ECONOMIC ANALYSIS

original reports abstract

Elicitation of Health Utilities in Oncology in the Kingdom of Saudi Arabia

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PURPOSE Health utilities (HUs) are quantitative measures of quality of life that are used to derive outcomes such as quality-adjusted life years in cost-effectiveness analyses. In the Kingdom of Saudi Arabia, there are no HUs for cancer. This study aimed to generate HU estimates for various health states associated with cancer in the Kingdom of Saudi Arabia.

METHODS Adult citizens of the Kingdom of Saudi Arabia, patients with cancer, and patients without cancer were recruited to participate in an online version of the Time Trade-Off (TTO) survey, a direct method that asks participants to indicate the amount of time they are willing to trade off in return for full health. The time horizon was 10 years. Patients were surveyed on their own health state; patients without cancer were presented with a scenario describing stage III colon cancer and were asked to act as proxies.

RESULTS Mean HU score was 0.398 (n = 398), 0.315 for patients with cancer (n = 199), and 0.482 for patients without cancer (n = 199). Among patients, the largest subgroup with colorectal cancer (n = 105), had a mean HU of 0.296; the subgroup with the lowest mean HU was patients with hepatocellular cancer (n = 3; 0.047), and the subgroup with the highest mean HU was patients with cholangiocarcinoma (n = 5; 0.508). Overall, the initial stage I subgroup (n = 7) had a mean HU of 0.456; initial stage II (n = 25), 0.240; stage II (n = 67), 0.319; and initial stage IV (n = 77), 0.320.

CONCLUSION To our knowledge, this is the first study of this size to elicit HU scores for cancer in the Kingdom of Saudi Arabia. Patients may have had clinically worse disease than the patients in the scenario that was presented to patients without cancer. Further analyses are warranted for specific types of cancer. These HUs can in turn be applied in cost-utility analyses.

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INTRODUCTION

In performing pharmacoeconomic analyses, we need to simultaneously capture costs and outcomes. Outcomes include clinical end points such as survival, remission, relapse, or any other clinically relevant end point and also quality of life of patients who are affected by the disease itself or its treatment.[1] As a matter of fact, in disease states such as in oncology, in which survival, clinical end points, and quality of life are important, cost-utility analysis (CUA) is preferred over simple cost-effectiveness analysis (CEA), because CUA captures quality-of-life end points, whereas CEA captures only clinical end points. Some guidelines actually recommend the use of CEA only when it is inappropriate to perform a CUA.[2]

Although there are several qualitative and quantitative quality-of-life questionnaires, they may or may not be useful in CUAs in which the outcome of interest is quality-adjusted life-years (QALYs). In fact, in CUAs, the results of the pharmacoeconomic analyses are presented as incremental costs per QALY.[3] A QALY is the product of time multiplied by the quantitative measure of quality of life in a certain health state. Thus, a QALY combines measures of both survival and quality of life within the same continuum. In other words, to obtain a QALY, one has to multiply the quality-adjusted weight or utility by the time in that state and then sum the results for all the states on a continuum.[1] As a simple example, we can use the case of one QALY being 1 year in full health or 2 years in another health state in which quality of life is at 50% (2 years × 0.5 = 1 QALY). Health utilities (HUs) are basically the quantitative measure of quality of life. HUs are based on preferences rather than a specific clinical measure because they relate to how a patient or a proxy perceives a health state, usually on a scale of 0 to 1, or 0% to 100% in terms of quality of life.

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CONTEXT

Key Objective

There is a scarcity in the Kingdom of Saudi Arabia of health utilities (HUs) which are measures used to calculate quality-adjusted life-years (QALYs), especially in cancer. We estimated HUs in cancer in the Kingdom of Saudi Arabia with both patients and the general public so that we could use the data in Health Technology Assessments for calculating QALYs.

Knowledge Generated

This study provided HU measures for various types and stages of cancer in the Kingdom of Saudi Arabia. Mean HU was 0.398: 0.315 for patients and 0.482 for the general public. The results can be applied in pharmacoeconomic studies and can enable cost per QALY analyses.

Relevance

In the context of decreasing health-care resources in locations such as the Kingdom of Saudi Arabia, pharmacoeconomic studies help decision makers select cost-effective therapies. Thus, HUs will have an indirect impact on formularies that are based on selective reimbursement because they take economic implications into account in addition to clinical aspects.

Basically, zero is assigned to death and 1 (or 100%) represents a state of full health.

There is a clear absence of local data regarding solid values for HUs in the Kingdom of Saudi Arabia, especially in oncology. This absence, in turn, points to difficulties in carrying out incremental cost-utility analyses. To our knowledge, HU data are not readily available on patients in Saudi Arabia in the peer-reviewed literature. The results of our study can, among other things, generate QALYs specific to certain health states to be used for further pharmacoeconomic research (ie, CUAs). The ensuing economic studies can in turn generate evidence for submission to public or private reimbursement agencies. The results of this study combined with a willingness-to-pay exercise can also help us estimate the value of a QALY. Thus, this study was carried out to generate a quantitative estimate of the health-related quality of life, in terms of HUs, for various health states associated with cancer in the Kingdom of Saudi Arabia.

METHODS

Approach for Eliciting HUs

There are different approaches for measuring utility scores for given health states. Tools that elicit HUs can be broadly categorized into either direct or indirect measures. Indirect tools such as the EuroQol five-dimension scale (EQ-5D) require that the patient be able to answer questions on activities or symptoms typical of personal health state. Conversely, direct tools pose a series of preference-based questions to the study patient that do not require an implicit understanding of the minute details of living in that health state, but rather a broad understanding of how quality of life would be affected in that health state. For that reason, and because indirect tools are less sensitive than direct tools, the latter are preferred when surveying the general population, as is the case with a portion of the study participants in this study.

Two common direct HU elicitation tools are the standard gamble (SG) and the Time Trade-Off (TTO), both recommended as direct measures by some guidelines.[2] The techniques associated with the SG are understood to be more complex than those associated with the TTO,[4] introducing the concept of gambling with survival. Questions related to a risk of death are not easily accepted by at least part of the population, and some people would hesitate to risk their lives with instant death, albeit hypothetically, in the hope of gaining the state of full health, which is the basis for the SG approach.

In TTO, developed by Torrance[5] for use in health care, participants are presented with one of two choices: to live for a given length of time in the described health state followed by instant painless death or to live a shorter length of time but in full health followed by instant painless death. The second option is adjusted until the person is indifferent to both of the two options. In the case of patients, the given health state is based on their own health and medical history. The difference with SG is that in TTO, there is no risk of dying instantly. Instead, death is presented in both options as the ultimate outcome after a certain length of time, whereas the primary and immediate outcome is attainment of full health by trading off time. Thus, the preferred tool for eliciting answers to preference-based questions among members of the general public, and especially patients with cancer, is believed to be the TTO.

Process of Eliciting HUs

For the participants from the general public, a scenario was presented on a typical case of stage III colon cancer, with its symptoms, treatments, adverse effects, and prognosis. Participants were then asked to imagine that they were living in that health state and to evaluate their quality of life using a TTO instrument. Table 1 presents a description of the scenario in English, but it is also available in Arabic. For patients, no description was provided. Instead they were asked to think of their own health state, including type of

TABLE 1. Description of the Scenario for the Hypothetical Case Presented to Participants From the General Public

Slide	Hypothetical Scenario
1	Imagine that you have been diagnosed with colon cancer. You underwent abdominal surgery to excise the cancer. You were told the cancer is stage III and it has spread to adjacent lymph nodes. Colon cancer is the most common cancer in men in Saudi Arabia and the third commonest cancer in Saudi Arabian females. Your doctor has recommended that you undergo chemotherapy for 6 months. Chemotherapy means that your physician will insert a central venous catheter and give you the chemotherapy as a 46-hour infusion (through a special plastic pump) once every 2 weeks for a total of 12 cycles (6-month duration). This means that every time you receive your chemotherapy, you have to come back to the chemotherapy day unit 46 hours later to have the pump disconnected.
2	This chemotherapy (the regimen is called FOLFOX) might cause nausea (in 20% of patients), vomiting (20%), or numbness of varying degrees in your hands and feet (70%), which may take several months or years to resolve. It might also cause reversible skin darkening (in 30% of patients), low white blood cell count that might predispose you to infection (10%), diarrhea (10%), and sore mouth (10%). Without receiving this chemotherapy, the chance of cancer recurrence is around 45% and the chance of dying at some point in the next 5 years is 40%. If you undergo this chemotherapy, the chance of cancer recurring is reduced to around 30% and the chance of dying is around 25% in the next 5 years.

Abbreviation: FOLFOX, oxaliplatin, leucovorin, fluorouracil.

cancer, stage, treatment, and its success or failure. Patients were then asked to evaluate their quality of life in that health state using the TTO instrument.

The TTO survey was provided online using an electronic software platform, and participants logged in with unique usernames and passwords. This platform was based on a computerized TTO questionnaire used in other studies.[6] Figure 1 is a screenshot of a page on the TTO Web site, which has both English and Arabic options available.

The computerized software was programmed to present the TTO over a 10-year period, or in other words, to make an offer to live in the described health state for the general public or actual health state for the patients or to trade off time in months and expect in return to have a life with full health in the remaining time followed by instant painless death. The answer from the participant would be elicited either by having a no preference situation, or when the computer ran out of options to propose as it reached the point of neutrality. This was done in a ping-pong fashion, with the tool initially proposing a trade-off in months equal to half the entire period of 120 months (60 months), and then each time a new number of months was traded off as a reply to the participant's answer, the mean between the answer and the previously proposed period (up or down from 60 months) was always used. For instance, if the participant said "No" to the proposed 60 months, the software tool then proposed half-way between 60 months and 120 months (90 months). If the participant had answered "Yes" in the first instance, then the software tool would propose half-way between 60 months and zero. This would continue until either the software tool ran out of numbers to propose and reached an equal number of months between the one proposed and the one answered by the participant or when the participant indicated equality between the choices presented. All English texts on the TTO tool were translated into Arabic. Arabic texts consecutively followed the corresponding English page or segment, and the bilingual version of the tool was presented to all participants.

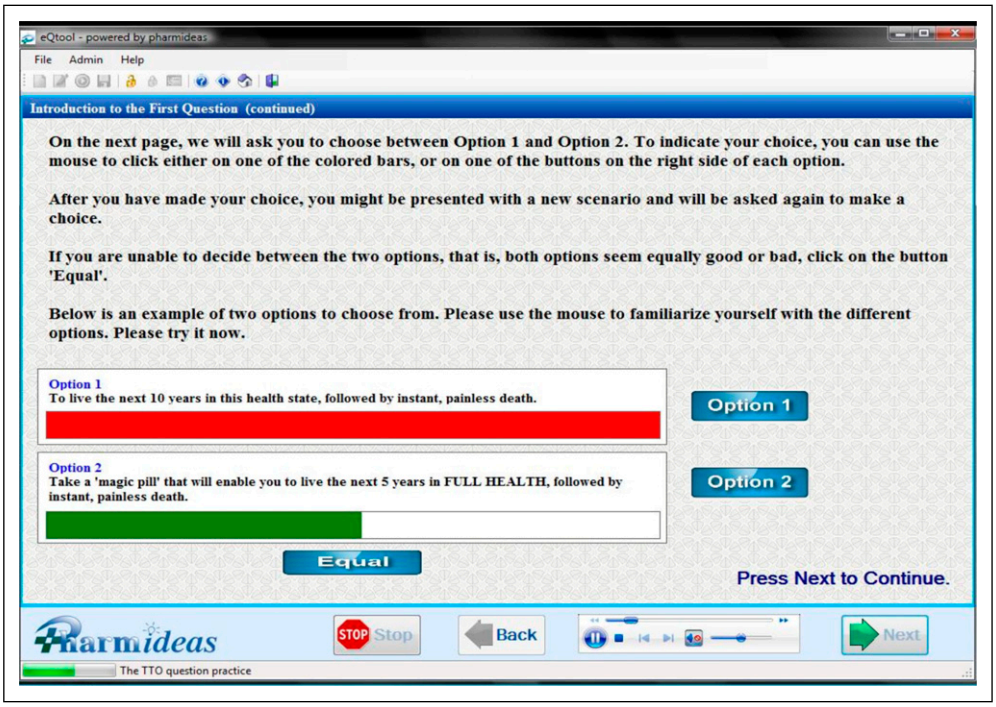

FIG 1. A screenshot of the computerized Time Trade-Off instrument.

TABLE 2. Inclusion and Exclusion Criteria

Criteria	Patients	General Public
Inclusion		
Age, years	18 or older	18 or older
Residency	Kingdom of Saudi Arabia	Kingdom of Saudi Arabia
Disease condition	Cancer	NA
Treatment location	King Faisal Specialist Hospital and Research Centre	NA
Recruitment location	King Faisal Specialist Hospital and Research Centre	King Faisal Specialist Hospital and Research Centre
Language understood	Arabic and/or English	Arabic and/or English
Informed consent	Understood and provided	Understood and provided
Exclusion		
Disease condition	Nonsolid tumors	NA

Abbreviation: NA, not applicable.

Study Population

The study population consisted of an opportunistic cohort recruited at the King Faisal Specialist Hospital and Research Centre over a period of 6 months in 2017. Table 2 summarizes inclusion and exclusion criteria for both the patient group and the general population group. Informed consent was received from each participant before the survey was administered. The study was approved by the ethics review board of King Faisal Specialist Hospital and Research Centre. Recruitment was consecutive, and random assignment was not carried out because it was not necessary for this type of study.

Calculations and Analyses

From the TTO questionnaire, we estimated the remaining time in months that was not traded off, which we then divided by 120 (the number of months in 10 years) to obtain the utility measure. For instance, if 90 months was reached as a final answer (ie, 30 months were traded off), then 90 was divided by 120 and yielded 0.75 as a measure for utility. Demographic statistics were also assessed in term of sex, age, level of education, employment status, and income level. Mean utility was calculated for the overall cohort, the two groups (patients with cancer and patients without cancer), and each subgroup within the patient's groups, as available. Those subgroups were type of cancer, initial stage, presence or absence of metastases, and active treatment or follow-up at interview time. SAS version 9.4 was used for statistical calculations.

RESULTS

Demographics

Table 3 provides the demographics for the overall sample and for the two subgroups. In the overall sample, about three quarters of participants were male, age groups 26 to 35 years and 36 to 45 years had the most participants, more than one third had earned a bachelor's degree, about 40% were employed by the government, and the subcategory with income of 6,001-12,000 Saudi Riyals (SR) had the highest percentage of participants (27%). All of the demographics showed wide differences between the two subgroups of patients and the general public except for sex. Specific subcategories with the least variation were secondary school diploma or equivalent and university certificate or diploma below bachelor's degree.

HUs

Mean HUs of 0.398, 0.482, and 0.315 were determined for the overall group (n = 398), the general population subgroup (n = 199), and patient subgroup (n = 199), respectively, with a statistically significant difference ($P < .001$). Figure 2 illustrates the differences between the general public group and the patient group.

Among patients, the largest subgroup (patients with colorectal cancer; n = 105) had a mean HU of 0.296; the subgroup with the lowest mean HU (0.047) was patients with hepatocellular cancer (n = 3) and the subgroup with the highest mean HU (0.508) was patients with cholangiocarcinoma (n = 5). Overall, the Initial stage I subgroup (n = 7) had a mean HU of 0.456; Initial stage II (n = 25), 0.240; Initial stage III (n = 67), 0.319, and Initial stage IV (n = 77), 0.320. Figure 3 illustrates results by stage of disease. Kruskal-Wallis rank-sum test yielded nonsignificant differences ($P = .55$).

Overall, the Metastases subgroup (n = 85) and No metastases subgroup (n = 104) had similar mean HUs of 0.321 and 0.315, respectively. Overall, the Active treatment at interview subgroup (n = 121) had a mean HU of 0.337, whereas the Follow-up at interview subgroup (n = 68) had a mean HU of 0.275. Table 4 presents detailed results in terms of median and mean for the group of patients.

DISCUSSION

Eliciting HUs is an important step in the calculation of QALYs, which in turn are used as the outcome of interest in CUA, a type of pharmacoeconomic analysis. Pharmacoeconomic analyses assess the cost-effectiveness of a new intervention, such as chemotherapy in oncology and compare it with

TABLE 3. Demographics for Each Group of Participants (relative percentages)

Characteristic	Overall Sample (%) (N = 398)	General Population (%) (n = 199)	Patients (%) (n = 199)	Citizens of the Kingdom of Saudi Arabia (%)[a]
Participant type				
Patient	50.0	NA	100.0	NA
Member of the general public	50.0	100.0	NA	NA
Sex				
Male	76.0	77.0	75.0	51.0
Female	24.0	23.0	25.0	49.0
Age group, years[b]				
18-25	7.8	14.5	1.0	11.2
26-35	21.5	39.0	4.0	19.3
36-45	21.5	26.5	16.5	12.6
46-55	18.0	12.5	23.5	8.2
56-65	20.5	5.5	35.5	4.1
66-75	8.5	1.5	15.5	2.2
76+	2.2	0.5	4.0	1.1
Education level				
Attended but did not complete secondary school	24.3	8.0	40.5	12.8
Apprenticeship or trade certificate/diploma	2.0	1.5	2.5	NA
Secondary school diploma or equivalent	18.5	19.5	17.5	34.6
University certificate or diploma below bachelor's degree	8.5	8.5	8.5	NA
Bachelor's degree	37.2	51.5	23.0	38.9
University certificate or diploma above bachelor's degree	9.5	11.0	8.0	3.2
Employment status				
At home (spouse, not working)	11.5	7.0	16.0	NA
Unemployed, including student who does not work	11.7	17.5	6.0	12.7
Retired	21.5	8.0	35.0	NA
Employed (privately)	9.8	13.5	6.0	NA
Employed (government)	39.7	51.0	28.5	NA
Employed (self-employed/business owner)	5.8	3.0	8.5	NA
Income level, SR (monthly)				
Declined to answer	1.0	0.5	1.5	NA
0-3,000	10.0	3.5	16.5	NA
3,001-6,000	15.3	14.5	16.0	NA
6,001-12,000	27.0	30.0	24.0	NA
12,001-20,000	21.7	23.5	20.0	NA
> 20,000	25.0	28.0	22.0	NA

Abbreviation: NA, not available; SR, Saudi Riyals.

[a]General statistics on the population of the Kingdom of Saudi Arabia (related to citizens) are presented for comparative purposes of demographics. Source: General Authority for Statistics, Kingdom of Saudi Arabia.[13]

[b]General statistics for age groups are slightly different for Kingdom of Saudi Arabia citizens (1 year younger).

existing treatments. In turn, results of pharmacoeconomic analyses will help decision makers at public or private drug plans decide which drugs to include in the list of reimbursed drugs. This may have an impact on the way patients are treated because it would affect the choices offered to clinicians within a drug formulary in a specific health system.

To our knowledge, this is the first study to use a cross-sectional survey to report HUs in cancer in the Kingdom of

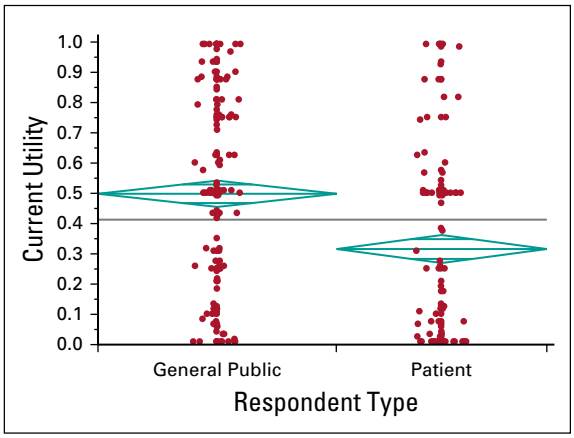

FIG 2. Comparison of health utility scores between patients and members of the general public.

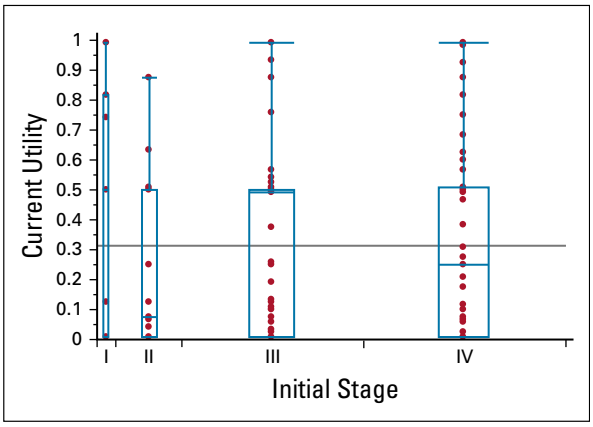

FIG 3. Utility values by stage of disease (patients, n = 176).

Saudi Arabia. We determined HU scores using a computerized TTO tool. The study cohort included participants from the general public who were presented with a scenario describing stage III colorectal cancer and patients with cancer. The proportion of males and females between the two groups was very similar. However, there were differences between the two groups for almost all other sociodemographic characteristics.

Overall, the mean HU for the group of participants from the general public was significantly greater than the mean HU for the patients. It was also quantitatively greater than the means for all the various types of cancer in patients except for cholangiocarcinoma. Among the subgroups of patients, only four (colon, gastric, rectal, or renal cancer) had more than 10 patients. Nevertheless, we reported median and mean HUs for all subgroups of three or more participants. This fragmentation of the data may have introduced some bias; however, we believe it was more important to report these results than to not report at all because of the scarcity of HUs elicited in the Kingdom of Saudi Arabia.

When comparing our results with those from other studies in other countries, there are some similarities and some differences. For instance, in a meta-analysis of HUs, Djalalov et al[7] mention a negative difference of 0.19 between stage IV and stages I to III in colorectal cancer. In our study, we determined that HUs for stage IV were smaller than those for stage I by 0.14. However, our results for stage II were smaller than our results for stage IV, which we considered an anomaly. In another Korean survey of 407 patients with various diagnoses related to liver diseases,[8] the condition with the lowest HU (0.17) was hepatocellular carcinoma with palliative therapy; we also determined hepatocellular carcinoma to have the lowest HU at 0.047, albeit with a small sample size. It is worth noting that both studies reported the same conditions to be associated with the lowest HUs. The same study group also reported another survey of 326 patients with gastric carcinoma who had HU scores of 0.399 for recurrent gastric cancer and 0.404[9] for metastatic gastric cancer. We reported 0.298 as the mean HU for gastric cancer. A Canadian study with a relatively large sample of 585 prostate cancer survivors[10] reported a mean HU of 0.78 using the Health Utilities Index-3 (HUI-3), whereas we determined a mean HU of 0.298 for a small sample of eight patients. This large difference may be due in part to the fact that Krahn et al[10] targeted survivors of prostate cancer, but our subgroup consisted of patients who had prostate cancer. Swinburn and colleagues[11] reported a mean HU of 0.612 for progressive disease in patients with neuroendocrine tumors, whereas in our study, the mean HU for neuroendocrine tumors was 0.312.

Our study had several limitations. First, demographic characteristics of our sample do not correspond to those of the population in general in the Kingdom of Saudi Arabia. Furthermore, our cohort was recruited from only one hospital in Riyadh. Thus, our sample may not be representative of HUs that could be determined in other hospitals or in other parts of the country. This study does present a set of HUs for various types of cancer, and until a more representative and broader sample can be gathered, it offers a glimpse of what could be expected in terms of quantitative elicitation of HUs.

There were some inconsistencies in our results. For instance, the mean HU reported for the subgroup of Initial stage II is smaller than for subgroups with stages III and IV. Moreover, the mean HU reported for Active treatment at interview is a little higher than the mean HU for Follow-up at interview. One would expect that a follow-up visit would mean better health and thus a greater HU; however, the reason for follow-up was not determined, nor was the overall health improvement or deterioration of health, and for some patients, it could be for reasons other than improvement in health. In a study of colorectal cancer in the United Kingdom and the Netherlands,[12] mean HUs for patients after their disease

TABLE 4. HU Results for All Patients

Characteristic	No. of Patients	HU			
		Median	Mean	Standard Error of the Mean	95% CI
Overall patient group	199	0.250	0.315	0.021	0.272 to 0.357
Cancer type[a]					
Bladder	6	0.496	0.415	0.150	0.215 to 0.389
Cholangiocarcinoma	5	0.500	0.508	0.142	0.113 to 0.904
Colon	62	0.192	0.297	0.038	0.220 to 0.373
Colorectal[b]	105	0.208	0.298	0.029	0.239 to 0.352
Gastric	12	0.200	0.298	0.088	0.104 to 0.492
GI stromal tumor	4	0.163	0.208	0.110	0.000 to 0.558
Hepatocellular	3	0.008	0.047	0.039	0.000 to 0.215
Neuroendocrine	7	0.500	0.319	0.112	0.044 to 0.594
Pancreatic	3	0.508	0.439	0.203	0.000 to 1.000
Prostate	8	0.375	0.358	0.118	0.080 to 0.636
Rectal	44	0.254	0.302	0.043	0.199 to 0.970
Renal	20	0.375	0.340	0.073	0.189 to 0.492
Testicular	7	0.250	0.368	0.129	0.053 to 0.683
Initial stage of cancer					
I	7	0.500	0.456	0.155	0.076 to 0.836
II	25	0.075	0.240	0.052	0.132 to 0.348
III	67	0.492	0.319	0.034	0.251 to 0.386
IV	77	0.250	0.320	0.036	0.249 to 0.391
Metastases v no metastases					
Metastases	85	0.275	0.321	0.033	0.255 to 0.387
No metastases	104	0.250	0.315	0.029	0.258 to 0.372
Active treatment *v* follow-up					
Active treatment at interview	121	0.492	0.337	0.027	0.283 to 0.391
Follow-up at interview	68	0.155	0.275	0.036	0.203 to 0.346

Abbreviation: HU, health utility.

[a]Results for types of cancer with fewer than three patients are not reported.

[b]Regrouping of colon cancer and rectal cancer.

progressed with active treatment were greater than those for patients with no treatment (0.824 and 0.662, respectively). These results (although they are much greater than our reported mean HU of 0.298 for colorectal cancer) also suggest that after progression with treatment yielded greater HU scores, as in our study, Active treatment had greater mean HUs than Follow-up (without active treatment).

In conclusion, this cross-sectional TTO-based survey of a cohort from King Faisal Specialist Hospital and Research Centre is, to our knowledge, the first study of this magnitude on elicitation of HUs. Approximately 200 participants from the general public and 200 patients provided answers that were included in the analyses. Participants from the general public who were given a scenario presenting stage III colorectal cancer had greater HU scores than the patients. Among the patients, HUs were elicited for various types of cancer and stages of the disease. The three types of cancer for which we had a sample of 20 or more patients were colon, renal, and rectal.

This study consisted of an exercise to elicit HUs in which patients with cancer and members of the general public from the Kingdom of Saudi Arabia participated in a survey using the TTO. Despite its limitations, this enabled us to determine quantitative measures of quality of life (ie, HUs), which could in turn be used to estimate QALYs in pharmacoeconomic analyses in the Kingdom of Saudi Arabia.

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