Evidence based guideline development

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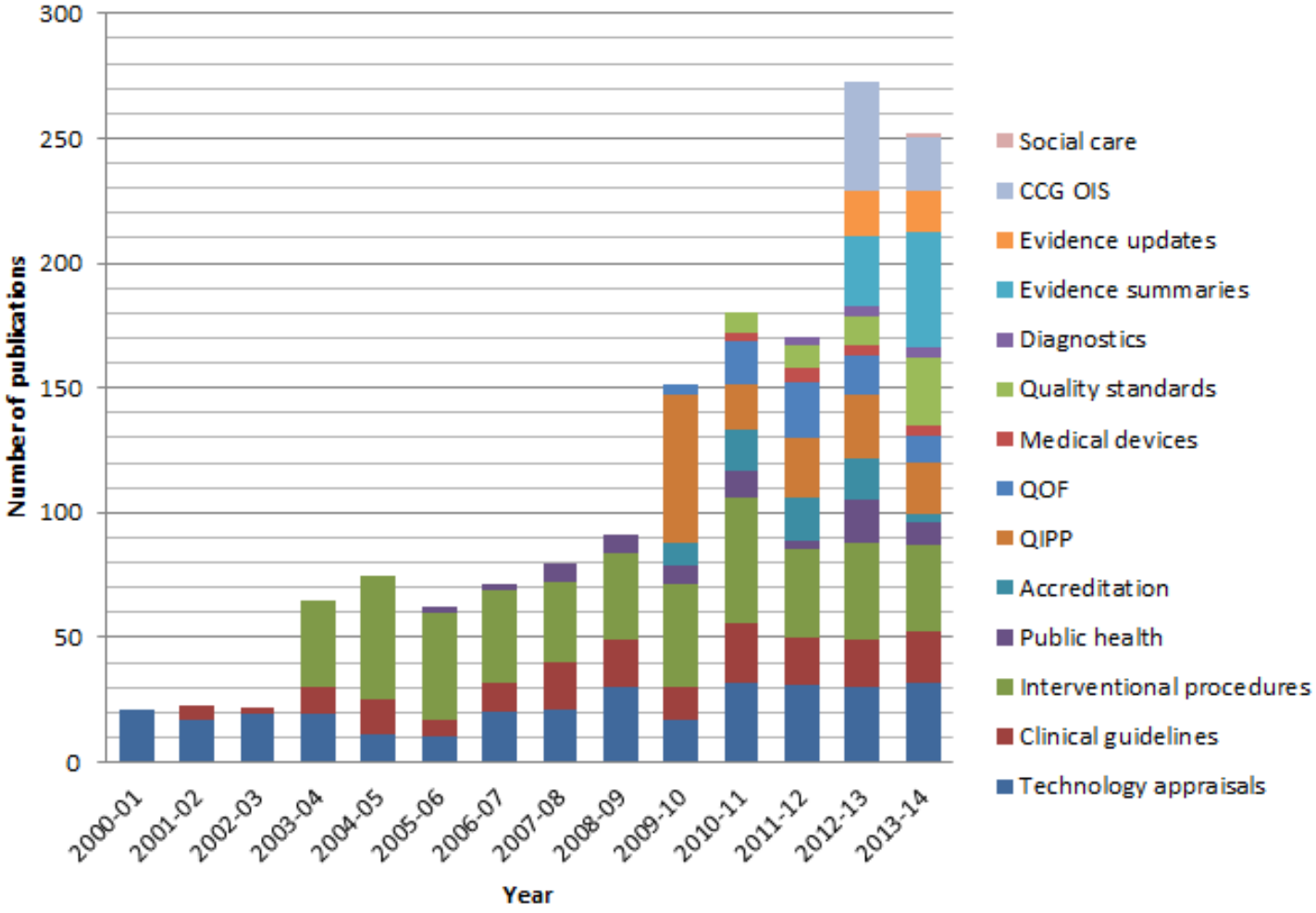
Why have guidelines?

- Inappropriate variations in practice
- Persisting use of ineffective treatments and interventions
- Need for clinical and cost effectiveness.
- The “post code lottery”
- Impossible for health and social care practitioners to read and appraise all new evidence themselves.

The NICE Guidelines Programme

- NICE established in 1999 to reduce variation in the availability and quality of treatments and care (‘postcode lottery’)
- Is now the worlds largest publicly-funded national guidelines programme
- 239 guidelines published since 2002 (178 new topics; 61 updates)
- Involving >1000 people (most on a voluntary basis)
- Includes areas of public health, social care and service delivery

NICE Guidance by Year



NICE guidelines

- Range of topics, from preventing/managing conditions to service planning, public health and social care
- Incorporates other NICE guidance (ie technology appraisals) where relevant
- Recommendations are **advisory only** but can be used to develop quality standards to assess practice and inform commissioning

Guidelines do:

- Describe the care of individuals by health and care professionals
- Take account of patients' and service user perspectives
- They are based on the best available evidence of clinical and cost effectiveness

Guidelines do not:

- Replace professional judgement
- Take the place of a 'wish list'
- Provide a textbook – cannot cover everything

Core principles for developing all NICE guidance

- Independent advisory committees free from CoIs
- Comprehensive evidence base
- Expert input
- Public involvement
- Genuine consultation
- Regular review
- Open and transparent process
- Social values and equity considerations

Guideline Committees

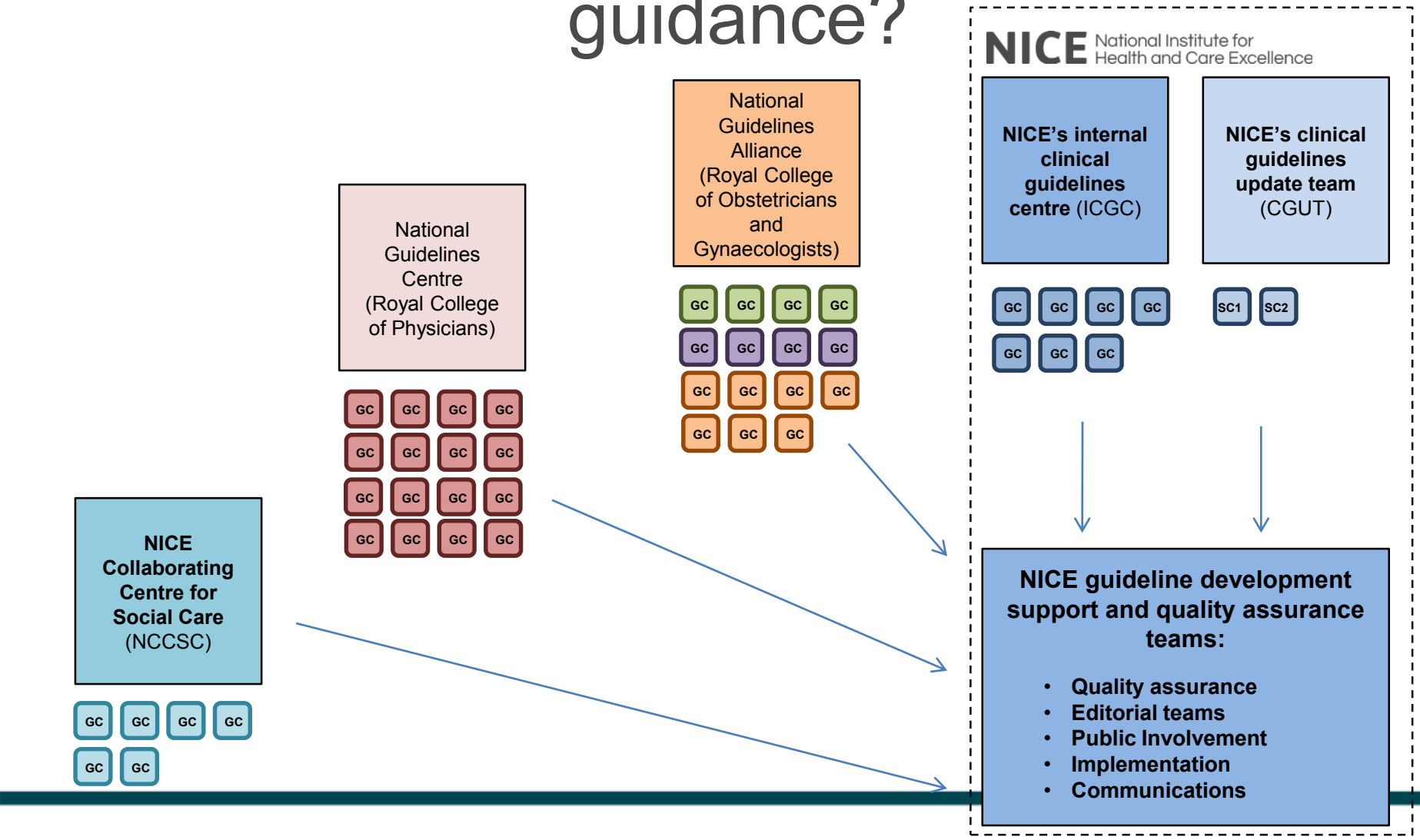
Multi-disciplinary;

- Health & Social Care professionals
- Service managers;
- Methodologists;
- Economists;
- Patients, carers, service users;

Voluntary;

Free from CoIs

Who is involved in developing NICE guidance?

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RAISE YOUR HAND IF YOU HAVE ANY FINANCIAL CONFLICTS OF INTEREST IN THIS DECISION...
FDA DRUG DECISION PANEL
CONCEPT-MIKE ADAMS -ART-DAN BERGER-WWW.NEWSTARGET.COM

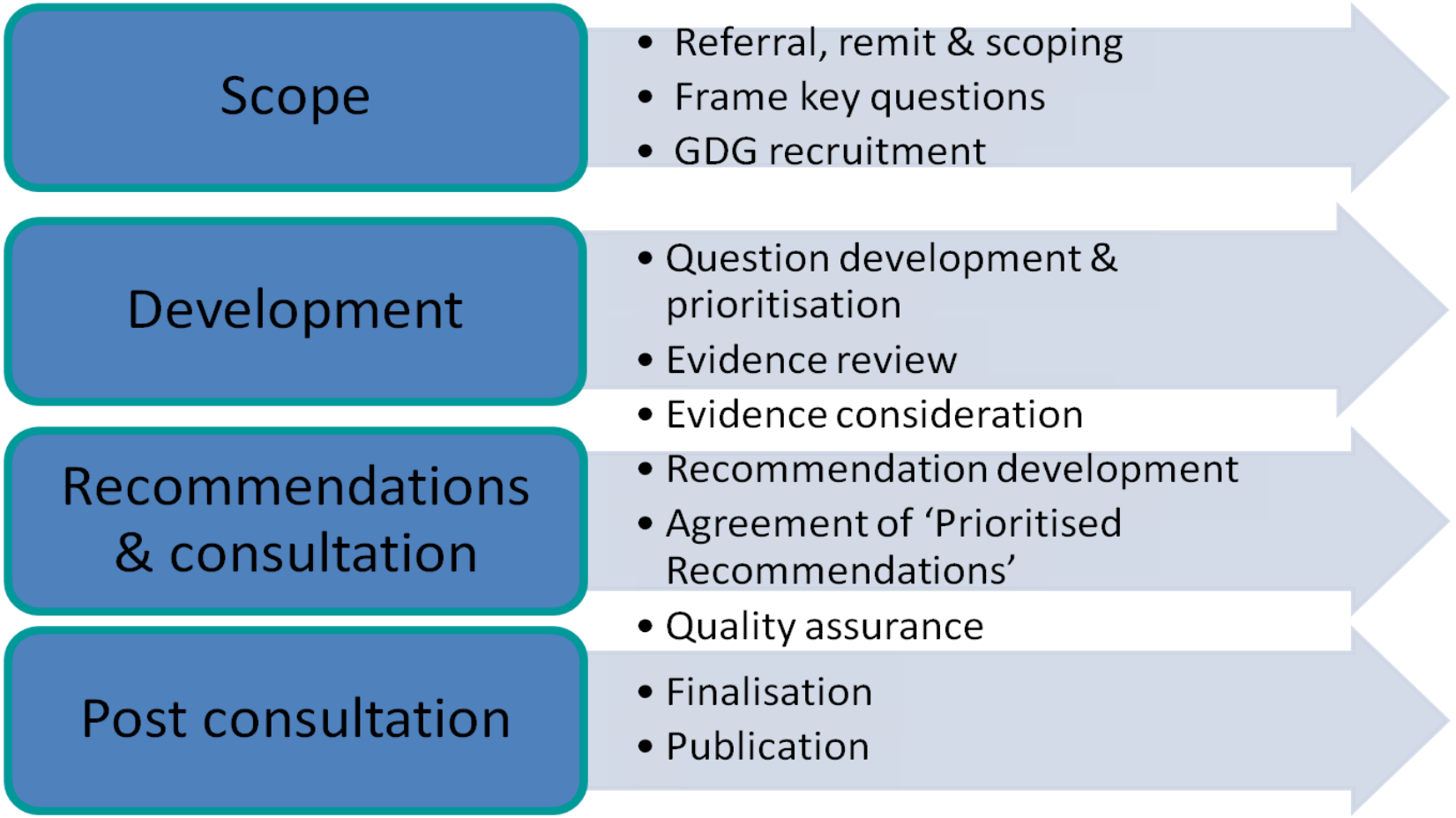
Why is it important to us?

- Need to ensure that there isn't undue influence on the recommendations.
- Need to have a clear, transparent and robust process which is understood by the wider world
- *Perceived* conflicts of interest can undermine the integrity and consequently, impact of the individual guideline and potentially NICE's wider work programme

How do we manage DoIs?

- The NICE policy on Conflicts of Interest;
- Applies to:
  - All NICE Employees, Contractors;
  - All Committee Chairs, Members;
- Interests can be:
  - Specific or non-specific
  - Financial or non-financial
  - Personal or non-personal
- Not all DoIs are CoIs

Guideline Development-stages



Framing a question

Effectiveness of an intervention

Example – Parent skills training for the treatment and management of emotional and behavioural disorders in children

P	Children (aged 0-12) with emotional or behavioural disorders
I	Parent skills training programme
C	No treatment
O	Internalising behaviours (anxiety, depression) Externalising behaviours (non-compliance, aggression) Functioning of child in school (cognitive development) Family functioning (parent-child interaction)

Searching for evidence

- Search methods should balance precision and sensitivity
- The aim is to identify the **best available** evidence to without producing an unmanageable volume of results.
- The GC are asked to review and advise on search strategies
- GC may also know of other studies or research ('in progress' or 'unpublished')
- **Calls for evidence** can also be made - where information is believed to exist but has not been found using standard searches

Assessing the evidence

GRADE (Grading of Recommendations, Assessment, Development and Evaluation)[1]

- Assessment of the quality of the evidence by **outcome**
- Separates out judgements about the quality of the evidence from judgements about the strength of the recommendation

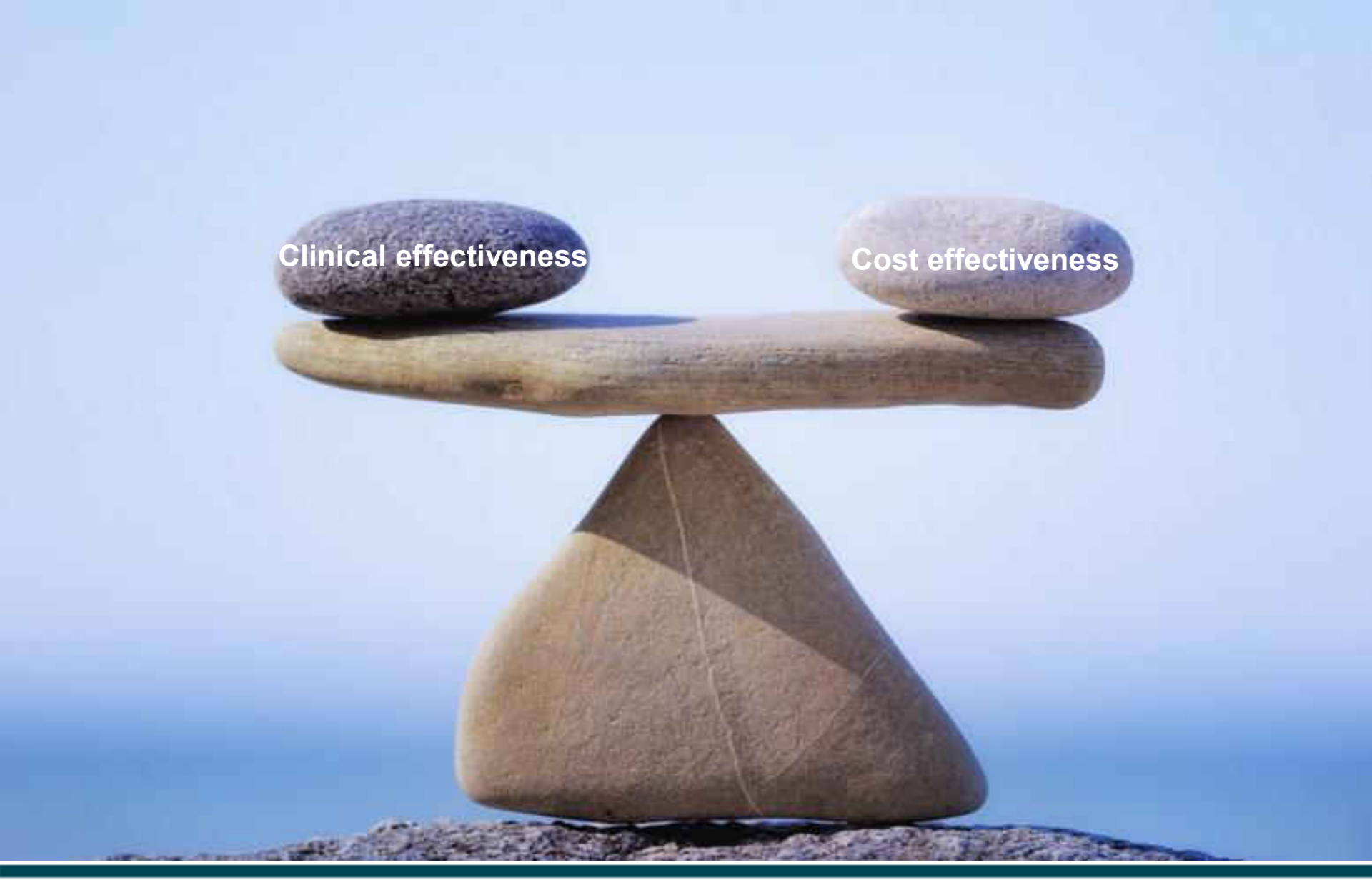
NICE use **elements** of GRADE

- No 'summary grades' for overall quality of the evidence or strength of a recommendation
- Integrates a review of the quality of cost-effectiveness studies

[1] http://www.gradeworkinggroup.org/

GRADE Criteria

1. Study design
2. Study limitations
3. Consistency of an effect across studies
4. Directness of evidence
5. Precision
6. Reporting bias
7. Strength of association
8. Dose response gradient
9. Confounding



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Cost Effectiveness

- If the NHS spends more on one thing, it has to do less of something else
- Could we do more good by spending the extra money in other ways?
- This is called the 'opportunity cost'
  = the value of the best alternative use of resources

"The sorts of questions that NICE decides are at the heart of the debate over U.S. health care reform. Can we automatically fund any advance in health care, regardless of how marginal the benefit might be, or is it possible to introduce a transparent, rule-based, evidentiary form of health care rationing?"

- Kerr & Scott (2009).'British Lessons on Health Care Reform' NEJM September 9th.

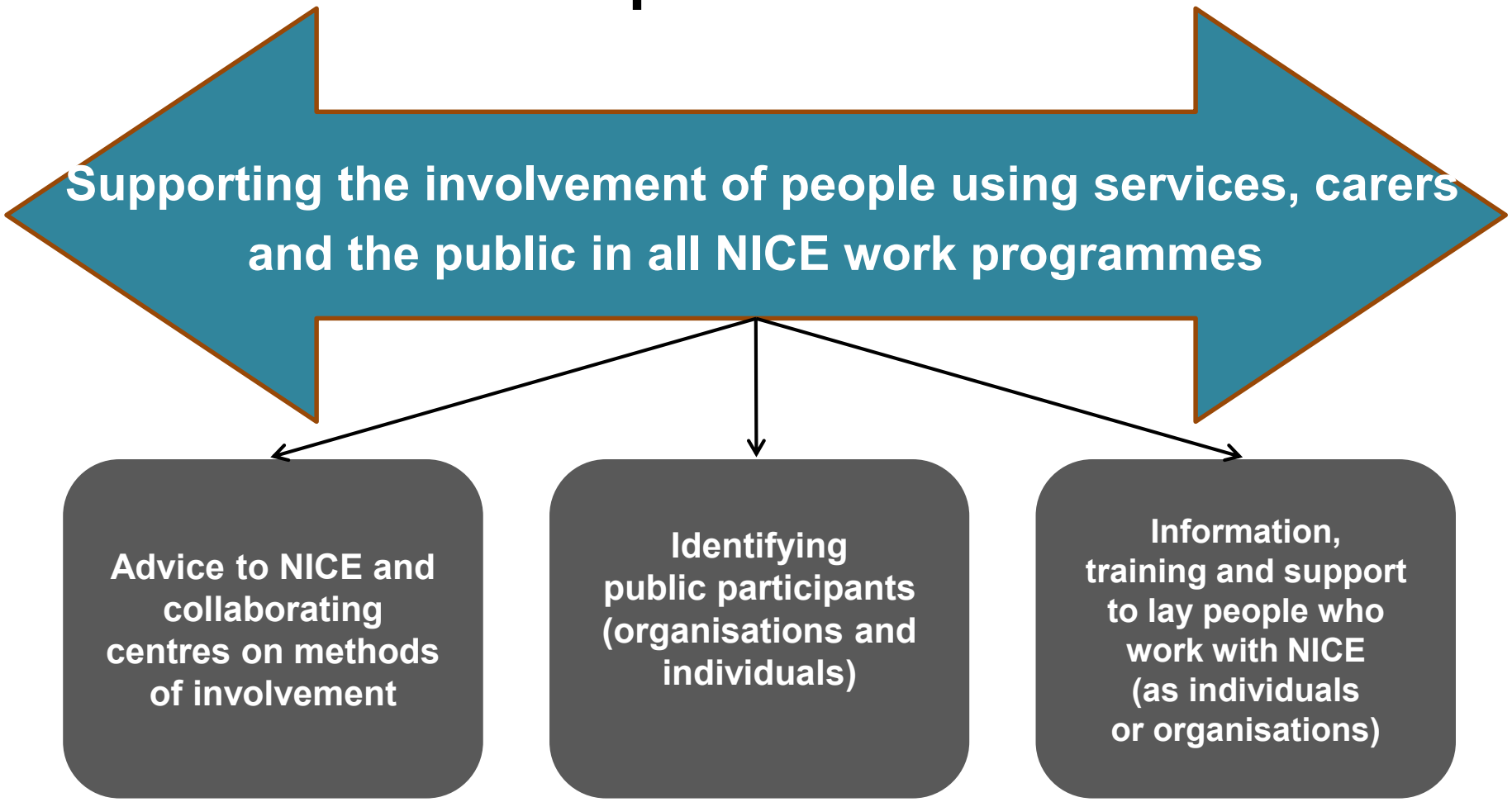
Assessing cost-effectiveness

- "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." (Principle 2, SVJ, NICE 2008)

However

- "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." (Principle 3)

Patient and public involvement



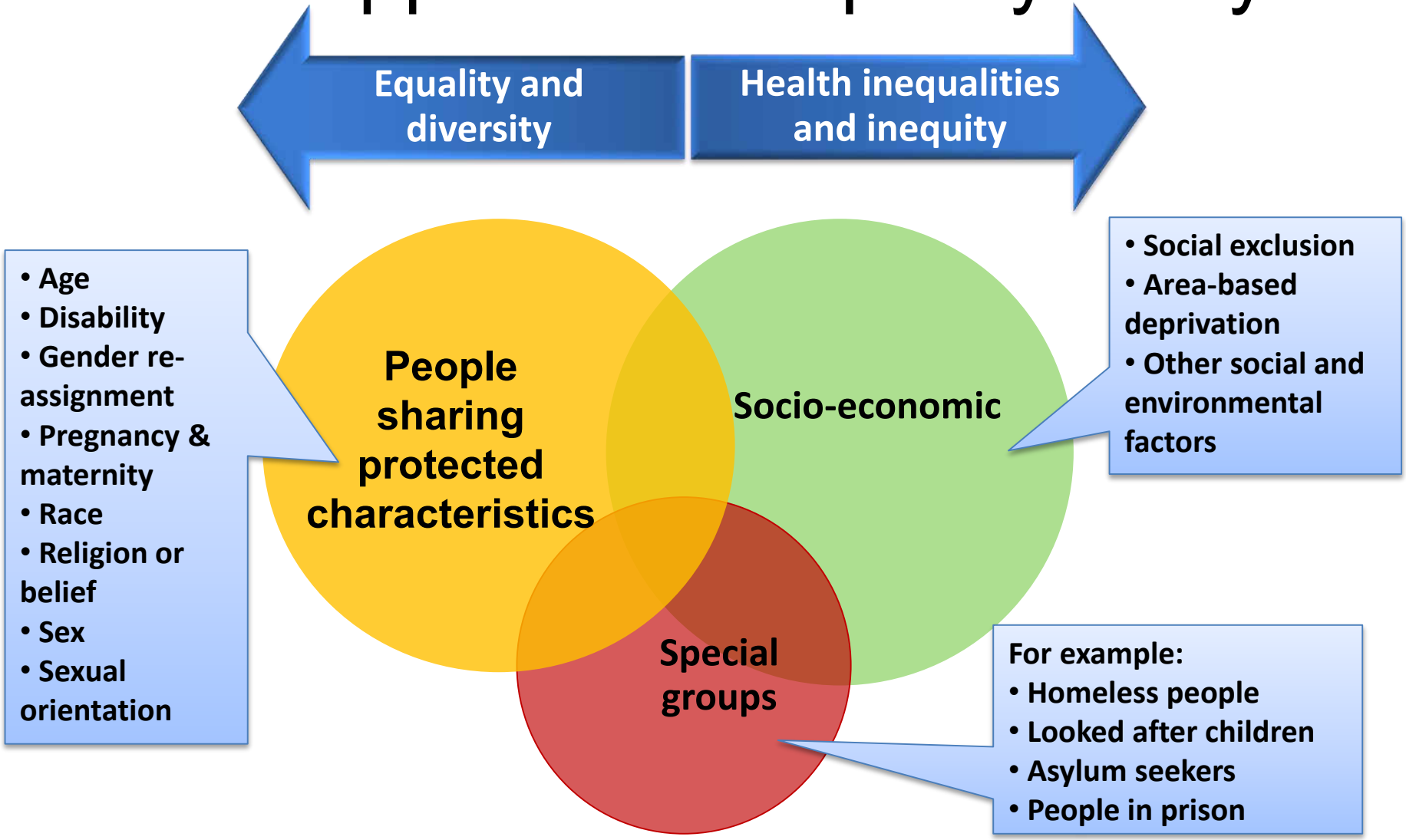
NICE Social Value Judgements

Describes the principles behind judgements that NICE and its advisory bodies should apply when making decisions about recommendations such as:

- Additional factors to consider than costs and benefits alone
- Targeting health inequalities
- Avoiding discrimination
- Considering ‘rare’ diseases

The current (2008) edition of Social Value Judgements is under revision. It pre-dates the Equality Act 2010. The Act's requirements now govern NICE's approach to applying social value principles when considering legally protected groups.

NICE's approach to equality analysis



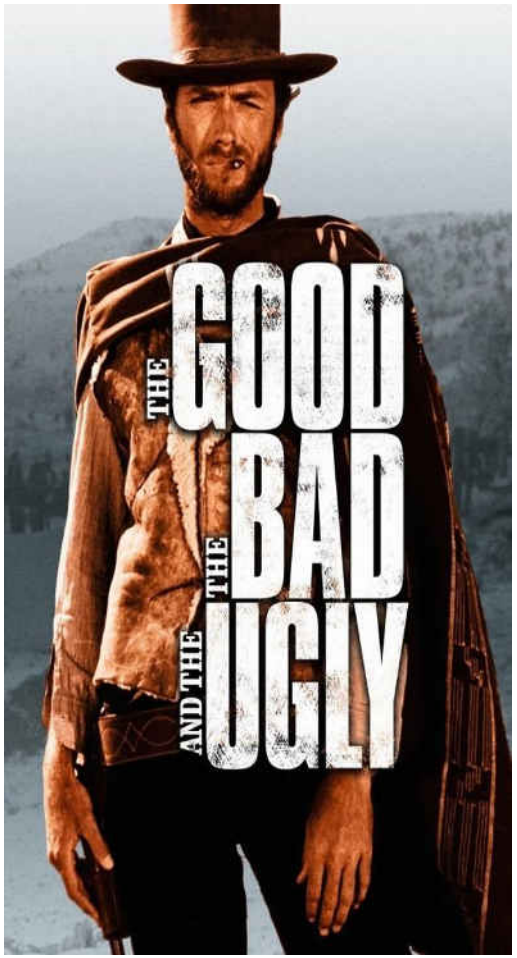
Why involve lay people in guideline development?

- Intrinsic value
- Promotes democracy
- Redistributes power
- Allows patients to influence the health system
- A goal in itself that does not require justification
- A role in gaining legitimacy
- Shows responsiveness to public need
- Support for implementation

Lay members' feedback

How easy did you find it to contribute to the work of your committee?

- "The Chair always made me feel my contribution was important."
- "I found that as a lay member, I was treated with respect and as an equal member of the group. My views were given equal consideration to others."
- "A lot of medical terminology for a lay person to get used to."
- **"**I sometimes felt like the views of the lay members weren't taken seriously or given the same 'weight' as the academic or clinical members. This meant that after a while I was reluctant to contribute unless it was something I felt very strongly about."



Shared decision making

- Using evidence to support conversations about values, preferences, risk- aversion, goals, hopes…
- Using guidance to support clinicians to have these conversations
- Using tools to support patients to make decisions
- Cultural change

Challenges for guideline programmes

Methodological and process:

- Ensuring guidelines are up to date with new evidence (surveillance, updates);
- Methodological advance
  - E.g. GRADE, NMAs
- Ageing population
  - Co- and multi-morbidities
- Resourcing constraints
  - Adaptation/contextualisation

Further challenges – putting guidance into practice

- Lack of trust in guidance
- Redefining health as ‘disease’

  (eg HSDD)
- Lack of organisational support and resources - structures and processes
- Guidance recommendations at a population level versus individual decision making

Implementation support available from NICE includes…

- Regional field team for personal support
- Audit tools
- Costing templates
- Patient Decision Aids

Some of our “person-centred” guidelines…

- Patient experience in adult NHS services
- Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence
- Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes

Further reading

CASSELS, A. (2016) Patient speaking for patients. What constitutes genuine patient input into pharmaceutical policymaking? Int J. Health Gov. 21:89-95

GREENHALGH T, Howick J, Maskery N. (2014) Evidence based medicine: a movement in crisis? BMJ;348:g3725;

PHAM-KANTER, G. (2014), Revisiting Financial Conflicts of Interest in FDA Advisory Committees. Milbank Quarterly, 92: 446–470;

ARNSTEIN, SR (1969), A Ladder of Citizen Participation. JAIP, Vol. 35, No. 4; 216-224

RASHID, A., THOMAS, V., SHAW, T. et al. (2016). Patient and Public Involvement in the Development of Healthcare Guidance: An Overview of Current Methods and Future Challenges. The Patient. Vol 1, 1-6.

Developing NICE guidelines: the manual (Oct 2014)