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SYSTEMATIC REVIEW

Valuing the Health States Associated with *Chlamydia trachomatis* Infections and Their Sequelae: A Systematic Review of Economic Evaluations and Primary Studies

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ABSTRACT

Objectives: Economic evaluations of interventions to prevent and control sexually transmitted infections such as *Chlamydia trachomatis* are increasingly required to present their outcomes in terms of quality-adjusted life-years using preference-based measurements of relevant health states. The objectives of this study were to critically evaluate how published cost-effectiveness studies have conceptualized and valued health states associated with chlamydia and to examine the primary evidence available to inform health state utility values (HSUVs). **Methods:** A systematic review was conducted, with searches of six electronic databases up to December 2012. Data on study characteristics, methods, and main results were extracted by using a standard template. **Results:** Nineteen economic evaluations of relevant interventions were included. Individual studies considered different health states and assigned different values and durations. Eleven studies cited the same source for HSUVs. Only five primary studies valued relevant health states. The methods and viewpoints adopted varied, and different values for health states were generated.

Conclusions: Limitations in the information available about HSUVs associated with chlamydia and its complications have implications for the robustness of economic evaluations in this area. None of the primary studies could be used without reservation to inform cost-effectiveness analyses in the United Kingdom. Future debate should consider appropriate methods for valuing health states for infectious diseases, because recommended approaches may not be suitable. Unless we adequately tackle the challenges associated with measuring and valuing health-related quality of life for patients with chlamydia and other infectious diseases, evaluating the cost-effectiveness of interventions in this area will remain problematic.

Keywords: chlamydia, economic evaluation, health states, infectious diseases, valuation.

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Introduction

Evidence about the cost-effectiveness of health care interventions is an integral requirement for key decision-making bodies in many countries, including the United Kingdom [1,2]. Many decision-making bodies require interventions to be assessed in terms of their cost per quality-adjusted life-year (QALY), which combines improvements in health-related quality of life (HRQOL) and life expectancy with people's relative preferences for health states [3]. Preference-based health state utility values (HSUVs) assign a value to the health states experienced by the patient. A value of "1" represents full health, and a value of "0" indicates a health state equivalent to being dead. Utility values can be generated directly or indirectly. Standard gamble or time trade-off (TTO) techniques generate direct valuations from patients or the public on the basis of their experiences or hypothetical

scenarios. Indirect methods typically use an instrument to measure HRQOL and then apply preference values obtained from surveys of the general public [4]. The conceptualization of health states and the application of HSUVs can have a major effect on results of cost-effectiveness studies [5,6]. There is a growing body of literature with estimates for HSUVs for a wide range of conditions that can be used to inform cost-effectiveness studies when reliance on primary data is not possible or valid [7]. There are many disease areas, however, in which HSUVs are less widely available, and there are subsets of populations for whom preference-based measurements of HRQOL are less well researched or in whom such measurement is perceived as more difficult [8,9].

Cost-effectiveness studies influence decisions about funding for particular interventions, and so their methodological quality is extremely important [10]. While there has been a growing literature aimed at improving the standard of economic

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evaluations and the decision-analytic models that inform them, less attention has been devoted to the methods involved in identifying and applying HSUVs [6,11]. The conceptualization and structure of a decision-analytic model determines how health states are defined and represented, and so disease processes must be represented appropriately [12].

As with all model input parameters estimated from secondary sources, a systematic review of the literature should be done to identify, assess, and synthesize information to estimate HSUVs and uncertainty needs to be fully reported and examined [11,13,14]. Two sets of criteria are relevant to the assessment and selection of HSUVs [5]. The first relates to the descriptive systems, methods, and sources used to generate the values; in the United Kingdom, these are likely to be assessed against recommendations from the National Institute for Health and Care Excellence (NICE) [15,16]. The second relates to the relevance of the population in the utility study to that in the economic evaluation, in terms of factors such as the condition, its severity, and patients' age profiles.

Many investigators have studied the cost-effectiveness of interventions to prevent, control, and treat *Chlamydia trachomatis* [17–19]. Chlamydia is the most common bacterial sexually transmitted infection (STI) worldwide [20] and in the United Kingdom [21], with an estimated prevalence of 3% to 6% in sexually active 15- to 25-year-olds in the general population [22–24]. Chlamydia first infects the lower genital tract, causing cervicitis in women and urethritis in men, both of which are usually asymptomatic [25] and last more than a year, on average, if untreated [26]. Infection can clear spontaneously or can ascend to the upper genital tract at any time [27], causing symptoms of pelvic inflammatory disease (PID) in 10% to 15% of women [28,29] and epididymo-orchitis in a smaller proportion of men [25]. Symptoms of PID include lower abdominal pain and pain during sexual intercourse. Fallopian tube inflammation can, rarely, cause tubo-ovarian abscess. Tubal scarring and blockage can cause chronic pelvic pain, ectopic pregnancy, and tubal factor infertility [30]. There is uncertainty about the incidence, duration, and timing of late complications because contraception can delay their diagnosis for many years and chlamydia is only one cause [31]. Chlamydial infection during pregnancy is associated with premature labor, and neonatal infection can cause conjunctivitis and pneumonia [32,33].

Screening for chlamydia infection in asymptomatic sexually active young adults is recommended because of the frequency of asymptomatic infections, the severity of complications, and the easy availability of both reliable diagnostic tests and efficacious antibiotic treatment. If decision makers are to interpret cost-effectiveness analyses of interventions to prevent and control chlamydia appropriately, their HSUVs must reflect the effect on those experiencing complications.

The Challenges Associated with Valuing Health States for Chlamydia

We believe that there are several challenges to the identification, assessment, and utilization of appropriate information on HSUVs for use in economic evaluations of STIs such as chlamydia. First, there are considerations relating to the actual state of infection itself. Chlamydia, like many STIs, is often asymptomatic, and so most infected individuals do not experience any apparent detriment to their quality of life at the time of infection [34], even though the average duration of untreated infection is more than 1 year and people are infectious throughout [26]. There is qualitative evidence, however, to suggest that being tested for chlamydia and receiving a positive diagnosis does have an impact on quality of life, particularly for women [35,36]. Second, owing to the obvious ethical and practical issues associated with studying untreated chlamydia, there is considerable uncertainty about the

natural history of infection and disease, including the timing, incidence, and duration of complications [37,38] and rates and risks associated with reinfection [31].

Third, chlamydia is only one cause of many of the late sequelae associated with the infection. There is limited evidence about whether the etiology of conditions such as chronic pelvic pain or infertility affects HRQOL [39–41]. Qualitative evidence suggests that the stigma associated with STIs mediates the experience of being in the health state [35], and so HRQOL might differ between women with infertility secondary to an STI and those with cancer, for example. Fourth, the health states associated with chlamydial disease last for different amounts of time; tubal infertility might be permanent, while the infection itself and some of its sequelae, such as PID and ectopic pregnancy, are temporary states [42,43]. Temporary health states might involve different methods for valuation, and there is a need to consider how preferences for temporary and permanent states are combined [44]. Fifth, the sequelae associated with chlamydia sometimes occur many years after the initial infection [37], and so issues of time preference are likely to have an effect on the valuation of the health states [45,46]. Finally, the burdens associated with the disease are asymmetrical; although both men and women experience infection, the main complications associated with chlamydia affect women of reproductive age [31], but fertility problems can affect others besides the woman herself. This might affect the conceptualization of health outcomes and decisions about whose preferences should count [47,48].

The objectives of this study were to identify and critically evaluate economic evaluations that included QALYs as an outcome measure to identify how health states have been conceptualized and valued within cost-effectiveness studies. Primary studies that valued relevant health states were also located to examine the data that could be used to inform cost-effectiveness studies incorporating HSUVs for chlamydia and its sequelae.

Methods

We conducted a systematic review following UK Centre for Review and Dissemination guidelines for methods and Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for reporting, where appropriate [49,50].

Inclusion Criteria

Articles were included if they met the following criteria: the participants were men or women with, or at risk of, sexually transmitted chlamydia or its sequelae; the intervention (for economic evaluations) was any medical procedure to prevent, control, or treat chlamydia infection or its sequelae; the main outcomes were either cost per QALY (for economic evaluations) or the measurement and valuation of health states associated with chlamydial infection and its sequelae. We excluded articles that were wholly concerned with conditions affecting the pelvic area and not likely to be connected with STIs.

Search Strategy

The search strategy was constructed to be as inclusive as possible. Six electronic databases were searched (EMBASE, MEDLINE, ISI Web of Science, NHS Economic Evaluation Database, Database of Abstracts of Reviews of Effects, and Health Technology Assessment) up to December 2012 (see Appendix 1 in Supplemental Materials found at <http://dx.doi.org/10.1016/j.jval.2013.10.007>). The reference lists of potentially relevant articles were then manually searched to identify additional studies. We used a three-stage process to identify studies for inclusion, using methods that have been described in detail elsewhere [51]. Two reviewers initially

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