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An outcomes study: Outpatient versus inpatient hernia repairs

Marie Therese Cantwell

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AN OUTCOMES STUDY: OUTPATIENT VERSUS INPATIENT

HERNIA REPAIRS

———

A Thesis

Presented to the

Faculty of

California State University,

San Bernardino

———

In Partial Fulfillment

of the Requirements for the Degree

Master of Science

in

Health Services Administration

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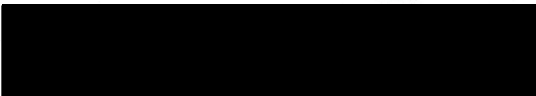by

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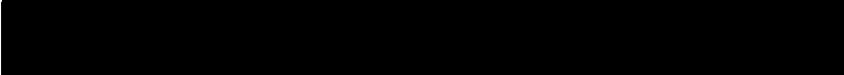
June 1994

Approved by:

_____   5/17/94
Dr. Joseph Lovett, Chair, Associate Professor   Date
Department of Health Science & Human Ecology

_____   17 May 94
Dr. Thomas Timmreck, Professor   Date
Department of Health Science & Human Ecology

_____   5-17-94
Michael Davidson, Administrative Associate   Date

Abstract

The objective of this study was to investigate the quality of clinical outcomes in the surgical setting. The outcomes that were measured include: infection rate, bleeding rate, and readmission rate. The demographic and clinical characteristics of 149 hernia repair patients were evaluated. Of these 149 patients, 52 were inpatients and 97 were outpatients.

Results of the study showed that there is no difference in infection rates between inpatient and outpatient hernia repair patients. A difference was found in bleeding/hemorrhage rates between the inpatient inguinal hernia repair patient and the outpatient inguinal hernia repair patient, showing that outpatient inguinal hernia repair patients have a higher bleeding rate. There was no difference in bleeding rates found among other types of hernia repair patients. Inpatient hernia repair patients that received antibiotic therapy were found to have a higher bleeding rate than outpatient hernia repair patients that received antibiotic therapy. There was no difference found in readmission rates between the inpatient inguinal hernia repair patient and the outpatient inguinal hernia repair

patient. A difference was found in the readmission rate of other hernia types (excludes inguinal) . Outpatient hernia repairs of types other than inguinal were found to be readmitted at a higher rate than inpatient hernia repairs (excludes inguinal). A difference was found in readmission rates between inpatient and outpatient hernia repair patients that received antibiotic therapy. There were no hernia repair patients readmitted that had not received antibiotic therapy.

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Chapter One - Statement of the Problem

Introduction

Over the past decade there has been a dramatic shift in the provision of medical and surgical care. Conditions in the health care arena are in a constant state of change. Patients that were in the hospital for surgery ten years ago were in for several days to weeks depending on the extent of their surgical procedure. The length of hospital stay for a coronary artery bypass has decreased from two weeks to one week, and for tonsillectomies from two days to three hours. Shorter lengths of stay are partly attributed to advances in medical equipment and technology, and refinement in surgical techniques, but these are not the only attributes. Along with these reforms in health care we are seeing changes in the allocation of monies for the care of the surgical patient by governmental agencies, private insurance companies, and health maintenance organizations. Payers for medical care prefer paying for lower cost outpatient care than more expensive inpatient stays. Health care costs consume over 12% of the gross national product and continue to rise. Hospitals receive forty percent of all dollars spent on health care and are under pressure to provide services at a lower cost.

With changes in production and consumption of health care dollars comes issues related to quality. Does having less money to spend on health care change the quality of care provided? Is the system of health care providing us with quality care or just cheaper care? Is the health status of Americans being compromised due to changes in funding from the government? Are health care providers providing the best treatment money can buy or are they providing simply what they can afford? Is managing the system of health care more efficient by providing technologically advanced quality health care at a lower cost? These are all questions that health care providers and consumers are forced to examine. Health care officials have realized that a system of quality measurement is necessary to assure quality and to provide evidence of what is actually best for the consumer in terms of quality of health and economics.

Health care providers today have to be very flexible and adaptable. An efficient health care system must provide services that are accessible, available, and affordable. Today's consumers of health care are seeking high quality service at an affordable price.

Quality improvement has evolved from post hoc, case-based assessment to managed processes of continuous quality improvement. To measure the performance of a system it is

necessary to collect data over a period of time. The data that needs to be analyzed are the actual outcomes of the health care provided. It is this data that will provide information such as: (1) would a surgical procedure provide the best outcome for a particular health problem?, (2) is there a more efficient alternative?, (3) would a modified procedure be good enough for an individual or is something more radical needed?, or (4) would the best surgical approach be through inpatient or through outpatient care?

Statement of the Problem

A large portion of the services that we provide in the surgical department have changed from the inpatient setting to the outpatient setting, this is without a change in the surgery itself. Patients are now discharged to home, post-operatively with a family member or friend to care for them. The previous approach consisted of the patient remaining in the hospital with a team of nurses and doctors providing the necessary care. Rising health care costs are impacting the delivery of care. Cost analysis shows that it is less expensive for a hospital to perform a surgical procedure in the outpatient setting than it is in the inpatient operating room. There are minimal data and analysis on outcomes of

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the outpatient surgical patient versus the inpatient
surgical patient. The time has come to address this very
important issue.

The purpose of this study is to determine differences
in quality outcomes between surgical outpatient treatment
and recovery and surgical inpatient care. Outcomes to be
assessed in this study are: (1) infection rates, (2) post-
operative hemorrhage / bleeding rates, and (3) re-admission
rates of the hernia repair patient.

Questions

The purpose of this study is to determine differences
in outcomes of care for inpatient and outpatient hernia
repair patients. There are three specific questions to be
addressed by the research: (1) Is there a higher or lower
rate of infection in the outpatient hernia repair patient
versus the inpatient hernia repair patient?, (2) Is there a
greater or lesser incidence of post-operative bleeding /
hemorrhage in the outpatient hernia repair patient versus
the inpatient hernia repair patient?, and (3) Is there a
greater rate of re-admission to the hospital post discharge
from the hospital in the outpatient hernia repair patient or
in the inpatient hernia repair patient?

Chapter Two - Review of the Literature

Introduction

Cost and quality of health care is high on the agenda for all health care providers and consumers. With continuous rising costs, health care administrators are forced to find ways to provide and receive medical care in the least expensive manner available. There is great concern that the provision of care at a lower cost may not be the best care available. There are those that believe that there may not be a fair tradeoff between efficiency and quality. "For example, patients may be discharged too soon, they may receive fewer services; the quality of the service they receive may be reduced; and hospitals may not keep up with the latest technological advances to provide state - of - the - art care" (Shortell, Kaluzny and Associates, 1988, p. 442). On the other hand, there are those who believe that while finding ways to be more productive and efficient may also make improvements in quality provided. There is only one sure way to tell if our health care has been compromised by reducing costs. That is to do cost and quality analysis of outcomes.

Cost has been viewed as an easy variable to measure. Quality on the other hand has been an ambiguous issue and

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more difficult to assess. It wasn't until the late 1980's

that outcome measurements for health care were introduced.

In the past, quality had typically been measured by

mortality rates. This was the only health care outcome that

was identified as measurable at that time. "The Joint

Commission on Accreditation of Hospitals and Organizations,

(JCAHO) announced an outcomes - oriented program to be

implemented in the 1990's" (Griffith, 1992, p. 48). The

outcomes research agenda provides us with something new.

"It focuses on the systematic and objective evaluation of

all of the outcomes that are relevant to patients. These

are mortality, morbidity, complications, symptom reduction,

and functional status improvement" (Wennberg, 1990,

p. 45). This is a beginning towards providing care and

assessing the actual quality outcome of the care provided as

opposed to the quality measurement of the care provided.

With a look at the quality of health care outcomes come the

realization that our quality of life in general is effected

by how well patient's health care outcomes affect their

lives. "The centerpiece and unifying ingredient of outcomes

management is the tracking and measurement of function and

well - being or quality of life" (Ellwood, 1988, p. 1552).

Health care outcomes measurement and documentation has

been limited to the inpatient population, yet, this is

rapidly changing. With more and more health care services

being provided in the outpatient setting there is a greater need to formally collect outpatient outcomes data.

An important question faced today is that we do not know for sure that changing all of these inpatients to outpatients provides a better course of treatment or is actually better for the quality of life of the patients. There has been minimal data collection and comparison of these two treatment approaches. "The results from ambulatory surgery are open to interpretation because of the limited verifiable empiric evidence" (Pasternak, Smith, and Piland, 1991, p. 24).

"The Agency for Health Care Policy and Research, (AHCPR), has been directed by Congress to study outcomes of treatment" (Clinton, 1991, p. 2057). Patient Outcome Research Teams (PORTS) have been formed and are examining the outcomes of clinical interventions and developing recommendations based on their research findings. "PORT projects focus on variations in clinical practice and evaluate the outcomes and costs of alternative treatments" (Outcomes, 1992, p. 4). They are addressing twelve different health conditions at this time. This research project directs us towards the assessment of what is the best quality outcome for the patient and what is the best alternative treatment for the patient. Health care

providers and consumers alike are seeking more information

on this subject so they can make more informed decisions.

Specific Studies of Surgical Outcomes

Some studies have been performed that have actually

shown that there is a difference in patient outcomes among

similar groups of patients. These outcomes have been

associated with different variables, such as; the setting,

care of the patient, and attitudes and background of the

patient.

Jaggar, Orkand, Hurwitz, and Coyle (1978) evaluated the

costs, quality, and system effects of ambulatory surgery

performed in alternative settings. The study took place in

Phoenix, Arizona at a large Surgicenter. The objectives of

the study were to identify utilization of surgical services

in Phoenix and to examine changes in the availability of

surgical resources. Another important issue addressed was

the response of the Phoenix health system to the new

competitive Surgicenter. For this study, a population of

900 patients were traced through the surgical process.

Medical record review, financial record review, interviews

of patients and physicians, and physician questionnaires

were the primary sources of data. Five surgical settings

were identified for this study. They were as follows;

hospital inpatient, traditional hospital outpatient, hospital - affiliated ambulatory surgical center, freestanding ambulatory surgical center, and physician office. Twelve different surgical procedures were selected for study based on frequency of performance, representation of Medicare patients, and usefulness for quality evaluation. Findings of the study revealed that the free standing ambulatory surgical center experienced lower average total costs for most surgeries. There were three exceptions and they were: (1) inguinal herniorraphy, (2) myringotomy and adenoidectomy, and (3) ganglionectomy. These three procedures had lower total costs in the inpatient setting. In terms of patient satisfaction, the inpatient and free standing ambulatory surgical center had the highest percentages of very satisfied patients at 85.5% and 86.8%, respectively. The outpatient level of very satisfied patients was at 78.1%. Specific problems reported during recuperation by patients revealed that severe problems such as bleeding and difficulty breathing occurred most frequently in the inpatient facility, (20.9%). These were followed by the hospital-affiliated ambulatory surgery center, (14.2%). The highest levels of infection were reported at the inpatient facility (3.2%) followed by the traditional hospital outpatient (2.8%). The lowest rate of infection as perceived by the patient was reported at the

free standing ambulatory surgical center, (1.0%). There were no reports of reactions to anesthesia by the inpatient sample while the other settings evaluated reported low percentages of reactions; the outpatient, (8.3%); hospital - affiliated ambulatory surgical center, (1.2%); free standing ambulatory surgical center, (1.7%). There was no abnormal bleeding during the recuperative phase according to medical record abstracts.

This study revealed that it was less costly, for the most part, to have a surgical procedure performed as an outpatient with lower incidences of post procedure complications occurring in the Free Standing Ambulatory Surgical Center. A serious limitation to this study was that physician records were not utilized in the outpatient population for data collection of post procedure complications or problems. This data was collected as perceptions of the patient. To add reliability to this study it would have been ideal to have obtained this data from physician files. In terms of cost, these are ever changing over time and varies at each facility. Reimbursement is of issue to the patient and the facility and needs to be further investigated.

In the study, "Variations in Length of Stay and Outcomes foe Six Medical and Surgical Conditions in Massachusetts and California", (1991), significant

differences in length of stay were noted for all conditions except for myocardial infarction. Outcome measures that were analyzed were: (1) in-hospital complications, (2) deaths, (3) length of stay, (4) functional status after discharge, (5) readmission, and (6) patient satisfaction with hospital care. A cohort of 2484 selected patients who had been hospitalized for acute myocardial infarction, rule out acute myocardial infarction, coronary artery bypass graft surgery, total hip replacement, cholecystectomy, or transurethral prostatectomy were included in the study. These patients were selected from six teaching hospitals in Massachusetts or California. Patient questionnaires and review of medical records were the source of data collection. One of the goals of the study was to investigate the differences in the lengths of stay of different procedures in six different institutions and to possibly explain these by differences in patient characteristics. Investigators controlled for sociodemographic characteristics, prehospitalization functioning, comorbidity, and complication rates. Results of this study are significant. Hospitals with the longest postoperative length of stay coincided with those having the longest preoperative stay. The adjusted average length of stay was significantly longer for patients hospitalized in Massachusetts for acute myocardial infarction, rule-out

myocardial infarction, and for patients having transurethral

prostatectomy higher readmission rates were associated with

these three medical conditions in California than in

Massachusetts. A result of this study was that across all

conditions, length of stay explained less than 2% additional

variance in functional status after discharge. This may

indicate that shortening hospital stay may not have adverse

effects to patients. That is something that needs greater

attention in future studies.

This particular study showed that there is still

further need for study with regards to different practices

by different physicians and facilities in different

settings. Different outcomes did occur in varying settings

however, these findings should not be associated with all

health care facilities. Future studies should be more

specific and include different physician practices in

multiple settings across the country. This information

could be effective in determining standards for physician

practice across the country.

In "The Medical Outcomes Study: An Application of

Methods for Monitoring the Results of Medical Care", by

Tarlov et al (1989), an overview of the objectives,

framework, design, and data collection for the study is

given. The Medical Outcomes Study was a two year

observational study that was designed to determine whether

variations in patient outcomes are explained by differences in systems of care, clinician specialty, and clinicians' technical and interpersonal styles. Another objective of the study was to develop more practical tools for the routine monitoring of patient outcomes in medical practice. Outcomes included in this study were; physical, social, and role functioning in everyday living. Also considered were the patient's perceptions of their general health and well-being; and satisfaction with treatment. Physicians that participated were randomly sampled (n = 523) from different health care settings in Boston, Massachusetts; Chicago, Illinois; and Los Angeles, California. Adult patients (n = 22,462) evaluated their health status and treatment in the cross-sectional portion of this study. In a sample of 2349 of these patients, diabetes, hypertension, coronary artery disease, and/or depression were selected for the longitudinal portion of this study. Results of independent physical and laboratory examinations performed at the beginning and end of the study to verify diagnosis, severity, and comorbidity were utilized.

The Medical Outcomes Study's conceptual framework included structure of care and process of care as important in determining outcome of care. Structure of care includes system characteristics, provider characteristics, and patient characteristics. Process of care includes technical

style and interpersonal style. Technical style includes issues such as: visits, medications, and referrals. Outcomes included clinical end points such as laboratory values, functional status, general well-being, and satisfaction with care. Implementation of the study was a five step process. First was selection of appropriate geographic sites, then selection of systems of care, and then selection and recruitment of physicians. The fourth step was selection and recruitment of patients followed by data collection. The study sites met the following three criteria: (1) presence of a health maintenance organization with at least 100,000 enrollees that had been in existence for at least three years; (2) presence of numerous multispecialty groups with at least 10 physicians in each, that have been in existence for at least three years, that include fee for service and prepaid payment arrangements; and (3) the willingness of health maintenance organizations and multispecialty groups and physicians in solo practice to participate in this study. Telephone interviews and self-administered questionnaires and forms were used to collect data from providers. For patients, self-administered questionnaires, telephone interviews, face to face interviews, diaries, clinical examinations, and review of inpatient medical records were all utilized for data collection.

One objective of this study that was met was to advance
the state of the art of methods for monitoring health
outcomes and patient satisfaction. A development of this
study was the medical outcomes study short form health
survey and the coop function charts which are both practical
tools for assessing functional status and well-being. These
assessment tools will be useful in detecting functional
capacity, changes in function over time, and make it
possible to consider the patient's total functioning when
choosing among therapies.

Reisenberg and Glass (1989), note in their editorial,
a summary of the findings of the cross-sectional portion of
the study. Interrelationships were found among emotional
well-being, health perceptions, and physical functioning.
This was true for both physical and mental disorders. For
example, patients with diabetes experienced reductions in
both physical and social functioning. Patients with a
depressive disorder also had decreased physical, social and
role functioning as well as perceptions of poor health
status.

These findings need to be taken into consideration when
planning recuperation for a patient from a surgical or
medical intervention. There will be different outcomes for
different interventions that will vary from person to person
based upon perceptions by the patient and the health care

provider. The longitudinal phase of this study will correlate the structures, processes, and outcomes of the medical treatments investigated. The cross-sectional phase of this study leaves us with valuable information, "Treat the patient, not the disease" (Reisneberg and Glass, 1989, p. 943).

In "Differences in the Mix of Patients Among Medical Specialties and Systems of Care", by Kravitz et al (1992), further information from the Medical Outcomes Study is provided. The objective of this portion of the study was to determine the differences in the mix of patients among medical specialties and among organizational systems of care. The data collection tool was a self-administered questionnaire that made reference to the physician and the patient. Adults (n = 20,158) who visited providers' offices were given the questionnaire. Outcome measures assessed were demographic characteristics, prevalence of chronic disease, disease-specific severity of illness, and functional status and well-being.

Results in this phase of the study reveal that among patients with selected physician-reported chronic illness, such as diabetes, increasing levels of severity were associated with decreasing levels of functional status and well-being and with increased hospitalizations more physician visits and a number of prescription drugs.

Patients of cardiologists were found to be older compared to patients of family practitioners who were younger. Patients of fee for service physicians were also found to be older and with more chronic conditions than those patients in a health maintenance organization. The conclusion of this section of the study is that patient mix (sociodemographics, disease prevalence, disease-specific severity, and functional status and well-being) is related to utilization and differs significantly across medical specialties and systems of care. These differences must be taken into account when interpreting outcomes across specialties and systems, and when determining policies for payment. "The Medical Outcomes Study suggests that one way to gain some control over escalating health care expenditures is to pay attention to the mix of physicians providing health care and the way in which they are organized" (Rosenblatt, 1992, p. 1666).

The large sample size seems to provide a strong statistical foundation. The large mix of physicians among specialties and different systems of care also adds to the validity of the study, however, there was a lower response rate of solo practitioners than other practitioners. As in other studies, major cities were used for the study and results should not be generalized to include smaller rural areas. Quality of care and outcomes results from the

longitudinal phase of this study will be presented in future literature. The results available to date however, already provide us with much information that policy makers need to take into consideration when planning the health care for our nation.

MacDowell and Bixel (1992) examined one measure of the quality of ambulatory care. This was unscheduled admissions within a short time after an outpatient visit. The outpatient occurrence and the admission for the study episode had to involve a primary diagnosis related to physical health. The Veterans Administration Medical Center was utilized for the study. Those patients who had unscheduled admissions within 84 hours for a problem related to their outpatient visit were identified via computer search. During a 12 month time interval, 1,918 episodes were identified. These admissions composed 21% of all admissions during this time interval. Chart review then revealed that 16% of this sample were actually scheduled admissions. The sample size was further reduced because 78 charts were either lost or lacked sufficient information. The resulting sample size was 120. Demographics and patient characteristics were identified. Reason for outpatient visit and for unscheduled admission were assessed. Results of the study showed that the average time between outpatient visit and unscheduled admission was approximately 47 hours.

There was no particular health condition identified among the unscheduled admission. Chronic airway obstruction was diagnosed in 10.8% of the sample and cardiac problems in another 10.8% of the group. Reasons for unscheduled admission were as follows: 69.2% had exacerbation of a medical problem that could not have been anticipated, 15.8% were related to physician error, 8.3% were due to failure of the patient to comply with recommended outpatient treatment, and 3.3% were related to unavailability of needed medical test information at the time of the outpatient visit.

This study revealed that there is a need for quality assessment and refinement in the outpatient population and that an efficient screening tool must be in place when scheduling a patient for an outpatient visit. It would be ideal for this type of outpatient data to be in a national database.

A study conducted by Simchen, Wax, Galai, and Isreali (1992) in Isreal, set out to identify risk factors for infections that occurred during the hospitalization and post discharge from the hospital. They note that with the rising costs of hospital stays, there is a need to shorten the hospital visit. Surgical complications that were once identified in the inpatient population will no longer be seen in the hospital for these patients are being discharged to home. The risk factors for post-discharge infections

have yet to be clearly identified. Post-discharge infections may result in rehospitalization and reoperation. Identifying risk factors for post-discharge infection may reduce the number of infections post-discharge.

According to Schwartz, Shires, and Spencer (1991) there are factors that influence the occurrence of wound infections. These factors include: sterile technique, traumatic wounds, age, diabetes, steroids, malnutrition, patients with other infections, duration of surgery, use of drains, prolonged preoperative hospitalization, and multi-antibiotics.

Schwartz, Shires and Spencer (1991) also indicate that individuals receiving anticoagulant therapy, polycythemia vera, and myeloproliferative disorders, and in patients with coagulation defects are at greater risk for wound hemorrhage.

A multi-center study of 2846 hernia operations was utilized and these patients were followed-up for 30 days after surgery, whether at home or still hospitalized. At the time of this study, hernia repair patients were hospitalized an average of six days post-operative. The data collection method for patients while in the hospital included demographic and clinical history, daily follow-up, detail of the operative procedure, and post-operative observations of the surgical wounds at least three times per

week. Follow-up data was collected until the 30th post-operative day. This data was collected by telephone interview and included a wound description. Outpatient records were rarely used for this information since many of these patients did not return to the hospital for post-operative follow-up care. Twenty risk factors had been screened for possible association with infection. Of these twenty risk factors, twelve were found to have significant association. Patients with incarcerated hernias were ranked at highest risk for infection. They were followed by re-current hernia diagnosis. Patients with chronic illness such as diabetes were ranked third. The fourth group, at lowest risk for infection, was the simple hernia repair with none of the above mentioned criteria. In the initial analysis of the study it was found that patients with chronic illness such as diabetes had the same infection attack rate as those patients who had simple hernia repairs. For further analysis, the simple hernia repairs and the uncomplicated hernia repair patients with chronic illness were grouped together.

Of the 2846 patients in this study, 95 (3.3%) developed an infection at the surgical wound site. Of these, 47 (1.65%) were in-hospital, and 48 (1.9%) were infections discovered after discharge. Some patients (268) were lost to home follow-up and 47 patients had already been diagnosed

with infection while in the hospital so, this left 2531 patients to be at risk for infection post discharge. Infections of the wound site occurred generally between the 3rd and 14th post-operative day. Of the 95 infections only one in-hospital and 10 post-discharge occurred after the 15th post-operative day. In patients with open drains, of ethnic minorities (not Jewish), and those with more than one surgical operation during the hospitalization, a higher in-hospital infection rate occurred. Patients with ventral hernia repairs, wounds requiring special treatment, or operations with greater than 90 minutes operative times, infectious complications continued to occur post-discharge from the hospital.

This study shows that there are a multitude of variables that need to be taken into consideration when planning the recuperative phase for the hernia repair patient. Post-operative infections can be physically and economically costly to the health care system and to the patient. It was difficult to find risk factors associated with post-discharge infections. Future studies should exam what goes beyond the hospitalization and closer attention be given to simple procedures within the hospital as well as a further understanding of the post-discharge environment. They recognize that this study was limited due to follow-up information obtained by telephone interview. Patient

perception of whether they have infection or not is very difficult to measure (pus was the indicator for infection), and this too was a limitation of this study.

Herbert Natof (!980), shared results of his study, "Complications Associated With Ambulatory Surgery". The objective of this study was to provide a prospective study of the medical, surgical, and anesthetic complications associated with ambulatory surgery. A second objective was to compare published morbidity and mortality data associated with certain surgical procedures performed in both the inpatient and outpatient settings. The study was conducted at Northwest Surgicare Ltd, a free-standing ambulatory surgical center. This study included 13,433 patients who were treated at this surgical center, between 1974 and 1978. Three surgical types were included: tonsillectomy and adenoidectomy, laparoscopy with tubal coagulation, and augmentation mammoplasty. General anesthesia was used on 83% of the patients. Almost half of the population was less than 20 years of age. Only 3% of the population had serious systemic disease. All patients received a prepaid postcard before discharge and they were to return it completed two weeks post discharge. The information on the postcard was actually an inquiry regarding complications. If no postcard was returned, a follow-up phone call was performed within

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one month of the date of surgery. This method of data collection resulted in a 99.8% follow-up of all patients.

Of the 13,433 patient population, 106 complications occurred. Hemorrhage and infection ranked highest in the list of complications (74 and 10, respectively). This infection rate also included infections not located at the wound site such as pneumonia. Patients with serious systemic disease, classified as ASA 3 (American Society of Anesthesiologists) showed no statistical difference in complications when compared with those in lower risk groups, ASA 1 and ASA 2. Of the 13,433 patients, 403 were classified as ASA 3. Natof concludes from this study that many surgical procedures can be performed as safely in the outpatient setting as in any other setting.

This study was conducted in 1980 and since that time technology has had significant changes. More patients with ASA 3 classification are seen in the outpatient setting than in years past. This particular study was limited in the number of patients who were classified as ASA 3. It is common today to see a larger number of elderly in the outpatient setting. This type of study should be repeated today and on a larger scale for it to be reproducable scientifically today.

"Surgical Wound Infections Documented after Hospital Discharge" by Brown, Bradley, Opitz, Cipriani, Pieczarka,

and Sands (1987), was a study that was conducted over a
three month period, which analyzed 1644 surgical procedures,
and documented surgical wound infections both before and for
one month after hospital discharge. It was conducted at the
Baystate Medical Center, a 950-bed tertiary care and
community hospital and is an affiliate of a medical school.
Surgical procedures were stratified by standard criteria
(see Appendix B) into: clean (class I), clean-contaminated
(class II), contaminated (class III), and dirty (class IV).
For purposes of analysis, class III and class IV operations
were combined. Criteria for wound infection to be met was
that there be purulent drainage from the wound. Positive
cultures were not required. Self-administered question-
naires to the patients and letters sent to the physician
inquiring about infections in their patients post-discharge
from the hospital were the tools used for data collection.
The questionnaire was sent to the patient approximately 30
days post-operative. The return rate of the questionnaires
was 59.3% by patients and 71.9% by physicians.

Of the 1644 surgical operations followed in this study,
108 infections were documented. The clean wound infection
rate was 5.2% and the rates for both clean-contaminated and
contaminated-dirty were 7.5%. Fifty-eight infections
(53.7%) were documented in-hospital with 46.3% noted after
discharge from the hospital. This study was limited by the

response rates of the patients and the physicians. It was also limited in that there was a questionnaire used by the patient for infection data as opposed to direct observation of the wound by the study team.

Brown et. al. noted that surgical wound infections continue to represent an important source of morbidity and increasing hospital charges. With decreasing lengths of stay we will witness a higher incidence of these infections occurring post discharge from the hospital. Our present documented surgical wound infection rates are skewed in that they do not include outpatient data. There is a need for more specific data in terms of surgical procedure, patient characteristics, and the recuperative environment.

Further study is needed in this area of surgical outcomes to completely define the ramifications of procedures performed in the outpatient setting versus inpatient setting. Research to date is inconclusive with regards to patient outcomes of the patient in the outpatient setting. There is an identified need for more research of this nature and on a much larger scale.

Research Hypotheses

A difference does exist between infection rates of the inpatient hernia repair patient and the outpatient hernia repair patient.

A difference does exist between bleeding/hemorrhage rates of the inpatient hernia repair patient and the outpatient hernia repair patient.

A difference does exist between readmission rates of the inpatient hernia repair patient and the outpatient hernia repair patient.

Chapter Three - Methodology

General Methods

This was a retrospective study that addressed outcomes of the outpatient hernia repair patient versus the inpatient hernia repair patient. The clinical outcomes that were evaluated in this study were: infection rate, bleeding/hemorrhage rate, and readmission rate of the inpatient and outpatient hernia repair patient.

Specific Procedures

A letter defining the intentions of this study was sent to the chief operating officer, chief nurse executive, director of medical records, and five general surgeons at a southern California hospital. Permission to conduct this study at this hospital was first obtained in writing from the chief operating officer and chief nurse executive. Permission was then obtained by the director of medical records. Two of the five physicians responded immediately with a positive response. The third physician had a positive reply initially, however, being part of a large medical group this particular physician felt that it was best to get administrative approval for his allowing their

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patients files to be reviewed by an outside source. As a result of the administrative inquiry the physician then replied negatively. After several weeks there was no response from the other two physicians. Phone calls to the two physicians then resulted in one more physician replying positively to participation in the study. In summary, three physicians out of a possible five agreed to participate in this study.

Research Population and Sample

The population studied was the inpatient and outpatient hernia repair patients at a southern California hospital during January 1991 through January 1994. Most inpatient hernia repair patients (excluding patients initially diagnosed with incarcerated hernia) operated on during the specified time period were first evaluated. The patients that were under the care of the two general surgeons that did not grant permission for study were extracted and discarded from the data collection. For the outpatient sample selection, cases that met the criteria for inclusion were selected from the computer. Patients with the diagnosis of incarcerated hernia were excluded from the sample. A random sample was selected extracting eight patients of each physician per year to be studied. One of the three

physicians performed fewer than eight outpatient hernia repairs in the selected time period (1993). As a result of this simple random sampling method, 52 inpatients and 97 outpatients were selected for study.

An inpatient was classified as inpatient if the hospital visit was more than 23 hours. The outpatient was classified as outpatient if the hospital visit was 23 hours or less. Hernia repair types included in this study were: inguinal, ventral, umbilical, bilateral inguinal, incarcerated (one), hernia repair with mesh, more than one hernia, and in the rare case hernia repair along with another type of surgery.

Methods

A demographic and clinical characteristics data collection tool was developed for this research study. The characteristics of the tool itself were based on related research literature and basic demographic data collection for general research studies (See Appendix C). The data collection tool was utilized for both inpatient and outpatient samples. The tool was utilized during review of the inpatient and outpatient charts in medical records. This same tool designated for each patient was then completed in the physicians' office. The researcher was the

only individual to have utilized this tool for data
collection.

The demographic and clinical characteristics
investigated for this study included but were not limited
to: patient classification, length of stay, surgical
procedure, surgeon, wound classification, operative time,
insurance status, medical history, antibiotic therapy,
gender, race , and age.

Each subject was classified as inpatient or outpatient
based on their length of stay. Other traits of
classification included: the surgical procedure performed
and the post-operative diagnosis recorded; the surgeon,
start and end times of the surgery, and wound classification
documented on the operative report. The medical history
investigation focused on those medical history
characteristics mentioned in the literature review. The
first part to the medical history was the identification of
risk factors towards infection and/or bleeding. Risk
factors included factors such as: diabetes, obesity, anti-
coagulant therapy and steroid use. The second part of the
medical history was the identification of other health
conditions that may influence whether the patient would be
at risk for readmission to the hospital. Some of the
factors included in this section were: cardiovascular
history, respiratory history, and renal failure history.

The use of antibiotic therapy for each patient was also part of the study. This included whether an antibiotic was provided or not and if so, when the antibiotic was administered. Antibiotic administration was recorded as provided if an antibiotic was given pre-operatively, intra-operatively, post-operatively or any combination of the three. Questions directly related to the questions and hypothesis of this study were then asked as part of the study. The questions included on each research profile were: (1) Did post-operative infection occur ?, (2) Did post-operative bleeding/hemorrhage occur that required treatment?, and (3) Was the patient readmitted to the hospital for post-operative complications?

Other characteristics included as part of the research tool were race, marital status, and physician office visit post discharge from the hospital. Insurance status information was obtained from the face sheet in the medical record and then confirmed with the physicians' files. This information included whether or not the patient had health insurance and if so, what type of health insurance did they have. These were not found to be of relevance in the literature review however for demographic and clinical information for this study it was included.

Data Collection

Clinical outcomes was the focus of the data collection process. According to the literature review there is a relationship between clinical outcomes and demographic and clinical variables. The data collected for this study included: physical, demographic, and socioeconomic characteristics of each patient. Data related to the type of procedure and wound type were collected. Information regarding the treatment of the patient by the physician with antibiotics was also collected. The occurrence of infection, post-operative hemorrhage, and readmission of the patient to the hospital setting was investigated as part of the data collection process.

The data collection took place in the medical records department of the one specified California hospital and in the offices of three general surgeons affiliated with the hospital. A list of the patients' names, their operation date, and their medical record number were given to the director of medical records and in turn had one of the employees retrieve the selected patient's charts for review. The medical record review of charts took approximately twenty hours.

Each participating physicians' office received a list of patient names with dates of operations. They were asked which method would be best for them to have chart review

performed. They were to determine if it would be best for them to retrieve the charts themselves and then have them researched by the researcher or did they want the researcher to retrieve the charts from their files. Two of the physicians' office staff retrieved the charts to be researched. The other physicians' office staff thought that it would be best for them if the researcher retrieved the charts and then replaced the chart into its place of origin. There were approximately ninety charts reviewed in the two physicians' offices where the charts were retrieved by the office staff. In the physicians' office where the staff did not retrieve the charts approximately sixty charts were reviewed. Questions on the data collection tool were answered by review of the charts. In some cases (12) there was incomplete chart review due to insufficient data in the medical record or physician file.

The information collected for the data collection tool was maintained as confidential.

Treatment of the data

The information from each data collection tool was coded and entered into a computer using Microsoft Excel. After completion of entering the data into the computer charts and frequency tables were constructed. Statistical analysis was then performed on the data. One purpose of the data analysis was to determine if there existed any variables that influenced the clinical outcomes of the patient post surgery. The other purpose for data analysis was to determine if there was any difference in the outcomes of the inpatient surgical patient in comparison to the outpatient surgical patient.

For parametric data, the means, standard deviations, and variances were calculated and analyzed. The t-test with pooled variance was used for analysis on both age and operative time. Frequency distributions were produced for all groups of variables. For non-parametric data chi-square analysis was performed. The fisher's exact test was used for non-parametric data with frequencies of five or less in more than one row or column of a table. The level of significance was set at 0.05.

Chapter 4 - Findings

Introduction

The purpose of this investigation was to determine the answers to the questions: (1) Is there a difference in infection rates between the inpatient hernia repair patient and the outpatient hernia repair patient?, (2) Is there a difference in the bleeding/hemorrhage rate between the inpatient hernia repair patient and the outpatient hernia repair patient?, and (3) Is there a difference in the readmission rate between the inpatient hernia repair patient and the outpatient hernia repair patient? Findings for these questions are included in this chapter. Also included with these findings are data related to other demographic and clinical characteristics that were found to have a relationship with the outcome of a surgical patient. The original sample of hernia repair patients consisted of 161 patients. Initial chart review in the physicians offices and in medical records led to the exclusion of twelve patients in the sample due to insufficient data in their files. Insufficient data in this case was defined as no clinical outcomes documented in the record by the physician or no record at all of the patient. As a result of the simple

random sampling method there was an inpatient sample of 52 (35%) and an outpatient sample of 97 (65%).

Demographics of the Study Population

The age range for the sample was 11 months to 88 years of age with a mean age of 51 years. The mean age for the outpatient sample was 43.6 years of age. The mean age for the inpatient sample was 51.4 years of age. The most prevalent age range groups were the less than nine years of age category, 22 (15%), and 22 (15%) patients in the 60 - 69 age range (See table 1). With a t value of 1.76 (t = 1.76, df. = 145, p. $\geq$ 0.05) the null hypothesis of equal sample means cannot be rejected. In this study, there is no evidence that age has an effect on whether an individual is categorized as inpatient or outpatient (See Table 2).

Table 1.   Age Categories of Study Subjects, Percent by Site
of Surgery

Age Category	Inpatients	Outpatients	Totals
0-9yrs	17%	15%	15%
10-19	2	4	3
20-29	2	7	6
30-39	8	14	12
40-49	12	16	15
50-59	17	10	13
60-69	15	16	14
70-79	15	9	11
80-89	12	9	11
Totals	100%	100%	100%
N = 100% =	48	96	144

Table 2   Age of Study Subjects, Mean and Standard
Deviation, by Site of Surgery

Age	Inpatient	Outpatient
Mean	51.37	43.57
SD	27.36	24.50
N = 100% =	48	96

$t = 1.76$, df. $= 145$, p. ≥ 0.05

There were 101 (71%) males and 41 (29%) females in this study population. The outpatient hernia repair group was comprised of 68 (76%) males. There were 33 (66%) males in the inpatient hernia repair group (See table 3). Chi-square analysis found a value of 2.34. With a chi-square value of 2.34 (x^2 = 2.34; df = 1, p $\geq$ 0.05) the null hypothesis that gender and patient site classification are independent cannot be rejected.

Table 3. Gender of Study Subjects, Percent by Site of Surgery

Gender	Inpatient	Outpatient	Totals
Male	63%	76%	71%
Female	37	24	29
Totals	100%	100%	100%
N = 100% =	52	90	142

Chi-square = 2.34; df. = 1, p. $\geq$ 0.05

Risk Factors

According to the literature review, hernia type was indicated as a variable having an effect on the outcome The

literature indicates that incarcerated and ventral hernia repairs have a higher incidence of post operative complications.

Inguinal hernia repairs were found to be the most frequent hernia surgery performed. There were 64 (66%) outpatient inguinal hernia repairs and 18 (35%) inpatient inguinal hernia repairs. Umbilical hernia repair was the next most frequent type for both inpatients (19%) and outpatients (16%). Incarcerated hernia repair patients (diagnosed pre-operatively) were excluded from the study. One patient in the inpatient group was diagnosed post-operatively with an incarcerated hernia. There were 5 (10%) inpatient ventral hernia repairs and 1 (1%) outpatient ventral hernia repair patient (See Table 4). For purpose of analytical analysis hernia types were split into dichotomous groups. The hernia repair was classified as inguinal or all other types of hernia repairs (See table 5). A chi-square value of 13.4 was found. With a chi-square of 13.4 (x^2 = 12.4; df = 1, p $\leq$ 0.05) the null hypothesis that hernia repair type is independent of inpatient or outpatient status can be rejected. There is a significant difference in the percent of inpatients versus outpatients having inguinal hernia repairs.

Table 4.   Hernia Types of Study Subjects, Percent by Site of Surgery

Hernia Type	Inpatients	Outpatients	Totals
Inguinal	35%	66%	55%
Bilateral Inguinal	12	10	11
Umbilical	19	16	17
Ventral	10	1	4
Incisional	6	0	2
With Mesh	2	1	1
+ Other surgery	8	1	3
> 1 Hernia	8	5	6
Incarcerated	2	0	1
Totals	100%	100%	100%
N = 100% =	52	97	149

Table 5.   Classified Hernia Types of Study Subjects, Percent by Site of Surgery

Hernia Class	Inpatient	Outpatient	Totals
Inguinal	35%	66%	55%
All others	65	34	45
Totals	100%	100%	100%
N = 100% =	52	97	149

Chi square = 13.4; df. = 1, p. $\leq$ 0.05

Operative Time

The literature review did not provide evidence that operative time had an effect on infection, bleeding, or readmission to the hospital post-operatively. One study did suggest that procedures greater than 90 minutes were at higher risk for complications however, results for that study were inconclusive with regards to operative times and their effects on outcomes.

Investigation of the operative time revealed a mean operative time of 59.50 minutes for inpatient hernia repair patients. The outpatient hernia repair operative time mean was 48.06 minutes (See table 6). The operative time recorded ranged from 20 minutes to 300 minutes. Operative times greater than 60 minutes comprised 23% of the sample. Operative times recorded as 60 minutes or less comprised 74% of the sample.

The method used for testing was the t-test with pooled variance. A t value of 2.01 was found. With a t value of 2.01, ($t = 2.01$; $df = 144$, $p \leq 0.05$) the null hypothesis of equal sample means can be rejected. There is a significant difference between inpatient and outpatient operative times.

Table 6.   Operative Time of Study Subjects, Mean and Standard Deviation by Site of Surgery

Operative Time	Inpatient	Outpatient
Mean	59.50 (min.)	48.06 (min.)
SD	44.22 (min.)	20.05 (min.)
N = 100% = 146	50	96

$t = 2.01$; df. $= 144$, p. ≤ 0.05

Length of Stay

According to literature, length of stay has a relationship with the outcomes of the surgical patient.   One study indicated that outpatients had lower incidences of post procedure complications.

Length of stay in this study was measured in two different methods.   A hospital visit equal to or less than 23 hours was classified as an outpatient.   The outpatient hours were recorded and measured as "equal to or less than 23 hours", (was not measured as per hour).   Inpatient status was equivalent to a hospital visit greater than 23 hours. Length of stay of the inpatient was measured by the number of hours of hospitalization.   The average length of stay for the inpatient was 3.70 days.

Table 7.   Length of Stay of Study Subjects,
Mean and Standard Deviation by Site of Surgery

Length of stay	Inpatient	Outpatient
Mean	3.70 days	<23 hrs
SD	2.64 days	0 hrs
N = 100% = 146	50	96

Wound Classifications

There are four different types of wound classifications
ranging from clean to dirty-contaminated. A Class I (clean)
wound is a wound that is uninfected without inflammation and
has no entry to the respiratory, alimentary, or
genitourinary tract. A Class II (clean-contaminated) wound
has entered one of these three mentioned tracts and is
without unusual contamination. A Class III (contaminated)
wound is an open, fresh wound or a surgical wound involving
major breaks in technique or spillage from the
gastrointestinal tract. A Class IV (dirty-contaminated)
wound is a wound that involves existing clinical infection
or perforated viscera. In one study, wound classes I and II
were combined for analysis. This study found a lower rate
of infection in class I and II wounds.

The most prevalent wound classification found in both
inpatient and outpatient settings was wound class I followed

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by class II. There were no wound classifications type III
(See table 8). For purpose of analytic analysis wound types
were classified into wounds I and II in one group and wounds
III and IV in the other group (See table9). Chi-square
analysis found that the null hypothesis cannot be rejected.
There is no significant difference in wound types between
inpatient and outpatient hernia repair patients.

Table 8. Wound Classifications of Study Subjects, Percent
by Site of Surgery

Wound Classification	Inpatient	Outpatient	Totals
Class I	77%	90%	86%
Class II	21	9	13
Class III	0	0	0
Class IV	2	1	1
Totals	100%	100%	100%
N = 100% =	52	94	146

Table 9. Wound Classifications (Dichotomous), Percent by Site of Surgery

Wound Class	Inpatient	Outpatient	Totals
Class I & II	98%	99%	99%
Class III & IV	2	1	1
Totals	100%	100%	100%
N = 100% =	52	94	146

Chi-square = .17; df. = 1, p. $\geq$ 0.05

Anesthesia Class

Literature review found that most outpatients are ASA class I or II. One study found no significant difference in complications between inpatient class III (with severe systemic disease) patients and outpatient class III patients.

Each patient was classified into one of four anesthesia classes The ASA Physical Status Classification was used for classification (See Appendix A). This classification was done by their assigned anesthesiologist. Most patients were either Class I (healthy) or Class II (mild systemic disease)in both the inpatient and outpatient setting. There were no patients classified as ASA III (severe systemic disease). There were a few Class IV (severe systemic

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disease) patients in both groups. A chi square value of 5.5
was found (See table 10). With a chi-square value of 5.5
(x^2 = 5.5; df. = 3, p $\geq$ 0.05) the null hypothesis cannot be
rejected. There is no significant difference in anesthesia
classifications between inpatients and outpatients.

Table 10. Anesthesia Class of Study Subjects, Percent by
Site of Surgery

Anesthesia Class	Inpatient	Outpatient	Totals
I	36%	57%	49%
II	34	22	26
III	24	18	20
IV	6	3	5
Totals	100%	100%	100%
N = 100% =	47	85	132

Chi-square = 5.5; df. = 3, p. $\geq$ 0.05

Medical History

The literature review suggested that there were medical
history characteristics that influenced the outcome of a
procedure or placed an individual at a higher risk for post-
operative complications. Some of the risks cited were:
diabetes, steroid use, and anti-coagulant therapy.

The most frequent risk factor identified was smoking (17%) of the total sample. Diabetes and obesity were the next most frequently found risk factors. This study found that 68% of the population had no medical history related to the risk factors identified in the literature review (See table11). For purpose of analytic analysis patients were classified into dichotomous groups. They were classified as with risk or without risk (See table 12). Chi-square analysis was performed to identify if there was any difference in risk factors between the inpatient and outpatient hernia repair patient. With a chi-square value of 0.25 (x^2 = 0.25; df. = 1, p $\geq$ 0.05) there was no significant difference in medical risks found between the inpatient and outpatient hernia repair patient.

Table 11.   Medical Risk History

Medical Risk	Inpatient	Outpatient	Totals
Smoker	17%	17%	17%
Diabetes	4	4	4
Obesity	6	2	4
Steroid Use	2	2	2
Anti-Coagulant	0	2	1
More than 1 risk	0	6	4
None	71	67	68
Totals	100%	100%	100%
N = 100% =	48	90	138

Table 12.   Medical Risk History

Medical Risk	Inpatient	Outpatient	Totals
Yes	29%	33%	32%
No	71	67	68
Totals	100%	100%	100%
N = 100% =	48	90	138

Chi-square = 0.25; df. = 1, p. $\geq$ 0.05

The medical history of the patient was ascertained not only for identification of risk factors for infection and

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bleeding but, also for possible risks for readmission to the hospital. Reasons for readmission may vary according to the operation performed. The literature review revealed that most unscheduled admissions to the hospital post-operatively were for exacerbation of a pre-existing medical condition. The medical conditions found to be of highest incidence in re-admission were cardiovascular and respiratory related.

Medical history data was assessed according to system and/or significant health feature (See table 13). A history of respiratory ailment or disease was found to be the most prevalent (8%) in this study. The second most prevalent medical condition found was drug and/or alcohol abuse (7%). There were 108 (78%) patients without medical condition or risk (related to systems noted in table 13). For purpose of analytic analysis medical history was split into dichotomous groups. One group was with medical history and one was without medical history (See table 14). Chi-square analysis was performed to determine if there was any difference in medical risks related to systems in the outpatient versus inpatient hernia repair population. A chi-square value of 2.36 was found. With a chi-square of 2.36 (x^2 = 2.36; df = 1, p $\geq$ 0.05) the null hypothesis cannot be rejected. There is no significant difference in medical history between the inpatient hernia repair patient and the outpatient hernia repair patient.

Table 13.   Medical History of Study Subjects, Percent by
Site of Surgery

Medical History	Inpatient	Outpatient	Totals
Respiratory	9%	7%	8%
Cardiovascular	0	1	1
Renal failure	5	1	2
Drug/Alcohol abuse	9	7	7
Mental Retardation	2	0	1
Psychiatric	0	1	1
Sarcoma (cured)	0	2	1
Bleeding disorder	0	1	1
None	75	80	78
Totals	100%	100%	100%
N = 100% =	43	95	138

Table 14.   Medical History of Study Subjects, Percent by
Site of Surgery

Medical History	Inpatient	Outpatient	Totals
Yes	26%	20%	22%
No	74	80	78
Totals	100%	100%	100%
N = 100% =	43	95	138

Chi-square = 2.36; df. = 1, p. $\geq$ 0.05

Antibiotic Therapy

The literature review did not indicate whether the timing of an antibiotic had an effect on the incidence of post-operative complications however, for purpose of this study antibiotic use was noted according to when the antibiotic was administered to the patient. The antibiotic was administered pre-operatively, intra-operatively, post-operatively, or in any combination of the three. Some of the patients did not receive any antibiotic therapy over the course of their surgical event. All inpatient hernia repair patients received antibiotic therapy at some point in time during their hospitalization. Outpatient hernia repair patients did not receive any antibiotic treatment in 28% of the cases (See table 15). For analytic analysis of antibiotic use dichotomous groups were formed. Those receiving antibiotic therapy related to the surgical episode were categorized into one group. The other group were those patients that did not receive any antibiotic (See table16). Chi-square analysis found that the null hypothesis can be rejected. There is a significant difference in antibiotic therapy between inpatient hernia repair patients and outpatient hernia repair patients.

Table 15.   Antibiotic Therapy of Study Subjects, Percent by Site of Surgery

Antibiotic therapy	Inpatient	Outpatient	Totals
Pre-operative	2%	1%	2%
Intra-operative	66	15	36
Post-operative	14	7	10
Pre & intra-op	0	3	2
Pre & post-op	0	3	2
Intra & post-op	16	14	14
Pre, intra, & post-op	2	0	1
None	0	57	33
Totals	100%	100%	100%
N = 100% =	51	72	123

Table 16.   Antibiotic Therapy of Study Subjects, Percent by Site of Surgery

Antibiotic therapy	Inpatient	Outpatient	Totals
Yes	100%	43%	67%
No	0	57	23
Total	100%	100%	100%
N = 100% =	51	72	123

Chi-square = 648; df. = 1, p. $\leq$ 0.05

Infection Rates

Analysis revealed that two variables needed to be controlled for in order to determine the infection rates for the inpatient and outpatient hernia repair patients. The two variables that needed to be controlled for were hernia repair type and antibiotic therapy. Hernia repair type was split into dichotomous groups: inguinal hernia repairs in one group and all other hernia repairs in another group. Antibiotic therapy was split into dichotomous groups also: hernia repair patients who received antibiotic therapy were in one group and those that did not receive antibiotic therapy in the other group. The fisher's exact test was used for hypothesis testing in those cases where there were frequencies less than five. Chi-square was used for all other hypothesis testing.

The fisher's exact test was used for analysis of infection rates in inguinal hernia repair patients. Controlling for hernia type, there was no difference found in infection rates between the inpatient inguinal hernia repair patient and the outpatient inguinal hernia repair patient (See table 17). Chi-square was used for analysis of the infection rate of all other hernia repair patients (excluding inguinal). Results showed chi square = 3.80. With a chi-square = 3.80 (x^2 = 3.80, df = 1, $p \geq 0.05$) the null hypothesis cannot be rejected. Excluding inguinal

hernia repair patients, there is no difference in the infection rate between inpatient and outpatient hernia repair patients (See table 18).

Table 17.   Infection Rates of Inguinal Hernia Repair Patients, Percent by Site of Surgery

Infected	Inpatient	Outpatient	Totals
Yes	6%	5%	5%
No	94	95	95
Total	100%	100%	100%
N = 100% =	18	64	82

Fisher's exact test = 0.00

Table 18.   Infection Rates of All Other Hernia Repair Patients (excludes inguinal hernia repairs), Percent by Site of Surgery

Infected	Inpatient	Outpatient	Totals
Yes	18%	3%	10%
No	82	97	90
Total	100%	100%	100%
N = 100% =	34	33	67

Chi-square = 3.80; df. = 1, p. $\geq$ 0.05

Infection rates were determined for those patients that received antibiotic therapy and for those patients that did not receive antibiotic therapy. Analysis revealed that all infected patients had received antibiotic therapy (pre-diagnosis of infection). A chi square of 0.01 was found. With a chi-square of 0.01 (0.01; df = 1, p $\geq$ 0.05) the null hypothesis cannot be rejected. Controlling for antibiotic therapy, there was no difference found in the infection rate between inpatient and outpatient hernia repairs (See table 19).

Table 19.   Infection Rates for Hernia Repair Patients that Received Antibiotic Therapy, Percent by Site of Surgery

Infected	Inpatient	Outpatient	Totals
Yes	14%	13%	13%
No	86	86	87
Total	100%	100%	100%
N = 100% =	51	31	82

Chi-square = 0.01; df. = 1, p. $\geq$ 0.05

Bleeding/Hemorrhage Rates

Bleeding rates were investigated for hernia repair patients. The literature review noted several medical variables that increase the risk of post surgical hemorrhage. This study found no difference in the medical risk variables between inpatient and outpatient hernia repair patients. Hernia repair type and antibiotic therapy were variables that had significant difference between inpatient and outpatient hernia repairs. These two variables were controlled for when analyzing bleeding rates of hernia repair patients.

There were no inpatient inguinal hernia repair patients that bleed and one (2%) outpatient inguinal hernia patient that bleed post surgical treatment (See table 20). Fisher's exact test revealed that the null hypothesis can be rejected. There was a significant difference found in bleed rates between the inpatient inguinal hernia repair patient and the outpatient inguinal hernia repair patient.

All other hernia repair patients (excluding inguinal) were analyzed using chi-square. There were no outpatients in this group that bleed. The inpatient bleed rate for this group was 6% (See table 21). Chi-square was found to be = 2.02. With a chi-square = 2.02 (x^2 = 2.02, df = 1, p $\geq$ 0.05) the null hypothesis cannot be rejected. There was no significant difference found in bleed rates between the

inpatient and outpatient hernia repair (excluding inguinal) patient.

Table 20.   Bleeding Rates for Inguinal Hernia Repair Patients, Percent by Site of Surgery

Bleed	Inpatient	Outpatient	Totals
Yes	0%	2%	1%
No	100	98	99
Total	100%	100%	100%
N = 100%	18	64	82

Fisher's exact test = 0.78, p. $\geq$ 0.05

Table 21.   Bleed Rates for All Other Hernia Repair Patients (excludes inguinal hernias), Percent by Site of Surgery

Bleed	Inpatient	Outpatient	Totals
Yes	6%	0%	3%
No	94	100	97
Total	100%	100%	100%
N = 100% =	34	33	67

Chi-square = 2.02; df. = 1, p. $\geq$ 0.05

There were no hernia repair patients that received antibiotic therapy that bleed found in this study. There were 3 (4%) patients that did receive antibiotic therapy that bleed post surgical treatment (See table 22). The fisher's exact test was used for analysis. With a fisher's exact test = 0.44, the null hypothesis can be rejected. There was a difference found in bleed rates between the inpatient and outpatient hernia repair patients who received antibiotic therapy.

Table 22.   Bleed Rates for Hernia Repair Patients that Received Antibiotic Therapy, Percent by Site of Surgery

Bleed	Inpatient	Outpatient	Totals
Yes	14%	13%	13%
No	86	87	87
Total	100%	100%	100%
N = 100% =	51	31	82

Fisher's exact test = 0.44

Readmission Rates

Hernia type and antibiotic therapy were controlled for when analyzing readmission rates for hernia repair patients.

The literature review indicates that there are risk factors such as cardiovascular and/or respiratory ailments that may influence the readmission rate of a patient to a hospital.

This study found no difference in medical history or risk between the inpatient and outpatient hernia repair patient. Analysis of the readmission rate found that 2% of inguinal hernia repair patients were readmitted to the hospital and 4% of all other hernia repair types were readmitted to the hospital (See tables 23 & 24). The fisher's exact test was used for analysis of the inpatient and outpatient inguinal hernia repair patient. Controlling for hernia type, there was no difference found in readmission rates between inpatient and outpatient inguinal hernia repair patients.

The fisher's exact test was used for analysis of all other hernia repair patients in relation to bleed rates. Controlling for hernia type, there was a difference found in bleed rates between the inpatient and outpatient hernia repair (excluding inguinal) patient.

Table 23.   Readmission Rates for Inguinal Hernia Repair
Patients, Percent by Site of Surgery

Readmitted	Inpatient	Outpatient	Totals
Yes	11%	0%	2%
No	89	100	98
Total	100%	100%	100%
N = 100% =	18	64	82

Fisher's exact test = 0.04

Table 24.   Readmission Rates for All Other Hernia Repair
Patients (excludes inguinal hernia repairs), Percent by Site
of Surgery

Readmitted	Inpatient	Outpatient	Totals
Yes	3%	6%	4%
No	97	94	96
Total	100%	100%	100%
N = 100% =	34	33	67

Fisher's exact test = 0.37

The readmission rate for hernia repair patients
receiving antibiotic therapy and for hernia repair patients
not receiving antibiotic therapy was examined. All patients

that were readmitted to the hospital had received antibiotic therapy as part of their initial surgical treatment. There were 3 (4%) inpatient hernia repair patients that received antibiotic therapy that were readmitted. There were 2 (3%) outpatient hernia repair patients that received antibiotic therapy that were readmitted (See table 25). The fisher's exact test revealed that there is a significant difference in the readmission rate between inpatient and outpatient hernia repair patients who receive antibiotic therapy.

Table 25. Readmission Rates for Hernia Repair Patients that Received Antibiotic Therapy, Percent by Site of Surgery

Readmitted	Inpatient	Outpatient	Totals
Yes	6%	6%	6%
No	94	94	94
Total	100%	100%	100%
N = 100% =	51	31	82

Fisher's exact test = 0.21

Chapter 5 - Conclusions

Conclusions and Implications

The results of this study found answers to the
questions: (1) Is there any difference in the infection rate
between the inpatient hernia repair patient and the
outpatient hernia repair patient?, (2) Is there any
difference in the bleeding / hemorrhage rate between the
inpatient and outpatient hernia repair patient?, and (3) Is
there any difference in the readmission rate between the
inpatient and outpatient hernia repair patient?

Analysis of the variables studied indicated that hernia
type and antibiotic therapy needed to be controlled for when
analyzing the infection, bleeding, and readmission rates of
the hernia repair patient. Analysis of operative time
revealed a difference in mean operative time between the
inpatient and outpatient hernia repair patient. The mean
operative time for inpatients was 59.50 minutes and for the
outpatient it was 48.06 minutes. Literature review does not
support operative time as a variable having an effect on
clinical outcomes unless, the procedure is greater than 90
minutes, and in cases that do have operative times greater
than 90 minutes the results are still inconclusive.

Hernia repair types were split into dichotomous groups for analysis One group was inguinal hernia repairs and the other was all other hernia repair types. Controlling for hernia types, there was no difference found in infection rates between the inpatient hernia repair patient and the outpatient hernia repair patient. When controlling for antibiotic therapy, there was no difference found in infection rates between the inpatient and outpatient hernia repair patient.

The literature review indicated that ventral and incarcerated hernia repair patients are at higher risk for infection. This study did not find ventral and incarcerated hernia repair patients to have a higher infection rate. Other risk factors for infection identified in the literature review were pre-existing infection, diabetes, and obesity. This study found no difference in medical risks between the inpatient and the outpatient hernia repair patient and were not found to have influenced the infection rate of the hernia repair patient. One other clinical characteristic identified as a risk factor for infection was the wound classification. In research, wound classifications of class 3 and/or 4 have suggested a higher rate of complication. This research study found no difference in wound classifications in the inpatient and

outpatient hernia repair patients and found no indication that wound type had an effect on infection rate.

This study does suggest that the careful screening of risk factors for infection in both inpatient and outpatient settings may lead to a low infection rate. Surgical techniques have improved over the past centuries and that too may be the reason for improved infection rates over time. The identification of signs and symptoms of infection post-operatively by the physician implies that follow-up evaluation of the patient does have importance.

Hernia repair type and antibiotic therapy were controlled for when analyzing the bleeding rate for hernia repair patients. Controlling for hernia type, a difference in bleed rates was found between the inpatient inguinal hernia repair patient and the outpatient inguinal hernia repair patient. There were no inpatient inguinal hernia repair patients that bleed. There was no difference found in bleed rates between the inpatient hernia repair (excluding inguinal) patient and the outpatient hernia repair (excluding inguinal) patient. Hernia repair patients that received antibiotic therapy showed a difference in bleeding rates between inpatients and outpatients. Inpatients receiving antibiotics had a higher rate of bleeding than outpatients receiving antibiotics. Literature review does not indicate any rational for this finding.

There were several risk factors for bleeding identified in the literature review. Risk factors include anti-coagulant therapy and pre-existing bleeding disorders . There was no difference found in risk factors between inpatient and outpatient hernia repair patients. The outpatient inguinal hernia repair patient was found to have a significantly higher rate of bleeding. This implies that there may be need for further screening of medical conditions and that there may be need for more follow-up evaluation of the patient post discharge from the hospital. There is also an implication for further study of antibiotic therapy and bleeding rates.

Overall, there was a low bleeding / hemorrhage rate found in this study. This may be a result of the new technological advances with cautery equipment. Screening for risk factors related to bleeding should be evaluated stringently. It is probably the careful screening of patients that has led to the low bleeding /hemorrhage rates found.

There was no difference found in the readmission rate between the inpatient inguinal hernia repair patient and the outpatient inguinal hernia repair patient. In the all other types of hernia group there was a difference found in readmission rates. The outpatient hernia repair (excluding inguinal) patient was found to have a higher rate of

readmission. Controlling for antibiotic therapy, there was a difference found between the inpatient hernia repair patient and the outpatient hernia repair patient that received antibiotic therapy. There were no patients readmitted to the hospital that did not receive antibiotic therapy. Findings of the readmission rates and information from the literature review do not indicate a significant cause for readmission. It does indicate that there is a need for further investigation in relation to clinical characteristics and readmission rates to health care settings.

Readmission to the hospital setting does mean more dollars spent by the institution, patient, and insurance company therefore careful screening of the patient prior to surgery and prior to discharge from the hospital are extremely important and should remain stringent.

Limitations of the Study

The size of the population investigated in this study was limited to the inpatient and outpatient hernia population at one hospital. The years in review covered a three year period only and this was due to the unavailability of written medical records prior to that period. It would have been preferred to have had a larger

sample size for study. The investigation was limited to one surgical facility where inpatient and outpatient procedures where performed in the same operating suites with similar physician and nursing staff. This explicitly controlled for variations between facility and surgical staff characteristics but it limited the ability to generalize beyond this site.

Outpatient information was limited in two ways: (1) patients referred to surgeons by HMO groups are not seen by the surgeon after discharge from the hospital, making it more difficult to assess their outcome and (2) physician office files are not readily accessible for review. Inpatient information was also limited. In several cases there were no records of the patient in the physician's office because the physician was called in for consultation by a primary physician. This primary physician then performed the patient outcome evaluation post discharge from the hospital.

Recommendations

In order to understand risk factors for post discharge complications, large studies following patients beyond the hospitalization are required where closer attention is given to the many variables that make up an individuals health

status. Present research studies are identifying outcomes of medical care however, outcomes related to demographic and clinical risk factors for inpatients and outpatients remains to be conclusive. As mentioned in the literature review the objectives of the PORTS study is to identify outcomes which include physiological and functional capacity along with use of health care resources. The findings to this study may provide us with some conclusive answers to the question: what is the most cost effective and high quality producing treatment for a particular patient?

The typical hospital surgery department has a significantly high capital and operational budget as well as a high patient volume. A recommendation to health care facilities is to develop performance improvement measures that are directly related to the cost and quality of care provided for the surgical patient (if they have not done so already).

With the soaring costs in health care expenditures it would be beneficial to have conclusive research that shows what medical treatment provides the best outcome with relation to quality and cost. Cost and quality assessment must take precedence at all health care facilities if they have any hopes of surviving in this turbulent health care market.

Appendix A

ASA Physical Status Classification*

Class 1   A normally healthy patient.

Class 2   A patient with mild systemic disease.

Class 3   A patient with severe systemic disease that

                 is not incapacitating.

Class 4   A patient with an incapacitating systemic

                 disease that is a constant threat to life.

Class 5   A moribund patient who is not expected to

                 survive for 24 hours with or without

                 operation.

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* (Owens, Felts, and Spitznagel, 1991, p.239).

Appendix B

Wound Classifications

Class I: Clean Wounds

Uninfected wounds without inflammation. No entry to the

respiratory, alimentary, genitourinary tracts. Primary

closure. Drained with closed drains.

Surgical incisions that follow non-penetrating (blunt)

trauma with above criteria met also fall in this category.

Class II: Clean- Contaminated Wounds

Respiratory, alimentary, genitourinary tracts entered under

controlled conditions and without unusual contamination.

Procedures involving biliary tract, appendix, vagina and

oropharynx are included provided there is no evidence of

infection or major break in technique.

Class III: Contaminated Wounds

Open, fresh accidental wounds. Surgical procedures

involving major breaks in technique or gross spillage from

the gastrointestinal tract.

Incisions with acute non-purulent inflammation encountered.

Class IV: Dirty-Contaminated Wounds

Old traumatic wounds with retained devitalized tissue.
Wounds that involve existing clinical infection or
perforated viscera.
Organisms that cause post-operative infection present in
those wounds before surgery.

Appendix C

Demographic and Clinical Characteristics

Name:_____   Inpatient [] Outpatient []
Address:_____   Op Date:_____
Zip Code:_____   Date of office visit:_____
                                                LOS:_____
Diagnosis:_____   Physician:_____
Surgical Procedure:_____
Anesthesia Class:_____   Wound Class:_____

Operation start time:_____   Operation stop time:_____

Male []   Female []   Age:_____   Height:_____ Weight:_____

Race: White []   Black []   American Indian []   Asian []   Hispanic []   All other []

Marital Status: Single []   Married []   Divorced []   Widowed []

Health Insurance Status: None   []
                                Private   []
                                HMO   []
                                Medicaid   []
                                Medicare   []
                                Medimedi   []
                                >1 type   []
                                Other   []

Received Workers Compensation?   Yes [] No[]

Present medical history includes
        Smoking   Yes [] No [] Other []_____
        Infection   Yes [] No [] Other []_____
        Diabetes   Yes [] No [] Other []_____
        Obesity   Yes [] No [] Other []_____
        Steroid Use   Yes [] No [] Other []_____
        Anti-coagulant therapy Yes [] No [] Other []_____
        Cancer or Chemotherapy Yes [] No [] Other []_____
        Other   Yes [] No [] Other.[]_____

Received antibiotic therapy pre-operatively?   Yes [] No []
Received antibiotic therapy during the operation?   Yes [] No []
Received antibiotic therapy post-operatively?   Yes [] No []

Did post-op infection occur?   Yes [] No [] Other []
Did post-op hemorrhage / bleeding occur that required treatment?   Yes [] No [] Other []
Was the patient re-admitted to the hospital for post-operative complications?

                                                                         Yes [] No [] Other []

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