Journal of Health Organization and Management

Emerald Article: A proposal for a new social values research program and policy network

Peter Littlejohns, Kai Yeung, Sarah Clark, Albert Weale

A proposal for a new social values research program and policy network

Peter Littlejohns
Division of Health and Social Research, King's College London, London, UK
Kai Yeung
Pharmaceutical Outcomes Research and Policy, School of Pharmacy, University of Washington, Seattle, Washington, USA, and
Sarah Clark and Albert Weale
School of Public Policy, University College London, London, UK

Abstract

Purpose – The purpose of this paper is to demonstrate that the social values framework developed by Clark and Weale could be applied to publicly available data and to explore the concordance between the framework values and those present in the statements of decision-making protocols of Health Technology Assessment Agencies.

Design/methodology/approach – The web sites of the National Institute for Health and Clinical Excellence (NICE); the All Wales Strategy Medicines Group; and the Scottish Medicines Consortium were searched for references to social value statements and assessed according to the social values framework.

Findings – The framework was easy to apply and demonstrated that it is possible to find statements of operational expression of a range of social values in the description of the decision protocols used by the public agencies. Most of the framework's values find some expression in the statements of the decision protocols, but there are differences. For example, the All Wales Group, when discussing clinical effectiveness, explicitly refers to an assessment via "pathways of care" in a way that neither of the other two do. The value of autonomy is explicitly mentioned by NICE but not by the other two, whereas the value of solidarity (a value most typically associated with European social insurance systems) finds only indirect expression in the guidance notes of all.

Practical implications – The paper provides further information that will be useful in revising the framework in preparation for its role in future data collection.

Originality/value – This is the initial step in developing a social values instrument that will support health policy decisions. While there are other check lists of social values, this is the first time that an approach to creating a framework is being tested empirically.

Keywords Health care, Health systems, Social values, Priority setting, Health technology assessment

Paper type Viewpoint

The papers in this special edition demonstrate that in many countries social values have a role to play in health policy decision making. However rarely is their contribution recognized in any formal way and it is often unclear as to what influence they have in priority setting decisions.

Over the last few years there has been no shortage of calls encouraging policy makers to incorporate concepts of fairness and equity into deliberations on efficiency. These are often presented as lists of issues and criteria that should be considered

Journal of Health Organization and Management
Vol. 26 No. 3, 2012
pp. 407-421

1477-7266
DOI 10.1108/14777261211239043

(Culyer and Bombard, 2011; Norhiem, n.d.; Shelton, 2012) by policy makers when making priority decisions or health technology assessment (HTA) organizations assessing the value of new interventions (Orr *et al.*, 2011). However the challenge remains how to apply these criteria on a routine basis and in a consistent manner. While there has been considerable debate on which ethical theory should predominate in discussions on how to maximize public health (Roberts and Reich, 2002) less attention has been focused on how to make these decisions. Daniels has sought to fill this gap though an examination of the processes underpinning decisions (Daniels, 2000) and others have resorted to creating frameworks reflecting the multidimensional nature of such decisions (Nancy and Sussex, 2011). But the result is that in practice most decision makers, certainly in the UK Health system (and we suspect elsewhere) make up their own processes (Iqbal *et al.*, 2006) or have no formal processes at all (Brown, 2005; Robertson et al., 2011).

We consider that there is a need to move this applied research agenda forwards. The papers emanating from these workshops prepare the basis for a new multidisciplinary research agenda and the establishment of an international policy research network. The initial research program sets out to achieve two main aims.

The first is to identify the role that social values play in the setting of health care priorities by conducting a cross-national comparative empirical analysis of current policy and experiences. In specific terms the research will:

- Map the institutionalisation of social values in priority-setting decisions in health care, looking at decisions that lead to a "value" being placed on certain interventions. Such interventions include health technology assessment but also cover major issues like the priority to be given to preventive measures. The mapping will cover a number of countries but particular attention will be given to South Korea, Thailand, the UK and the USA.
- Assess the role that social value considerations play in the policy paradigms of those countries both in terms of process and substance.
- Evaluate decision making protocols and processes by reference to an explicit normative theory based on the idea of social contract.

The second aim is to develop guidance for decision makers which is relevant cross-nationally and locally, and that identifies best practices for incorporating social value judgments in health priority decisions which could be encapsulated into a practical decision support tool. This would be aimed not only at policy makers but also at patients and the public both as participants in the decision-making process, and as those who are affected by priority setting and to whom decisions must be justified. We found that the social values draft framework developed for the workshop could be the means of linking the two aims of the program.

The primary aim of the social values framework was to allow practitioners from different countries and disciplines to collect and present comparable data on key process and content parameters. In this context it proved useful. However it was being applied by people who already had a sound understanding of the system of health priority setting in their organization, and in their national setting more widely. This left open the question of how useful the framework might be if employed as part of the broader research program. Would it capture the relevant data? Would a researcher,

who would be unlikely to have prior knowledge of the structures and processes under consideration, be able to use it?

After the workshops we undertook to further test the framework's usefulness and applicability. Three public bodies involved in Health Technology Assessment in the UK were chosen to be in the pilot; the National Institute for Health and Clinical Excellence (NICE) in England; the All Wales Medicines Strategy Group (AWMSG) in Wales and the Scottish Medicines Consortium (SMC) in Scotland. All of these agencies have established health technology assessment programs and have published extensively on how they conduct assessments. A researcher with no prior knowledge of these organizations (Kay Yeung) undertook a reviews of website content and documentation of each of the three HTA bodies in order to identify references to and descriptions of social values by those organizations (NICE, 2011a; SMC, 2011a; AWMSG, 2011a). All references to and descriptions of social values were collated and the compared with the values described in the framework.

Comparison of values "lists"

There was a close match between the values in the draft framework and those contained in documents published by the HTA bodies. Both NICE and AWMSG make statements relating to all seven process and content values Tables I to VIII (clinical effectiveness is separated from cost-effectiveness in the tables whereas they are combined in the framework). The SMC made statements regarding five out of seven of the values; no explicit statements regarding the values of autonomy and solidarity were found. The HTA bodies mentioned three values that were not included in the draft framework: independence, timeliness, and innovation. Independence, as defined by NICE, means that HTA guidance should be conducted without relevant conflicts of interest. Timeliness as defined by NICE means that HTA guidance should be conducted in time to meet the needs of society yet without compromising quality. Innovation as defined by AWMSG suggests that HTA guidance should give particular consideration to therapies which can treat a condition where there was previously no effective treatment, no consistently satisfactory treatment, treatment that was less safe or treatment that was less convenient (AWMSG, 2011b). The values of accountability and transparency were used interchangeably: both values are concerned with identifying individuals involved in making decisions and identifying the rationale behind the decisions (Tables II to III).

Comparison of values descriptions

Not surprisingly, the descriptions of the values by the HTA bodies were more detailed than in the framework although the accompanying paper was more expansive (Clark and Weale, 2012). The concept of "challenge" refers to opportunities for appealing an unreasonable decision and, in its description of accountability, NICE outlines the need for opportunities for challenge and review (Table II). Challenge also refers to opportunities for updating decisions based on new evidence. Additional details regarding the value of participation include considerations about the degree to which different categories of participants might have influence over the decision making process. Consideration was also given to identifying and addressing barriers to participation: for example, SMC is implementing a patient and public involvement group and hiring a public involvement officer (SMC, 2011b).

Source	Value description	Ref.
Accountability		
Framework	Being accountable in health priority setting means having the obligation to answer questions regarding decisions about which interventions are prioritized and why Who is held accountable? Who does the holding to account? For what are the parties accountable? How are the parties accountable? Report of decisions Explanation of reasons behind decisions	Clark and Weale (2011)
NICE	NICE takes into account legislation on human rights, discrimination and equality NICE must follow the principles of the social values judgments document if NICE guidance is to meet NICE's legal and moral obligations to the people it serves. Together the principles fulfill the requirements of "accountability for reasonableness" NICE membership and their roles are listed on the NICE website NICE recommendations and explanation of decisions are posted on the NICE website	NICE (2008, 2011b, c)
SMC	SMC acknowledges the benefits of fostering greater transparency in carrying out its functions and, to that end, has adopted a culture of openness, wherever possible in its dealing with information and wishes to act within the spirit of the [Freedom of Information] legislation by providing a response to information requests NHS Boards will be expected to: Have a written policy which describes the range of systems and processes for the managed entry of newly licensed medicines Describe the process to make formulary decisions SMC membership and their roles are listed on the SMC website SMC recommendations and explanation of decisions are posted on the SMC website	SMC (2011c, d, e, f)
AWMSG	The AWMSG is putting systems in place to strengthen accountability The fair and transparent allocation of drug budgets across all sectors is fundamental to strengthening accountability. AWMSG membership and their roles are listed on the AWMSG website AWMSG recommendations and explanation of decisions are posted on the AWMSG website	AWMSG (2011c, d, f)

Notes: Points for framework development. Challenge: are there opportunities for challenging decisions that are unreasonable, that are reached through improper procedures, or that exceed the proper powers of the decision-maker? (Clark and Weale, 2011); Review: are there mechanisms for revising decisions if more evidence becomes available? (Clark and Weale, 2011)

Table I.
Comparison of process value: accountability

Source	Value description	Ref.
Transparency		
Framework	Everyone knows who makes decision Everyone knows who makes decisions and by what processes Everyone knows who makes decisions, by what processes and for what reasons	Clark and Weale (2011)
NICE	Procedural justice provides for "accountability for reasonableness". For decision-makers to be "accountable for their reasonableness," the processes they use to make their decisions must have four characteristics: publicity, relevance, challenge and revision, and regulation. Publicity: Both the decisions made about limits on the allocation of resources, and the grounds for reaching them, must be made public The names of Appraisal Committee members are posted on NICE's website NICE publishes descriptions of all its guidance development processes to ensure that its work is as transparent as reasonably possible … NICE guidance tries to explain the reasons for the advice and the way NICE has interpreted the available evidence NICE membership and their roles are listed on the NICE website NICE recommendations and explanation of decisions are posted on the NICE website	NICE (2008, 2011b, c)
SMC	SMC acknowledges the benefits of fostering greater transparency in carrying out its functions and, to that end, has adopted a culture of openness, wherever possible in its dealing with information and wishes to act within the spirit of the [Freedom of Information] legislation by providing a response to information requests NHS Boards will be expected to: Have a written policy which describes the range of systems and processes for the managed entry of newly licensed medicines Describe the process to make formulary decisions SMC states the members in attendance at meetings. SMC recognizes the need to pursue as transparent a process as possible and publishes a diagram of the SMC assessment process. Final SMC recommendations are published on the SMC website SMC membership and their roles are listed on the SMC website SMC recommendations and explanation of decisions are posted on the SMC website	SMC (2011c, d, e, f)
AWMSG	The fair and transparent allocation of drug budgets across all sectors is fundamental to strengthening accountability and maximizing the use of available resources Transparent and operate in a way that puts patients' healthcare needs first, whilst providing the most appropriate outcome for the wider population of Wales AWMSG membership and their roles are listed on the AWMSG website AWMSG recommendations and explanation of decisions are posted on the AWMSG website	SMC (2011e, f, g)

Table II.
Comparison of process value: transparency

Source	Value description	Ref.
Participation		
Framework	Involving a range of people in making priority setting decisions – for example, patients, the public, health professionals – can be a way to help improve the quality of those decisions by bringing relevant information and experience to the process Who might participate? Why value participation?	Clark and Weale (2011)
NICE	NICE endorses the value of inclusiveness: the development of NICE guidance should include all parties with a legitimate interest in the guidance This includes relevant professional bodies, patients and patient-carer organizations, health-related industries and the wider public health community. They should be involved in determining the scope of the guidance at the start of the development process, and have an opportunity to comment on drafts of the guidance	NICE (2008)
SMC	SMC membership SMC decisions are made by a panel of experts from different fields including clinicians, public partners, health economists, NHS Board Chief Executives and the Association of the British Pharmaceutical Industry Recruitment of public partners is via advertising through the SMC website and other relevant bodies, i.e. NHS Quality Improvement Scotland, Scottish Health Council, Voluntary Health Scotland and Directors of Public Involvement within Health Boards www.scottishmedicines.org.uk/files/CEL2010_17.pdf www.scottishmedicines.org.uk/About_SMC/Who_we_are/Membership/Membership	
AWMSG	Medical/clinical expert opinion, patients/patient carers/patient organizations www.wales.nhs.uk/sites3/page.cfm?orgid = 371&pid = 37513	

Table III.
Comparison of process value: participation

Notes: Points for Framework development. To what degree might each category of participants participate? i.e. To what degree can a participant have influence over the decision making process? Are there significant barriers to participation?

In terms of clinical effectiveness, the HTA bodies also discussed the types and sources of evidence considered (whether they are randomized trials from the manufacturer or patient testimony). In regard to the value of cost-effectiveness, the HTA bodies discussed acceptable forms of economic modeling (budget impact, cost-effectiveness etc.) and the perspective used (patient, third party payer, societal etc.). Although a payer's perspective is generally accepted, a societal perspective may also be relevant in helping to assess the wider societal costs and benefits of a therapy, for example, whether patients, their families and/or their communities may stand to benefit from the treatment of an individual (AWMSG, 2011b). Additional considerations include whether an HTA body used a formal cost-effectiveness threshold, to what extent

Source	Value description	Ref.
Clinical effectiveness		
Framework	Refers simply to the quality of the benefits it provides for patients: Any intervention showing some evidence of benefit Only interventions that definitely provide benefits Only interventions that definitely provide benefit to patients, and are better than available alternatives	Clark and Weale (2011)
NICE	NICE should not recommend an intervention (that is, a treatment, procedure, action or program) if there is no evidence, or not enough evidence, on which to make a clear decision. But NICE's advisory bodies may recommend the use of the intervention within a research program if this will provide more information about its effectiveness, safety or cost	NICE (2008)
SMC	Considers evidence of the clinical benefits with the drug relative to the most relevant active comparator(s) used in clinical practice. If active-controlled studies are not available, SMC will consider placebo-controlled or uncontrolled studies should be included. Placebo-controlled and uncontrolled studies can also be included if they provide evidence of relevant clinical benefits not demonstrated in active-controlled studies www.scottishmedicines.org.uk/Submission_Process/Submission_Guidance_and_Templates_for_Industry/Templates-Guidance-for-Submission/Templates-Guidance-for-Submission	
AWMSG	AWMSG's judgments on clinical effectiveness take account of the following factors: the nature and quality of the evidence derived from: the robustness and appropriateness of the statistical analyses employed the possible differential effectiveness or greater risk of adverse events in different subgroups of patients the harms and benefits of the medicine as seen from the patient's perspective the position of the medicine in the overall pathway of care and the alternative treatments that are available, including use of unlicensed comparators www.wales.nhs.uk/sites3/Documents/371/Guidelines%20for%20appraising%20medicines.pdf	

Notes: Points for framework development. What are the types of evidence considered? What is the source of the evidence (manufacturer submission, clinical experience, patient experience)

Table IV.
Comparison of content value: clinical effectiveness

thresholds were modifiable in light of specific criteria (such as the potential to generate substantial health gains over existing treatments) and, in cases when a medical technology was denied for reasons of cost-effectiveness, whether there were alternative mechanisms for obtaining that technology.

Source	Value description	Ref.
Cost effectiveness		
Framework	Cost effectiveness aims to maximize the amount of health gained, given the limitations of a certain budget How important is cost-effectiveness, relative to other values? It's just one factor amongst many and should not have privileged status It's one of the most important factors but not always decisive – however it might be unusual for other values to over-rule it It's of primary and decisive importance	Clark and Weale (2011)
NICE	Those developing clinical guidelines, technology appraisals or public health guidance must take into account the relative costs and benefits of interventions (their "cost effectiveness") when deciding whether or not to recommend them Decisions about whether to recommend interventions should not be based on evidence of their relative costs and benefits alone. NICE must consider other factors when developing its guidance, including the need to distribute health resources in the fairest way within society as a whole	NICE (2008)
SMC	The SMC assesses new medicines or treatments for clinical and cost effectiveness www.scottishmedicines.org.uk/files/CEL2010_17.pdf The cost per QALY is only part of a wider judgment of the value of a new medicine. Where the cost per QALY is relatively high, other factors also play a role in SMC's assessment and may modify the final decision www.scottishmedicines.org.uk/About_SMC/Policy_Statements/A_Guide_to_Quality_Adjusted_Life_Years	
AWMSG	All involved with Prescribing and Medicines Management will work together to ensure equity of access to the most appropriate and cost-effective medicines for the people of Wales AWMSG do not use a fixed ICER threshold above which a medicine would automatically be defined as not cost-effective or below which it would. The SMC considers additional factors which can modify the threshold such as the innovative nature of the treatment, the potential to generate substantial health gains over existing treatments, society's priority for the expensive relief of a very serious condition over the relatively inexpensive relief of a mild discomfort etc.	

Notes: Points for framework development. Which form of economic modeling is accepted (budget impact, cost-effectiveness)? What is the accepted perspective of the economic modeling (patient, third party payer, societal etc.). Is there a formal cost-effectiveness threshold? Are there specific criteria which can modify the cost-effectiveness threshold? When a medical technology is denied based on cost-effectiveness, are there alternative means of obtaining the technology?

Table V.
Comparison of content value: cost effectiveness

Source	Value description	Ref.
Justice/equity		
Framework	Patients who are alike in relevant respects should be treated the same, and those who are unlike in relevant respects should be treated in appropriately different ways. All patients with the same condition should be treated the same Some patients should be "positively" prioritized because of their status – e.g. vulnerable populations, the young, the poor, people with dependents Some patients should be "negatively" prioritized because they are responsible for their condition	Clark and Weale (2011)
NICE	Justice, as it relates to healthcare, is concerned with providing services in a fair and appropriate manner NICE subscribes to the widely accepted moral principles that underpin clinical and public health practice including distributive justice "NICE is committed to promoting equality, eliminating unlawful discrimination, and actively considering the implications of its guidance for human rights. It therefore aims to comply fully with legislation on human rights, discrimination and equality Positive prioritization: When choosing guidance topics, developing guidance and supporting those who put its guidance into practice, the Institute should actively consider reducing health inequalities including those associated with sex, age, race, disability and socioeconomic status No negative prioritization: NICE should not take into consideration whether or not a particular condition was self-induced. It was often impossible, in an individual, to decide whether the condition was dependent on their own behavior or not; and receiving NHS care should not depend on whether people 'deserved' it or not	NICE (2008)
SMC	The NHS Boards are expected to equality impact assess their written policy www.scottishmedicines.org.uk/files/CEL2010_17.pdf	
AWMSG	Equity implies the fair distribution of health across individuals All involved with prescribing and medicines management will work together to ensure equity of access SMC takes into account how its judgments have a bearing on distributive justice or legal requirements in relation to human rights, discrimination and equality. Such characteristics include, but are not confined to: age; sex/gender or sexual orientation; people's income, social class or position in life; race or ethnicity; disability; and conditions that are or may be, in whole or in part, self-inflicted or are associated with social stigma www.wales.nhs.uk/sites3/Documents/371/Enc%208%20Update%20to%20AWMSG%20Prescribing%20Strategy.pdf www.wales.nhs.uk/sites3/Documents/371/Guidelines%20for%20appraising%20medicines.pdf www.wales.nhs.uk/sites3/Documents/371/AWMSG%20guidance%20notes%20June11.pdf	

Notes: Points for framework development. What other populations are considered for positive prioritization (populations from lower socioeconomic classes, minorities, those with rare diseases, those facing the end of life)? Is there a statement regarding the rule of rescue? In other words, is there an attempt to resolve the tension between the desire to "rescue" identified individuals who have a dire need regardless of costs vs the need to conserve resources for anonymous patients who may be helped in a more cost-effective manner (SVJ)

Table VI.
Comparison of content value: justice/equity

Source	Value description	Ref.
Solidarity		
Framework	A commitment to the idea that all members of society will stand together and will not exclude or leave anyone behind, no matter how needy or disadvantaged All have access to "comprehensive care", however defined All have access to a "basic package", however defined Entirely private arrangements	Clark and Weale (2011)
NICE	NICE recognizes importance of individual choice and of respecting individuals' values, cultural attitudes and religious views. However, it recognized that it might sometimes be necessary to limit individual choice in the interests of the population as a whole Decisions about whether to recommend interventions should not be based on evidence of their relative costs and benefits alone. NICE must consider other factors when developing its guidance, including the need to distribute health resources in the fairest way within society as a whole	NICE (2008)
SMC	N/A	
AWMSG	The AWMSG works to ensure that the health of the most and least deprived will be more similar www.wales.nhs.uk/documents/designed-for-life-e.pdf Inequalities addressed include the health of children and young people, minority ethnic groups, older people, people with mental health problems, rural health, and women's health www.wales.nhs.uk/documents/designed-for-life-e.pdf	

Table VII.
Comparison of content value: solidarity

In considering the value of justice/equity, the HTA bodies also included additional details. Regarding positive prioritization, the HTA bodies discussed additional populations for prioritization including lower socioeconomic classes, minorities, those with rare diseases, and those facing the end of life. Additionally, NICE discussed the rule of rescue, attempting within that discussion to resolve the tension between, on the one hand, the desire to "rescue" identified individuals who have a dire need regardless of costs and, on the other hand, the need to conserve resources for anonymous patients who might be helped in a more cost-effective manner (NICE, 2008). The definitions for accountability and transparency were found to be highly overlapping. To better define the distinction between these two values, the concepts of independence and timeliness (currently not in the framework) could be considered as part of accountability since it is largely concerned with ensuring that the process of decision-making is acceptable to society (Merriam-Webster, 2011). The value of innovation was important to the HTA organizations but not specifically mentioned in the framework. Innovation could be considered as part of both clinical and cost-effectiveness. For example innovation may modify the perceived value of clinical and cost-effectiveness in cases where an

Source	Value description	Ref.
Autonomy		
Framework	The ability of individuals to be self-directing and to make decisions for themselves about important matters	Clark and Weale (2011)
	We should give low priority to individual preferences, and individual responsibility should not condition access to treatment	
	People should be able to exercise some preferences over some care	
	People are responsible for spending their own money and for their own lifestyle choices	
NICE	Respect for autonomy recognizes the rights of individuals to make informed choices about healthcare, health promotion and health protection. From this arises the concept of "patient choice". The moral principle of respect for autonomy cannot, however, be applied universally or regardless of other social values	NICE (2008)
	NICE subscribes to the widely accepted moral principles that underpin clinical and public health practice including respect for autonomy	
SMC	N/A	
AWMSG	AWMSG/NMG will consider carefully which individuals benefit most from the medicine and whether there are subgroups of individuals for whom the effectiveness evidence suggests differential cost effectiveness. AWMSG/NMG may recommend the use of an intervention for subgroups of the population only when there is clear evidence that the characteristics defining the subgroup influences the effectiveness and/or cost-effectiveness of the intervention	

Table VIII.
Comparison of content value: autonomy

intervention is the first treatment available in a given therapeutic area and when there is still uncertainty regarding the evidence.

Implications for the future research and policy network

In a presentation at the London workshop for which the draft framework was developed, Weale and Clark highlighted that there could be a graded response to whether a criteria has been addressed (see Figure 1 for an example). We intend to explore the possibility of grading the values on a scale from, for example, weak to strong, as it may provide a way of converting qualitative data into a quantitative form which will be useful in assessing the characteristics – that is, the reliability and validity – of the final framework when it is developed into a prioritization support tool. Such a tool could then be used proactively in supporting decision making rather than just assessing decisions retrospectively. Such an approach was used by the AGREE collaboration to create an instrument that was initially used to *assess* the quality of

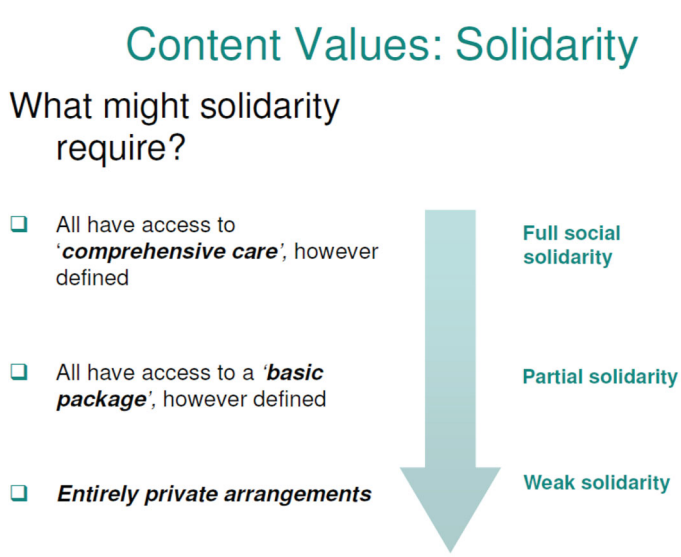

Figure 1.
Showing how a value could be graded by varying degrees of strength, corresponding to features of the relevant system

guidelines but then became a vehicle to help improve the quality of guidelines (Brouwers *et al.*, 2010).

The utility of the framework can be viewed from a number of perspectives – for example, as a means of data collection which allows cross-national institutional comparisons (which is the where the current emphasis is). However, with further development it could be used as reflective tool which aims to help HTA and similar bodies to systematically assess what social values are embedded (implicitly or explicitly) in their decision-making processes and to compare these to what their constituency values. Country-specific set of values interpretations could function as guiding principles for HTA decision makers in designing socially responsive processes and socially responsive assessments of individual interventions (NICE, 2008; Rawlins, 2005).

However, the current purpose of the framework is as a working template for a cross-national comparative research project, in which it will act as a tool to help policy makers and researchers in different contexts to identify when social values are in play, which social values they are, how the balance between values is struck, and whether that balance is socially justifiable. The overall research project is a highly collaborative venture between researchers and policy-makers, and it is envisaged that the framework will evolve over time and be revised and refined in light of the lessons learnt during its use.

References

All Wales Medicines Strategy Group (2011a), "Home page", available at: www.wales.nhs.uk (accessed 28 December 2011).

All Wales Medicines Strategy Group (2011b), "Guidance notes on the completion of Forms A, B & C", available at: www.wales.nhs.uk/sites3/Documents/371/AWMSG%20guidance%20notes%20June11.pdf (accessed 28 December 2011).

All Wales Medicines Strategy Group (2011c), "Getting the best outcomes from medicines for Wales: supporting tactical document 1: quality, safety and effectiveness", available at: www.wales.nhs.uk/sites3/Documents/371/Medicines%20Strategy%201%20Quality%20endorsed%20AWMSG%20April08.pdf (accessed 28 December 2011).

All Wales Medicines Strategy Group (2011d), "AWMSG members", available at: www.wales.nhs.uk/sites3/page.cfm?orgid=371&pid=3159 (accessed 28 December 2011).

All Wales Medicines Strategy Group (2011f), "AWMSG recommendations", available at: www.wales.nhs.uk/sites3/page.cfm?orgid=371&pid=24773 (accessed 28 December 2011).

All Wales Medicines Strategy Group (2011g), "Getting the best outcomes from medicines for Wales: supporting tactical document 2: timely access to medicines", available at: www.wales.nhs.uk/sites3/Documents/371/Medicines%20Strategy%202%20Access%20endorsed%20AWMSG%20April08.pdf (accessed 28 December 2011).

Brouwers, M., Kho, M.E., Browman, G.P., Burgers, J.S., Cluzeau, F., Feder, G., Fervers, B., Graham, I.D., Grimshaw, J., Hanna, S., Littlejohns, P., Makarski, J. and Zitzelsberger, L. (2010), "AGREE II: advancing guideline development, reporting and evaluation in healthcare, for the AGREE Next Steps Consortium", available at: www.agreetrust.org/resource-centre/agree-ii/ (accessed 28 December 2011).

Brown, A. (2005), "Setting priorities for health: an investigation of priority setting for health by primary care trusts in England", submission to the part 11 examination of the Faculty of Public Health of the Royal College of Physicians of Ireland (supervisor: Littlejohns, P.).

Clark, S. and Weale, A. (2012), "Social values in health priority setting", *Journal of Health Management and Organisation*, Vol. 26 No. 3, pp. 293-316.

Culyer, A.J. and Bombard, Y. (2011), "An equity checklist: a framework for health technology assessments", unpublished, available at: http://ideas.repec.org/p/chy/respap/62cherp.html (accessed 12 January 2012).

Daniels, N. (2000), "Accountability for reasonableness", *British Medical Journal*, Vol. 321 No. 7272, pp. 1316-8.

Devlin, N. and Sussex, J. (2011), *Incorporating Multi Criteria in to HTA: Methods and Processes*, OHE, London, available at: www.ohe.org/publications/article/incorporating-multiple-criteria-in-hta-methods-and-processes-8.cfm

Iqbal, Z., Pryce, A. and Afza, M. (2006), "Rationalizing rationing in health care: experience of two primary care trusts", *Journal of Public Health*, Vol. 28 No. 2, pp. 125-32.

Merriam-Webster (2011), *The Merriam-Webster Unabridged Dictionary*, Merriam-Webster, available at: www.merriam-webster.com/ (accessed 28 December 2011).

National Institute for Health and Clinical Excellence (2008), "Social value judgements", 2nd ed., available at: www.nice.org.uk/aboutnice/howwework/socialvaluejudgements/socialvaluejudgements.jsp (accessed 28 December 2011).

National Institute for Health and Clinical Excellence (2011a), "Home page", available at: www.nice.org.uk/ (accessed 28 December 2011).

National Institute for Health and Clinical Excellence (2011b), "Who we are", available at: www.nice.org.uk/aboutnice/whoweare/who_we_are.jsp (accessed 28 December 2011).

National Institute for Health and Clinical Excellence (2011c), "NICE guidance", available at: http://guidance.nice.org.uk/

Norhiem, O. (n.d.), "WHO guidance for priority setting", personal communication.

Orr, S., Wolff, S. and Morris, S. (2011), *What Values Should Count in HTA for New Medicines under Value Based Pricing in the UK?*, Centre for Philosophy, Justice and Health, University College, London, available at: www.ucl.ac.uk/cpjh/mcda.pdf

Rawlins, M. (2005), "Pharmacopolitics and deliberative democracy", *Clinical Medicine*, Vol. 5 No. 5, pp. 471-5.

Roberts, M.J. and Reich, M.R. (2002), "Ethical analysis in public health", *Lancet*, Vol. 359 No. 9301, pp. 1055-9.

Robinson, S., Dickinson, H., Williams, I., Freeman, T., Rumbold, B. and Spence, K. (2011), *Setting Priorities in Health: A Study of English Primary Care Trusts*, Nuffield Trust, London.

Scottish Medicines Consortium (2011a), "Home page", available at: www.scottishmedicines.org.uk (accessed 28 December 2011).

Scottish Medicines Consortium (2011b), "Patient and public involvement group", available at: www.scottishmedicines.org.uk/Public_Involvement/Role_of_Patient_and_Public_Involvement_Group (accessed 28 December 2011).

Scottish Medicines Consortium (2011c), "Templates/guidance for submission", available at: www.scottishmedicines.org.uk/Submission_Process/Submission_Guidance_and_Templates_for_Industry/Templates-Guidance-for-Submission/Templates-Guidance-for-Submission (accessed 28 December 2011).

Scottish Medicines Consortium (2011d), "Introduction and availability of newly licensed medicines in the NHS in Scotland", available at: www.scottishmedicines.org.uk/files/CEL2010_17.pdf (accessed 28 December 2011).

Scottish Medicines Consortium (2011e), "Membership", available at: www.scottishmedicines.org.uk/About_SMC/Who_we_are/Membership/Membership (accessed 28 December 2011).

Scottish Medicines Consortium (2011f), "2010 briefing notes", available at: www.scottishmedicines.org.uk/SMC_Advice/Briefing_Note/2010 (accessed 28 December 2011).

Shelton, J.D. (2012), "Twenty criteria to make the best of scarce health resources in developing countries", *British Medical Journal*, Vol. 344, pp. 26-9.

About the authors

Professor Peter Littlejohns has recently joined King's College London from the National Institute for Health and Clinical Excellence (NICE) where he was the founding Clinical and Public Health Director for 12 years. He holds an MBBS degree from St George's Hospital Medical School and an MD and has a professorial chair at the University of London. Previous posts include Director of the NHS-funded Healthcare Evaluation Unit and Chief Scientist on the EU BIOMED II project, which developed the critical appraisal instrument for clinical guidelines (AGREE). He is a Fellow of the Royal College of Physicians, Fellow of the Royal College of General Practitioners and a Fellow of the Faculty of Public Health. His research interests are directed towards improving the cost effectiveness of healthcare. Professor Peter Littlejohns is the corresponding author and can be contacted at: Peter.littlejohns@kcl.ac.uk

Kai Yeung is a PhD candidate at the Pharmaceutical Outcomes Research and Policy Program at the University of Washington. His research interests include justice in healthcare, and issues around priority setting and health technology assessment.

Sarah Clark is Research Associate on the Economic and Social Sciences Research Council funded project "Social Contract, Deliberative Democracy and Public Policy" at UCL. Her research interests include resource allocation in health, bioethics, theories of justice and the ethics and process of public policy making.

Albert Weale is Professor of Political Theory and Public Policy in the Department of Political Science, University College London. His research has concentrated on issues of political theory and public policy, especially the theory of justice and the theory of democracy, health policy and comparative environmental policy. His principal publications include *Equality and Social Policy* (Routledge and Kegan Paul, 1978), *Political Theory and Social Policy* (Macmillan, 1983), *The New Politics of Pollution* (Manchester University Press, 1992), *Democracy* (Macmillan, 1999 and 2007 revised), *Democratic Citizenship and the European Union* (Manchester University Press, 2005) and, with others, *The Theory of Choice* (Blackwell, 1992) and *Environmental Governance in Europe* (Oxford University Press, 2000), as well as a number of edited works and papers.