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Utility scores for vesicoureteral reflux and anti-reflux surgery

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Summary

Background—Management of vesicoureteral reflux (VUR) continues to be controversial. In conditions of uncertainty, decision analytic techniques such as cost-utility analysis (CUA) can help to structure the decision-making process. However, CUA analyses require a "utility," a value between 0 (death) and 1 (perfect health) corresponding to the quality of life associated with a health state. Ideally, utility values are elicited directly from representative community samples, but utilities have not been rigorously measured for pediatric urology conditions.

Objectives—To elicit utility scores for VUR and open anti-reflux surgery (ARS) from a representative, well-characterized community sample of adults who have been parents.

Methods—Cross-sectional survey of nationally representative adults who had ever been parents. Each respondent saw one of four descriptions of VUR, with or without continuous antibiotic prophylaxis (CAP) and occurrence of febrile urinary tract infection (UTI). A 6-week postoperative health state following ARS was also assessed. We used the time trade-off (TTO) method to elicit utility scores. Factors associated with utility score were assessed with a multivariate linear regression model.

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Conflict of interest

None.

Results—The survey was completed by 1200 individuals. Data were weighted to adjust for demographic differences between responders and non-responders. Mean age was 52 ± 15 years, 44% were male, and 68% were White. In terms of education, 29% had a college degree or higher. The mean utility score for VUR overall was 0.82 ± 0.28. VUR utility scores did not differ significantly based on inclusion of CAP or UTI in the health state description (p=0.21). The 6-week postoperative period garnered a utility of 0.71 ± 0.43.

Discussion—Our results showed that VUR has a mean utility score of 0.82, which indicates that the community perceives this condition to be a substantial burden. For comparison, conditions with similar utility scores include compensated hepatitis B-related cirrhosis (0.80) and glaucoma (0.82); conditions with higher utilities include neonatal jaundice (0.99) and transient neonatal neurological symptoms (0.95); and conditions with lower utility scores include severe depression (0.43) and major stroke (0.30). Our results suggest that parents consider the burden associated with VUR to be significant, and that the impact of the condition on families and children is substantial.

Conclusions—VUR is perceived as having a substantial impact on health-related quality of life, with a utility value of 0.82. However, use of CAP and occurrence of UTI do not seem to affect significantly the community perspective on HRQOL associated with living with VUR.

Keywords

Urology; Pediatric; Vesicoureteral reflux; Utility

Introduction

Management of vesicoureteral reflux (VUR) continues to be controversial, with clinicians disagreeing about treatment because of a lack of high-quality evidence on which to base care. When uncertainty exists regarding optimal treatment for a condition, decision analytic techniques such as cost-effectiveness analysis (CEA) and cost-utility analysis (CUA) can help to structure the decision-making process, and make estimates as to which treatment alternative is likely to provide the greatest benefit to the most patients [1]. CEA, CUA, and related techniques seek to provide quantitative comparisons of the relative costs and outcomes of one or more treatment strategies for a particular condition.

However, tools such as CUA require condition-specific “health utility” values. A utility is a numerical score (usually between 0 and 1) that quantifies the impact of a health state on the person’s health-related quality of life (HRQOL), with 1.0 representing perfect health and 0 representing being dead. A utility score can be used to calculate a “quality-adjusted life-year,” a measure of the relative decrease in quality of life for a year spent in a given health state, compared with a year spent in perfect health. Elicitation of utility scores from the public can be costly and time-consuming, and many medical conditions have no available utility scores; in such cases, investigators seeking to perform CUA must estimate utilities using clinical judgment and expert opinion. Utility values for most pediatric urologic conditions have not been measured directly.

Utility scores for VUR were previously obtained using a convenience sample through the Amazon.com 'Mechanical Turk' (MTurk) online platform [2], which is not necessarily representative of the general population. Thus, additional assessment using similar VUR health state descriptions in a more representative sample would serve to further define utility values for this high-morbidity condition.

The purpose of this study was to elicit utility scores for health states associated with VUR and anti-reflux surgery from a large, well-characterized national sample of adults who were or have ever been parents.

Patients and methods

Study design

We performed a cross-sectional assessment of utility values using the time-trade off (TTO) approach, to assess utility values for four different VUR health states, as well as anti-reflux surgery. Our institutional review board deemed the study to be exempt from formal review.

Study participant sampling

We conducted the survey using the KnowledgePanel (GfK USA, Inc., New York). This large-scale online panel is based on a random sample of the US population. Subjects are recruited using an address-based sample (ABS) frame; free internet access is provided to those without access. We derive our address-based sample (ABS) frame from the US Postal Service's Computerized Delivery Sequence File (CDSF). The CDSF is essentially a complete list of all US residential addresses, including those that are cell phone-only and often missed in RDD sampling. Several strategies are used to minimize bias in the final sample. Statistical weighting adjustments are made to offset known selection deviations (e.g. oversampling of the four largest states while the panel was being built [c. 2000]). These adjustments are incorporated in the sample's base weight. Other sources of survey error inherent to any survey process, such as non-coverage and non-response are addressed using a panel demographic post-stratification weight as an additional adjustment. These weights are applied prior to selection of a study sample from the KnowledgePanel. Once the sample has been selected, the survey fielded, and the data collected, a post-stratification weight is computed to adjust for any survey non-response as well as any non-coverage, or under- and over-sampling resulting from the study-specific sample design. Benchmark distributions included gender, age, race/Hispanic ethnicity, education, income, region, urban/rural, and internet access.

Instrument development and VUR health states

We developed the survey instrument using a description of VUR based on a literature review, and clinical experience of the investigators. The health states were intended to depict typical experience of a child with moderate VUR, and were intended to be brief but complete (Appendix A). Respondents were randomly assigned to view one of four VUR health states, which varied only by inclusion of continuous antibiotic prophylaxis (CAP) and occurrence of recurrent/breakthrough urinary tract infection (UTI). In addition to the chronic VUR health state, we also developed a shorter-term health state describing a typical 6-week

recovery period after open anti-reflux surgery. Subjects initially completed a practice module on paraplegia, to familiarize them with the format and concepts.

Once developed, the survey and TTO algorithms were tested in-person on a convenience sample of 15 adults (both parents and nonparents), to assess basic comprehension and usability. After modifications, the survey was further pilot tested online in a subset of 40 subjects from the KnowledgePanel. The finalized survey was completed by a sample of 1200 KnowledgePanel adult subjects who were or had ever been parents (300 for each VUR health state). These results served as the basis for the analysis.

Utility elicitation

In our TTO algorithm, subjects read a description of the health state (see Appendix A for the exact wording of the VUR health state description). They were then asked if they would prefer their child to live for the full 10 years with VUR, or if they would prefer that their child live less than 10 years in perfect health (i.e. "trading off" some of the 10 years in exchange for perfect health for the remainder). Depending on their willingness or unwillingness to trade off time for perfect health, subjects progress through the algorithm until reaching the point of indifference. The time remaining at the point of indifference becomes the "time in perfect health" for utility calculation. For subjects consistently unwilling to trade off any time (even a single day), time in perfect health was assigned a value of 0.015 months (approximately 0.5 days).

The health state question were phrased to present the parent and child (or family) as a single unit to minimize difficulties associated with proxy-measurement via the parent [1]. The parent is not asked to separate their child's quality-of-life from their own, or to ignore their own feelings of guilt or obligation as it relates to their child's illness. Thus, our health state descriptions used phrases such as "imagine that your family has a child with kidney reflux…," and "We see that you and your child will live with this condition for 10 years."

The anti-reflux surgery algorithm was structured similarly except that the duration of the health state was 6 weeks (instead of 10 years) and subjects were asked to give up weeks/days of life, instead of months/years.

Utility values were calculated using the formula: [Utility = (time in perfect health)/(time in disease state)]. The "time in disease state" was 10 years (120 months) for the paraplegia and VUR health states, and 6 weeks (42 days) for the anti-reflux surgery health state. The "time in perfect health" was defined as the amount of time in perfect health offered at the point of indifference in the TTO algorithm.

Statistical analysis

For each of the utility scores (reflux and surgery), univariate associations with demographic covariates were investigated using weighted linear regression. Multivariate weighted linear regression models were constructed for each of the utility scores using a stepwise selection procedure. Iagnostic plots were examined to ensure model assumptions were satisfied and sensitivity analysis was performed for outliers of the final fit models. Analyses were

conducted using SAS v 9.3 (SAS Institute Inc., Cary, NC, USA). A *p* value of <0.05 was considered to be statistically significant.

Results

Of 2398 KnowledgePanel panelists assigned to the survey, 1238 completed it, of whom 1200 qualified for inclusion in the study. (As noted in the *Patients and methods* section, the final data were weighted to adjust for demographic differences between responders and the general population.)

The weighted demographic characteristics of the sample are shown in Table 1. The mean age was 52 ± 15 years, 44% were male, 68% were White, and 29% had a college degree or higher.

Utility scores for the four VUR health states are shown in Table 1. The mean utility score for the VUR health state overall was 0.82 ± 0.28. Scores did not differ significantly among four VUR health states (with CAP/with UTI: 0.84± 0.26; with CAP/without UTI: 0.79± 0.30; without CAP/with UTI: 0.82± 0.28; without CAP/without UTI: 0.81± 0.27, p=0.21). Factors significantly associated with VUR health state utility score on univariate analysis included gender, race, and housing type. In the multivariate model, higher score for the VUR health state was associated with female gender (0.04 ± 0.02, *p*=0.008), living in a single family house (0.04 ± 0.02, *p*=0.03), Black (0.10 ± 0.04, *p*=0.008) or Hispanic (0.07 ± 0.04, *p*=0.048) or White race/ethnicity (0.08 ± 0.03, *p*=0.02) compared with “other” race/ethnicity, and having at least one child between 0 and 12 years living at home compared with no children living at home (0.04 ± 0.02, *p*=0.03).

The 6-week post-anti-reflux surgery health state garnered an overall utility of 0.71 ± 0.43 (Table 1). Anti-reflux surgery did not differ significantly across the four VUR health states about which the subjects were asked (with CAP/with UTI: 0.70± 0.42; with CAP/without UTI: 0.71 ± 0.43; without CAP/with UTI: 0.69 ± 0.45; without CAP/without UTI: 0.72 ± 0.42, *p*=0.90). Univariate factors associated with higher utility scores for anti-reflux surgery included White race, higher education, single-family housing, and higher income (Table 1). In the multivariate model, higher score for anti-reflux surgery was associated with higher education (obtaining bachelor’s degree [0.13 ± 0.04, *p*=0.004] or high school degree [0.09 ± 0.04, *p*=0.03] compared with lower than high school education), White race/ethnicity compared with Black race/ethnicity (0.09 ± 0.04, *p*=0.02) or compared with Hispanic race/ethnicity (0.09 ± 0.04, *p*=0.02), and living in a single family home (0.07 ± 0.03, *p*=0.01).

The paraplegia practice health state garnered a mean utility score of 0.71 ± 0.34.

Discussion

Many medical decisions are made in a setting of therapeutic uncertainty. This is certainly the case for VUR, and optimal management is controversial. A recent review identified 10 separate published (and conflicting) treatment guidelines for moderate VUR, indicating uncertainty and confusion, even among experts [3].

In such situations of uncertainty, CUA and CEA offer tools that can provide structure and rationality to the decision-making process. Using these techniques, clinicians, patients and families can estimate the expected benefits - at a population level - of a given treatment approach. Such calculations should not be considered mandates or requirements to treat a particular patient in a particular way; rather, they provide supplemental information to guide decision-making.

One of the major barriers to CUA/CEA in pediatric urology is the lack of available preference-based utility values. Utilities are necessary to conduct CEA and CUA analyses that value appropriately the relative impact of specific conditions and treatments on children and their families. This is particularly true for the many pediatric urologic conditions that, although not fatal, do affect health-related quality of life [4].

Our results showed that VUR has a mean utility score of 0.82. This indicates that the general population, from which our respondents were sampled, perceives this condition to be a substantial burden. The prior elicitation effort using the Amazon Mechanical Turk platform found a utility score of 0.87, with a smaller sample [2]. For reference, published studies have elicited similar utility scores for other conditions including compensated hepatitis B-related cirrhosis (0.80) [5], progression-free survival with chronic lymphocytic leukemia (0.82) [6], and glaucoma (0.82) [7]. Conditions reported to have higher utility values include neonatal jaundice requiring phototherapy (0.99) [8] and transient neonatal neurological symptoms (0.95) [8]. Conditions with lower utility scores include severe depression (0.43) [9] and major stroke (0.30) [10]. Our results suggest that parents consider the burden associated with VUR to be significant, and that the impact of the condition on families and children is substantial. Utility did not vary by inclusion of incident UTI or CAP in the VUR description; apparently, the relative contributions of these elements were not perceived to substantially impact overall HRQOL beyond that associated with VUR itself.

As might be expected, we found a substantially lower preference for the postoperative health state, with a utility of 0.71. Short-term health states in children typically have lower utility values compared with chronic health states [11–13]. However, the overall effect of such short-term disutility is low, as scores are averaged out over the entire year; thus, the 6-week postoperative utility score of 0.71 averages out to a net utility score of 0.97 for the full year (assuming perfect health for the remaining 46 weeks). Thus, brief, temporary health states such as a postoperative period are unlikely to have major impact on the results of CEA or CUA analyses, even if the disutility of the temporary health state is very large, as long as the child is in good health for the rest of the year.

This study should be interpreted in light of its limitations. We did not actively select either patients with VUR or parents of patients with VUR. Although there has been some debate among decision analysis experts regarding the optimal survey population, the consensus is that a sample including both patients and non-patients is most representative of the community perspective on a condition [14]. However, we did limit the study to adults who had ever been parents. Given the structure of our health state descriptions (which require the subject to envision living with and caring for their child who has VUR), we thought that parents would be better able than non-parents to imagine the scenario and estimate their

willingness to trade time for health. However, the parent restriction may have influenced the results, as caregivers (particularly parents) tend to be less willing than non-caregivers to trade time in a TTO, resulting in inflated utility scores [15]. If this is the case, then the utility score from a sample of all adults may actually be even lower than the observed 0.82.

Although the KnowledgePanel is highly representative of the US population, there may be differences between members and non-members, and between responders and non-responders, that influence the results, making our findings less representative of the true community perspective. These differences were minimized by both pre-survey and post-survey mechanisms to make the sample more representative, which adjust for differences between responders and non-responders, but it is unlikely that all such differences can be accounted for. In addition, although the TTO method has become widely adopted because of its feasibility, discriminative power, and face validity [16], the use of this methodology to assess health states in children remains an evolving field, complicated by the need for proxy measurement. As noted in the *Patients and methods* section, we sought to minimize difficulties associated with proxy-measurement by assessing utilities for the parent and child (or family) as a single unit [1]. This approach, however, is not universally accepted.

Some respondents might not have understood the TTO process. Prior research has found that web-based TTO has reliable results [17,18]. Although many internet-based studies are biased by the fact that only respondents with internet access can participate, this effect was mitigated by the fact that the KnowledgePanel actively recruits and enrolls participants both with and without internet access using address-based sampling.

Conclusion

In a community-based sample, VUR is perceived as having a substantial impact on health-related quality of life, with a utility value of 0.82. However, use of CAP and occurrence of UTI do not seem to affect significantly the community perspective on HRQOL associated with living with VUR.

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Appendix A

Respondents to the survey were asked to read descriptions of health states for vesicoureteral reflux and for the postoperative health state after open anti-reflux surgery. The health state description for VUR was as follows, with the sections on CAP and UTI in brackets. Respondents were randomly selected to view health state descriptions with or without the CAP and UTI sections, resulting in four groups (+CAP/+UTI, +CAP/−UTI, −CAP/+UTI, −CAP/−UTI):

> Kidney reflux is a medical condition where the urine backs up into the kidneys from the bladder. It mostly affects young children under the age of 5. Most children

are diagnosed with kidney reflux as babies or young children, usually after a urine infection (sometimes called urinary tract infection). Some children have many infections and these infections may damage the kidneys.

[To prevent these infections, a child will take a small amount of antibiotic medicine each day. This medicine may have minor side effects. There is a tiny risk of serious side effects from the medicine.]

[When a child has a urine infection, they usually have a high fever. They may feel pain or burning with urination and pain in their side or belly. This is treated with antibiotics several times each day for 1–2 weeks. Some children need to be in the hospital for a few days and may need stronger antibiotics. Most children recover, but these infections can cause kidney damage.]

Most children may grow out of kidney reflux over a period of several years, so children with kidney reflux are tested about once a year to see if the kidney reflux has gone away. To do this test, a small tube called a catheter is passed through the urethra and into the bladder. Fluid is put through the tube into the bladder and several x-rays will be taken as the bladder fills. More x-rays are taken as the child urinates. This reflux test takes about 20 minutes.

A few children will need surgery to fix the kidney reflux. This happens if the child has many urine infections, or if the kidney reflux does not go away on its own. In some children, kidney damage from reflux and infections can cause serious medical problems as they get older, including high blood pressure or problems with kidney function.

Now imagine that your family has a child with kidney reflux as just described. Now imagine that we can see your future. We see that you and your child will live with this condition for 10 years. However, we can make you the following offer: instead of living for 10 years with kidney reflux, your child will be in perfect health, but, your child's life will be shorter. In other words, you will have to give up a certain amount of time of your child's life, in exchange for perfect health.

The health state description for recovery from anti-reflux surgery was as follows:

Some children need surgery to fix their kidney reflux. The child needs to be put to sleep using general anesthesia, which has a low risk of problems, including a very tiny risk of death. During the surgery, the surgeon will re-attach the tube connecting the bladder to the kidney in such a way that the reflux is corrected. Most children will stay in the hospital for 1 or 2 nights. They may have pain from the incision and from the bladder. A catheter tube will drain the bladder for 1–2 days. After surgery, a child may have some blood in the urine for about a week, and feel strong urges to urinate for up to 6 weeks. The child will have a scar on the lower belly, below the swimsuit line. There are no long-term side effects of the procedure.

Now, imagine that your family has a child with kidney reflux and your child needs this surgery. Now imagine that you and your child will experience the recovery period from this surgery, as we just described it, for 6 weeks. However, we can

make you the following offer: instead of recovering from the surgery for a period of 6 weeks, your child will spend the recovery period after surgery in perfect health, with none of the problems described above. But, in exchange, your child's life will be shorter. In other words, you will have to give up a certain amount of time of your child's life, in exchange for perfect health during the recovery from surgery.

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Table 1

Utility Scores for VUR and anti-reflux surgery stratified by demographic characteristics (weighted linear regression, univariate analysis).

	Weighted *N* (%)	VUR utility (± SD)	Univariate *p*	Anti-reflux surgery (± SD)	Univariate *p*
Overall sample	**1200**	**0.82 ± 0.28**	--	**0.71 ± 0.43**	--
VUR health state group			0.209		0.898
+antibiotic prophylaxis, +UTI	303 (25)	0.84±0.26		0.70±0.42	
+antibiotic prophylaxis, −UTI	292 (24)	0.79±0.30		0.71±0.43	
−antibiotic prophylaxis, +UTI	313 (26)	0.82±0.28		0.69±0.45	
−antibiotic prophylaxis, −UTI	293 (24)	0.81±0.27		0.72±0.42	
Age, years			0.358		0.814
18–29	71 (6)	0.82±0.27		0.71±0.44	
30–44	356 (30)	0.83±0.30		0.70±0.48	
45–59	381 (32)	0.82±0.27		0.72±0.43	
60+	391 (33)	0.79±0.27		0.70±0.40	
Gender			0.007		0.279
Male	525 (44)	0.79±0.28		0.72±0.41	
Female	675 (56)	0.83±0.27		0.69±0.45	
Education			0.909		0.002
Less than high school	135 (11)	0.81±0.27		0.60±0.47	
High school	375 (31)	0.82±0.28		0.72±0.45	
Some college	344 (29)	0.81±0.27		0.69±0.42	
Bachelors degree or higher	346 (29)	0.81±0.29		0.76±0.40	
Race			0.037		<0.001
White non-Hispanic	813 (68)	0.82±0.25		0.74±0.38	
Black non-Hispanic	138 (11)	0.84±0.31		0.61±0.55	
Hispanic	165 (14)	0.82±0.35		0.63±0.55	
Other	85 (7)	0.73±0.38		0.65±0.54	
Housing type			0.033		<0.001
Single family detached	882 (74)	0.83±0.26		0.73±0.41	
Other	318 (26)	0.79±0.32		0.63±0.49	

	Weighted *N* (%)	VUR utility (± SD)	Univariate *p*	Anti-reflux surgery (± SD)	Univariate *p*
Household income			0.200		0.023
Less than $25,000	203 (17)	0.82±0.28		0.64±0.47	
$25,000 to $49,999	273 (23)	0.78±0.30		0.67±0.46	
$50,000 to $74,999	220 (18)	0.81±0.27		0.74±0.39	
$75,000 to $99,999	189 (16)	0.84±0.28		0.76±0.42	
$100,000+	315 (26)	0.83±0.26		0.73±0.42	
Marital status			0.676		0.350
Married	353 (29)	0.81±0.28		0.69±0.45	
Not married	847 (71)	0.82±0.28		0.71±0.42	
Metropolitan status			0.414		0.783
Metro (Urban)	994 (83)	0.81±0.28		0.71±0.43	
Non-metro (Rural)	206 (17)	0.83±0.26		0.71±0.41	
Region			0.711		0.309
Northeast	213 (18)	0.80±0.29		0.67±0.45	
Midwest	267 (22)	0.83±0.25		0.73±0.39	
South	459 (38)	0.82±0.29		0.69±0.46	
West	261 (22)	0.82±0.28		0.73±0.42	
Children in house			0.138		0.496
None	764 (64)	0.80±0.28		0.70±0.42	
Yes, some age 0–12 years	433 (36)	0.84±0.28		0.71±0.45	

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