•	•
3.2.2 a) How were departmental or “frontline” staff told about the organization’s decision to implement Lean? To the best of your knowledge, how did they first react when they heard of this decision? What types of questions did they ask?		•			
3.2.2 b) In your opinion, how does the departmental/frontline/non-management staff view Lean? To what extent do they support or not support Lean? Are they excited about Lean or not? Do they feel positively or negatively? Please let me why you think this.		•	•		
3.2.2 c) What infrastructure was needed to support the Lean implementation on the department or organizational level? Please explain.		•	•	•	•
3.2.2 d) What, if any, resources (training, monies, staff) did you give to departmental staff in order to implement Lean?		•		•	
<b>Telephone Interview Topic Guide Questions</b>					
1.1 In the past three months, what, if any, Lean/TPS projects have been completed in your department? Please describe the completed projects and the activities involved.	•	•			
1.2 In the next three months, what Lean/TPS projects are currently being planned in your department? Please describe these expected projects.	•	•			
1.3 What, if any, Lean/TPS projects are currently ongoing in your department? Please tell me about these projects.	•	•			
1.4 In the past three months, what training and/or resources have been provided to YOU for Lean/TPS implementation? What training and/or resources have been provided to other staff in your department? Resources might include external coaches, consultation with other successful teams, time assigned just to Lean, extra staff, IT support, etc.		•	•		
1.5 Thinking back on the Lean/TPS work you have done in your unit (including all Lean projects in your department), what were the 2 or 3 greatest challenges?		•			
1.6 Thinking back on the lean work you have done in your unit (including all Lean projects in your department), what were the 2 or 3 greatest facilitators?		•	•		
1. 7 Please describe any surprises or unintended consequences (positive or negative) of the intervention and its implementation (e.g., staff morale improved or got worse, new ways to utilize advanced practice nurses) surfaced during the implementation process? If so, please describe.		•			
2.1 In your opinion, how have the Lean/TPS projects progressing in the past three months? In general, have these Lean/TPS projects been successful?	•				
2. 2 Please describe the impacts or outcomes of each Lean project. What has changed in your department since Lean/TPS implementation? Have these changes been positive or negative? Please describe these impacts.	•			•	
2.3 For all of these outcomes, what methods did you use to measure the impact? Are you still collecting data on these outcomes? How long do you anticipate collecting these data?	•			•	
2.4 Have any of these results undergone independent review? Have any of these results been published? If so, where?	•				
2.5 Please tell me how, if at all, these results have been validated?	•				
3.1 In the past three months, have improvements from the projects been sustained? Have the successes or improvements decreased over time, remained the same, or continued to improve? Why do you say this?	•		•		

3.2 What do you think are the challenges to the sustainability of Lean in both the department and the organization? What about things that facilitate sustainability?	•	•			
3.3 In the past three months, how, if at all, have you been involved in the sharing of information about Lean work and spread of Lean techniques? Please consider dissemination to other staff, other departments within your organization, other organizations, and/or the general.	•		•		•
3.4 Based on what the project team has learned to date, what are the insights and/or lessons learned for your own system and practices as well as others? If you were advising others about Lean and its implementation, what would you most want them to know? What should they be aware of, what should they do, what should they NOT do?		•	•		•
4.1 Do you have any additional comments about the Lean/TPS implementation in your department in the past three months?	•	•	•	•	•
<b>Digital Diary Topic Guide Questions</b>					
1.1.1 Please describe the events, tools, and progress of Lean implementation in the past week, including all of the projects or activities in which you were involved.		•			
1.2.1 What facilitated the project team and/or your department's progress toward achievement of their goals during the past week? For each of the facilitators you mention, please describe what made implementation easier.	•	•			
1.3.1 What were the challenges to implementing Lean in your department / organization or to each specific project? Please describe these challenges.		•			
2.1 Have any unintended consequences or effects (positive or negative) of the intervention and its implementation surfaced during the past week (e.g., staff morale improved or got worse, new ways to utilize advanced practice nurses)? If so, please describe.	•	•			
2.2 Based on what the project team and your department have learned to date, what are the insights and/or lessons learned for your own system and practices as well as others? If you were advising others about Lean/TPS and its implementation, what would you most want them to know? What should they be aware of, what should they do, what should they NOT do?		•	•		•
3.1 What do you have planned for Lean/TPS implementation in your department and/or within a specific project in the next week? Please briefly describe.	•	•			
3.2 Please share anything else you think may be important for us to know about Lean/TPS and its implementation and use in departments like yours, or in other departments.	•	•	•	•	•
<b>Documentation</b>	•	•	•	•	•

## **2. Purpose and Use of Information**

Lean/TPS is a philosophical, strategic approach to reducing waste in production systems that makes use of a number of tools, but is much more than the sum of those tools. Imported to health care from the automobile industry, Lean/TPS comprises a family of process-based redesign tools which include standardized work, value stream mapping, visual control, etc. Lean/TPS can be considered an overall strategy, or can be implemented as specific tools. Thus, the approach to implementation and the choice of which tools to use may vary by organization, by department, and by project. This variation will be found within geographic locations, different organized delivery systems, within clinical departments at a single site, and by the topic of the individual project. For example, at its most fine-grained level, a single clinical department may use one approach and one set of tools for one redesign project and another approach with a different set of tools to redesign another part of its care delivery system. Despite this variation, both approaches and tool sets can be characterized as Lean/TPS because they share the common strategic philosophy and draw individual tools from the same composite toolkit. Thus, even though every case study project will be a Lean/TPS project, the study will encompass considerable project-by-project variation. As a result, depending on what each site is hoping to achieve with its redesign projects and what measures they decide to collect, the project topics and the measures of success will vary.

The purpose of this project, then, is not to evaluate a single technique or project. Instead, we want to identify a range of organizations and projects to describe and assess both the similarities and differences in the ways in which these sites have implemented Lean/TPS, the way the sites went about determining their success, and related challenges and solutions. At a practical level, we want to help potential users imagine how they could use Lean/TPS effectively, by providing detailed descriptions of the settings (community, market, hospital, outpatient clinic) and the Lean/TPS implementation, including the barriers encountered and the solutions to those barriers.

We will use several qualitative methods to describe and monitor the sites. We will use document review, in-depth interviews (by phone and in-person), and digital diaries to collect data for the case studies. These methods share key strengths. They help provide increased context and depth to understand people's experiences and they can be used to gather information to better understand how and why events have occurred. We will use these methods to identify and assess critical aspects of the implementation of Lean/TPS principles and the redesign efforts and any impacts of Lean/TPS.

Qualitative methods (interviews via phone and in-person, observation during site visits, document review, and digital diaries) will also be used to generate and provide the rich description and examples required to develop useful dissemination information and more robust tools that focus on the implementation of Lean/TPS in diverse markets and settings, organizational and delivery structures, type and size of institution, type of Lean/TPS work flow, and experience with Lean/TPS.

The lessons learned and the business case will be published in the peer-reviewed and trade literatures so that they will be available to a wide range of delivery system managers, clinicians, architects, designers, and systems engineers for use in the redesign of existing departments and processes and in the design of new facilities. These publications and presentations will explicitly state the limitations of our case-study methodology and will also discuss threats to internal and external validity of each site's evaluation methods and techniques. After each site visit, we will send OMB a briefing document that outlines the various goals and outcomes/measurements each site plans to undertake. We will also include a short description on each site's internal evaluation.

### ***3. Use of Improved Information Technology***

Digital diaries will be used in place of formal interviews. In this data collection procedure, participants (who in this case will be those involved in Lean/TPS projects) will use a topic guide and speak into a recorder. These recordings will be sent to AIR and saved on AIR's secure server. This procedure for data collection decreases burden compared to interviews, because respondents may complete these "digital diaries" at their leisure or when their time allows in a simple and convenient format.

### ***4. Efforts to Identify Duplication***

The existing literature on Lean/TPS implementation in health care settings consists of a small number of case studies. Since these studies employed different methodologies and measured/reported on different outcomes, meta-analyses of these studies are not feasible. Nor, is it feasible to generalize results outside of the specific settings in which these studies were conducted.

The few existing case studies were reported by the individuals who implemented the Lean projects. Thus, there have been no comparative case studies of Lean/TPS implementation in health care settings by independent observers. This study will be the first to provide an independent, comparative analysis of the application of Lean/TPS in a variety of health care settings and institutions.

### ***5. Involvement of Small Entities***

Collection of information will not impact small businesses or other small entities, as information will be collected for existing hospitals and health systems which are not considered to be small.

### ***6. Consequences if Information Collected Less Frequently***

This is a one-time study. There are no plans to repeat it. Data will be collected only once for each of the retrospective case studies. However, in order to improve the quality and value of the data, we plan to collect data at several points in time within each prospective case. Data collection for all prospective case studies will run for approximately 36

weeks. During this period, data will be collected from hospital/health system staff working on Lean/TPS projects every week (digital diaries), every four months (telephone interviews), and twice in the lifetime of the project (site visit in-person interviews). This frequency of collection is necessary in order to track the implementation of Lean/TPS in real time. The weekly digital diaries are necessary to ensure accurate data collection of these fast-paced projects. Only 36 weeks are necessary as the early impacts of Lean/TPS implementation are expected to be measurable very soon after the project is initiated. Based on the literature and our recruiting efforts, it appears that hospitals only implement Lean/TPS projects if they anticipate fairly rapid system improvement. We will track implementation and sustainability for the 36 weeks, but sustainability of the prospective case studies after this time period is a limitation to our study. For a complete discussion of limitations, see Supporting Statement Part B.

## ***7. Special Circumstances***

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

## ***8. Federal Register Notice and Outside Consultations***

### ***8.a. Federal Register Notice***

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on November 21, 2008 on page 70648 for 60 days (see Attachment G).

### ***8.b. Outside Consultations***

AHRQ has consulted with staff of American Institutes for Research, the Mayo Clinic, Virtua Health, and NYCHHC to implement this project. AIR staff are experts in case study design and qualitative methodology and Mayo Clinic staff are experts in Lean/TPS implementation. Mayo, Virtua, and NYCHHC have implemented Lean.

## ***9. Payments/Gifts to Respondents***

We will not provide any payment or gifts to respondents.

## ***10. Assurance of Confidentiality***

The information that you provide will be kept private and confidential to the extent permitted by law.

## ***11. Questions of a Sensitive Nature***

Questions of a sensitive nature will not be asked during the data collection activities. Social Security numbers and/or Medicare numbers will not be collected.

## 12. Estimates of Annualized Burden Hours and Costs

Exhibit 4 shows the estimated annualized burden hours. The table includes burden for both the retrospective and prospective case studies in separate sections. As this project will collect data from establishments, we have defined each establishment as the medical or administrative department that is implementing the Lean/TPS project to be studied.

In Exhibit 4, the total burden hours in each row (Column F) is calculated as the product of the values in the other columns (Columns B-E). Thus, for each of the 9 prospective case studies, we will conduct in-person interviews with 15 administrative and clinical personnel. Each person will be interviewed twice during the 36 week data collection period. The estimated time per response is 1.0 hour for a total of 270 burden hours for in-person interviews. Using the same calculation approach, we project 41 burden hours for telephone interviews, 96 burden hours for digital diaries, and 36 burden hours for assembling documents for a subtotal of 443 burden hours for the 9 prospective case studies. For each retrospective case study, we have defined establishment as the department from which we will collect data. A total of 15 in-person interviews will be conducted with the administrative and clinical personnel during a site visit. The estimated time per response is 1.0 hour. For all 4 retrospective case studies, we estimate a total of 60 burden hours. Similar to the prospective case studies, administrative staff from each site will be asked to provide training materials, reports on Lean/TPS implementation, and/or any other documentation or existing data from previous or current Lean/TPS projects implemented and will take 4 hours. The total estimated burden for the retrospective case studies is 76 hours. The total burden hours for all 13 case studies is 519 hours.

### Exhibit 4. Estimated annualized burden hours

A	B	C	D	E	F
Data Collection	Number of Establishments	Number of Respondents per Establishment	Number of Responses per Respondent	Hours per Response	Total Burden Hours <sup>1</sup>
<b>Prospective Case Studies &amp; Hospital Case Study</b>					
In-person interviews	9	15	2	1	270
Telephone interviews	9	3	3	30/60	41
Digital Diaries	9	2	32	10/60	96
Collection of documentation	9	1	1	4	36
<b>Prospective Subtotal</b>	<b>36</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>443</b>
<b>Retrospective Case Studies</b>					

In-person interviews	4	15	1	1	60
Collection of documentation	4	1	1	4	16
<b>Retrospective Subtotal</b>	<b>8</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>76</b>
<b>Grand Total</b>	<b>44</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>519</b>

Exhibit 5 shows the estimated cost burden for the respondents' time to provide the requested data. The hourly rate of \$35.07 is an average of the administrative personnel hourly wage of \$14.53 and the clinical personnel hourly wage of \$62.52 for physicians and \$28.15 for registered nurses. The average hourly wage of administrative and clinical personnel is used to estimate the cost of in-person interviews, telephone interviews, and digital diaries, because all kinds of staff may be asked to participate in these three activities. The average hourly wage for administrative personnel--\$14.53—is used to estimate the cost of assembling documentation, because administrative support staff will perform this task. The total estimated cost burden is about \$17,134.

**Exhibit 5.** Estimated annualized cost burden

<b>Data Collection</b>	<b>Number of Establishments</b>	<b>Total Burden Hours</b>	<b>Average Hourly Wage Rate*</b>	<b>Total Cost Burden</b>
<b>Prospective, Retrospective, &amp; Hospital Case Studies</b>				
In-person interviews	13	330	\$35.07	\$11,573
Telephone interviews	9	41	\$35.07	\$1,438
Digital Diaries	9	96	\$35.07	\$3,367
Collection of documentation	13	52	\$14.53	\$756
<b>Total</b>	<b>44</b>	<b>519</b>	<b>n/a</b>	<b>\$17,134</b>

\*Based upon the average hourly wages of administrative support personnel, physicians, and registered nurses, National Compensation Survey: Occupational Wages in the United States 2005, U.S. Department of Labor, Bureau of Labor Statistics.

**13. Estimates of Annualized Respondent Capital and Maintenance Costs**

There are no direct costs to respondents other than their time to participate in the study.

**14. Estimates of Annualized Cost to the Government**

The total cost to the Federal Government for this three year project is \$644,992. Exhibit 6 shows the basic cost components.

## **Exhibit 6. Estimated Cost**

<b>Cost Component</b>	<b>Total Cost</b>	<b>Annualized Cost</b>
Project Development	\$19,885	\$6,628
Data Collection Activities	\$308,729	\$102,910
Data Processing and Analysis	\$101,316	\$33,772
Publication of Results	\$72,859	\$24,268
Project Management	\$21,349	\$7,116
Overhead	\$105,668	\$35,223
Government Oversight	\$15,186	\$5,062
<b>Total</b>	<b>\$644,992</b>	<b>\$214,997</b>

### **15. Changes in Hour Burden**

This is a new collection of information.

### **16. Time Schedule, Publication and Analysis Plans**

AIR's contract for this project lasts from July 1, 2008 to June 30, 2011. Data collection will occur after OMB clearance is received

Dissemination activities will occur throughout the project. The dissemination plan will be finalized in March 2010 (after the case study analysis is completed) and the manuscripts, conference presentations, and articles for the departmental-level studies will be submitted or conducted in May and June 2010. Dissemination activities for the case study of the new hospital will be completed by June 2011. Our publications and presentations of study findings will explicitly state the limitations of our case-study methodology.

### **17. Exemption for Display of Expiration Date**

AHRQ does not seek this exemption.

#### **List of Attachments:**

Attachment A: Healthcare Research and Quality Act of 1999

Attachment B: In-person interview guide

Attachment C: Telephone interview guide

Attachment D: Email notification to schedule in-person and telephone interviews

Attachment E: Digital diary instructions

Attachment F: Collection of documentation guidelines

Attachment G: 60-Day Federal Register Notice