

# Implementing a Systems Engineering Intervention for Improving Safety in Outpatient Surgeries

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## Abstract

This paper describes the systems engineering intervention the researchers implemented in their study of patient safety in outpatient surgery. The intervention process is based on the SEIPS (Systems Engineering Initiative for Patient Safety) model of work-system and patient safety. The paper provides details on the steps in the intervention process (e.g., overall structure, decisionmaking criteria for selection of intervention, participants) and the various data collection tools and methods that were used at each step of the intervention process. The systems engineering intervention process consists of three steps: (1) defining and designing the content and the implementation plan of the intervention, (2) implementing the intervention, and (3) institutionalizing the intervention. Data collection methods used for defining and designing the intervention include an initial employee questionnaire and patient shadowing. An employee questionnaire and a patient survey are the two methods used to evaluate the impact of the systems engineering intervention.

## Introduction

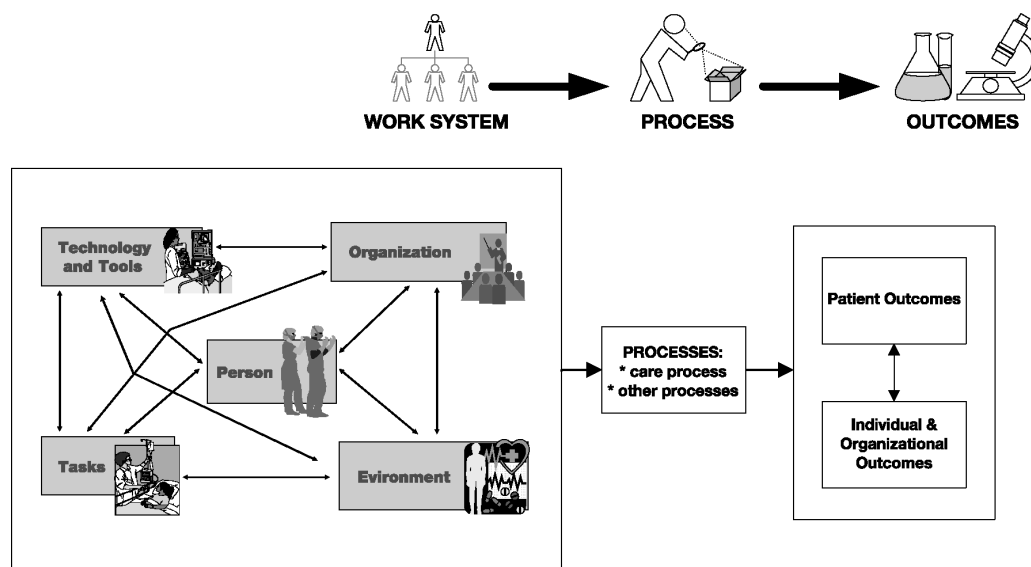
In our Systems Engineering Initiative in Patient Safety (SEIPS)\* study, “Patient Safety in Outpatient Surgery,” we have developed an intervention process that targets changes in health care systems with the aim of improving both patient safety and employee and organizational outcomes.<sup>1</sup> In this paper, we describe our systems engineering intervention process. Our SEIPS study in outpatient surgery is used as example of the application of the intervention process.

There is an underlying conceptual framework that drives the systems engineering intervention process. In the SEIPS model of work system and patient safety (Figure 1),<sup>1</sup> we integrate Donabedian’s Structure-Process-Outcome framework<sup>2</sup> and the work system model developed by Smith and Carayon.<sup>3, 4</sup> The structure of an organization (or more generally, the work system) affects the extent to which safe care is provided (the process). The means of caring for and managing the patient (the process) affects the likelihood the patient completes his or her experience without harm (outcome). It also influences employee and

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\* For additional information on SEIPS, please consult the SEIPS Web site at <http://www2.fpm.wisc.edu/seips/>.

**Figure 1. Systems Engineering Initiative in Patient Safety (SEIPS) model of work system and patient safety**



organizational outcomes.<sup>1</sup> The goal of the systems engineering intervention is to make changes to the structure and process elements to improve patient outcomes as well as to improve employee and organizational outcomes.

This paper provides details on the steps in the intervention process (e.g., overall structure, decisionmaking criteria for selection of an intervention, participants) and the various data collection tools and methods that can be used at each step of the intervention process. We also emphasize the major challenges in implementing systems engineering interventions aimed at improving patient safety and strategies that can be used to mitigate those challenges. The specifics of the intervention (the content and implementation plan of the intervention) need to be adapted to the particular organization. However, the intervention process itself can be replicated in any organization.

## The organizational context for intervention

In this paper, we describe the systems engineering intervention process as it was applied to our SEIPS pilot project. The study was conducted in collaboration with five outpatient surgery centers located in Madison, Wisconsin. One surgery center is hospital-based and is managed by a physician-directed corporate entity. Excluding medical staff, it employs 39 full-time equivalent employees (FTEs). Another surgery center is free-standing and is managed by the same physician-directed corporate entity. Excluding medical staff, it employs 22.1 FTEs. Two other centers are managed under the auspices of a joint venture between a large medical group and the hospital at which the group's physicians primarily practice. Excluding medical staff, both surgery centers employ 49 FTEs. The fifth surgery center is a government-run provider of ambulatory and inpatient care, and

employs 18.2 FTEs, excluding medical staff. The total patient volume of the combined surgery centers was about 25,000 cases in fiscal year 2001–2002.

All five outpatient surgery centers are members of the Madison Patient Safety Collaborative (MPSC). MPSC was established in September 2000 when Madison’s hospitals and medical groups collectively decided to form a group focused on developing and implementing patient safety practices to further improve the safety of care received by all consumers in the greater Madison area (additional information is available at [www.madisonpatientsafety.org](http://www.madisonpatientsafety.org)). The collaborative was founded on the tenets that patient safety is a common goal of health care institutions rather than a competitive issue, and that, through cooperation, Madison providers will be able to implement safety improvements that go well beyond the scope of any single organizational effort.

Each member of the collaborative has made an organizational commitment to improving patient safety by dedicating infrastructure, intellectual capital, and fiscal resources to MPSC projects. With funding from five members, the MPSC has established a community-based center to coordinate, record, and communicate patient safety initiatives. The center has identified leaders to coordinate efforts among member organizations, share “lessons learned” and progress achieved, secure external support for MPSC activities, and establish key partnerships with local and national organizations concerned with patient safety. The SEIPS project on patient safety in outpatient surgery was conducted under the auspices of MPSC.

## **The collaborative intervention process**

Data obtained during the initial data collection phase were analyzed (see section below on “Initial data collection”) and presented to the outpatient surgery centers. The sites collectively decided to make changes to the pre-operative process with the goal of improving the coordination and communication of care among providers. In addition, the current patient follow-up process at each site was to be changed to become more active. Four meetings were held with representatives of the outpatient surgery centers and the research teams to discuss the initial data, identify areas of opportunity for improvement, and decide the nature of the intervention. The content of each of these four meetings, as well as the rest of the meetings, is described in Table 1. The first two meetings were primarily led by the research team. At “meeting #3” and at subsequent meetings, representatives of the five surgery centers contributed to most of the interaction during the meetings. Starting with “meeting # 5,” each of the surgery centers was asked to provide an update on their activities, and they became even more engaged in the collaborative intervention process.

It is important to note that at each of the meetings, each of the five surgery centers was represented by at least one individual (and in most cases two individuals). The individuals participating in the meetings included the physician-directors of two surgery centers, the vice-president and manager of two surgery

**Table 1. Collaborative intervention process**

<b>Meeting</b>	<b>Date</b>	<b>Attendance</b>	<b>Content</b>
Meeting #1	October 2002	<ul style="list-style-type: none"> <li>• 7 SEIPS research team members</li> <li>• MPSC coordinator</li> <li>• 7 representatives from the 5 outpatient surgery centers</li> </ul>	<ul style="list-style-type: none"> <li>• Presentation of SEIPS project</li> <li>• Discussion of project objectives and timeline</li> <li>• Discussion of initial data collection</li> <li>• Brainstorming discussion on patient safety issues experienced by the surgery centers</li> <li>• Organization of project</li> </ul>
Meeting #2	February 2003	<ul style="list-style-type: none"> <li>• 3 SEIPS research team members</li> <li>• MPSC coordinator</li> <li>• 7 representatives from the 5 outpatient surgery centers</li> </ul>	<ul style="list-style-type: none"> <li>• Presentation of initial data collection results</li> <li>• Discussion of criteria for selecting intervention</li> <li>• Discussion of timeline</li> </ul>
Meeting #3	March 2003	<ul style="list-style-type: none"> <li>• 4 SEIPS research team members</li> <li>• MPSC coordinator</li> <li>• 5 representatives from the 5 outpatient surgery centers</li> </ul>	<ul style="list-style-type: none"> <li>• Discussion of initial data analysis</li> <li>• Brainstorming discussion of possible interventions</li> </ul>
Meeting #4	March 2003	<ul style="list-style-type: none"> <li>• 7 SEIPS research team members</li> <li>• MPSC coordinator</li> <li>• 6 representatives from the 5 outpatient surgery centers</li> </ul>	<ul style="list-style-type: none"> <li>• Agreement on content of intervention</li> <li>• Discussion of main data collection tools and procedures</li> </ul>
Meeting #5	July 2003	<ul style="list-style-type: none"> <li>• 5 SEIPS research team members</li> <li>• MPSC coordinator</li> <li>• 9 representatives from the 5 outpatient surgery centers</li> </ul>	<ul style="list-style-type: none"> <li>• Presentation of preliminary employee questionnaire data analysis</li> <li>• Update on intervention by each of the surgery centers</li> </ul>
Meeting #6	February 2004	<ul style="list-style-type: none"> <li>• 6 SEIPS research team members</li> <li>• MPSC coordinator</li> <li>• 11 representatives from the 5 outpatient surgery centers</li> </ul>	<ul style="list-style-type: none"> <li>• Presentation of employee questionnaire data and patient survey data</li> <li>• Update on intervention by each of the surgery centers</li> <li>• Discussion of post-intervention data collection</li> </ul>
Meeting #7	September 2004	<ul style="list-style-type: none"> <li>• 3 SEIPS research team members</li> <li>• MPSC coordinator</li> <li>• 6 representatives from the 5 outpatient surgery centers</li> </ul>	<ul style="list-style-type: none"> <li>• Update on post-intervention data collection</li> <li>• Update on intervention by each of the surgery centers</li> </ul>
Meeting #8	November 2004	<ul style="list-style-type: none"> <li>• 5 SEIPS research team members</li> <li>• MPSC coordinator</li> <li>• 4 representatives from the 5 outpatient surgery centers</li> </ul>	<ul style="list-style-type: none"> <li>• Presentation of final data analysis</li> <li>• Discussion of lessons learned and institutionalization</li> <li>• Presentation of followup project on pre-operative information flow at one surgery center</li> </ul>

centers, the nurse managers of all five surgery centers, and patient safety and quality improvement personnel of each of the surgery centers.

## **Steps in the intervention process**

Designing or redesigning work systems and processes can represent a major organizational investment, requiring the involvement of numerous people; substantial time to conduct evaluations, analyze data, and design and implement solutions; adequate resources; and sufficient expertise and knowledge. Like any major organizational or technological change, system redesign needs to be managed. A process needs to be implemented for coordinating all the personnel, activities, and resources involved in the redesign project. Many work design processes have been identified and proposed.<sup>5</sup> They take different forms, have different levels of specifications, and use different terminologies. Wilson<sup>5</sup> proposes an ergonomics design process with 12 steps:

1. Setting objectives and requirements for analysis.
2. Initiating consultation and participation.
3. Identifying priorities and critical issues for data collection.
4. Conducting task analysis and synthesis.
5. Conducting task design, allocation, and division of function.
6. Analyzing workspace layout.
7. Analyzing work environment.
8. Analyzing job design.
9. Analyzing job aids, manuals, procedures, and training specifications.
10. Analyzing work organization.
11. Evaluating and redesigning the aspects of work.
12. Monitoring the redesign.

This ergonomics design process is very detailed with regard to analysis, but may lack details and specifications for redesign implementation and evaluation. The structured work redesign process proposed by Parker and Wall<sup>6</sup> includes eight phases:

1. Set the direction.
2. Diagnose the situation.
3. Formulate the work design.
4. Consider the wider context.
5. Plan the implementation.
6. Conduct a prechange assessment.
7. Implement, re-assess, evaluate, fine-tune.

8. Spread the work design and sustain the change.

We have synthesized Wilson's 12-step process<sup>5</sup> and Parker and Wall's 8-step process<sup>6</sup> into a 3-step intervention process as follows:

1. Definition and design of the intervention:
  - a. determine the content of the intervention
  - b. determine the implementation plan of the intervention
2. Implementation of the intervention
3. Institutionalization of the intervention.

Steps 1–10 of Wilson and steps 1–6 of Parker and Wall are included in our first step of defining and designing the intervention. Step 5 of Parker and Wilson is similar to our second substep on determining the implementation plan. Step 11 of Wilson and step 7 of Parker and Wall are similar to our second step. Step 12 of Wilson and step 8 of Parker and Wall are similar to our third step.

## Defining and designing the intervention

In the first step of the systems engineering intervention process, the specific problem to be solved needs to be identified (i.e., defining the content of the intervention). This step involves steps 1–10 of Wilson's ergonomics design process.<sup>5</sup> Following Wilson's recommendation and based on the work system model of Smith and Carayon,<sup>3,4</sup> we examined a range of system variables (e.g., tasks, tools and technologies, workspace layout, work environment, job design, work organization). The methods used to conduct this analysis are described below (see the section on "Initial data collection"). After a phase of initial data collection and analysis, an intervention is decided upon (phase 3 of Parker and Wall's work-redesign process<sup>6</sup>). Several elements come into play into this decisionmaking process. The team agreed that certain criteria were to be met when selecting the cross-center intervention. These criteria included:

- the intervention coincides with SEIPS objectives
- all organizations are willing to participate
- all organizations are committed—need to identify a contact person
- the intervention provides balance between research and practice *and* provides high research rigor
- the intervention is clinically relevant
- the timeline is feasible
- data evaluation can occur (measurement sensitivity)
- the magnitude of impact on patient safety is substantial
- the intervention is sustainable
- the intervention fits the budget and resources available

Given the theoretical basis of the SEIPS model and the systems engineering intervention, we attempted to identify interventions that affect both the work system and patient safety. Figure 2A shows the kind of intervention that we were looking for. The intervention was to have a high impact on both the work system *and* patient safety.

The goal of the systems engineering intervention is to affect patient outcomes as well as both individual and organizational outcomes. The patient safety issues of interest in our SEIPS study conducted in outpatient surgery are as follows:

- providers are fully informed of their patient’s clinical status
- the surgery is performed appropriately (e.g., correct site surgery) and clinically accurate
- patients are adequately prepared pre-operatively
- patients are well educated for post-operative self-management (including an understanding of their medications)

In determining the content of the intervention, the SEIPS team targeted specific patients for the intervention and the evaluation (Figure 2B). The targeted patients involve “high acuity” patients as well as those undergoing high-risk procedures. We chose this strategy for a number of reasons. First, we recognized that having a fully representative sample of patients from each surgery center would include a proportion of patients and procedures that present minimal risk or that would be unique to the respective center. We would, for that reason, have needed a larger sample of patients to obtain any type of statistically meaningful results. Therefore, by choosing “at-risk” patients as our subjects we were more likely to obtain greater variation in responses. Secondly, we had limited time and resources to conduct the intended study. Finally, we had to identify homogenous patient groups among the five centers. The types of procedures selected allowed us to then perform cross-center comparative analyses.

**Figure 2A. Determining a systems engineering intervention**

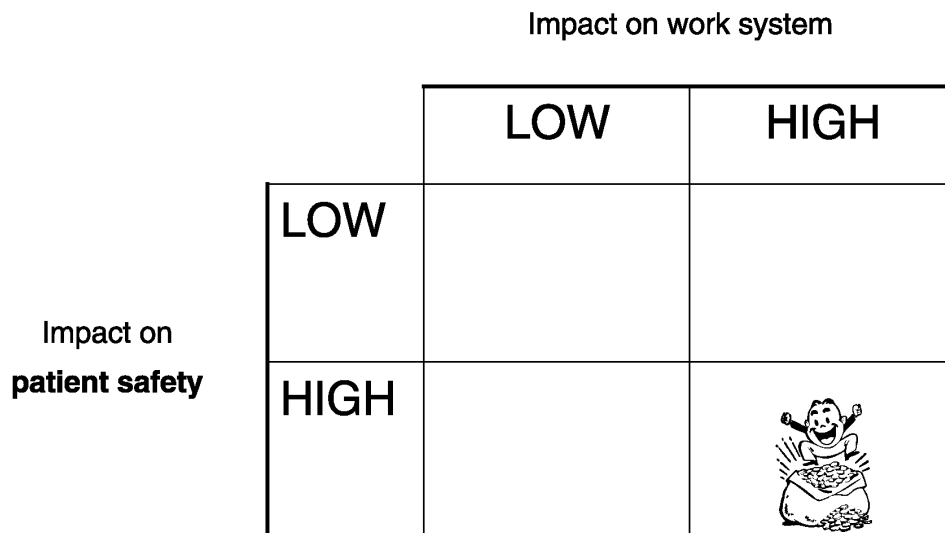
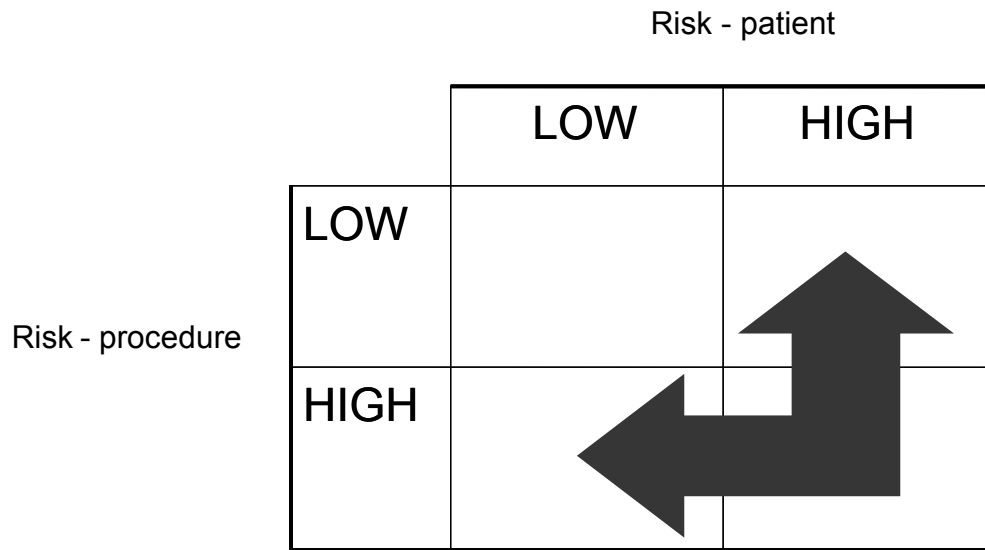


Figure 2B. Targeting patients for the intervention and the evaluation



## Implementation of the intervention

Using the process described above, along with information captured from the initial data collection, the team chose to address two themes in the intervention: (1) the adequacy of patients' pre-operative clinical information, and (2) active patient follow-up. At this point, each outpatient surgery center had to determine strategies it would employ to attempt to ensure that it had all of the clinically relevant and necessary information needed to safely, accurately, and appropriately proceed with surgery. A variety of "interventions" resulted, including (1) implementing an institutional policy requiring that all patient information is provided to the surgery center by noon on the working day prior to the surgery; (2) updating center policy-and-procedure manuals and then distributing them to the offices of relevant referring physicians; (3) integrating relevant clinical information in the medical center's newly implemented electronic medical record, and providing the surgery centers with access to this information; and (4) creating an electronic anesthesia clinic record that logs necessary clinical information pre-operatively.

Each outpatient surgery center developed its own specific implementation plan. What each site chose to change, as well as how they implemented the change, depended on the unique systems in place at each site. In addition, the research team met with each of the surgery centers separately to refine the implementation plan as well as the specifics of the intervention to be implemented at each site. These meetings were guided by findings of the initial data collection (i.e., the intervention should address issues identified in the initial effort), the two themes (pre-operative patient assessment and active patient follow-up) that were collectively identified for the intervention, the process analysis performed for each of the surgery centers, center-specific criteria for selection/design of the intervention, and center-specific patient safety issues.



## Data collection

In the systems engineering intervention process, data are collected and used to design the intervention and to evaluate the impact of the intervention as follows:

- **Data to define and design the intervention.** This included various tools and data sources—an initial questionnaire to gather staff input, patient shadowing to evaluate the patient care process, flowcharting and process analysis, review of various data sources (e.g., physical layout, data on quality and safety of care), and a participatory design process.
- **Data to evaluate the impact of the intervention at various levels.** Data were collected pre- and post-intervention to evaluate the impact of the intervention on staff and patients. These data were collected by means of an employee questionnaire and a patient survey that addressed the different elements of the SEIPS model of work system and patient safety.

### Initial data collection

To begin our study, we needed to gain an overall understanding of the various participating surgery centers. We accomplished this by collecting position descriptions for all of the health care provider roles at each site; obtaining floor plans for each surgery center; asking staff to complete surveys aimed at identifying both the quality of care and the patient safety issues they perceive exist at their center (as well as the performance obstacles they encounter in their work); and “shadowing” patients (having a member of the research staff accompany the patient through the entire experience at the center) to capture the outpatient surgery experience from the patient’s perspective. Our interaction with the individual surgery centers also involved flowcharting and process analysis of the outpatient surgical experience.<sup>7</sup> The participatory process analysis involved gathering input from the surgery centers regarding steps of the outpatient surgery process, flowcharting the process, discussing the process with the center staff, and making changes to the flowchart. In this paper, we briefly describe two of the initial data collection methods: the initial employee questionnaire and patient shadowing.

### Initial employee questionnaire

The objective of the initial employee questionnaire was to evaluate employee perceptions of quality- and safety-of-care issues, and to assess the factors in the work environment that facilitate or hinder employee performance (i.e., performance facilitators and obstacles). While attending staff meetings at each of the sites, we introduced and explained our research project and then distributed questionnaires to all staff present. Attendance was taken at each site’s single meeting, and questionnaires were later distributed by supervisory staff to those not present at the meeting. The presentations were well received and staff expressed interest and a willingness to participate in the study. We attached

Institutional Review Board-required cover sheets to all of the questionnaires (in lieu of obtaining subjects' individual written consent) to ensure that staff fully understood the intent and consequences of participation. We also offered staff the option of completing paper or electronic versions of the questionnaire. The electronic versions included a Web-based format and an RTF-formatted file on a diskette. Seventy-seven of the 79 responses received were completed on the paper version, and two respondents utilized the Web format. Completed paper surveys were deposited in locked mailboxes at each site to assure confidentiality. Research staff collected the surveys twice a week for the 3 weeks during which the surveys could be completed and returned.

The initial employee questionnaire included the following three items plus specific context and directions for each:

1. What do you think are the main quality of care and patient safety issues in your outpatient surgery center?
2. Please think of instances in the past year when you feel your performance was challenged or below par due to problems in the outpatient surgery center "system."
3. Please think of instances in the past year when you were able to perform your job very well.

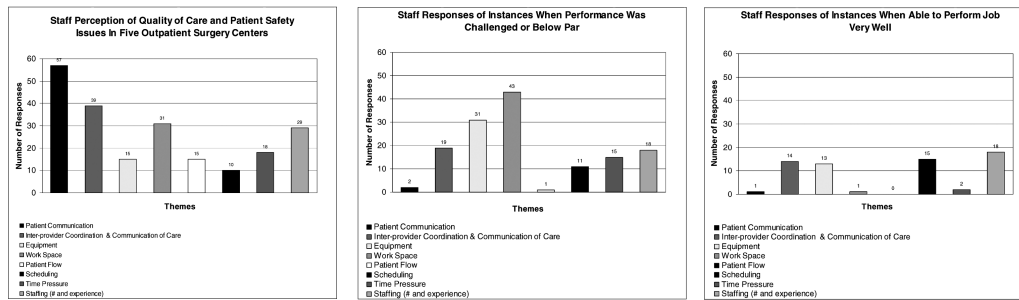
We then performed content analysis on responses to all three of the survey questions. The first question asked staff to identify quality-of-care and patient safety issues they believe affect patient outcomes and experience at specific stages of the outpatient surgery process—from the work-up (prior to presenting for surgery) to patient follow-up at home. The second question asked staff to identify "instances when your performance was challenged or below par," and question three asked staff to describe "instances when you were able to perform your job very well." The format of the questionnaire included one blank page per question. The questions were written and clarified by providing examples listed at the top of the page. This was done so that staff might understand the number and magnitude of issues they could consider and include in their responses. Figure 3 shows data that were presented to the five surgery centers and summarizes initial employee questionnaire data.

The overall performance-obstacles approach used in the initial employee questionnaire is described in the paper on "Performance Obstacles and Facilitators of Health Care Providers" to be published in Volume 4 of the *Organizational Psychology and Health Care* book series.<sup>8</sup> Data obtained during the initial data collection of our outpatient surgery study are reported in a paper that was presented at the 2003 Conference of the Human Factors and Ergonomics Society<sup>9</sup> and in a paper submitted for publication.<sup>10</sup> These publications include details about data collection, data analysis, and results.

### **Patient shadowing**

We also performed "shadowings" on patients undergoing outpatient surgery to better understand the complexity of the outpatient surgery experience from the

Figure 3. Analysis of initial employee questionnaire data



Preliminary results of the **staff completion of an open-ended questionnaire** aimed at identifying the areas of concern staff have regarding quality and patient safety, as well as those aspects of the work units and their associated systems that promote patient safety and a healthy work environment.

patient’s perspective. The work system model served as the basis for summarizing the experience.<sup>3,4</sup> Individuals with clinical training and expertise followed patients having outpatient surgery from the point of admission to the unit/center until discharge. There was no intent to scrutinize the quality of care provided by the providers (e.g., the surgical technique).

Patients were chosen by the medical director of each unit based primarily on the complexity of the case and the availability of the individual to shadow the patient. The patient’s surgeon also had to agree to the shadowing. To eliminate any difficulties in communication, only individuals who spoke English fluently were considered. Once the patient agreed with his/her surgeon to be “shadowed” (after being given an overview of the shadowing process that included following the patient and recording observations on a data collection form), written consent was obtained from the patient by the “shadower.” The patient was assured that participation was totally voluntary and that no identifiable information concerning them or those participating in their care would be collected. Minimal verbal interaction occurred between the researcher and patient, and only questions such as: “How far did you travel to get here?” and “How long ago was your surgery scheduled?” were asked. All responses were ultimately summarized and reported using a work system worksheet. Using this procedure, a total of 12 patient shadowings were performed at five different outpatient surgery centers. This patient shadowing method is further described in a paper that was presented at the 2003 Congress of the International Ergonomics Association.<sup>11</sup> Table 2 displays an example of data collected in the patient shadowing.

Table 2. Example of patient shadowing data

Tasks	Tools & Technologies	Environment	Organization
<p><b>Beginning time: 6:30 AM Pre-Op</b>  <b>Ending time: 7:30 AM</b></p> <p><b>Anesthesia:</b> Anesthesiologist meets patient; goes over chart at bedside; reviews allergies, past surgeries, medications, and reactions to past anesthesia. Tells patient what he will do and about the CRNA that will be with her all through the operation. Asks if she has questions about the anesthesia and her eye procedure.</p> <p>Notes pre-op consent is missing a possible procedure that may be done.</p> <p>Prepares pre-op medications for blocking eye. Fills syringes and caps sterile needles for later delivery to patient.</p> <p>Communicates to pre-op RNs about missing procedure on consent.</p> <p>Verbal communication patient needs a pre-op blood sugar.</p>	<p>Walls are folding screen and curtain in front</p> <p>Chart hand written on bed or on top of cabinet unit at head of pt. bed wall</p> <p>Needles, syringes, multidosed medication vials, IV bags, tubing, Vacutainers</p> <p>Cell phone</p> <p>Overhead Paging</p>	<p>No privacy if other pts. were around.</p> <p>Lots of conversation from nursing area as they have no patients to take care of and are talking among themselves.</p> <p>Charting is done in patient bay on top of cabinet that holds monitors, supplies, and resuscitation equipment on wall, right side of patient bed headboard. It is high and hard to use for short person, Meds are in way, other chart elements are in the way; IV supplies are in way.</p> <p>Anesthesia uses top of supply cabinet for drug preparation. Small area (9–10") filled with charts and supplies on top of a cabinet the nurse must enter on a regular basis for supplies.</p> <p>Lighting is good.</p> <p>Space is small and MD and RN need same spaces on occasions.</p>	<p>The space is small for all the activity that can be going on.</p> <p>Anesthesiologist does not have a designated space for medication preparation.</p> <p>Hard to read chart and get all the pre-op information and prepare pre-op anesthesia medications with nurse needing same space for supply access.</p> <p>Information not transferred and missing on pre-op consent from surgeons office.</p> <p>Anesthesia picks this up.</p>

“Shadowing” of patients undergoing outpatient surgery by a researcher, to better understand from a patient’s perspective the information flow within the system and any associated shortcomings and strengths.

## Main data collection

In order to evaluate the systems engineering intervention, we utilized two means of data collection: patient telephone interviews and an employee survey/questionnaire. Patient surveys and questionnaire data are collected at two points in time: immediately prior to and 12 months after the implementation of the intervention.

### Employee questionnaire

All employees working in the five outpatient surgery centers were asked to voluntarily respond to an employee survey. A cover letter and information sheet explaining the study accompany each questionnaire. An employee's completion of the written or electronic version of the survey implied their consent to participate. Because of the need to track the results by respondent over time, employees were asked to record a unique, easily remembered number to allow for tracking and analysis (the final four digits of their social security number). The surveys were distributed to all staff at the beginning of their daily rounds when an overview of the survey was presented. The surveys were returned via a locked secure drop box at any of the five sites, U.S. or University interdepartmental mail, or via the Internet if they chose to complete the web version of the survey. Follow-up written and verbal reminders were used to encourage participation by the staff.

The objective of the employee questionnaire was to evaluate staff perceptions of (1) work system elements targeted or possibly affected by the intervention (communication, coordination, workplace facilities, equipment and supplies, workload), (2) quality of working life (job satisfaction, stress), (3) perceived quality and safety of care provided, (4) patient safety climate in the outpatient surgery center, and (5) demographics and background information. Additional information on the employee questionnaire can be found in a paper to be published in *Advances in Patient Safety: From Research to Implementation*.<sup>12</sup>

### Patient survey

The objective of the patient survey was to evaluate (1) symptom management; (2) patient understanding of medication, surgery preparation and post-op instructions; and (3) demographics and background information. We examined the impact of the intervention on symptom management and patient understanding. Additional information on the patient survey can be found in a paper to be published in *Advances in Patient Safety: From Research to Implementation*.<sup>13</sup>

Patients who presented a high clinical acuity for surgery or who were undergoing high-risk procedures were asked to participate in the follow-up telephone interviews. This included patients classed as non-ASA 1, or those having procedures that have a higher likelihood of post-operative problems. We selected 100 patients at one center, 50 each at two centers, and 25 patients at two other centers for each of the data collection phases. First, patients' eligibility for

participation was determined. Then, prior to having surgery, patients were approached by a nurse involved in their care to determine if they were interested and willing to participate in the study. If the patient initially agreed to participate, s/he was given an informed consent and HIPAA (Health Insurance Portability and Accountability Act of 1996) authorization to review and sign. Patients were assured that no identifiable information concerning them, those providing care to them, or the surgical procedure they were undergoing was collected during the interview and that there would be no “link” between the consent and interview forms. Follow-up telephone calls were placed to patients. If after multiple follow-up calls, the patient was not reached, the patient was excluded from the study. If they were excluded their respective consent form was shredded. Minors and those in “altered states,” e.g., those with dementia and known psychiatric history, were not included.

Data collection occurred over approximately four months, depending on the availability of the interviewer and patient to complete the patient telephone interview. A 63 percent response rate from patients who agreed to participate in the interview was attained. Patients were able to change their mind at any time prior to or during the phone interview and to drop out of the study without penalty.

## **Discussion**

The systems engineering intervention process described in this paper summarizes a successful collaborative process between a research team (Systems Engineering Initiative for Patient Safety team comprised of engineering and health care researchers) and five outpatient surgery centers under the auspices of the Madison Patient Safety Collaborative. The success of the collaborative process is demonstrated via continuing sustained participation of all surgery centers in the research study. The collaborative process has facilitated data collection by the researchers and also has provided a unique opportunity to demonstrate the feasibility of implementing a systems engineering intervention aimed at improving both patient outcomes and individual/organizational outcomes. The surgery centers involved in the systems engineering intervention process also have largely benefited from interacting with the research team, but probably more importantly from interacting with each other. At most of the meetings, significant interaction took place directly between representatives of the various surgery centers. They often exchanged information on systems and processes (e.g., process of patient follow-up after surgery), on various tools and technologies used (e.g., H&P forms), and procedures (e.g., wrong-site surgery procedure). Other city-wide collaborative initiatives led by the Madison Patient Safety Collaborative (e.g., site marking project) also have benefited from the involvement of the five surgery centers in our systems engineering intervention process. These can be considered as indicators of the success of the SEIPS research study and the intervention process.

Initially the bulk of the interaction between the research team and the surgery centers took place in meetings involving all the surgery centers. In further defining the intervention, the interaction with the surgery centers involved “one-on-one” activities with each surgery center. For communication and coordination purposes, a member of the research team was designated as a liaison for each of the surgery centers. Over time, the interaction between the research team and the surgery centers evolved from a one-way interaction (i.e., the research team asking the centers for specific action or input) to a two-way interaction. The centers have individually approached the research team to continue the project, which indicates the value they perceive in interacting with the SEIPS research team.

Our systems engineering intervention process fits with the overall approach of action research.<sup>14, 15</sup> Action research is a research approach that focuses on simultaneous action and research in a participative manner. The term of action research is generic and refers to a range of approaches, such as participatory action research,<sup>16</sup> action science,<sup>15</sup> and reflective practice.<sup>17</sup> Our SEIPS research study fits the traditional model of action research where a collaborative problem-solving relationship was established between a group of researchers and five outpatient surgery centers. The double objective of the SEIPS study was to (1) generate new knowledge (research objective), and (2) solve a problem (action objective). Center representatives repeatedly commented that the project facilitated and expedited change within their respective organizations because the “pressure” associated with participating in a collaborative effort offered greater impetus to change. In the action research framework, the research aspect of the project was used to produce pressure on each of the five participating surgery centers for implementing actions in response to identified patient safety problems. The researchers provided data and information that were then used by the center representatives to foster and accelerate change in their respective organizations. The researchers were often called on by the center representatives to present data to their staff. This seemed to increase the “credibility” of the data and the change proposed in response to the problems identified by the data.

## **Conclusion**

The focus of this paper is on a detailed description of the systems engineering intervention process based on a clear conceptual framework (i.e., the SEIPS model of work system and patient safety)<sup>1</sup>. This detailed description can be of value to other researchers and practitioners interested in pursuing the avenue of patient safety improvement through human factors and systems engineering approaches. The specifics of the content of the intervention need to be adapted to the particular organization; however, the intervention process itself can be replicated and adopted by any organization. Additional information on the data collection methods and their results can be found in a series of publications (see list of references). Future publications will provide further information on the actual impact and effectiveness of the intervention with regard to patient outcomes as well as individual and organizational outcomes.

## Acknowledgments

This research is funded by AHRQ Grant # P20 HS11561-01 (PI: Pascale Carayon). We would like to thank the five outpatient surgery centers participating in this project and to acknowledge the support of the Madison Patient Safety Collaborative.

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