

# Outcomes Research and the Challenge of Evidence-Based Surgery

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## KEYWORDS

- Outcomes research • Quality assurance
- Evidence-based surgical practice
- Patient-oriented research

The purposes of this article are to introduce a definition of outcomes research, to review how outcomes research may guide evidence-based surgical practice and health care processes, and to review a model for outcomes research.

## WHAT IS OUTCOMES RESEARCH?

Almost invariably, when the author mentions outcomes research, audiences or readers raise their collective eyebrows quizzically as if to ask, "What does that mean?" It is an excellent question. In general, outcomes research focuses on the end products or results of health care practices, interventions, and processes.

As practiced, however, outcomes research means different things to different people. To some, outcomes research means developing clinical benchmarks or practice guidelines. To others, outcomes research is used for quality assurance and patient safety activities. To others still, outcomes research tries to explain variability in clinical practice or linking types of care to outcomes. Regardless of an individual's definition of outcomes research, outcomes research has similar goals (eg, improve the patient care or the

health care process) and uses similar clinical epidemiologic investigative tools.

At the Center for Applied Clinical Investigation (CACI) based in the Department of Oral and Maxillofacial Surgery at Massachusetts General Hospital, outcomes research is one area of focus. Outcomes researchers at CACI measure what happened and why it happened.

CACI's outcomes research activities are grouped into two areas. First, researchers want to estimate how often events of interest occur, that is, what happened. Frequency, incidence, or survival estimates of outcomes are measured for patient care activities (eg, nerve repair, complications after third molar surgery, or implant survival).<sup>1-5</sup> This information is used to inform clinical care and practice.

Equally important is estimating the results of health care processes or practices (eg, satisfaction with telephone follow-up after dentoalveolar procedures or following nerve repair, frequency of completed consent forms, or length of hospitalization after orthognathic surgery).<sup>6-8</sup> This information can be used for benchmarking, patient education, or improving quality or safety processes.

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The Center's second outcomes research activity focuses on identifying factors or variables associated with the outcome (ie, why did the event of interest happen?). These factors can be classified as prognostic (ie, associated with a favorable outcome or result) or risk (ie, associated with an unfavorable outcome or result). For example, one could look at factors associated with implant survival (prognostic) or implant failure (risk).<sup>9</sup> The factors associated with an outcome of interest are then categorized as immutable (eg, age or sex) or potentially modifiable (eg, perioperative antibiotic use). Immutable factors may be used to predict prognosis or risk for outcomes of interest. Modifiable factors may be used to improve outcomes.

## **USING OUTCOMES RESEARCH TO ENHANCE AND GUIDE EVIDENCE-BASED SURGICAL PRACTICE AND HEALTH CARE PROCESSES**

### ***Enhancing Evidence-based Surgical Practice***

Systematic collection of outcome data can inform clinical practice. Frequency, incidence, or survival data can be used to inform patients of the likelihood of a good (or bad) result. For example, these types of data can be used to inform the average patient about the likelihood for postoperative infection or nerve injury after third molar surgery or the chance that an implant will survive.

As noted above, factors associated with outcomes are identified and grouped into two categories: immutable (eg, age and sex) or modifiable (eg, tobacco use, implant length, timing of implant loading, use of antibiotics). Since immutable variables cannot be changed, data regarding these variables can be used to inform the patient of prognosis or risk. For example, an older patient may have an increased risk for intra- or postoperative complications associated with third molar surgery. One cannot change the patient's age, but can use that information to help set treatment or prognosis expectations.

In contrast, modifiable variables may be used to enhance prognosis or decrease the risk for an adverse outcome. Modifying tobacco use may affect the risk of postoperative complications. As such, the clinician may suggest that a patient stop smoking before implant insertion to improve the likelihood of implant survival or decrease the risk for a postoperative inflammatory complication.

Modifiable variables can be used to generate additional studies to test a hypothesis that changes in the modifiable variable results in changes the outcome. Absent additional data, one should be quite cautious in translating the findings from an outcomes study directly to patient

care. In most cases, outcomes studies are not designed to identify variables associated with the outcome of interest. These findings are valuable "side-effects" of the study. As such, biases in study sample selection, incomplete data collection, subject follow-up, or variable definitions could produce spurious associations. Instead, new, controlled trials should be implemented, guided by hypotheses arising from the outcomes research, to confirm or refute the observed relationship between the factor and outcome of interest.

### ***Enhancing Evidence-based Healthcare Processes***

Outcomes research can improve or inform health care processes. Outcomes research may be used to establish benchmarks and used as a quality assurance or safety activity. For example, national statistics suggest that the frequency of patients who are extremely or moderately satisfied with their deep sedation, general anesthesia experience is 94.9%.<sup>10</sup> Individual clinicians or practices may survey their patients' satisfaction with deep sedation, general anesthesia and compare the results to a prespecified target or nationally established benchmark. Adverse deviations from the target or benchmark may prompt a review of clinical protocols, and suggest changes, implementation of a new clinical protocol, and iterative measures of the outcome to see if the changes result in achieving or exceeding the benchmark.

Absent a prespecified national benchmark, the practice may survey its patients to establish its own baseline frequency of some outcome of interest (eg, use of two identifiers for patient identification). Once the baseline is established, the practice may repeat the survey on a regular basis to confirm that the baseline target is being achieved. If the target is consistently achieved, a new target may be specified or a different outcome evaluated.

Outcomes research can be used for patient education. Estimates of a practice's or specialties' frequency of inferior alveolar nerve injury or surgical site infection after third molar removal may be valuable information because, when conveyed to patients, it may help them determine the best management choice for third molars.

## **A MODEL FOR OUTCOMES RESEARCH**

**Fig. 1** summarizes CACI's outcomes research cycle. The first step is to generate a research question. There are two excellent sources to generate research questions. The first is the

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