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Health Utility Values Associated with Surgical Site Infection: A Systematic Review

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ABSTRACT

Background: Surgical site infection (SSI) is a costly postoperative complication whose impact on patients' health-related quality of life is highly uncertain and has not been summarized to date. **Objective:** The objective was to summarize the evidence base on SSI health utility values reported in patient-level studies and decision models. **Methods:** A systematic review of SSI utility values reported in patient-level and decision modeling studies was carried out. Studies in which utility values for SSI were either invoked (e.g., model-based economic evaluations) or elicited (e.g., valuation exercises), or at least one non-preference-based instrument was administered to patients with SSI after open surgery were included. Mapping algorithms were used, where appropriate, to calculate utilities from primary data. Results were summarized narratively, and the quality of the utility values used in the included modeling studies was assessed. **Results:** Of 6552 records identified in the database search, 28 studies were included in the review: 19 model-based economic

evaluations and 9 patient-level studies. SSI utility decrements ranged from 0.04 to 0.48, of which 19 ranged from 0.1 to 0.3. SSI utility decrements could be calculated for three patient-level studies, and their values ranged from 0.05 (7 days postoperatively) to 0.124 (1 year postoperatively). In most modeling studies, SSI utilities were informed by authors' assumptions or by secondary sources. **Conclusions:** SSI may substantially affect patients' health utility and needs to be considered when modeling decision problems in surgery. The evidence base for SSI utilities is of questionable quality and skewed toward orthopedic surgery. Further research must concentrate on producing reliable estimates for patients without orthopedic problems.

Keywords: health utility, surgical site infection, systematic review.

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Introduction

Surgical site infection (SSI) is a postoperative complication with incidence rates up to 27% in colorectal surgery [1]. SSI can develop only if the surgical site is contaminated with micro-organisms, which can originate either from the patient or from the environment in the operating room. When the skin is incised, the tissue is exposed to the flora on the patient's skin, mucous membranes, and hollow viscera, which constitute the causative agents of SSI in most cases [2]. Average European-wide SSI incidence rates range from 0.7% in knee prosthesis to 9.7% in colon surgery [3]. The burden of SSIs is even higher in low- and middle-income countries than in high-income settings [4].

SSIs are associated with discomfort to the patient, excess mortality, longer inpatient stays, and increased costs to the health care system, the patient's family, and the society at large [5–9]. The additional cost attributable to SSI after colorectal cancer alone has been estimated at £50 million per year in the United Kingdom [10]. Patients with SSI report reduced health-

related quality of life (HRQOL) compared to uninfected controls [11], and patients with SSI may experience pain, insecurity, and isolation over several months or even years [12].

SSI is preventable, although currently available technologies do not allow 100% prevention [13]. Most proposed medical interventions targeting SSIs address the known SSI risk factors, discussed comprehensively in clinical guidelines issued by the US Centers for Disease Control and Prevention [14] and UK's National Institute for Health and Care Excellence [15] together with SSI control strategies pertaining to the preoperative (e.g., hair removal, antibiotic prophylaxis, and bowel preparation), intraoperative (e.g., hand decontamination and skin preparation), and postoperative phases (e.g., changing dressings and wound debridement) [16].

There is, however, limited evidence on the incremental cost-effectiveness of SSI prevention measures compared with standard care (without the respective SSI control strategy). Such evidence is necessary to reimburse technologies that represent good value for money. One way to assess the effectiveness of interventions for health care decision making is in terms of

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quality-adjusted life-years, which capture simultaneously the effect of a condition on morbidity and mortality by combining the length of life with a preference-based quality-of-life measure in the form of health utility. There appears to be limited data to inform quality-adjusted life-year calculations for interventions targeting SSI [17,18]. Furthermore, SSI is a heterogeneous condition that displays various degrees of severity [19] (e.g., superficial, deep, and organ/space SSI) and can occur after a wide range of surgical procedures [20], with varying onset periods [21] and associated management costs [7]. As such, the health utility of patients with SSI can be expected to vary widely.

We conducted a systematic review of SSI health utility data to 1) identify and summarize the available information on the utility decrement associated with having an SSI and 2) explore the extent to which the type of SSI is reflected in available health utility values. The findings are of interest primarily to policy-makers with an interest in reducing SSI burden, to decision analysts faced with modeling surgical outcomes, and to clinicians aiming to incorporate SSI-related HRQOL measures in their practice and research. The review is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement [22].

Methods

The systematic review was conducted according to a prespecified protocol (available from the authors on request). Ethical approval was obtained from the London School of Hygiene & Tropical Medicine Research Ethics Committee (LSHTM Ethics Ref 8745).

Eligibility Criteria

The review included studies of any design in which utility values for SSI were either invoked (e.g., model-based economic evaluations) or elicited (e.g., valuation exercises), or at least one generic or specific non-preference-based instrument was administered to a cohort of patients with SSI (e.g., clinical trials and burden-of-illness studies). All explicit SSI definitions were accepted. Only those studies that investigated surgical wound outcomes in patients undergoing open surgery were included. No language restrictions were applied.

The following categories of studies were excluded: studies that did not explicitly report utility values or HRQOL data for a cohort of patients with SSI; studies that did not explicitly investigate surgical wound outcomes; studies that had as a primary outcome a composite of multiple surgical outcomes, even if it included SSI or wound healing; studies looking at nonsurgical wounds (e.g., burns, diabetic ulcers, and radiation wounds) or other types of infections (e.g., systemic infections); study protocols; and conference abstracts.

Information Sources

The following databases were searched from inception in April 2014: OVID MEDLINE and MEDLINE-In-Process, OVID EMBASE, ISI Web of Knowledge (Science Citation Index), NHS Economic Evaluation Database, and Wiley Health Economic Evaluation Database. The search strategy (see Appendix 1 in Supplemental Materials found at <http://dx.doi.org/10.1016/j.jval.2015.08.004>) included two categories of search terms: terms associated with wound infection, largely inspired by a previous systematic review of clinical effectiveness of Wound-edge protection devices (WEPDs) [23], and a range of terms relevant for HRQOL studies, thus capturing both widely used generic preference-based multi-attribute utility instruments, such as the EuroQol five-dimensional questionnaire (EQ-5D) [24], health utilities index 2 [25] and health utilities index 3 [26], Quality of Well-Being (QWB)

[27], and six-dimensional health state short form (derived from the 36-item short-form health survey [SF-36]) [28], as well as non-preference-based generic health status measures, such as the 12-item short-form health survey [29] and SF-36 [30,31] health surveys. The latter are of interest because their scores can be mapped through statistical algorithms to preference-based measures and thus generate utility values [32].

Study Selection

The study selection process comprised three phases. In phase 1, the titles and abstracts of returned articles were scanned against the inclusion/exclusion criteria by two independent reviewers (A.G. and H.D.). Articles demonstrating any of the exclusion criteria were eliminated. If a decision could not be taken on the basis of the title and abstract, the article was entered into phase 2. In phase 2, full-text versions of the articles resulting from phase 1 were scanned against the inclusion/exclusion criteria by two independent reviewers (A.G. and G.M.) and assigned a category (A–E) and a subcategory (1–8), as follows: (A) the study mainly reports primary data (i.e., collected specifically for the study) on SSI utility or quality of life; (B) the study contains useful primary or secondary (i.e., unoriginal data collected from already published or other sources) SSI quality-of-life or utility data; (C) the study may have useful economic information on aspects of SSI care, but does not obviously fall into (A) or (B); (D) the study discusses aspects related to SSI care, but neither (A) nor (B) above; (E) the study has no relevance to SSI; (1) economic evaluation (cost-minimization, cost-effectiveness, cost-utility, cost-benefit); (2) cost study; (3) effectiveness study with SSI quality-of-life or health utility data relevant AND an SSI-free control group; (4) effectiveness study other than (3); (5) methodological study on aspects of economic assessment of SSI; (6) review of medical or economic information; (7) other study, for example, purely clinical content, survey of resources and facilities, survey of utilization, estimate of economic burden, health policy, and financing; and (8) foreign language, to be translated. Studies in categories A (1), A (3), B (1), B (3), C (1), and C (3) were carried forward, whereas studies in foreign languages were translated and reassessed. Agreement between the independent reviewers (inclusion/exclusion) was measured using Cohen's kappa [33], and disagreements were resolved through discussion. In phase 3, backward and forward reference searches were conducted for articles retained in phase 2 to identify other potentially relevant articles.

Data Extraction

The following data items were extracted from the articles included after phase 3: study type; setting; type of surgery; population; sample size (for primary studies); HRQOL instrument(s) or utility measure used, as applicable (e.g., EQ-5D); elicitation method; time of elicitation (e.g., 4 weeks after surgery); source(s) for utility values; and utility values/HRQOL scores. Data were extracted independently by two reviewers (A.G. and G.M.), and disagreements were resolved through discussion. In the case of relevant articles reporting primary data on SSI HRQOL scores that could be mapped to health utilities using available statistical algorithms, the authors were contacted with a request to make available a partial, completely anonymized individual patient data set with the detailed HRQOL scores necessary to conduct the mapping, as per the published mapping algorithm. When such primary data were not available, relevant mapping algorithms relying on aggregate scores were sought in the literature and, if available, were applied to derive utilities.

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