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A Methodology to Improve Quality and Decrease Cost in Health Care

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In today's health care environment, clinicians are faced with a clear dilemma: how to control costs while maintaining quality and improving medical practice. Stimulated by concerns about quality, effectiveness, and the rising cost of health care, both practitioners and payers need a method to continually assess the outcome of medical care and its relationship to the patient's risk factors. A powerful new methodology, Clinical Practice Improvement (CPI), does just that. Rather than focusing on profiling physicians, CPI profiles the care process by analyzing the content and timing of individual steps of a medical care process to determine how to achieve superior medical outcomes for the least necessary cost over the continuum of a patient's care. CPI is a methodology to help clinicians determine what are the best interventions to be used, given a patient's specific disease(s) and severity of illness. This methodology assesses not only variation in cost, length of stay, and mortality due to possible medical interventions, but also measures morbidity by accounting for changes in the patient's physiologic signs and symptoms. The goal is to determine best practices over the continuum of care and identify critical information to support clinical decision making designed to achieve desirable patient outcomes.[1]

Many clinical practices have no firm basis in published scientific research. One method of clinical guideline development, expert consensus, is an inexact tool that often generates different, even conflicting, guidelines on the same topic.[2] CPI is an explicit approach to the evaluation of health practices and the design of research-based protocols to facilitate decision making.

CPI's main strength is its power to use information from a provider's own setting and apply rigorous statistical analysis to determine associations between practice and outcome, controlling for patient differences. CPI is not, however, an easy solution. It requires multidisciplinary involvement, clinical and administrative champions, an investment of clinician time, information system resources, study design, and expertise.[3]

CPI provides practitioners with data for evaluating and improving clinical practice. It is a method to put clinicians back in control of clinical decision making and help them take accountability for medical outcomes. Clinicians evaluate what interventions are best based on data reflecting patient outcomes and decide how those interventions should be delivered most effectively. This is in contrast to today's managed care environment, which tends to restrict clinical decisions by focusing on costs, e.g., use of the least costly medication or least costly provider. By not focusing on the entire care process and all dimensions of outcomes, efforts to contain costs may lead to suboptimal outcomes or greater total cost per episode.

A fully functional CPI environment:

- generates valid statistical inferences about the operational, day-to-day practice of medicine
- accelerates and enhances current quality improvement efforts
- tracks outcomes and feeds the resulting information back to practitioners so that they can evaluate objectively the effects of treatments controlling for patient differences
- requires multidisciplinary participation of individuals with fundamental knowledge of the care process
- creates a clinical laboratory, built into the everyday practice setting, to find and test best practices.

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BEYOND RANDOMIZED CONTROLLED TRIALS

Formal patient randomization (a randomized controlled trial or RCT) is the safest study design approach. RCTs use a protocol document to create an artificial practice environment that allows valid statistical inference. While this structure eliminates practice variation, it usually covers a very limited subset of patients and practices.

CPI uses alternative study designs that provide a pragmatic balance of study overhead, clinician participation, rapid patient accrual, and the need for timely information. CPI addresses the same issues as RCT—practice variation and valid statistical inference—from another point of view. It identifies process variation, then eliminates it through a combination of statistical analysis, clinical interpretation, consensus, and feedback. Invalid inferences are likely to be found and corrected over time.

RCTs tend to be limited in time; in most circumstances, they explicitly modify clinician behavior only for the duration of a study and only for the individuals directly involved in the trial. In contrast, the goal of CPI is to establish a permanent feedback loop aimed at all clinicians in an institution. CPI integrates research into daily practice, giving clinicians the information necessary to understand and modify their own activities at a detailed, operational level.

SEVERITY OF ILLNESS MEASURES

In CPI an integrated database is compiled to study the process of care and relate it to patient outcomes. To make legitimate comparisons between patients who are treated by different processes, a mechanism is necessary to group patients according to the severity of their illnesses. One severity indexing system is the Computerized Severity Index (CSI), designed by Susan D. Horn, Ph.D., in collaboration with colleagues and clinicians across the country. The system was designed to measure the severity of the patient's conditions based on disease-specific indicators. Expert physician panels rated severity for each ICD-9-CM diagnosis code. An Ambulatory Patient Severity system has also been developed.

The CSI includes more than 2,000 individual criteria subdivided into more than 2,500 disease-specific groups. Treatment approaches, such as surgical procedures, are not used as criteria. Instead, the severity criteria are based on objective clinical findings, such as temperature, blood pressure, lab values, or radiology findings. There are on average thirty-two criteria per patient that are measured. Disease-specific and overall severity levels are rated on a scale of 0-4 for each patient diagnosis. Scoring is done: 1) at the time of admission (the first twenty-four hours), 2) on admission to an ICU, 3) at various points defined by a clinical pathway or protocol, and 4) at discharge (the last twenty-four hours). This allows a consistent, objective assessment of the patient's condition at various points in the care process. As an example, see Table 1, which provides a computerized severity index for malignant neoplasm of the large intestine.

CPI

integrates research into daily practice, giving clinicians the information necessary to understand and modify their own activities at a detailed, operational level.

THE CPI WORK PLAN

A CPI study is an analysis of the content and timing of the individual steps in a medical care process to produce superior medical outcomes for the least necessary cost over the continuum of a patient's care. Systematic determination of individual medical process steps that improve patient outcomes is the best way to develop demonstrably better care and practice. The individual steps of the medical process are defined over time with increasing precision and comprehensiveness. Statistical regression analyses are used to determine whether and how much a particular step actually improves medical outcomes.[4] From these analyses, clinicians interpret and confirm the significant associations between care processes and outcomes (controlling for patient characteristics).

Fundamental to CPI is identifying three classes of information:

1) *patient characteristics*, which include specific indications for treatment and severity of illness measures

2) *processes*, which measure what happens during patient care, including clinical decision making, treatment delivery, and medication prescribing

3) *outcomes*, which include clinical information (readmission, complications, mortality), service quality and patient satisfaction, health status, and cost (cost/patient, cost/procedure, supply costs).

The medical literature, practice guidelines, critical paths, and the clinical experience/expertise of the team are typically used to identify these elements. Tables 2 and 3 show an example of patient, process, and outcome variables associated with colorectal cancer and bone marrow transplantation, respectively.

In the analysis phase, the resulting associations are then presented to the clinicians so that they can objectively evaluate the effects of their treatments on similar patients.

The CPI work plan involves four general steps: plan, do, study, and act.

1) *Plan*. The first step in any CPI study is to select team members and provide training in CPI concepts and methodology. Objectives include defining a clear area of focus, establishing improvement goals and questions, understanding the current process and/or problem through design of a flowchart, and identifying critical measures of the patient, care process, and outcomes.

2) *Do*. The second step is to create definitions for all variables, produce a self-coded data form, and conduct an inventory of available data (how and where existing data are stored). Often when the CPI team defines the necessary variables, all the data are not available. The task of the CPI team is to meet with the physicians to assess how they and their colleagues will actually use the

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Table 1. Computerized Severity Index: Malignant Neoplasm of Large Intestine (Proximal)

Category	Indicator	Level 1	Level 2	Level 3	Level 4
Cardiovascular	EKG Rhythm	No EKG ectopy	≥6 PVCs per minute Bigeminy Trigeminy Quadrigeminy Atrial fibrillation PACs or PVCs NOS EKG ectopy NOS Non-sustained ventricular tachycardia		Runs of ventricular tachycardia
Digestive	Nausea/vomiting	Nausea No nausea or vomiting	Vomiting	Persistent vomiting	
	Stools per day during hospitalization	Diarrhea NOS (≤4 stools per day) No diarrhea	Frequent diarrhea (5–10 stools per day)	Continuous diarrhea (>10 stools per day)	
	Ascites	No ascites	Ascites NOS	Ascites causing dyspnea	
	Lower gastrointestinal bleeding	No rectal hemorrhage, black tarry stools or guaiac positive stools	Guaiac + stools		Rectal hemorrhage
	Bowel habits	History of constipation with onset ≤4 weeks Tenesmus No obstipation/ constipation/ tenesmus	Constipation	Obstipation	
	Abdominal mass	Palpable right lower quadrant mass Palpable right upper quadrant mass Nodular abdominal mass Abdominal mass NOS No abdominal and/or flank mass			
Lab—Chemistry	Lowest albumin	≥3.2 g/dl	2.9–3.1 g/dl	2.5–2.8 g/dl	≤2.4 g/dl
Lab—Hematology	Lowest male hematocrit (HCT)	≥30.0 %	20.1–29.9 %	15.1–20.0 %	≤15.0 %
	Lowest male hemoglobin (HGB)	≥10.0 g/dl	6.6–9.9 g/dl	5.1–6.5 g/dl	≤5.0 g/dl
	Lowest female hematocrit (HCT)	≥30.0%	20.1–29.9 %	15.1–20.0 %	≤15.0 %
	Lowest female hemoglobin (HGB)	≥10.0 g/dl	6.6–9.9 g/dl	5.1–6.5 g/dl	≤5.0 g/dl
Vitals	Lowest pulse rate	≥51 beats/min	41–50 beats/min	31–40 beats/min	≤30 beats/min
	Lowest systolic blood pressure	≥90 mmHg	80–89 mmHg	61–79 mmHg	≤60 mmHg
	Highest % weight loss	≤5.9 %	6.0–15.9 %	16.0–20.9 %	≥21.0 %
	Cachexia	No cachexia	Cachexia		
	Highest pulse rate	≤99 beats/min	100–129 beats/min	≥130 beats/min	

Table 2. Bone Marrow Transplant Variables

Patient Variables	Process Variables	Outcome Variables
■ Cancer history • cancer type/stage • date of diagnosis ■ Nutritional status • weight/height • recent weight change • diet at home • vitamin/mineral supplements ■ Patient history • allergies • alternative therapies ■ Lab values on admission • cardiovascular • hematology • differential • chemistry	■ Preparative regimen • medications • radiation • radiation boost ■ Nutritional support • daily oral intake • daily calorie/protein intake • TPN • tube feeding ■ Transplant management • type of transplant • stem cell source ■ Medications • GI therapy • antimicrobials • immunosuppressives • corticosteroids • FK 506 ■ Blood products	■ Hospital LOS ■ Skin complications ■ GI complications ■ Infection ■ Engraftment ■ Unplanned hospitalizations ■ Mortality ■ Adverse events • GVHD • mucositis • esophagitis • veno-occlusive disease • hepatic dysfunction • renal insufficiency • respiratory distress

Table 3. Colorectal Cancer Variables

Patient Variables	Process Variables	Outcome Variables
■ Cancer history • date of diagnosis • histology • stage of cancer • positive lymph nodes • family history of cancer ■ Nutritional status • weight/height • weight change ■ Patient history • substance abuse/smoking • adverse reaction to prior treatment ■ Diagnostic test results • lab values • CT scan • prestaging MRI • CEA tumor marker • colonoscopy	■ Nutrition support • TPN • tube feeding • daily oral intake ■ Surgery • surgery time • type of surgery • resected tumor size ■ Post-surgery • pain medications • bowel function • first ambulation • first oral intake • patient education ■ Chemotherapy • administration of oncologic/non-oncologic agents • medications GI therapy analgesics ■ Radiation • radiation source • number of fractions • region radiated • duration of radiation therapy	■ Hospital LOS ■ GI complications • nausea/vomiting/diarrhea • stomatitis ■ Unplanned hospitalizations ■ Unplanned return to ED ■ Karnofsky score ■ ECOG performance status ■ Chemotherapy or radiation dose reduction, delay, or discontinuation

information. Next, a database is created and methods to collect the data are established.

3) *Study*. This step includes data analyses with advanced statistical techniques. It is a "dynamic" research protocol development, because clinicians actually take part in building it and finding what in fact are differences in patient outcomes. Step three is the analytic stage in which determinations are made about the processes and patient measures on which to focus, using descriptive statistics, flowcharts, histograms, scatter diagrams, and regression analyses. The collection of numerous and complex data elements requires information system resources, such as data abstractors and database managers, and a statistical analyst. Their responsibility is to identify which process steps have strong associations with better outcomes, controlling for patient factors.

4) *Act*. This step includes protocol implementation and then ongoing evaluation of protocols.

ONCOLOGY EXAMPLE: CPI STUDY DESIGN

Several providers of oncology services are currently using the CPI methodology to answer the following questions:

- What gastrointestinal problems are associated with the administration of chemotherapy and/or radiation therapy in patients diagnosed with colorectal cancer?
- Does type of intravascular access used for chemotherapy administration affect the rate of infection?
- Is there an association between early and more frequent patient education and improved patient outcomes (early discharge, compliance, reduced medication use)?
- Does the administration of an anti-emetic prior to therapy improve patient tolerance of chemotherapy?
- Is longer time between surgery and chemotherapy associated with better outcomes?
- Do patients have better outcomes when followed by an advance practice nurse from diagnosis to discharge?
- What impact does nutritional status of the patient prior to chemotherapy or radiation therapy have on the ability of the patient to tolerate or benefit from nutritional support?

Some CPI Results

A number of hospitals across the country are using CPI, including Glendale Adventist Medical Center in Glendale, Calif., and Methodist Hospital in Houston, Tex.

Some results:

- Reduction in post-surgical deep wound infection rate from 1.8 percent to 0.4 percent. Cost savings of more than $255,000 per year in one hospital.
- Improved survival rate of ARDS patients from 9.5 to nearly 60 percent by using protocol for ventilation managment. Cost savings: $50,000 per patient, plus the avoided cost of additional technology (heart-lung machine)
- More than a 40 percent reduction in major complication rates for cardiac bypass graft patients.
- A 51 percent reduction in rate of hospital-acquired lower respiratory infections. Cost savings of more than $1 million per year in a single hospital.
- Improved prevention of pressure ulcers in high-risk hospitalized patients. A 90 percent reduction in severity-adjusted incidence of ulcers. Cost savings of more than $1.25 million per year in one hospital.
- A 32 percent reduction in annual hospitalization rate for pediatric asthma patients in an HMO setting.

The CPI team's task is to identify the patient, process, and outcome variables necessary to better understand the associations between their practice patterns and these patient outcomes.

INFORMATION MANAGEMENT TO SUPPORT CPI

Implementation of CPI requires an information management system that brings providers into the process. The system must:

- create a common vocabulary
- define essential data elements
- be able to assess the indicators' reliability
- perform data analysis
- synthesize useful data
- provide feedback to the provider at the time of clinical decision making.[5]

CPI involves integration of existing systems and can include additional clinical data where necessary. Most data required for CPI can be collected as a byproduct of routine care and, thus, should not require additional work. Relational databases have been widely used in CPI studies. Data that meet the general requirements of the computer-based patient record will support CPI.

Instead of improving patient care management, some say that managed care simply tries to manage costs—with limited success. In contrast, CPI builds the infrastructure through which true managed care can occur by focusing on objective, systematic patient information that clinicians need to understand and improve their own care delivery. The goal of CPI is to discover and then implement best practice, not to identify and criticize bad performance.

Success in CPI depends on the ability of health care leaders to create a culture of cooperation and learning among all members of the team. Those leaders do not manage clinicians. Instead, they organize clinicians and supply them with the necessary tools to manage the health care processes they oversee. If a health care organization wants to survive financially, it must begin to provide the data that will allow its clinicians to truly manage care.

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