

Abstract

Objective: The aim of this study was to explore the feasibility of different health related quality of life valuation methods in a new setting. Based on a small feasibility study of one hundred young Russians, we trialed different methodologies and identified key differences that have implications for the further development of health outcome measurement and health technology assessment in Russia.

Methods: Values were elicited in face-to-face interviews among young Russians. Respondents completed a series of health self-assessments based on the modified version of the EQ-5D-3L, visual analogue scale, time trade-off (better than dead variant), standard gamble and best-worst scaling methodologies covering actual and hypothetical health states. A computer assisted method was used for the time trade-off and standard gamble assessments.

Results: We found that: (i) the visual analogue scale produced significantly lower health valuations and fewer logical inconsistencies than either time trade-off or standard gamble methodologies; (ii) the initial health state can be decisive in governing the value of a given health improvement; (iii) respondents tend to evaluate abstract health states more positively than their own actual health states; (iv) there is evidence consistent with the hypothesis that actual and hypothetical health state valuation, using three level EQ-5D in Russia, is an artefact of understanding rather than preference and that the incorporation of additional levels may therefore be no panacea if the dimensions themselves overlook important attributes; (v) the country context is important both in terms of how respondents relate to the survey tools and in how those survey tools are translated and delivered.

Conclusions: Russia is commencing its health technology assessment journey and should proceed cautiously as it moves towards the valuation of health benefits. These results suggest a useful framework for a more in-depth development of health valuation methodologies in Russia.

Introduction

The Russian healthcare system has undergone a radical transformation since the collapse of the Soviet Union, but its modernization into a more decentralized, insurance-based system remains substantially incomplete. A recent Bloomberg assessment ranked Russian healthcare last from 55 developed countries based on the efficiency of its healthcare system [1]. A combination of population aging, improved disease management, public health campaigns, new technologies and pharmaceutical innovations are further increasing the financial burden on the healthcare system which receives as little as 3.3-3.6% of GDP through government spending [2]. Russia is a laggard in embracing decision-making approaches and technologies in health resource allocation that incorporate the full range of stakeholders. While much of the rest of the developed world now routinely measure the costs and benefits of interventions within the framework of Health Technology Assessment (HTA), Russian health policy is rarely based on scientifically generated empirical evidence.

Moving to an evidence-based system is complex in any country setting, but nowhere more so than in the institutional settings of the former Soviet Union where the long embedded and often contradictory interests of the stakeholders involved, necessitate a careful and gradual evolution of reforms. In Russia, there has been a steady impetus towards the development of an evidence-based approach. In 2012, major reforms were initiated that have given rise to the introduction of a Diagnosis Related Group (DRG) system along with attempts at incorporating HTA (for medicine) into Russian laws. In 2015, the Ministry of Health established a Center for Healthcare Quality Assessment and Control which serves as the main official agency in Russia charged with delivering improved processes, guidelines, transparency and public education to the field of healthcare decision making.

Encouraging though this progress is, it represents only a start. While HTA now has a formal place in healthcare development strategies, the scholarly research and the associated knowledge exchange networks which connect providers, payers, policy makers, the healthcare industry, health economists and patients remain underdeveloped. There are a cluster of research teams from the health sector that have engaged in medical technology assessments for drugs and therapeutic interventions [3] and a small

number of health economists undertaking economic and cost-based evaluations in treatment and screening [4-6] but demand from policy-makers remains low as there is little knowledge of how to use economic evaluation. There are also growing numbers of studies [7-11] that use health-related quality of life (HRQoL) instruments, such as EQ-5D, in specific clinical settings (e.g. musculoskeletal and cardiovascular) but there has been no primary research comparing health valuation methods in Russia and only nascent attempts at establishing population norms for EQ-5D [10] and so the prospects for incorporating HRQoL into HTA for evaluating interventions remain distant.

Russia is not alone in beginning the transformation to value-based healthcare. The early experiences of similar countries, in exploring valuation methods, are generating important lessons relating to evaluation techniques and the decisive role – in shaping the values which emerge – of culture, society and religion [12, 13]. These lessons highlight the importance for Russia and other countries of exploring the various possible approaches and methods in the context of their own populations, norms and cultures, as well as the evolving scientific consensus. This paper provides a first attempt at that in the context of Russia by addressing two main questions: (i) how consistent are Russian respondents in evaluating actual and hypothetical health outcomes? (ii) how can health outcome methodologies be effectively implemented in Russia?

Methods

Of the numerous obstacles to the effective adoption of HTA, the measurement and valuation of the benefits associated with healthcare interventions is perhaps the most challenging. Accurate evaluation of these benefits, including as they pertain to HRQoL, is a requirement if HTA is to usefully influence funding, pricing and reimbursement decisions in Russia [14]. The European quality of life five-dimension (EQ-5D) survey tool, translated into a wide range of languages through a standardized protocol [15], is one of the principal instruments for measuring health benefits, allowing comparisons over time and across morbidity group, without relying on incompatible clinical outcome measures [16]. It takes the form of a descriptive system comprising five dimensions (mobility, self-care, usual activities, pain/discomfort and

anxiety/depression) which are rated over either three levels (EQ-5D-3L) or five levels (EQ-5D-5L) giving rise respectively to 243 or 3,125 unique health states. The 'value-sets' that accompany these methods provide population-based judgements, ranging from 0 (dead) to 1 (full health), for each EQ-5D health state. These judgements are ideally obtained from the population using so-called stated preference methods, such as time trade-off (TTO) or standard gamble (SG), or can be indirectly interpreted (from the sample population) through the visual analogue scale (VAS) that forms part of the EQ-5D self-assessment [17]. In the latter case, respondents situate their described health on a line between 0 (worst imaginable) and 1 (best imaginable); while in the former case, respondents effectively trade-off between length of life and quality of life. It is now well-known that different elicitation methods can yield different values [18,19] and that these values can vary within and across countries according to cultural beliefs, the availability of health care, and the structure of social institutions, but little is known about how these factors play out in the Russian context.

To explore the viability of different HRQoL approaches, we conducted a feasibility study, by interviewing a convenience sample of 100 Russian students (age 18-40) in two city campuses (Moscow and St. Petersburg) of the National Research University Higher School of Economics (HSE). The respondents were invited to a computer assisted interview (in Russian) that would last no more than one hour, during which they were asked to provide socio-demographic data and respond to a series of questions concerning different health scenarios. The interview comprised of 6 components: (i) background questions; (ii) EQ-5D-3L; (iii) VAS; (iv) Best-Worst Scaling (BWS); (v) SG (interchanged with); (vi) TTO. For all three preference elicitation methods (VAS, SG and TTO) we use variants measuring preferences for health states better than dead.

The first section included a standard set of questions, adapted for our student-based sample, concerning gender, age, health status, financial situation and marital status. In the second section respondents were asked to evaluate their current health status according to EQ-5D-3L. Drawing on earlier studies [20], respondents were then asked to evaluate, using the VAS, six hypothetical EQ-5D health states (11122, 22222, 21222, 33333, 21232, 11111), selected to include the best and worst states, along with the most

common states from the 2005 Russian Longitudinal Monitoring Survey (RLMS) which collected partial population data based on versions of the five dimensions [21]. We then used the BWS method to examine the respondents' consistency and logic when making judgements about their health [22, 23]. By identifying the best and worst health dimension in the first five hypothetical states listed above we can establish the relative importance of the different dimensions and spot inconsistencies in the logic applied.

Finally, the respondents were asked to evaluate the same five states using the stated preference methods of TTO and SG. We adapted the classical 'props' (board-based) method into an excel-based computer assisted variant in which: for SG, the probability and evaluated health states were adjusted until the respondent indicated equivalence; for TTO, the health states and their associated life expectancies were adjusted until the respondent indicated indifference between a given time in full health and the time spent in each state. To attenuate any bias arising from the order in which TTO and SG were administered we alternated them in delivery.

Prior to commencing the study, we piloted the various tools in a focus group setting where it became clear that there were inconsistencies in the official Russian translation of the EQ-5D-3L. Through further consultation with two certified English-Russian translators we introduced minor changes to the wording of the questions and so used a very close linguistic variant of the official EQ-5D instrument. We have since been in communication with the EuroQoL group concerning the translations and agreed changes to be incorporated in future official translations of the EQ-5D tools.

Results

Our (non-representative) sample was 56% male, drawn from diverse disciplinary degree programmes, 64% were aged 18-22, with the remainder being 40 or younger and the mean age being 21.7. The largest proportion (49%) were non-working students, living in student accommodation (39%) or with parents (38%), of whom 98% considered themselves to be from average or lower income backgrounds and 65% reported their health as 'good'. The EQ-5D-3L self-evaluations, show that 48% of respondents (57% of males and 36% of females) indicated a 'full' health state of '11111', corresponding to an average VAS of 84. A further 42%, indicating that they have one or two moderate problems (32% of females noted

moderate depression in combination with no other problems), were associated with VAS scores ranging from 70 to 77. The remaining 10%, with poorer health, reported VAS scores ranging from 40 to 76. The mean VAS score for those reporting 'good' health in the general questionnaire is 83.1, versus 69.5 for those reporting 'bad' health.

The descriptive statistics for the results of the health state valuation technologies (VAS, TTO and SG) are presented in Table 1. It is immediately striking that, while the mean TTO and SG scores are similar, VAS provides significantly lower evaluations, by more than 20 points in some cases, for each health state. The main difference in values moving between health states, is between 33333 and 21232: the VAS score for the latter is 23.3 higher; for TTO is 31.1 higher; and for SG is 28.2 higher. The reported variances are high, particularly for the TTO. Exploring the strength of the relationship between the three methods using non-parametric correlation tests (Spearman's rho and Kendall's tau) we find no evidence of a relationship between TTO/SG and VAS, while finding evidence of a weak positive relationship between SG and TTO. Kruskal-Wallis tests confirmed that the differences observed between the three methods are statistically significant at conventional 5% levels.

[Table 1 here]

Figure 1 captures the systematic pairwise differences between the different methods. The mean score differences between VAS and other methods are high and almost identical. For VAS-TTO the mean difference is -16.57, while for VAS-SG it is -16.61. The comparison of TTO-SG with VAS-TTO and VAS-SG suggests that VAS tends to collate "middle" values, while TTO and SG are more skewed to lower or higher values. In part, these higher (or lower) values, including the outliers, reflect the individuals attitude to risk as much as they reflect the valuation of health outcomes.

[Figure 1 here]

Having established large statistically significant differences in the results stemming from the three tools we then explored the relative importance of the different dimensions using BWS. Table 2 presents the standardized scores, calculated as the difference between the frequency of being chosen as the most and least preferred attributes in each state, divided by the number of respondents. The score indicates the

mean relative influence of each attribute. The first column (21232), with a single dominant positive and negative dimension provides a trivial example confirming that 'self-care' is the dominant positive attribute and 'pain/discomfort' the dominant negative attribute. The other four states are more instructive. In the case of moderate problems with health (11122), 'usual activities' is the dominant positive attribute, while 'pain/discomfort' is the dominant negative attribute. As health deteriorates (21222), 'self-care' is the only remaining positive dimension, but interestingly, 'usual activities' becomes the dominant negative attribute. As health then deteriorates further (22222), to consistently moderate levels of ill-health, the discrepancies obviously even out and there is no dominant negative attribute, though 'anxiety/depression' seems to assume a greater positive role. Finally, as we allow health to deteriorate evenly across the dimensions (33333), it is 'mobility', and to a lesser extent 'pain/discomfort' that become more important as negative attributes, while 'anxiety/depression' retains its role as the most important positive attribute. While only being based on 5 health states the overall analysis of BWS suggests that individuals understood the interview task and valued health states consistently, with only 4 respondents not altering their choice of the least favorable health dimension when other dimension scores changed.

[Table 2 here]

Finally, our survey was designed specifically to identify possible inconsistencies in the responses and the underlying reasoning for them. First, the ordinal structure of the health dimensions presumes that some health states are logically preferred to others (e.g. 11122 should be strictly preferred to 21222). Pairwise comparisons of these cases shows that, in the case of VAS, only 1% of comparisons breach the logic, while for SG and TTO this percentage reaches 14% and 13%, respectively. Second, our survey allows us to compare health states from the self-reported EQ-5D results with the corresponding states in the abstract VAS evaluation. We find that the respondents tend to evaluate hypothetical health states more favorably than their actual perceived health states. For example, the assessment of the "11111" (21222) health state is higher by 10 (13) points in the abstract evaluation. Third, we conducted a Mann-Whitney test to confirm that there was no substantive impact on the results of the order in which respondents undertook the SG and TTO sections of the survey. Finally, we asked respondents about their familiarity

with long-standing illness and confirmed the hypothesis that those with higher levels of awareness tend to rate their own health less positively.

Discussion

This feasibility study set out to provide the first systematic exploration in Russia of standard preference elicitation methods used for obtaining health state valuations. We find that, even within a relatively homogenous population sub-group, the choice of health elicitation methods has substantive effects on the valuation of both actual and hypothetical health states and that respondents in our sample appear to process and understand the instruments in cognitively distinct ways. Our findings are consistent with closely related studies. A recent Korean study [24], found large differences in the utility scores between SG/TTO and VAS and much narrower differences between SG and TTO. In our research we find no substantive difference between SG and TTO scores, which contrasts with much of the literature and is likely due to our use of the TTO variant that excludes health states worse than death [12, 24, 25]. It is likely that the homogenous and highly educated nature of our sample served to diminish the difference between SG and TTO and that, among the general population, less familiar with risk concepts, a gap would emerge in line with other studies. A Slovenian study [26], also drawing on a sample of university students found VAS scores of 79 ± 15 , compared to our findings of 78.3 ± 12.5 . A Moscow based Russian study, working with an older population cites a provisional VAS score of 75.4 [10].

The Slovenian study contends that psychological factors are more important than physical factors among young respondents, while noting that this is likely to be different among older cohorts. We argue that these claims could be more nuanced still. For example, our respondents tended to have a higher marginal change moving from 'full-health' (11111) to 'full-health' plus moderate 'depression/anxiety' (11112), rather than to 'full-health' plus moderate 'pain/discomfort' (11121), suggesting that psychological factors do indeed dominate. However, our BWS analysis makes very clear that respondents evaluate negative physical dimensions much more strongly than negative psychological dimensions, suggesting that to understand the value added of health interventions, requires consideration of the initial health state.

It is often argued that the 245 health states offered by the EQ-5D-3L are sufficient for any health measurement exercise since typical surveys rarely use even half of these states. However, discussions with our respondents raised separate concerns with using this three-level description method, as it became clear that there were very different views on the severity of the worst state (33333). Notably, some respondents remarked that many routine functions (e.g. computing, social media, gaming, audiovisual entertainment) would still be possible and that therefore there are many states worse than '33333'. In contrast, other respondents commented on the severely disabling nature of this state and compared it unfavorably with death as an alternative state. This highlights two issues. First, using EQ-5D-3L to value health may produce results which are an artefact of the understanding of the different states (e.g. '33333' as severely disabling or as an inconvenience which still allows for substantive routine function) rather than of the underlying preferences or values. Second, while the five-level version of the EQ-5D might attenuate some of the bias by providing for more subtle gradations in health states, the impact of changes in the health dimensions themselves may not be well understood, particularly by the younger population with their distinctive discounting of time.

In a similar vein, our study also explored the perceived difficulty that respondents had in understanding the different methodologies. Unsurprisingly, respondents overwhelmingly reported that the VAS was an easier to understand method than the TTO or SG, which were both considered difficult. A study of the Asian population in Singapore [27] explored in more detail the factors influencing individuals' preferences between the SG and TTO methods, finding only limited evidence that demographic factors determined the preference. However, our results draw attention to the fact that choosing an elicitation methodology also requires us to account for the fact that own health state values differ to hypothetical health state values for many reasons [20].

Consistent with the literature, the results from these different valuation approaches suggest that the method chosen is itself important and that the framing of questions can have a significant effect on respondents' reported health state preferences [28, 29]. VAS, which is not a choice-based method designed to extract individuals' utility directly, generates lower values than direct utility elicitation methods

(e.g. TTO and SG) due to well-known scaling biases inherent in this type of rating-based approach [30]. In general, these choice-based methods hold distinct advantages over rating-type approaches because, in reflecting lifetime experience choices based around evaluating perceived risks, rather than simple numerical ratings, they are conceptually more correct and directly extract individual utilities [31]. The VAS rating scale represents a preference-based method but lacks the equivalent conceptual richness and doesn't reflect how people actually form their preferences. So, while VAS – as part of the EQ-5D – is cheap and easy to administer it should be used in parallel with a choice-based utility elicitation method which takes into account the population context and characteristics [32, 33, 34].

Like all studies, ours has limitations. Most important of all, being a feasibility study, the sample is neither representative of the population nor large enough to do more than draw initial and preliminary conclusions. Related to this, the homogeneity of our sample doesn't allow us to tease out subtle differences in the way people interact with the complex SG and TTO methods. Our study was also constrained by the small number of health states we could plausibly interrogate with the elicitation methodologies. Finally, as in many studies, we were not able to evaluate the health state worse than death. Notwithstanding these limitations our feasibility study suggests some important results that should be explored more fully in a scaled-up study.

Conclusion

As resource constraints in health care delivery become ever more binding, embracing evidence-based decision-making approaches, such as those defined by the framework of HTA, becomes more significant in all countries. Russia is in the early stages of its engagement with HTA and efforts to spread the principles of evidence-based healthcare require continued support from and engagement with the international academy as well as enhanced communication between national and regional stakeholders. While the previous legislative changes embracing HTA (e.g. Law №429-FZ was signed on 22 December 2014), ultimately need to be expanded beyond the field of medicine, it is more urgently incumbent on the academic and industrial sectors to develop the collaborative expertise necessary to build a Russian

science base in Health Economic Evaluation that can provide the appropriate support to organizations, such as the Center for Healthcare Quality Assessment and Control, which are currently steering HTA efforts in Russia.

A central component of the required evidence base concerns the correct measurement and valuation of health outcomes. Although HRQoL data is often collected in Russia: there has been no systematic attempt to value health states; the data are not widely used for informing intervention decisions; and little is known about the attitudes of the Russian population to such approaches. In this feasibility study we describe the results from our survey of different measurement tools and preference elicitation methodologies, including EQ-5D-3L, VAS, TTO, SG, and BWS. We make several important claims relevant both to Russia as it develops its HTA framework and to the wider literature addressing these methodologies and approaches.

First, concerning VAS, TTO and SG, we find strong evidence, consistent with that widely reported in the literature, that VAS produces significantly lower health valuations than either TTO or SG. This may reflect our findings that VAS is the easiest of these methods to understand and produces the fewest logical inconsistencies and/or may reflect the discussion above that VAS is not a directly utility elicitation method. Either way, our sample is a relatively sophisticated one in terms of understanding complex, probability, risk and trade-off based choices and, in view of this, we note that the systematic differences we observe in the assessment methods should be considered when adopting processes of preference elicitation techniques in Russia. Future studies should trial other ordinal preference elicitation methods including discrete choice experiments. Second, regarding BWS, our results show that in considering the value of health improvements, the initial health state can prove decisive so that one 'unit' moves away from severe 'mobility' or severe 'pain/discomfort' states is likely to be of considerably more value than one unit improvements from the corresponding moderate conditions. Third, in terms of EQ-5D-3L, both the dimensions and the levels require careful consideration. Our results suggest that, using the three-level version may produce health values that stem from understanding rather than preference, and that while increasing the number of levels may attenuate this affect, the dimensions themselves may miss important

attributes of health related life quality. Additionally, the country context, including as that pertains to language, is crucial. Finally, our study confirms that who is asked and what they are asked is important: individuals in our sample consistently value abstract health states above actual health states, suggesting either that people may over estimate their own health state within the dimensions or that they adapt to their health experiences in ways that they overlook when making hypothetical health assessments.

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