

Outpatient Surgery and Patient Safety— The Patient's Voice

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Abstract

Four outpatient surgery centers from a large Midwestern community participated in this study assessing the impact of an intervention—aimed at improving the collection of patients' pre-operative clinical information—on both the patients' clinical outcomes and staffs' quality of working life. As part of this study the investigators developed a patient telephone survey to assess the incidence of common or undesirable postoperative symptoms and how they were subsequently managed. This survey was adapted from instruments developed in previous work in outpatient follow-up and anesthesiology. In addition to symptom assessment and management, the investigators were interested in determining how participants rated their medication teaching, pre-operative preparation, and postoperative education. The investigators recruited patients to participate in this study who had ophthalmic, open-joint, otolaryngological (ear, nose, and throat), or intra-/extra-abdominal surgery. The investigators contacted the participants via telephone at least 7 days after surgery and asked them a series of questions about symptoms they experienced, how they managed these symptoms, and the education they received. This paper will detail the development and content of the patient survey.

Introduction

The objective of this paper is to describe the patient survey developed for and implemented in the “Systems Engineering Intervention in Outpatient Surgery from a Collaborative Community Perspective” study, conducted under the auspices of the Systems Engineering Initiative for Patient Safety (SEIPS) at the University of Wisconsin-Madison. While some results are reported, the primary purpose is to describe the process of instrument development as a way of assessing patient safety.

Background

Limited research has been conducted in patient safety on the topic of outpatient surgery. Numerous obstacles such as the number of such centers and their geographical dispersion; lack of sophistication and/or incompatibility of information systems; and the heterogeneity of practice standards, patients, and staff¹ make this a difficult research area to address. Work on outpatient (nonsurgical) “results management” has identified the need to ensure

Report Documentation Page			Form Approved OMB No. 0704-0188		
Public reporting burden for the collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to a penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.					
1. REPORT DATE 2005		2. REPORT TYPE N/A		3. DATES COVERED -	
4. TITLE AND SUBTITLE Outpatient Surgery and Patient Safety-The Patient's Voice				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S)				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Agency for Healthcare Research and Quality 540 Gaither Road, Suite 2000 Rockville, MD 20850				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release, distribution unlimited					
13. SUPPLEMENTARY NOTES Published in Advances in Patient Safety: From Research to Implementation. Volumes 1-4, AHRQ Publication Nos. 050021 (1-4). February 2005. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/qual/advances/.					
14. ABSTRACT					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 16	19a. NAME OF RESPONSIBLE PERSON
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified			

identification and follow-up of abnormal test results.² Likewise, work has been done on drug complications in outpatients³⁻⁵ and admissions after outpatient surgery.⁶ A study of outcomes of anesthesia in outpatients identified, from the perspective of anesthesiologists, what outcomes are more common and/or should ideally be avoided.⁷ Similarly a review of the anesthesia literature has produced a summary of both the methods used to collect outcomes of anesthesia and the incidence of various symptoms.⁸ These authors conclude that efforts must be made to improve anesthesia use in outpatient surgery due to the continued growth expected in this area.

Methodologically, it is extremely challenging to capture information on quality of care and patient safety related to outpatient surgery. The “gold standard” of medical record reviews⁹ is difficult, not only because outpatient charting is frequently scanty and inconsistent, but even more so due to the nature of these surgery patients and their management. In most instances, outpatient surgery centers are entities that depend on their surgeon base for referrals as well as the use of their center. Patient work-ups (and later, follow-up) are performed elsewhere and surgery centers can be unaware of their patient outcomes—except for those instances when patients are admitted to a hospital with which the center is closely affiliated. Automated means of assessment⁹ require data or information systems that collect and report the desired information easily. Once again, more than one data system frequently exists, and integration of multiple systems requires a level of sophistication that has not been reached at most outpatient sites. Weinger et al.¹⁰ suggest a means of conducting retrospective data collection for nonroutine events, an approach that incorporates various means of data collection and analysis.

In this study we conducted a patient survey to gain a better understanding of the outcomes of outpatient surgery and to determine how effectively these patients are prepared for and educated about their pre- and postoperative self-management. In our work we define patient safety in outpatient surgery as comprised of the following:

- Patients adequately prepared pre-operatively.
- Patients well educated for postoperative self-management (including their understanding of medications).
- Providers fully informed of their patient’s clinical status.
- Surgery appropriately performed (correct-site surgery) and clinically accurate.

Through the patient survey we discuss below, we primarily assess the pre- and postoperative patient preparation and self-management aspects of the definition.

Development of SEIPS

The SEIPS is comprised of a group of researchers representing a variety of academic fields and interests, both in health care and industrial engineering. Members of the team have backgrounds in medicine, nursing, hospital

epidemiology, medical informatics, human factors engineering, management, health care administration, and public health. The research focus of the SEIPS is based on a model that reflects the integration of the work system model of Smith and Carayon-Sainfort¹¹ and Donabedian's framework for health care quality assessment.¹² The work system model emphasizes the interdependence of the *tasks* a worker performs, using *tools and technology*, in a given physical *environment* within *organizational* constraints. These five elements comprise the *structure* aspect of Donabedian's model. By introducing an intervention (in the study described later in this paper), aimed at improving communication between providers who perform outpatient surgery, we affect the *process* of providing care (from both a job-design and a patient-management perspective); that in turn affects the *outcome* of care. The outcome is measured in terms of a patient's well-being, the practitioner's (ideally, improved) ability to perform his/her job, and the practitioner's quality of working life.

Methods

Study setting

In late 2002, selected representatives of the Madison Patient Safety Collaborative, a group of Madison-based health care providers committed to improving patient safety in the community (www.madisonpatientsafety.org), convened and began discussing a collaborative pilot research project in outpatient surgery. Members of this "Pilot Team" included the SEIPS researchers as well as managers, medical directors, and nursing supervisors of the four major outpatient surgery centers in the area.

The combined annual patient volume of the four centers was approximately 22,500 cases in the year in which the study began (2002). Of the four centers, all but one (a center that primarily performs ophthalmic surgery) care for a heterogeneous patient population and perform a variety of types of surgery on patients presenting varied levels of clinical challenges. Administratively, there are two entities: a physician-driven corporate entity manages two centers (one hospital-based and one free-standing), and a joint venture between a large medical group and the hospital at which these physicians primarily practice manages the other two centers (one free-standing and the other housed in the same building as the physicians' clinics). All but one of the centers rely on a wide referral base well beyond the Madison area. This study was approved by two different Human Subjects Committees (i.e., institutional review boards), and each committee required compliance with its own HIPAA authorization protocol.

An initial data collection, intended to gain a better understanding of work system and patient safety issues at each of the four centers, aided the Pilot Team in two ways.¹³ First, these initial steps led to the Team's definition of patient safety in outpatient surgery (as presented earlier in this paper). Second, the data provided direction to the Team in regard to selecting the intervention.

We integrated this definition with our SEIPS model and developed measurement instruments. Because of design limitations, we separately measured the individual/organizational outcomes through an employee questionnaire and the patient outcomes through a patient telephone survey. The remainder of this paper describes the patient telephone survey.

Instrument

The patient telephone survey had multiple objectives. First, and foremost, we needed to develop an instrument specific to patient safety in the outpatient surgery population since, to our knowledge (and based on extensive literature searches), nothing existed that specifically assessed the outpatient surgery population in the manner we intended. Second, we wanted to determine the incidence of common or undesirable symptoms associated with outpatient surgery and how the respective symptoms were subsequently managed. Third, we were interested in determining how participants assessed their medication and pre- and postoperative teaching. Finally, we wanted to capture each participant's overall satisfaction with their outpatient surgery experience.

Based on prior survey development experience,¹⁴ we created the patient survey by agreeing on the content of currently-existing instruments^{3, 7, 15} that we adapted for our purposes, and by adding some of our own questions based on our survey objectives. The final survey contained six sections: (1) an introduction, (2) symptom incidence and management, (3) assessment of surgical preparedness and teaching, (4) overall satisfaction, (5) patient demographics, and (6) conclusion.

During the development process, internal peer review resulted in numerous, substantial revisions to the initial instrument, including changes related to both survey design and content. First, we scrutinized the content, flow of, and responses to the various symptom-related questions. As a result, we added surgical-site bleeding and signs of infection to the symptom list, and listed each of the various sites of pain separately. Second, we added a question on whether or not the participant contacted clinical personnel with any symptom-related question(s), and, if so, who was contacted. For completeness, we next added a question on symptom management for those participants who did not experience problems. Finally, to the symptom management section, we identified those questions that, when answered completely, could result in multiple responses. After considerable discussion, we agreed on the response categories (both in terms of number and respective measures) for our questions on surgical education and preparedness. We also added one question each on health status and satisfaction. To test the instrument, we (KF, MD) surveyed four individuals who had recently undergone outpatient surgery (1) to test the clarity and understandability of the questions posed, and (2) to evaluate the flow of the questions. After then making minor revisions representing simple rewording of questions, we initiated the formal telephone survey process. (The final Patient Telephone Survey instrument is available from the corresponding author.)

We selected 21 different symptoms, both common (e.g., nausea and vomiting) and others that ideally occur rarely (e.g., chest pain), and asked participants if

they experienced the respective symptom.^{7, 15} Based on physician input (MS, SS), we added the modifier “excessive” to seven selected symptoms (five pain-related, one infection-related and one assessing coughing) to distinguish those participants who experienced symptoms that might be normally associated with the respective medical procedure versus those who, because of the symptom, would more likely require some form of follow-up or be at increased risk of experiencing a patient safety issue. During the phone interview, the interviewers (KF, MD) felt that subjects responded without difficulty to these questions. We determined how the symptom was managed by asking varying combinations of 10 possible questions. These questions addressed issues such as when the symptom first occurred, whether the participant called a health care provider for help, how the symptom was managed, and if an unplanned visit to a health care provider resulted.¹⁵

We assessed medication education by using questions based on the extent to which the purpose of the medication was explained, how understandable this information was, and whether information on side effects of the medications was provided.³ In a similar fashion, we asked participants to evaluate their level of preparedness for surgery and recovery, based on information provided at different pre- and postoperative times. A single question elicited the participant's assessment of his or her overall satisfaction with outpatient surgery. The concluding open-ended question offered participants the opportunity to elaborate on their experience, explain why they rated their experience as they did, and what they would do to make it better.

Sample

All medically competent, English-speaking adults having any of the following types of outpatient surgical procedures were recruited to participate in the telephone survey: intra-/extra-peritoneal (e.g., laparoscopic cholecystectomy, umbilical hernia); major ear, nose, and throat/ENT (e.g., adult tonsillectomy and adenoidectomy); open orthopedic (e.g., anterior cruciate ligament repair); and any ophthalmic surgery for patients with an ASA (Anesthesia Society of America) class greater than one. We chose these cases because the procedure, the participant, or both posed a greater surgical risk than with less invasive outpatient surgery. In turn, we expected these participants to experience more symptoms or problems. In addition, we selected the procedures based on the surgical population of the participating centers. As stated earlier, one of the centers primarily performs eye surgery. For that center to participate, at least one other center had to perform similar types of procedures on a similar patient population (and one other center was indeed comparable).

Due to both logistical and resource issues, our goal was to achieve a sample of approximately 1 percent of each center's total volume as participants in the study (N = 225). We obtained the total annual volume of surgical procedures from the centers. We also obtained specific surgical volume data reported from each of the centers to the State of Wisconsin Department of Health and Human Services. From these surgical volume data, we determined the number of each of the procedure classes performed (as reported) during the first quarter of the previous

calendar year and then calculated a weighted distribution of each class of procedure. Based on the total recruitment sample and the weighted distribution of the classes of procedures for each center, we determined the number of participants in each of the surgical classes to recruit.

Methods

Recruitment

Due to limited time and resources, research staff did not recruit participants. Because of this, and prior to commencing participant recruitment, research staff attended staff meetings at each of the centers to discuss the patient telephone survey with nursing and clerical staff. Researchers described the objectives of the overall study as well as the specific objectives of the patient telephone survey. This served as a means of engaging staff in the study, since their understanding and commitment were critical to successful participant recruitment. The nurse manager at each facility identified eligible participants by reviewing daily procedure schedules and highlighting potential participants. Nursing and/or clerical staff (depending on the center) invited surgical patients to participate in the study by first asking if they were interested in hearing about a current city-wide study. If patients responded affirmatively, they were given a one-page study overview. After reading this, nursing staff again approached the participants to determine if they had any questions and whether they were willing to participate in the telephone survey. Signing and dating an informed consent and HIPAA authorization confirmed their willingness to participate. Of those recruited, we received only one written request from a participant to withdraw from the study (who was then eliminated from the recruitment sample).

Four hundred eighty-eight potential participants were approached, with 206 consenting to participate in the study (42 percent). Participants whom we were able to contact and who were willing to proceed with the survey, ranged from 39 percent at one center to 88 percent at the most successful center. We were unable to contact 24 percent of the potential participants and “lost” 6 percent because they withdrew from the study when contacted (Table 1).

Table 1. Study participants by center

Center	Volume - 2002	# patients approached	# patients recruited	# responding to survey	# unable to contact	# withdrew
A	9,232	287	102	71	24	7
B	2,815	30	17	12	4	1
C	6,542	92	33	13	18	2
D	4,060	79	51	45	2	4

Aside from the relatively small number of participants lost to participation because they voluntarily withdrew, we explained the “loss” of the remaining 24 percent ($n = 48$) of our participants by citing a number of factors. Since we conducted this survey during autumn, it was not uncommon, when attempting to reach participants on a weekend, to have a participant request that she be called back because she was “in the middle of the football game.” On subsequent calls we were unable to contact many of these participants. We also believe that other participants simply did not answer their telephone due to the fact that they had caller identification technology and did not recognize the interviewer’s phone number. Finally, those “healthier” participants whom we were unable to reach may have been more difficult to reach by telephone because they had returned to their hectic lifestyles. Information abstracted from the medical record (discussed in next section) was collected on all potential participants and will be fully analyzed to determine if there was any response bias.

Medical record abstraction

Each surgery center developed a means of maintaining the consents for their participants and then, upon completion of surgery, abstracting their medical record. This included verifying eligibility criteria and the presence of a signed informed consent and HIPAA authorization, then collecting information on the participant’s clinical history, ASA class, procedure(s) performed, and time spent in various stages at the center. This proved valuable for two primary reasons: (1) the nurses conducting the telephone surveys had a good clinical overview of the participants and were able to take this into account when conducting the phone interview (e.g., participant is hard-of-hearing, depressed, had complicated medical history); and (2) this information will be incorporated in future analyses evaluating surgical outcomes and participants’ clinical histories. The consents and associated abstract form for each participant were combined and secured in a locked drawer in the research office until the participants were at least 7 days postoperative. It was agreed upon by the Pilot Team that by waiting at minimum 7 days, most participants would have incurred any of the various symptoms being assessed.

Telephone survey/interview

Two nurse-researchers, both registered nurses enrolled in a master’s nursing program, conducted all of the telephone interviews (MD, KF). They used cellular phones to conduct the surveys, which also aided in maintaining the confidentiality of the researchers. The first attempt to conduct the survey occurred at least 7 days postoperative. If participants were unavailable, the date and time were recorded and subsequent phone calls were placed at a later date. Initially, we instructed the interviewers to only make four attempts to contact participants. When it became apparent that this was insufficient (too many participants would have been lost), we expanded the number of attempts to contact the participants, setting a time limit of at least 8 weeks postoperative for all participants. The number of days postoperative that participants were contacted ranged from 7 to 145, with a mean of 53 days. The most attempts made prior to successfully conducting an interview

was twelve. Calls were primarily placed in the evening, prior to 8:30 p.m., although elderly participants were relatively easy to reach during daytime hours. The nurse interviewers found that participants were generally interested in participating in the interview and that they were also open and honest about their experience.

After engaging the participant and ensuring his willingness to participate in the telephone survey, we queried him to determine if he experienced any of 21 different symptoms. Keeping in mind that a substantial number of procedures currently being performed on an outpatient basis were, years ago, performed as inpatients, we were interested in assessing the participant's pre- and postoperative education by determining how the participant prepared and cared for himself prior to and after surgery. For any symptom the participant experienced, we asked more detailed questions concerning when the symptom occurred, if it worsened once they arrived home, whether he felt it was related to surgery, and whether the symptom(s) led the participant to attempt to contact a health care provider. If he did not contact a clinician, he was asked why. If he did attempt to contact a provider, he was asked if he was able to reach anyone, and if so, whom it was. He was then asked what was done (e.g., change in medication order, instructed to call if symptom worsens) and if it required an unplanned visit to a medical provider (e.g., office or emergency room visit, hospital admission).

These questions were followed with assessments of the "completeness" of various aspects of medication teaching and the extent to which participants felt prepared for their surgery (at differing points in time). We then asked participants to rate their pre- and postoperative education (specifically related to the surgery performed) and their overall satisfaction with their outpatient surgery experience. These questions were followed by health-status questions, a series of five demographic questions, and a concluding open-ended question.

Respondents

Of the 141 participants, 52 percent of the participants had ophthalmologic, 11 percent had ENT, 12 percent had "open" orthopedic, and 23 percent had peritoneal surgery. Two percent were not identifiable surgery cases. Participants were primarily white (98 percent). Fifty-four percent were female, and the mean age of the participants was 57, with an age range of 18 to 95.

Results

Because a major focus of this instrument was to determine surgical preparedness, education, and self-management, we queried participants about the incidence of common or undesirable symptoms associated with outpatient surgery and how they subsequently managed each symptom experienced. We also found that participants' responses gave us an indication of surgical appropriateness and accuracy in their responses to both the satisfaction and final open-ended question. We also asked participants to assess their medication and pre-operative and postoperative teaching.

We found respondents to be both engaging and open to the questions posed. Younger, healthier participants were more difficult to contact than elderly, less healthy participants. Similarly, the nurse surveyors observed that younger participants tended to be more direct and critical in their responses and the elderly were more complimentary and willing to talk longer, although their interviews also lasted longer because of some participants' hearing problems and the need to clarify some of the questions.

When using the survey interview instrument, all of the questions offered response categories that aided in analyzing the results. We created an SPSS® (SPSS, Inc.; Chicago, IL) database and input all results of the interview except the comments participants offered. The comments made throughout the interview, as well as in response to the final open-ended question, are being analyzed through NVivo® content analysis software (QSR International Pty Ltd; Melbourne, Australia).

Symptom management

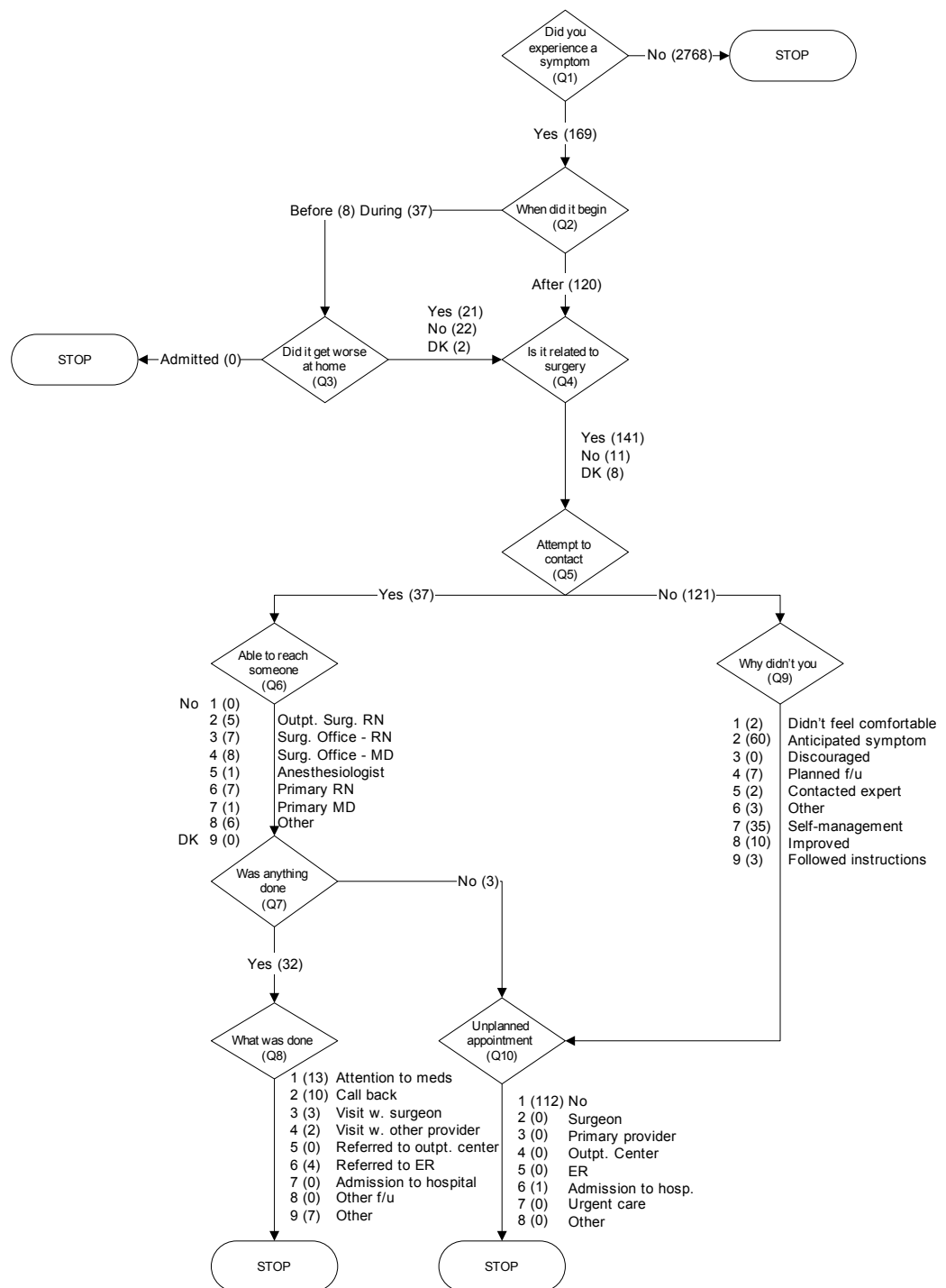
We conducted analyses of symptom management at the symptom level. We did this because a participant could potentially experience anywhere from no symptoms to 21 different symptoms and manage each of them differently. The number of symptoms participants reported experiencing ranged from zero to eight. Aside from the incidence of a symptom, we were interested in gaining a better understanding of how the participant managed his symptom.

Figure 1 explains the frequency of participants' responses to the questions concerning the incidence of the 21 symptoms and their associated management. Sixty-seven participants (47 percent) experienced at least one symptom. The participants experienced a total of 169 symptoms (the most common being nausea and vomiting), with the majority of the symptoms beginning after surgery ($n = 120$). Regardless of when the symptoms occurred, 88 percent ($n = 141$) of the symptoms were believed by participants to be related to surgery.

Participants attempted to contact a health care provider for only 23 percent (37 of 158) of the symptoms. When asked why they did not contact a provider for help, the majority of the time participants responded by stating the symptom was anticipated (49 percent, $n = 60$ symptoms) and/or she managed the symptom on her own (29 percent, $n = 35$ symptoms). Participants were allowed to give multiple reasons for not contacting a provider.

No participants indicated they were unable to reach a health care provider. Fifteen (43 percent) of the symptoms for which participants contacted a health care provider resulted in follow-up by the surgeon's office. Twelve symptoms (34 percent) were reported to a provider with whom a participant did not have a long-term "relationship" (surgery center, anesthesiologist or "other" provider—generally stated as a surgical resident). The remaining symptoms ($n = 8$, 23 percent) were reported to the participant's primary care provider's office. A participant could call for follow-up for more than one symptom. Of these 35

Figure 1. Flow of survey responses for symptoms incurred



symptoms reported for follow-up, 32 (91 percent) of them resulted in further instructions for the participant. (Multiple instructions could be given, which explains why 39 “things” were done.) For one-third of the symptoms ($n = 13$, 33 percent) a medication was either prescribed or changed and for 10 symptoms (26 percent) the participant was told to call back if the problem persisted.

We posed one question to participants who reported no symptoms to determine whether they were given instructions if they did incur any symptoms. In all instances, participants reported receiving instructions.

Education

We assessed various aspects of patient education addressing medication use, preparedness for surgery, and quality of information given at different points in time. From previous work by Ghandi and colleagues³ assessing outpatient medication use, we evaluated whether a health care professional explained the purpose of a prescribed medication and, if so, whether the explanation was understandable. Likewise, we asked if the provider explained the possible side effects of the medication(s). Three participants (2 percent) stated they received no explanation of the purpose of their medications, and 24 (18 percent) reported that explanations were given “somewhat.” There was only a slight change in responses when we queried participants as to whether the explanation of the purpose was understandable. Responses related to explanation of sides effects were considerably different, with 33 (26 percent) of the participants stating they received no education in this area (Table 2).

Table 2. Completeness of medication education (N = 133 patients receiving medications)

	Explained completely	Explained somewhat	Not explained	Already knew
Purpose of medications explained	96 (72%)	24 (18%)	3 (2%)	10 (8%)
Purpose explanation understandable	92 (70%)	29 (22%)	3 (2%)	8 (6%)
Side effects of medication explained	70 (55%)	18 (14%)	33 (26%)	7 (5%)

Row totals < 133 explained by participants not responding to respective question.

Our intent in asking the two questions regarding surgical preparedness was to determine whether participants, *after* having the surgical “experience,” felt more or less prepared than they did *prior to* their surgery. For the same reason, we asked them to rate the information they received prior to and after surgery that related to their home recovery. Participants responded with similar overall ratings of the information. The majority of respondents felt prepared or very prepared both before surgery (88 percent) and after surgery (86 percent). The majority of survey participants rated information received before surgery excellent or very good (74 percent) and information received after surgery excellent or very good (74 percent) (Table 3).

Table 3. Preparedness and level of information, before and after surgery

a. Level of preparedness felt

	Very prepared	Prepared	Somewhat prepared	Not prepared
Before surgery	52%	36%	11%	1%
After surgery	47%	39%	12%	1%

b. Rating of information given

	excellent	very good	good	fair	poor
Recovery info given before surgery	41%	33%	24%	1%	1%
Recovery info given after surgery	40%	34%	23%	3%	1%

Satisfaction

Participants' overall assessment of their outpatient surgery experience was favorable. On a five-point scale (excellent/very good/good/fair/poor), no one rated their experience as "poor" and only one rated it as "fair". The distribution of responses is found in Figure 2.

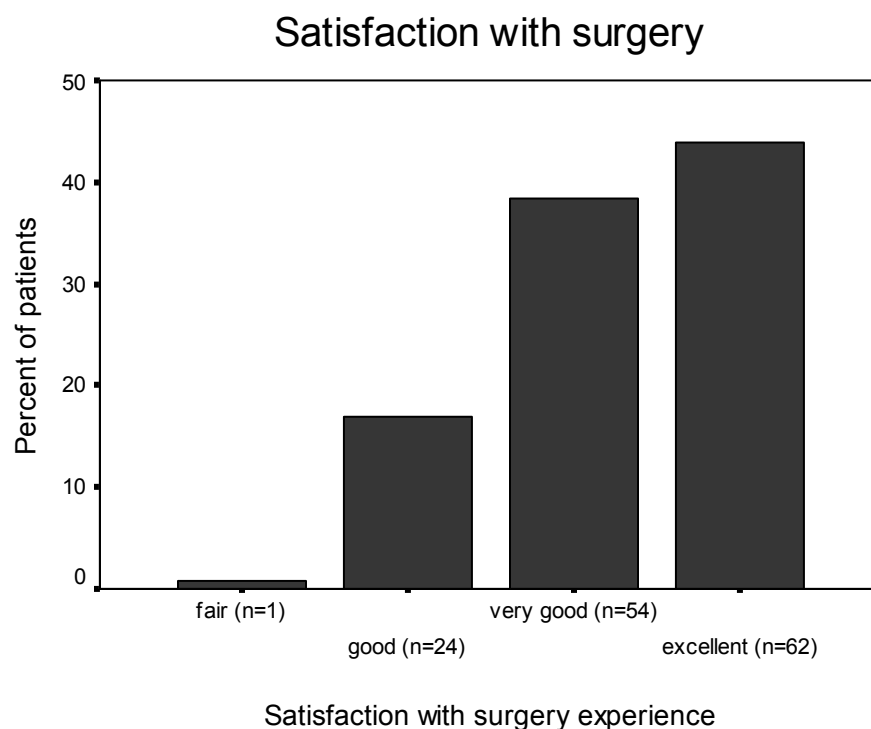
Overall assessment

Prior to concluding the interview, the nurse researcher asked participants an open-ended question to offer one final opportunity to comment on their experience and to suggest how their experience might have been better. In these responses, it became apparent that participants who previously had surgery came better prepared for subsequent surgery. In various instances participants stated that experience from a prior operation helped them to be better prepared for this and other subsequent surgery. In most instances the initial surgical experience was less than optimal, which caused them to become more proactive in their surgical care. Participants frequently made favorable comments about the surgery center staff. These and all other comments are being content-analyzed and will be reported at a later date.

Discussion

One major constraint of this project was that we were unable to validate what participants reported by any other means of follow-up. This was beyond the scope of our study and, if performed, would entail complex data collection. The complexity arises from the fact that not only are many of these participants referred from outside areas (in some instances located hundreds of miles away),

Figure 2. Participant satisfaction with surgery



but also their pre-operative as well as postoperative care are provided at clinics in these distant locations that have no formal administrative or medical ties to the Madison-area outpatient surgery centers.

Most of the questions posed required that participants be able to recall what they incurred at the outpatient center and in the respective physician's office at least 2 weeks, and in some instances, several months prior to the phone call. We recognize this as a constraint of the study, but, given the inability to review medical records, we had few alternative means of contacting participants. Potentially we could have attempted to contact participants more frequently (with more than one interview) at "critical" points in time, but we were made aware in the early stages of participant recruitment that they agreed to participate because there would be only *one* telephone contact.

Despite these limitations, the need to assess surgical preparedness and postoperative self-management are indeed critical issues as the volume of outpatient surgical procedures continues to grow. Feedback of the results of the patient surveys has been shared with each of the four surgery centers. As a result, further improvements are being developed at each site to capture and provide clearer and more thorough information to patients and their caregivers.

Based on our experience from the first round of interviews, we made minor modifications to the interview instrument. These changes were based on comments the participants made concerning how having had a previous surgical experience seemed to better prepare them for the outpatient surgery experience

“in question.” The queries we added capture whether the participant had previous surgery, what type of procedure (inpatient and/or outpatient) it was, how long ago the procedure(s) had been performed, and if the procedure was done at the same surgery center.

Conclusion

At this point, we are conducting round two of the patient surveys. We believe the experience we gained from the first round helped us improve both the instrument and procedures we now follow when conducting the survey interviews. We intend to perform further analyses of the clinical challenges posed by patients presenting for outpatient surgery. Furthermore, we will attempt to determine relationships between the presenting problems and the symptoms incurred. We will, of course, continue to provide feedback of the results to each site. In an ideal situation we would choose to validate responses to the interview questions. This would require working with a surgery center that had more direct administrative and clinical “control” over the patients to facilitate review of medical records and to ensure compliance with State and Federal health information laws.

Acknowledgments

This research is funded by AHRQ Grant # P20 HS11561-01 to Pascale Carayon.

We are grateful to the four outpatient surgery centers and their staffs for their willingness to participate in this and future research.

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