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Stakeholder opinions on value in healthcare

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ABSTRACT

Objectives To determine how the value of new medicines is defined from the perspective of different stakeholders in nine European countries.

Methods We carried out an explorative survey by conducting in-depth qualitative interviews with a range of experts with health technology assessment, clinical provision, health economics, payer, academic and industry experience. Experts were asked to distribute 100 points over a predefined list of attributes related to value. In total, 30 interviews were conducted with seven academics, five clinicians, nine economists, five payers and four providers. Each of these categories was represented in responses from France, Germany, the Netherlands and the UK.

Results Comments on the interview guide were all positive. There was substantial variation in definitions of value provided by respondents. Most respondents indicated that delivering benefits to the patient is a prerequisite for a healthcare product to be of value, but only half included costs or resource use in their definition. Quantitative responses showed that effectiveness and efficacy were considered the most important attributes of value, followed by safety and side effects. Lower scores were given to other attributes, such as dignity and individualism, and invasiveness of the treatment. Resources and costs associated with complications and readmissions were considered important by academics and economists, but not clinicians.

Conclusions The interview findings indicate that the value of a drug is subjective in being perceived differently by different stakeholders, and for different treatment types. Future research will require evaluation of the views of a larger number of stakeholders in more and different countries to confirm these findings.

INTRODUCTION

Healthcare costs have been rising in recent decades, and further significant rises are increasingly perceived to be unacceptable.¹ As a result, healthcare systems are faced with the challenging task of achieving maximal health benefits for the general population with the resources available. Increasingly, health technology assessment (HTA) is being used to evaluate the value of healthcare products and to decide how resources should be prioritised.^{2,3} However, despite recent moves to implement value-based approaches to pricing new pharmaceutical products,^{4–7} it remains a challenge to define what exactly constitutes value in healthcare, and how the value of a healthcare product should be measured.

Within a healthcare system with a fixed budget, value can be defined as health outcomes achieved per unit of money spent.⁸ However, although effectiveness and safety are key components of

value, the measurement of health outcomes is not straightforward, and commonly used methods may not capture all relevant aspects of value.⁹ In addition, some stakeholders within the healthcare system and society may perceive factors beyond health outcomes to be part of a product's value—for example, innovation and wider societal impact may be considered to be important.^{10–12} The literature does not provide a consistent and universal definition of value in healthcare.¹³ Published definitions range from those valuing outcomes, including health, in monetary terms^{14,15} to those taking into account healthcare system policy objectives, which represent societal rather than individual preferences for states of health,¹⁶ using constructed measures of health outcomes such as the quality-adjusted life-year (QALY).¹⁷ The value of healthcare products under the latter approach may include broader aspects such as the importance placed on a health state by patients or society, the social and psychological aspects of living with an illness or using a technology, and ethical implications.¹⁸ How value is exactly perceived may differ between various stakeholders. For example, Wiffen has recently underlined that for pharmacists understanding the value of healthcare products and interventions is vital, but that it is easy, instead, to become obsessed only with cost.¹⁹

The primary goal of this research was to determine how the value of new medicines is defined from the perspective of different stakeholders in different countries. Furthermore, we aimed to elucidate whether this definition of value might change depending on the type of treatment, as well as to investigate how value is measured. The research was conducted across nine selected countries (Austria, France, Germany, Hungary, Italy, Spain, Sweden, the Netherlands and the UK), selected to include the five largest European Union countries and to cover a range of different healthcare systems, including primarily Bismarck (Germany, the Netherlands, France, Hungary and Austria) and primarily Beveridge models (the UK, Spain, Sweden and Italy). Notably, the dichotomy is not as strict as suggested and many mixed systems exist (eg, Italy), while some countries are or have been in transition (eg, Hungary). We carried out in-depth qualitative interviews with a range of experts with HTA, clinical provision, health economics, payer, academic and industry experience in the nine countries of interest.

METHODS

Semistructured, anonymised interviews were conducted with experts from the nine European countries of interest. Participants were recruited from 120 experts from the broad network of the authors based on their experience as academics,

clinicians, economists, payers and providers. They were randomly approached until a total of 30 agreed to participate. The identity of the sponsor and the authors were concealed from the experts. Vice versa, neither the sponsor nor the authors were aware of which experts were interviewed.

Interviews were conducted between April and June 2015. Interviewees were briefed about the objectives of the research and all gave their informed written consent to participate and for the interviews to be recorded. To provide a level of consistency across the interviews, an interview guide (shown in supplementary material) was developed with open and closed questions based on themes identified from the published evidence base and any obvious gaps in the literature. Interviewees were asked about aspects of value including how they define and measure value in healthcare, and how the value of healthcare products can be recognised. A pilot interview was undertaken among the study team to eliminate any leading questions and reduce bias and possible language barriers before conducting the expert interviews.

A qualitative analysis must initially design the process used to obtain the information, then how that information was collected, transcribed and classified. Afterwards, information is coded so that it will be easier to integrate it in a final report. In order to run this process more accurately, the investigator has to analyse the situation avoiding previous beliefs so that empirical data will not be influenced by him.²⁰

This goal was achieved by organising and storing the interview responses using a software program (NVivo V.10, QSR International). Due to the limited sample size which did not allow a formal trend analysis, the identification of differences and similarities specific to the definition of value and how value is perceived by key opinion leaders, as well as what challenges exist for incorporating the full value of healthcare products were determined without using the NVivo V.10 software. For presentation of the results, anonymity of participants was protected by removing names and creating broad interview categories (eg, clinical expert or economist).

In addition to the qualitative analysis, participants were given a table listing a number of preselected attributes of value (the table was provided in advance of the interviews, and is shown in the supplementary materials), and were asked to distribute 100 points over the attributes, allocating the most points to the attributes that were most important to them. Mean ratings for the various attributes of value were calculated for each country and category of expert. Opinions on the interview were gathered, including views as to whether major issues were missed in our set of preselected attributes.

RESULTS

The 30 participants were distributed across countries as follows: five from France, five from Germany, five from the Netherlands, five from the UK, three from Austria, two from Hungary, two from Italy, two from Spain and one from Sweden. The 30 respondents interviewed comprised seven academics, five clinicians, nine economists, five payers and four providers. Comments on the interview guide were all positive, with no participants suggesting that certain sections were more difficult to answer than others. Despite differentiating between them when allocating points, many of the respondents felt that there was no relevant difference in rating between safety and side effects and no clear distinction between effectiveness and efficacy; accordingly, these two pairs of categories were combined before analysis.

Value from the perspective of different stakeholders

Participants were asked how they would personally define value. The results indicate that value is a subjective concept, with answers differing among the 20 interviewees who answered this question. Most respondents (17/20) indicated that delivering benefits to the patient is a prerequisite for a healthcare product to be of value; benefits were variously described in terms of clinical effectiveness, health-related quality of life (HRQoL), utility, QALYs, efficacy, life extension or improved benefit–risk ratio. Resources and costs associated with complications and readmissions (including cost-effectiveness) were mentioned by 10 experts: France (4), Italy (2), Netherlands (1), and UK (3) within their definition of value. By contrast, they were not mentioned by the Swedish, Spanish, Hungarian and Austrian experts. There was no clear relationship between stakeholder groups and responses.

Scores assigned to attributes of value

Interviewees were asked to distribute 100 points over six attributes of value. In total, 26 respondents completed this table, with mean scores shown in figure 1. Overall, effectiveness/efficacy was considered the most important attribute of value, followed by safety/side effects. Lower scores were given to other attributes, such as resource and cost implications associated with complications, the dignity and individualism of the patient, and time to feeling completely well. There was no suggestion that low scores in subjective categories such as time to feeling completely well were related to difficulties defining these attributes.

Figure 2 shows the distribution of mean scores given to attributes of value by each category of respondents. All groups ranked effectiveness/efficacy as the most important aspect of value, but there were some differences with regard to other aspects. Safety/side effects was considered to be important by most groups, but was scored as less important than resource and cost implications of complications by academics. In contrast to academics and economists, who scored resource and cost implications highly, clinicians gave this attribute a low score, with most weight given to efficacy and safety attributes. Time to feeling completely well was given a particularly low score by clinicians.

Overall, there was substantial variation in the answers of the academic experts and economists. All of the economists valued effectiveness/efficacy highly, with a mean score of 42.2 points. However, safety/side effects were ranked relevantly higher by the German and French economists than by those from other countries (40 and 45 points, respectively). Scores given by providers and payers were generally consistent.

Figure 3 shows the distribution of mean scores given to attributes of value by respondents from those countries for which experts in all categories were interviewed (France, Germany, the Netherlands and the UK). In all countries, effectiveness/efficacy was given the highest scores, but there were some differences among countries with regard to the other aspects of value. For example, respondents from France gave a higher mean score to safety and side effects than experts in other countries, with correspondingly lower weight given to other attributes. Resource and cost implications, as well as dignity and individualism, were ranked higher in Germany than in other countries, whereas the invasiveness of a treatment and time to feeling completely well were scored most highly in the UK. In addition to assigning points to different attributes, interviewees were asked whether they thought that any aspects of value were missing. Half of the respondents (12/23) suggested additional aspects of value that were missing from the list; in

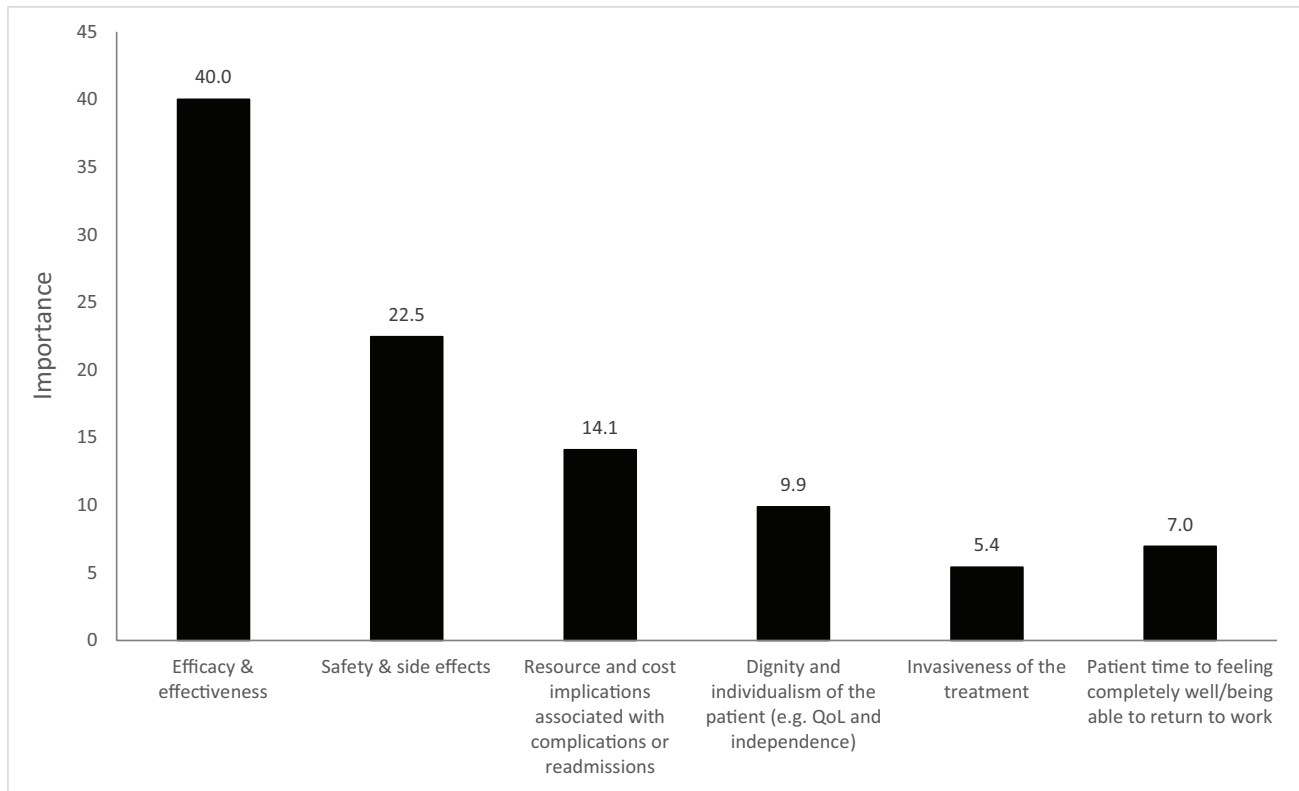


Figure 1 Mean scores assigned to attributes of value. QoL, quality of life.

particular, budget impact (five responses), impact on family or carers (three responses) and cost-effectiveness (two responses) were mentioned. Although interviewees were asked to consider value as an overall concept when scoring the various attributes,

half of the respondents (12/24) stated that they would distribute the points differently depending on the treatment type. For example, 10 interviewees mentioned that HRQoL would be a more important consideration for end-of-life treatments than for

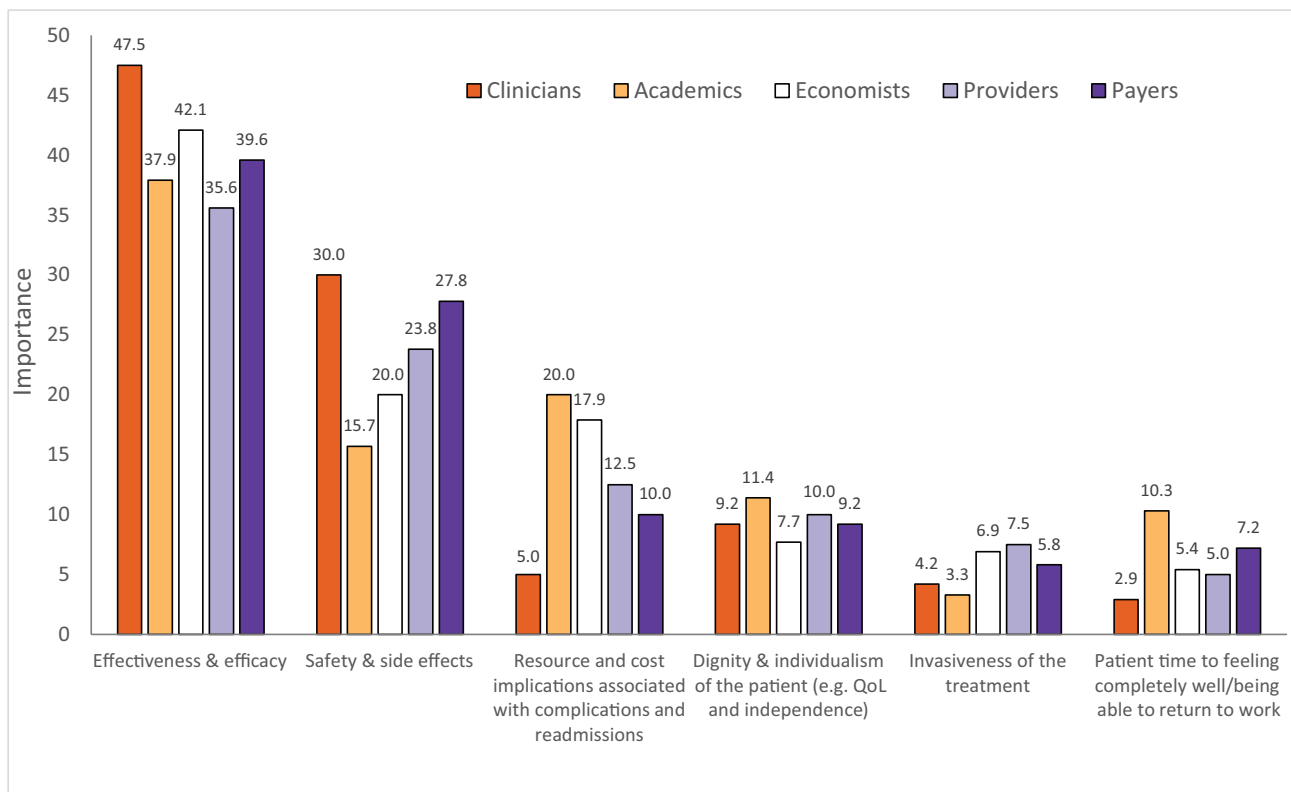


Figure 2 Distribution of mean scores given to attributes of value by each category of stakeholder. QoL, quality of life.

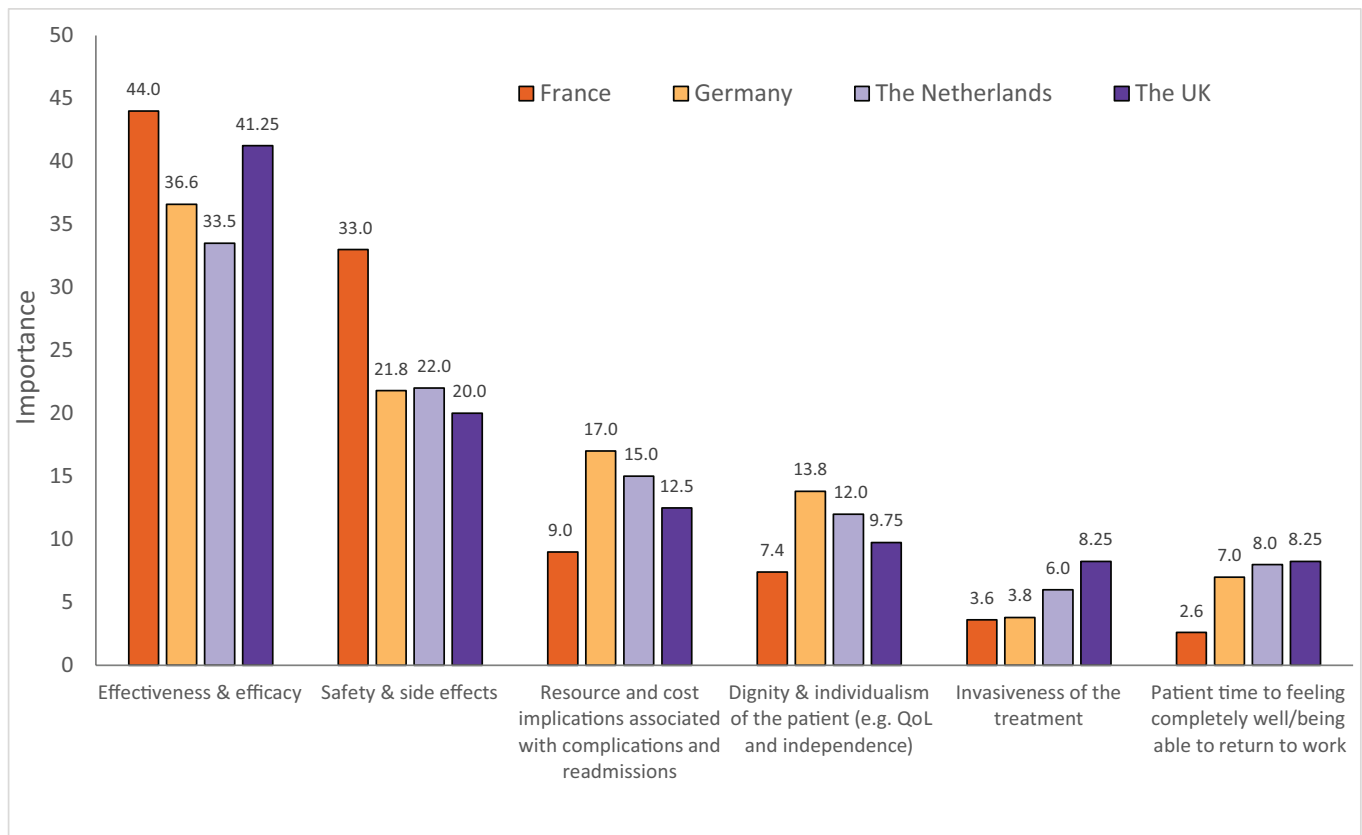


Figure 3 Distribution of mean scores given to attributes of value by respondents from each country. QoL, quality of life.

other therapies. However, only two respondents indicated that they would define value differently depending on the type of treatment being considered; one reason given was that value can vary depending on societal preferences.

Measuring value

Respondents were asked how the value of healthcare products is officially measured within their country. Specific methods of measuring value were provided by three respondents, who mentioned the 5-dimension European Quality of Life questionnaire and the use of discrete choice experiments. The remaining interviewees described the HTA, pricing and reimbursement processes in their countries. Among these, responses from Austrian, French, Hungarian, Italian, Dutch, Swedish and British experts mentioned the use of cost-effectiveness analysis (CEA) in decision making, although it was noted that in France CEA is used only in price negotiations, and that in Italy CEA is not a main driver of final decisions. Of the experts describing the use of CEA, five specifically stated that cost-utility analysis is the preferred tool within the broader context of CEA.

Several respondents discussed the role of different stakeholders within decision-making processes. It was explicitly suggested by three experts from Germany and Hungary that patients should be more involved within their countries. Where patient input is part of the decision-making process, it was noted that patient representatives attending hearings may often not truly be representative of the broader patient population because they could be healthcare professionals rather than having direct experience as patients, or could come from consumer protection organisations; in addition, they are not always an expert on the disease area in question.

In response to a question about resources and costs associated with complications and readmissions considered in the assessment of healthcare products, all 10 answers indicated that direct medical costs are considered, as well as other costs to the payer. For Germany, it was mentioned that healthcare (drug) cost savings are considered. The French experts stated explicitly that indirect costs are not incorporated in decisions, but that direct costs outside the healthcare sector are considered in the price negotiations. In addition, a number of other costs were mentioned that are potentially important. These included indirect costs (five responses), productivity losses (three responses), primary care costs (two responses) and costs associated with readmissions (two responses), emergency care visits (one response) and hospital stays (three responses). Most of these were considered difficult to measure due to lack of information about the actual costs themselves.

Interviewees were asked to describe which outcome measures are used in the assessment of healthcare products in their countries. In general, the parameters listed were similar to those described in the general literature, but a few unexpected factors were suggested, including mention of the use of QALYs by the Hungarian and Austrian experts and the consideration of invasiveness of the treatment, mentioned by one Spanish expert.

DISCUSSION

The objective of this study was to investigate how different stakeholders across nine European countries consider the value of healthcare products. The interview findings indicate that the value of a drug is subjective, and may be perceived differently by different stakeholders, and for different treatment types. The core of a healthcare product's value is the benefits it delivers

to patients, but other aspects are important to different degrees in different settings—for example, all the experts from the UK and most of the French experts viewed costs and resource use as important elements of value.

Using constructed measures of health outcomes such as the QALY can only cover a fraction of the overall value of a product, and often does not overlap with stakeholders' perception. Where a cost per QALY threshold has been applied, this is arbitrary and may not be universally agreed.²¹ In the UK, it has been suggested that the commonly applied threshold of £50 000 in oncology may lead to unequal distribution of the budget for medicines, leading to undertreatment and potentially to more deaths in other indications.²²

When experts assigned scores to a predefined set of attributes of value, effectiveness and efficacy, safety and side effects, and resource and cost implications were considered the most important aspects of value. The most striking difference between different stakeholder groups was between the clinicians who valued safety and side effects very highly, but resource and cost implications very poorly, and the academics who believed resource and cost implications to be important, but gave little weight to safety/side effects.

Today, neither pure Bismarck nor pure Beveridge systems exist, as, for example, both incorporate co-payments whether they are funded from social security premiums or from general taxes. In addition, systems have become mixed in various other aspects and some have transitioned or are transitioning from being primarily one type to being primarily the other. Therefore, a formal classification of insurance-based versus tax-based systems, or of systems with varying levels of co-payment, was not evaluated.

Similar differences in the perception of value by different stakeholders have been found in other studies. A UK study involving multiple stakeholders within the healthcare system, including patients, clinicians and managers, found that different stakeholder groups valued different aspects of healthcare products. While effectiveness, efficacy and safety were generally considered the most important benefits, the importance of other factors including resources and costs associated with complications and readmissions and long-term side effects varied among groups.²³ In particular, patients valued dignity, need for care, convenience, invasiveness of treatment and time to feeling completely well as being very important. Respondents also ranked costs to employers and the economy highly, although the authors noted that these are not typically incorporated into decision making.²¹ Differences in the value of healthcare products according to the type of treatment have also been found in previous studies. For example, a societal preference study in the UK found that respondents would prioritise treatments for severe diseases, and those that address unmet needs have wider societal benefits and are innovative (provided the innovation was associated with substantial health benefits), although no preference for funding end-of-life therapies was found.¹¹ Although both of these studies were conducted only in the UK, this study suggests that these differences in the value of a healthcare product according to the perspective of different stakeholders are also present in other countries.

From the perspective of HTA, four aspects of a product's value have been proposed: clinical utility, including effectiveness and safety; consumer demand, including unmet need; societal perspective, encompassing societal values and ethical considerations; and economic incentives, including the value assigned to innovation and factors related to market competition.²⁴ Many countries take factors other than direct clinical benefits into

consideration when evaluating new therapies, including societal preferences for life-extending treatments at the end of life and broader societal benefits such as burden of illness, availability of alternative treatments, equity and impact on health resources.^{25–27}

This study has some limitations. In particular, our study was conceived as an explorative study in the evaluation of perceptions of value in healthcare by different stakeholder groups in multiple countries. The way the interviews were obtained may have created an allocation bias. However, as we recruited stakeholders from different backgrounds belonging to several independent institutions from different countries for our sample, this bias—if it occurred—should be very low. Overall, the results of our study are in line with the previously published literature, which shows no consistent and universal definition of value in healthcare.^{13–16} The results of our study are in need of confirmation in larger studies, involving more experts and full representation of each of the types of stakeholder considered in this paper in all countries assessed. A larger sample would allow statistical analysis to be applied to the quantitative results of the questionnaire; no statistical testing was possible with the data in this explorative survey. Our study lacked some further potential stakeholder groups. Most notably, inclusion of patient representatives could provide important insights into perceptions of the value of healthcare products. With a number of the included countries lacking significant patient representation in the committees discussing and deciding on value,²⁸ the recruitment of experts reflecting the patient perspective was challenging. Further research into patient perspectives on value in healthcare is needed.

In summary, this study confirms previous literature findings with regard to the absence of clarity and consistency in defining value in healthcare, and illustrates some of the differences between stakeholders in how value is conceived—it is apparent from the survey responses that pharmacists' need for a wider perspective on value¹⁹ is shared by other key groups within the healthcare system. We have developed a set of questions that may be used to elucidate how stakeholders conceive value. Internal and external pilot interviews demonstrated the validity of the questionnaire, with no issues in understanding or interpretation of questions being reported. Future research will require evaluation of the views of a larger number of stakeholders to

What this paper adds?

What is already known on this subject?

- ▶ Despite increasing use of health technology assessment to evaluate new medicines, it remains a challenge to define what exactly constitutes value in healthcare, and how the value of a healthcare product should be measured.
- ▶ Previous studies have suggested that different stakeholder groups value different aspects of healthcare products.

What this study adds

- ▶ Qualitative and quantitative interviews revealed substantial variation in the definitions of value provided by respondents in nine European countries including academics, clinicians, economists, payers and providers.
- ▶ Effectiveness/efficacy was considered the most important attribute of value, followed by safety/side effects, but there was variation among stakeholder groups in the importance of other attributes, including costs and resources associated with complications and readmissions.

confirm these findings and extend the analysis of expert opinions on value in healthcare in additional countries.

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