

2005 SVJ Document	2008 SVJ Document	Proposed 2019 SVJs (Closest Parallel)
<p>Principles of Bioethics: Respect for Autonomy Non-Maleficence Beneficence Distributive Justice (understood as procedural justice: publicity; relevance; challenge and revision; regulation). Also discussed is the need for ‘broad accountability for reasonableness’ in the NHS because it is constructed on the principle of social solidarity – UK citizens are the ‘ultimate providers’ and therefore must be engaged in the broad principles by which NHS priorities are set.</p>	<p>Principles of Bioethics: Respect for Autonomy Non-Maleficence Beneficence Distributive Justice (understood as procedural justice / accountability for reasonableness: publicity; relevance; challenge and revision; regulation). <i>N.B. The consultation version of this doc was more explicit in highlighting the importance of distributive justice in addressing fairness issues owing to tensions between bioethics principles.</i></p>	
<p>Applying Principles through Process: Legal requirements underpinning NICE guidance.</p> <p>Procedural Principles: Methodological Robustness Inclusiveness Transparency Independence Appeals Review Implementation</p> <p>1. The fundamental principles that underpin the processes by which NICE guidance is developed should be maintained for current, and applied to future, forms of guidance.</p>	<p>Fundamental Operating Principles: Respect for legal obligations and promoting equality, eliminating unlawful discrimination, and actively considering the implications of its guidance for human rights.</p> <p>Procedural Principles: Scientific rigour Inclusiveness Transparency Independence Challenge Review Support for Implementation Timeliness</p>	
		<p>1. Prepare guidance and standards on topics that reflect national priorities for the population’s health and care.</p>
<p>Cost-Effectiveness and Setting Priorities</p> <p>2. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations.</p>	<p>Evidence-Based Decision-Making:</p> <p>1. NICE should not recommend an intervention if there is no evidence, or not enough evidence, on which to make a decision. 2. Those developing guidelines must take account of the relative costs and benefits of interventions.</p>	<p>2. Use evidence that is relevant, reliable and robust.</p> <p>3. Set out the frameworks for interpreting the evidence in our process and</p>

<p>3. NICE guidance should not support the use of interventions for which evidence of clinical effectiveness is either absent or too weak for reasonable conclusions to be reached.</p> <p>4. In the economic evaluation of particular interventions, cost-utility analysis is necessary but should not be the sole basis for decisions on cost effectiveness.</p> <p>5. NICE guidance should explain, explicitly, reasons for recommending – as cost effective – those interventions with an incremental cost-effectiveness ratio (ICER) in excess of £20,000 to £30,000 per QALY.</p> <p>11. Although respect for autonomy, and individual choice, are important for the NHS and its users, they should not have the consequence of promoting the use of interventions that are not clinically and/or cost effective.</p>	<p>3. Decisions about whether to recommend interventions should not be based on evidence of their relative costs and benefits alone.</p> <p>4. NICE usually expresses cost effectiveness in terms of the ICER.</p> <p>5. Although NICE accepts individuals will expect to receive treatment to which their condition will respond, this should not impose a requirement on NICE to recommend non-effective/cost-effective interventions.</p> <p>Orphan drugs are treated the same as others. The rule of rescue is rejected.</p>	<p>methods manuals, and review them regularly.</p> <p>4. Use independent advisory committees to develop recommendations.</p> <p>5. Take into account the advice and experience of people using the services, health and social care professionals, commissioners and providers.</p> <p>6. Base our recommendations on an assessment of population benefits and value for money.</p>
<p>Responding to Comments and Criticism:</p> <p>12. It is incumbent on the Institute and its advisory bodies to respond appropriately to the comments of stakeholders and consultees and, where necessary, to amend the guidance. The board is aware, however, that there may be occasions when attempts are made (directly or indirectly) to influence the decisions of its advisory bodies that are not in the broad public interest. The board requires the Institute, and members of its advisory bodies, to resist such pressures.</p>	<p>Responding to Comments and Criticism:</p> <p>6. NICE should consider and respond to comments it receives about its draft guidance.</p>	<p>7. Give people interested in the topic area the opportunity to comment on and influence our recommendations.</p>
<p>Social Value Judgements – Service Users</p> <p>6. Only recommend the use of a therapeutic or preventive measure for a particular age group when there is clear evidence of differences in the clinical effectiveness of the measure in different age groups.</p> <p>7. There is no case for NICE to distinguish between individuals on the basis of gender or sexual orientation unless these are indicators for the benefits or risks of interventions.</p> <p>8. No priority should be given based on individuals’ income, social class or position in life, and individuals’ social roles, at different ages, should not influence considerations of cost effectiveness. Nevertheless, in developing its approach to public health guidance, NICE wishes its advisory bodies to promote preventative measures likely to reduce those</p>	<p>Avoiding Discrimination and Promoting Equality:</p> <p>Only recommend an intervention for a particular racial (ethnic) group when there is clear evidence of differences in clinical effectiveness.</p> <p>Take special care of the needs of disabled people.</p> <p>In general, patients should not be denied NHS treatment simply because of age. But where certain conditions apply, age may be taken into account.</p> <p>Avoid distinguishing between individuals on basis of gender or sexual orientation, unless there are indicators for benefits or risks.</p>	

<p>health inequalities that are associated with socioeconomic status.</p> <p>9. Only recommend the use of an intervention for a particular racial (ethnic) group if there is clear evidence of differences between racial (ethnic) groups in the clinical effectiveness of the intervention.</p> <p>10. Avoid denying care to patients with conditions that are, or may be, self-inflicted (in part or in whole). If, however, self-inflicted cause(s) of the condition influence the clinical or cost effectiveness of the use of an intervention, it may be appropriate to take this into account.</p> <p>13. Priority for patients with conditions associated with social stigma should only be considered if the additional psychological burdens have not been adequately taken into account in the cost–utility analyses.</p>	<p>Stigma may be taken into account when relief of stigma affects quality of life considerations.</p> <p>Self-induced condition is not relevant to recommendation.</p> <p>Recommendations should be independent of income, social class or position in life.</p> <p>7. Recommend an intervention is restricted when clear evidence of effectiveness or other reasons related to fairness in society as a whole.</p>	
	<p>Public Health: List of considerations to be taken into account when recommending mandatory public health interventions. Accept the NCOB stewardship model.</p>	
	<p>Reducing Health Inequalities: 8. When choosing topics, actively consider reducing health inequalities.</p>	
	<p>Following the Principles: Work should follow the principles of document, which fulfil requirements of A4R. Responsibility to monitor.</p>	<p>8. Lead work with partners to encourage and support adoption of recommendations.</p> <p>9. Assess the need to update publications in line with new evidence.</p> <p>10. Propose new research questions and data collection to resolve uncertainties in evidence.</p>