HTA in the development of clinical guidelines and ethical considerations
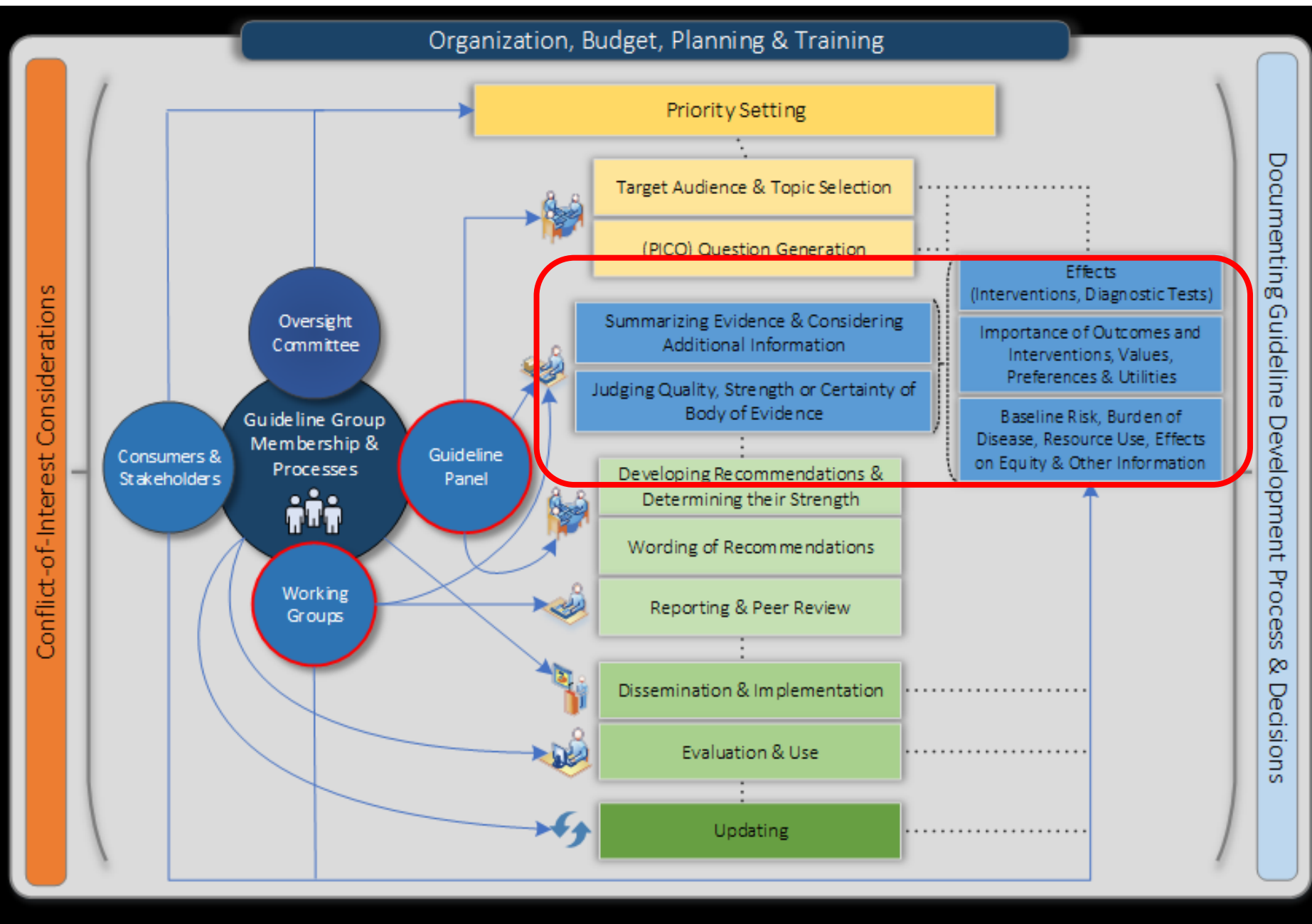
Shelley McGee

Fundisa Workshop 8th – 9th October 2019

Health Technology Assessment For Medicines In South Africa

Agenda

➢Clinical Guidelines – Technical efficiency

➢Ethical considerations – Allocative Efficiency; Fairness; Equity;

GIN-McMaster Guideline Development Checklist.

Clinical Guidelines in South Africa

Table 1. Overview of clinical practice guidelines in South Africa by developer type

	National Department of Health, *n*	Provincial department of health, *n*	Society/ association, *n*	Clinicians/ academics, *n*	Council for Medical Schemes, *n*	Total, *N*
Multiple conditions and populations	9	3	1	0	1	14
Detailed	45	10	104	37	14	210
Position statement	2	1	41	0	0	44
Poster/algorithm	3	4	10	0	0	17
Total	59	18	156	37	15	285

➢Majority developed by Clinical Societies / Associations

➢Majority were detailed Guidelines

Clinical Guidelines in South Africa

Table 2. Summary of findings: Items associated with good-quality CPGs

	National Department of Health (*n*=59)	Provincial department of health (*n*=18)	Societies / associations (*n*=156)	Clinicians and academics (*n*=37)	Council for Medical Schemes (*n*=15)
Funding statement	Funding source not stated* (81%) or unclear[†] (3%)		Funding source not stated* (73%) or unclear[†] (2%) 22% declared pharmaceutical industry involvement	Funding not stated* (59%) or unclear[†] (5%) 32% declared pharmaceutical industry involvement	Not stated (100%)
	n=1 stated pharmaceutical industry involvement	None stated pharmaceutical industry involvement			
Conflict of interest statements, %	0	17	21	30	0
References available, %	54	28	74	100	93
Description of stakeholder consultation process, %	32	28	26	30	0

CPG = clinical practice guideline.
*A CPG funding source was categorised as 'not stated' if there was no explicit statement in that regard. There were cases where the involvement of international partners or the pharmaceutical industry in CPG development was stated, but the nature of their involvement (human resources or financial) was not declared.
[†]A CPG funding source was categorised as 'unclear' if the funding source was not stated, but a commercial advertisement or logo of a pharmaceutical company appeared in the CPG.

NICE Guideline Development

Topic referred to NICE or update commissioned by NICE

Scoping
- Developer drafts scope, including key issues and review questions
- Stakeholders comment on draft scope
- Final scope published

Development
- Structured review questions agreed
- Literature searched
- Call for evidence from stakeholders if needed
- Evidence reviews and economic analysis prepared
- Committee discusses evidence reviews and expert testimony and develops draft recommendations

Consultation
- Stakeholders comment on draft guideline

Revision
- Committee revise guideline in response to stakeholders' comments

Quality assurance and sign off
- Quality assurance by NICE staff
- Guidance Executive sign off guideline

Publication
- Confidential advance copy released to stakeholders that commented on draft guideline
- Guideline, NICE Pathway and key messages for the public published
- Resources to support implementation published

Updating
- Regular checks to determine if an update is needed
- Part or all of guideline updated according to usual process and methods

Development of resources to support implementation

Quality assurance by NICE

Stakeholders can register at any time on the NICE website

Versus INAHTA – What is assessed in HTA?

➤ Technical properties

➤ Safety

➤ Efficacy and/or effectiveness

➤ Economic attributes or impacts

➤ Social, legal, ethical and/or political impacts

Developing NICE Guidelines: The Manual, 2018. INAHTA, 2008. Hta 101.:Introduction To Health Technology Assessment
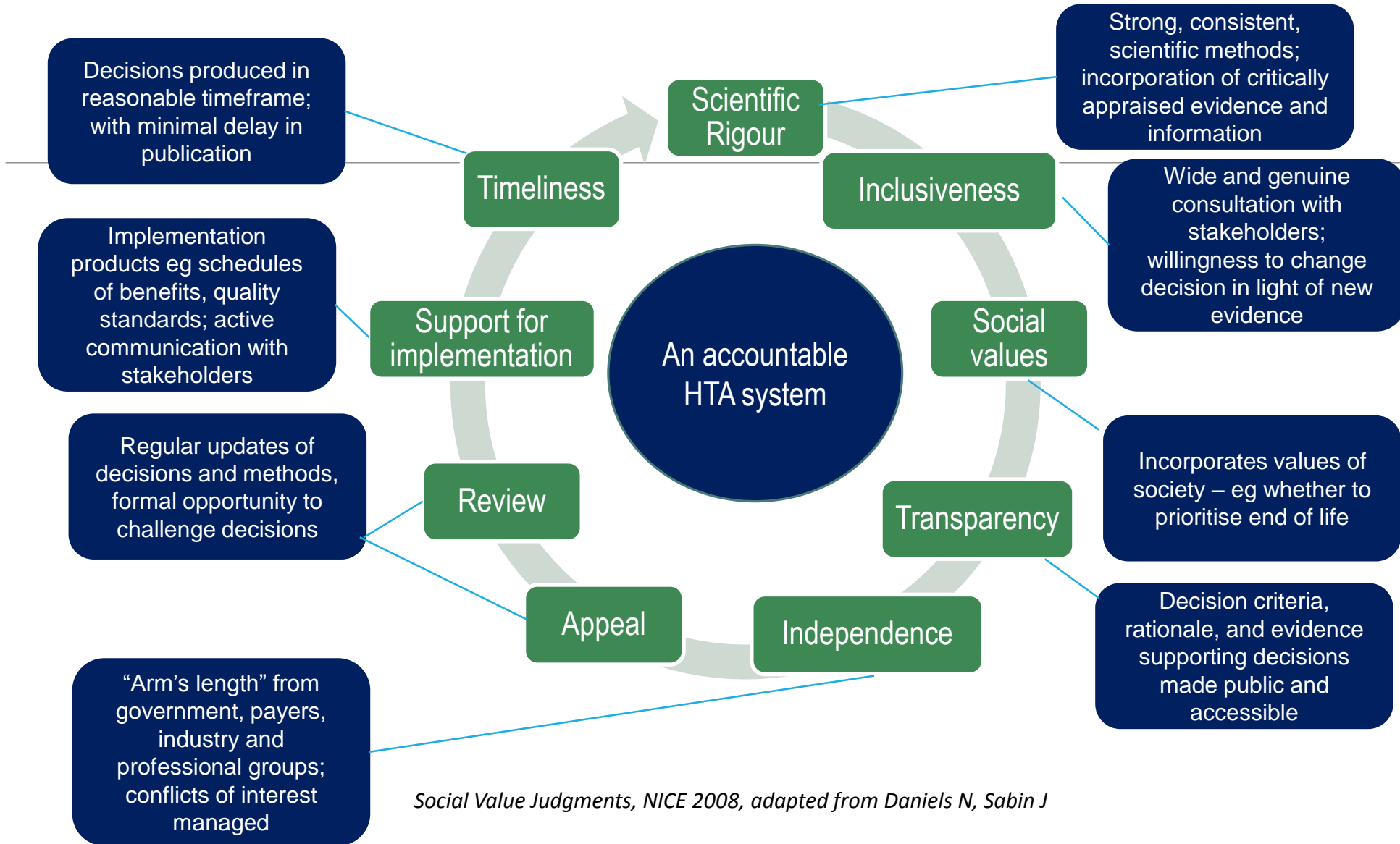
Ethics and HTA

➤ The term 'ethics' is broadly used to describe activities relating to the understanding and study of 'the moral life'.

➤ The term 'morality' encompasses beliefs, standards of conduct, principles and rules which may guide personal and professional behaviour and the behaviour of institutions.

➤ Morals are standards that are widely shared, and that form some degree of social consensus

➤ Performing an HTA should not be considered as a purely technical tool for maximising the health benefits of technology, since benefit maximising is of itself a normative aim that carries a priori assumptions about the goals of healthcare and healthcare expenditure.
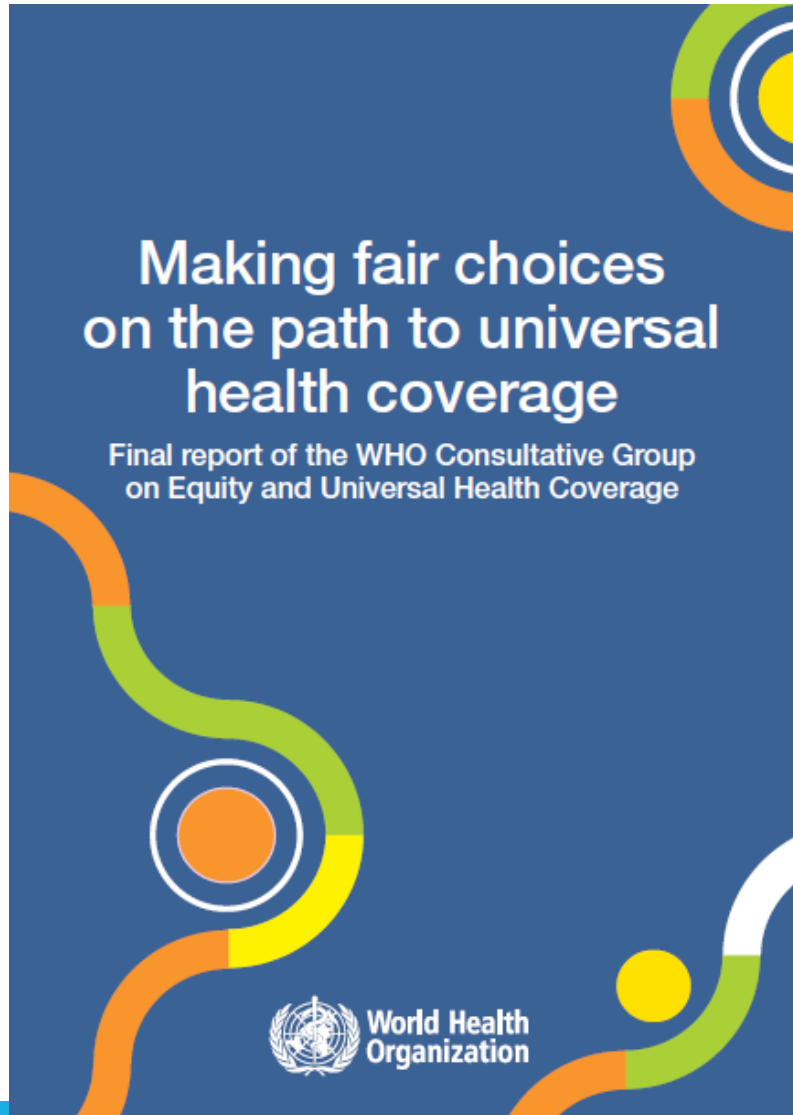
Ethics and HTA

Lehoux, P, Williams-Jones B. 2007. Mapping the integration of social and ethical issues in health technology assessment. February 2007 International Journal of Technology Assessment in Health Care 23(1):9-16
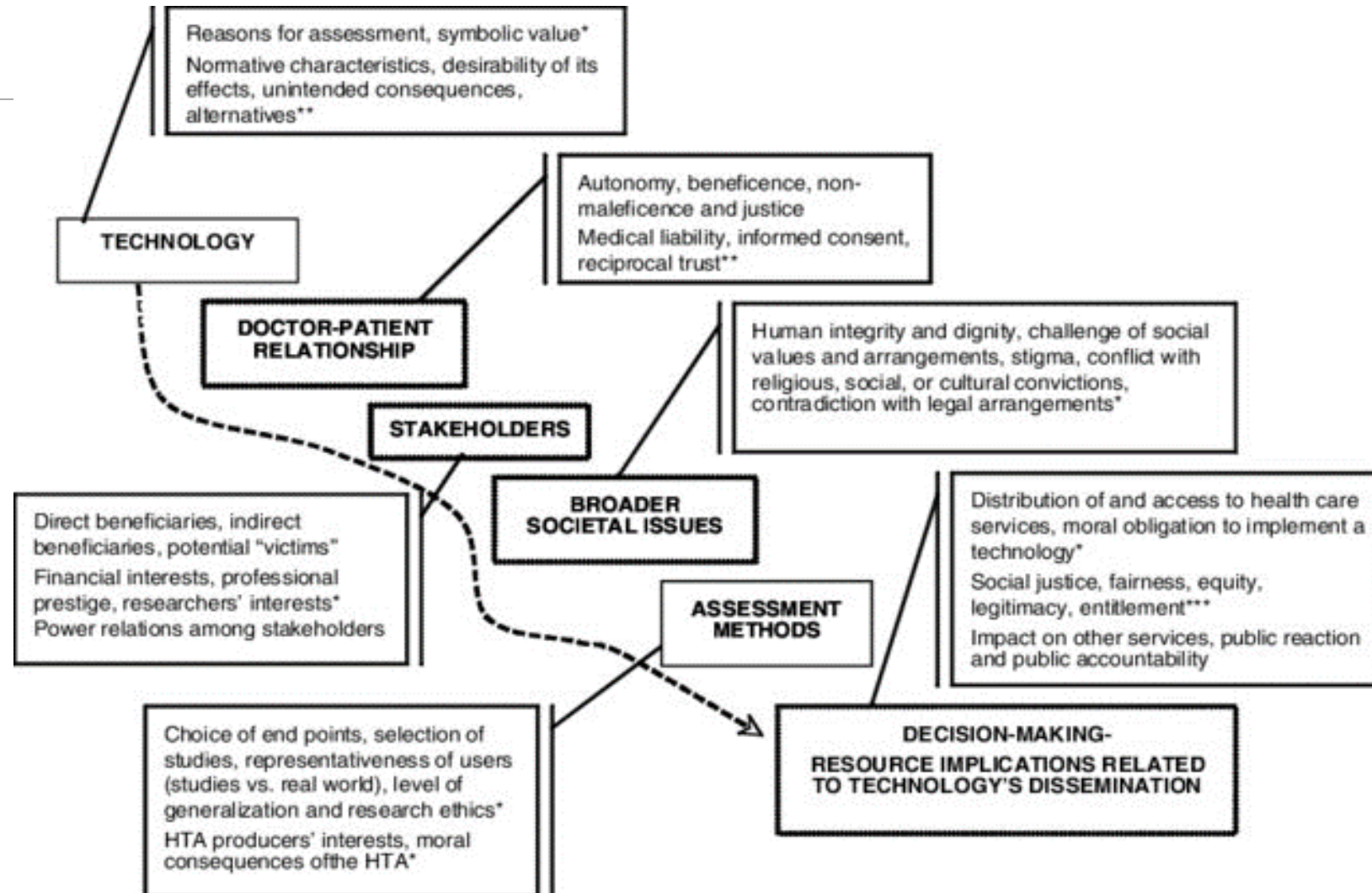
Approaches to addressing ethical issues

Name	Characteristics
Principalism / Deontology	Application of a core set of principles rooted in common morality such as respect for autonomy, justice, beneficence and non-maleficence
Utilitarianism	Holds that the most ethical choice is the one that will produce the greatest good for the greatest number.
EuNetHTA Core Model	18 Questions covering 8 topics (autonomy, human dignity, beneficence, non-maleficence, justice, equity, rights, legislation and efficacy
Coherence Analysis	Reflective procedure to arrive at an internally consistent equilibrium based on society's normative framework, expectations and objectives

An accountable HTA system

Scientific Rigour — Strong, consistent, scientific methods; incorporation of critically appraised evidence and information

Inclusiveness — Wide and genuine consultation with stakeholders; willingness to change decision in light of new evidence

Social values — Incorporates values of society – eg whether to prioritise end of life

Transparency — Decision criteria, rationale, and evidence supporting decisions made public and accessible

Independence — "Arm's length" from government, payers, industry and professional groups; conflicts of interest managed

Appeal / Review — Regular updates of decisions and methods, formal opportunity to challenge decisions

Support for implementation — Implementation products eg schedules of benefits, quality standards; active communication with stakeholders

Timeliness — Decisions produced in reasonable timeframe; with minimal delay in publication

Social Value Judgments, NICE 2008, adapted from Daniels N, Sabin J

Making fair choices

Making fair choices on the path to universal health coverage

Final report of the WHO Consultative Group on Equity and Universal Health Coverage

World Health Organization

"A more efficient system can meet more health needs per dollar spent, and this is of ethical concern and not simply an economic notion.

A three-part strategy:

➤ Categorize services into priority classes. Relevant criteria include those related to cost-effectiveness, priority to the worse off, and financial risk protection.

➤ Expand coverage for high-priority services to everyone. This includes eliminating out-of-pocket payments while increasing mandatory, progressive prepayment with pooling of funds.

➤ While doing so, ensure that disadvantaged groups are not left behind. These will often include low-income groups and rural populations."

Making fair choices on the path to universal health coverage. Final report of the WHO Consultative Group on Equity and Universal Health Coverage

Conclusions

➢Broader application of HTA becomes considerably more complex

➢Use in Clinical guidelines
  ➢Increased acceptance of resource considerations and costs in guideline development
  ➢multiple decisions and difficulty HTA integration into Guideline processes

➢Ethical issues are recognised part of HTA processes
  ➢Especially important in prioritisation decisions

Thank you!

Shelley McGee

shelleym@samedical.org

012 481 2043