

Can patient involvement in early dialogues increase the value of the advice given?

Moderator:
Speakers:

Nicholas Brooke, PARADIGM & PFMD
Neil Bertelsen, HTAi
Heidi Livingstone, NICE
Maggie Galbraith, HAS / EUnetHTA



PARADIGM

ADVANCING PATIENT ENGAGEMENT
ISPOR 2018 - Nicholas Brooke



PARADIGM

- A Distinct Voice In the Patient Engagement Landscape

Mission

Contribute to a sustainable framework that enables meaningful patient engagement (PE) and demonstrates 'return on engagement' for all players



Research and priority setting



Design of clinical trials



Early dialogues with regulators and HTA bodies



Objectives

Develop processes and tools for these three points in the medicine lifecycle
Develop a sustainability roadmap for patient engagement

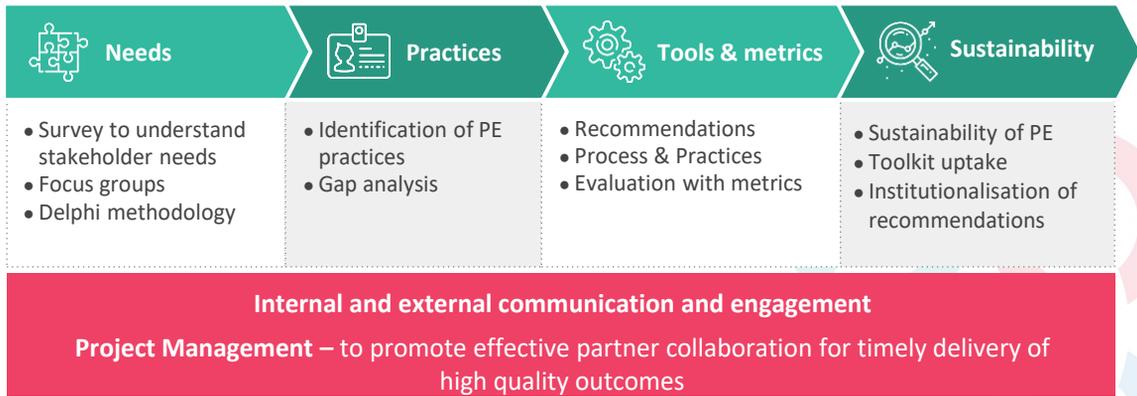


Multi-stakeholder collaboration

- to drive meaningful and systematic patient engagement



A Virtuous Development Process



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Collaborative Initiatives Dedicated to Patient Engagement

	 <small>PATIENT FOCUSED MEDICINES DEVELOPMENT</small>	 <small>Patients Active in Research and Dialogues for an Improved Generation of Medicines</small>	 <small>EUPATI</small>
	Global Focus	European Focus	European Focus
	Patient Engagement Guidance & Tools	Patient Engagement Guidance & Tools	Patient Capability Building
	Full Medicine Lifecycle	Time Points: Research Prioritization; Clinical Trials; Early Dialogue Regulatory & HTA Bodies	Full Medicine Lifecycle
	No Time Boundary	30 Months Duration	No Time Boundary
	http://patientfocusedmedicine.org/our-partners/	http://imi-paradigm.eu/project-partners/	https://www.eupati.eu/supporters-of-eupati/
<p>PARADIGM advances the patient engagement agenda. Integrated approach with initiatives like EUPATI and PFMD</p>			



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Patient involvement in Early Dialogues

Neil Bertelsen,

Chair HTAi Patient & Citizen Involvement in HTA Interest Group

Why do we involve patients in HTA?

The HTAi values and standards looked at this issue from the HTA assessment point in time

Relevance	Fairness	Equity	Legitimacy	Capacity building
Patients have knowledge, perspectives and experiences that are unique and contribute to essential evidence for HTA.	Patients have the same rights to contribute to the HTA process as other stakeholders and have access to processes that enable effective engagement.	Patient involvement in HTA contributes to equity by seeking to understand the diverse needs of patients with a particular health issue, balanced against the requirements of a health system that seeks to distribute resources fairly among all users.	Patient involvement facilitates those affected by the HTA recommendations/decision to participate in the HTA; contributing to the transparency, accountability and credibility of the decision-making process.	Patient involvement processes address barriers to involving patients in HTA and build capacity for patients and HTA organizations to work together.

<https://htai.org/interest-groups/pcig/values-and-standards/>

What about during Early Dialogues?

Early dialogues...

... are years before a HTA decision-making point

... are about complex decisions on study designs

... when there is little available evidence

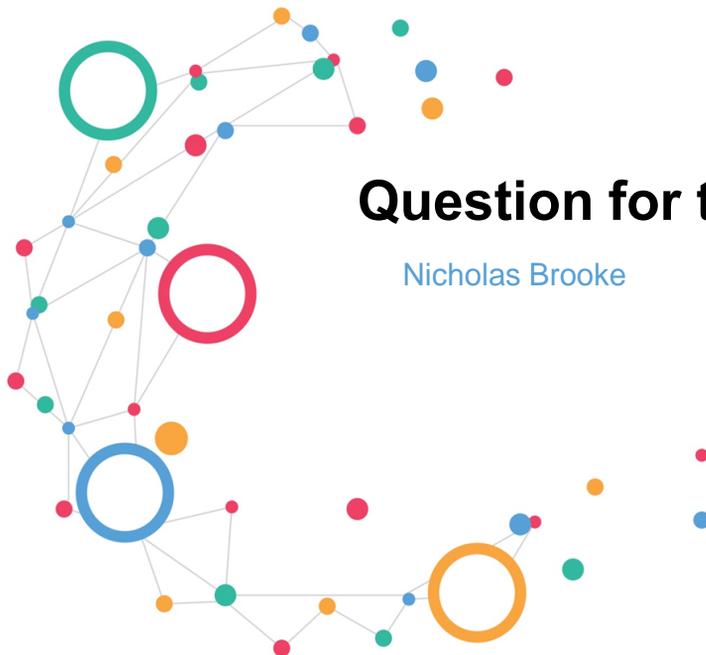
... and are confidential discussions

Is patient involvement at this point in time appropriate?

How can it be implemented?

How can it add value?

Does it really make a difference?



Question for the audience...

Nicholas Brooke

Scientific Advice at NICE; rationale for patient involvement

Heidi Livingstone, Senior Public Involvement Adviser

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Why do companies seek NICE Scientific Advice?

A: to increase: the likelihood that the company's clinical development studies and other plans meet NICE evidence requirements

How does it help if patients participate in NICE Scientific Advice projects?

A: because it increases: the likelihood that the company's clinical development studies and other plans meet the needs of patients

Why do we involve patients in Scientific Advice?



Patients

- The treatment is ultimately for them
- Can influence how clinical trials are set up
 - To provide the best evidence that the proposed outcomes meet patients' needs



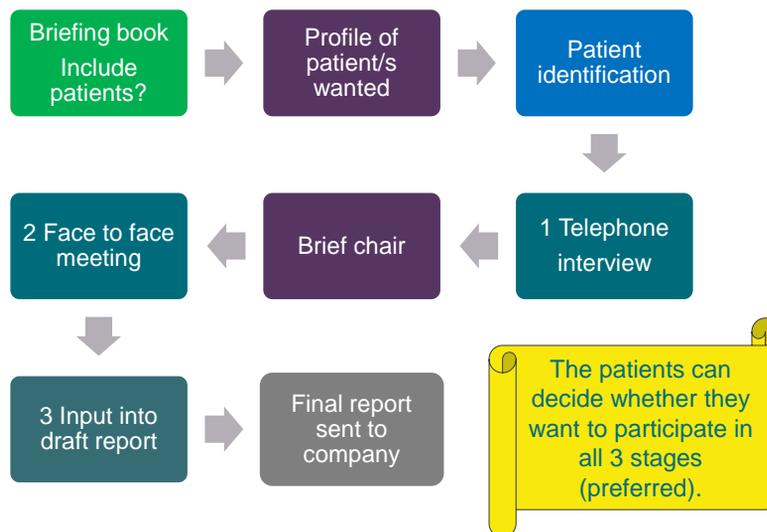
Companies

- Get powerful feedback on their decisions early in a product's development

NICE

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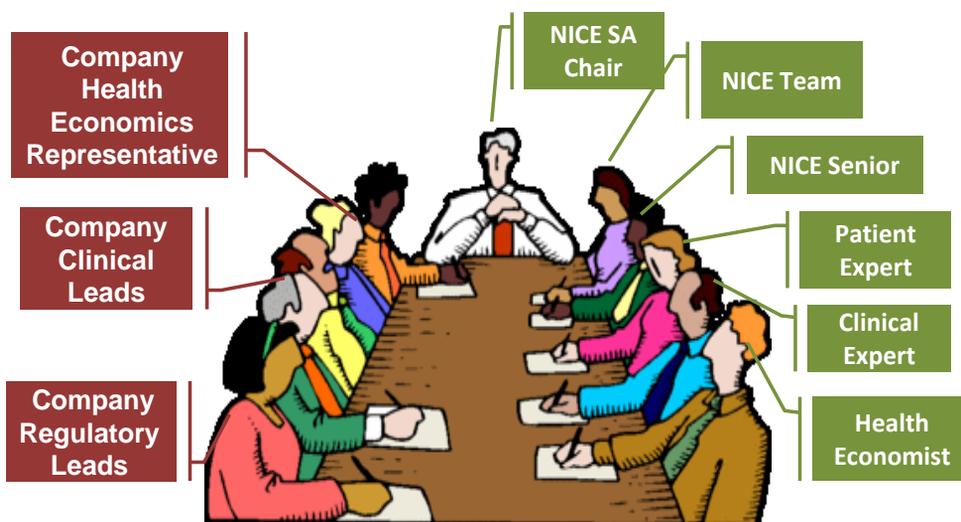
Stages of patient involvement



NICE

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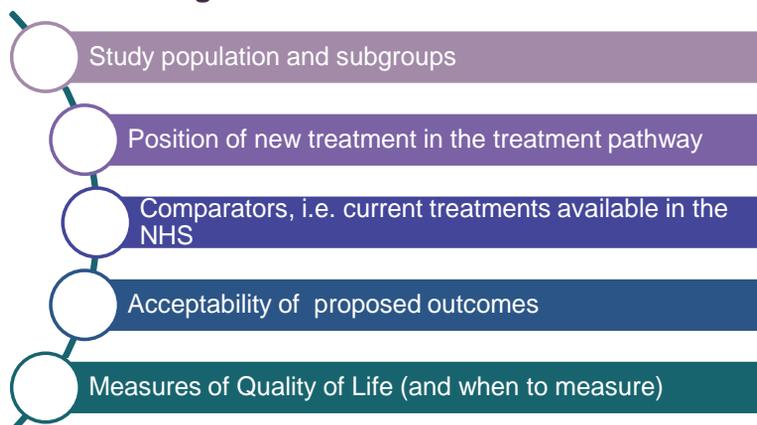
Scientific Advice Face to Face Meetings



NICE

Typical Issues Raised for NICE Scientific Advice where patients can help.

Value Proposition Clinical Trial Programme



NICE

How patients can help with quality of life – when and what to measure

Varies from condition to condition:

- cannot complete EQ5D data during an attack or episode and may have to capture it retrospectively
- suggested measuring quality of life weekly, for other conditions monthly was considered manageable
- suggested it would be needed only once and at what point that should be

Additional types of measures suggested:

- tiredness additional questionnaire (interrupted sleep, insomnia, fatigue)
- cognitive function



NICE

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Other examples of what patients can bring

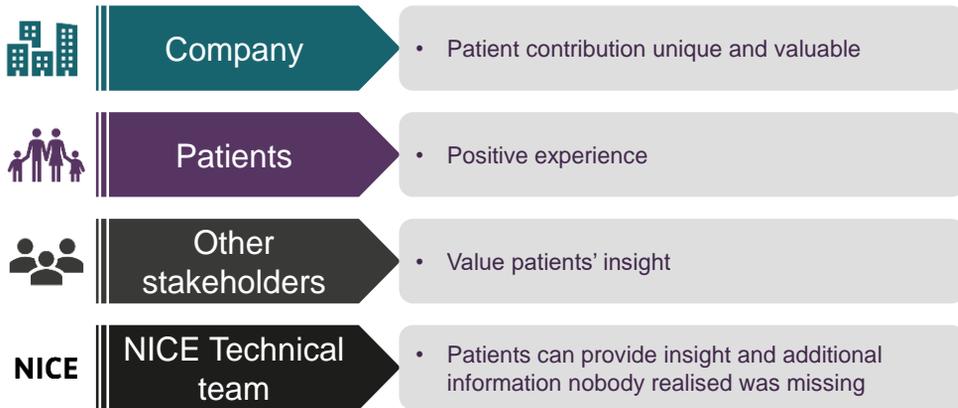


- Why a tablet might not be an option for patients with certain conditions
- Why the six minute walk test doesn't mean much to patients
- Why some population groups, or individuals, might not want a particular treatment

NICE

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Feedback



NICE

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NICE National Institute for
Health and Care Excellence

Thank you!

EUnetHTA

Patient engagement in Early Dialogues (ED)

Maggie Galbraith
Haute Autorité de Santé
EUnetHTA ED Secretariat

Principles of patient involvement in EUnetHTA EDs

- **Patient perspective essential for EUnetHTA EDs:**
 - At the time forming the advice
 - Respect Conflict of Interest and Confidentiality rules
- **Providing unique insight of living with the condition to ensure recommendations meet patient's need**
 - Advising on the signs and symptoms that have the greatest impact on their functional and psychological aspects of living
 - Impact on quality of life for patients and carers
 - (available) treatment & treatment expectation
- **Acceptability to participate in the proposed trial**

Testing 3 possible approaches

Approach	Patient contribution deliverables
Approach 1: Individual patient/patient's representative - interviewed regarding the disease and their experience	<ul style="list-style-type: none">- Minutes of the interview- Mention of patient contribution in final EUnetHTA recommendations- Feedback questionnaire
Approach 2: Approach 1 + discussion with local HTAB regarding submission file (without applicant)	<ul style="list-style-type: none">- Minutes of the interview- Mention of patient contribution in final EUnetHTA recommendations- Feedback questionnaire
Approach 3: Patient expert; Approach 1 + discussion with all participating HTABs regarding the submission file and participation in the F2F meeting with the Applicant	<ul style="list-style-type: none">- Minutes of the interview- Review final EUnetHTA recommendations- Feedback questionnaire

EUnetHTA experience thus far...

10 of 14 completed EUnetHTA EDs with patient contribution following the 3 approaches:

1. **6 interviews with patients** (France, UK, Spain)
2. **8 interviews with a national patient representative** (German patients' representative involved in any ED in which G-BA participates)
3. **4 EU patient representatives participating to overall ED process**

Method

An analysis based on feedback collected from 7 patients:

1. 5 patients (3 French, 1 Spanish and 1 English) (approach 1)
2. 1 German representative patient (approach 2)
3. 1 EU representative (approach 3)

Approach 1: Individual patient/patient's representative - interviewed regarding the disease and their experience

Approach 2: Approach 1 + discussion with local HTAB regarding submission file (without Applicant)

Approach 3: Patient expert; Approach 1 + discussion with all participating HTABs regarding the submission file and participation in the F2F meeting with the Applicant

Preparation for the ED

Feedback	Proposal for improvement
<p>While 5/7 patients never received training</p> <p>- Quite clear information in ED general objectives</p> <ul style="list-style-type: none">• 4/7 very satisfied• 2/7 mostly not; 1/7 not informed at all <p>- Quite clear understanding of what is expected from them</p> <ul style="list-style-type: none">• 5/7 yes completely• 1/7 mostly not	<ul style="list-style-type: none">• Training: using different tools (EUPATI, national training tool...) and supports• A list of definitions at the beginning of the questionnaire

As a reminder, all patients have been contacted by a patients' organisation

Interviews

Feedback	Proposal for improvement
<ul style="list-style-type: none"> - Positive feedback on the phone interview, and their overall interaction with EUnetHTA - Large use of the questionnaire to prepare the interview (5/7 used it) - Appreciate open questions with opportunity to develop topics at their convenience 	<p>Translation of the questionnaire in native language for HTAi questionnaire and feedback questionnaire</p>
<ul style="list-style-type: none"> - Patient had enough opportunities to express their opinion - Quite confident of the impact of their contribution 	
<p>Further access to Briefing Book and final recommendations requested</p>	<ul style="list-style-type: none"> • Briefing Book at disposal of interested individual patient? • List of Issue and Final recommendations to be shared Systematically with patients representatives

Face-to-face meeting

Feedback	Proposal for improvement
<ul style="list-style-type: none"> • Interest in participating in F2F (because of the psychological impact of their physical presence) • Appreciate the opportunities for reactive statement 	<ul style="list-style-type: none"> • Participation to F2F meeting proposed to individual/national representative with simultaneous translation

Time investment and administrative tasks

Feedback	Proposal for improvement
Clear understanding of the confidentiality agreement	
No difficulties to complete the DOICU and contract documents	
Investment: minimum of half day to review the Briefing Book and only few hours to prepare the interview	
No major burden of administrative task but still possibilities for improvement	Clarify payment and exchanges via IT system



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Thank you!

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Patient involvement in Early Dialogues

Neil Bertelsen,

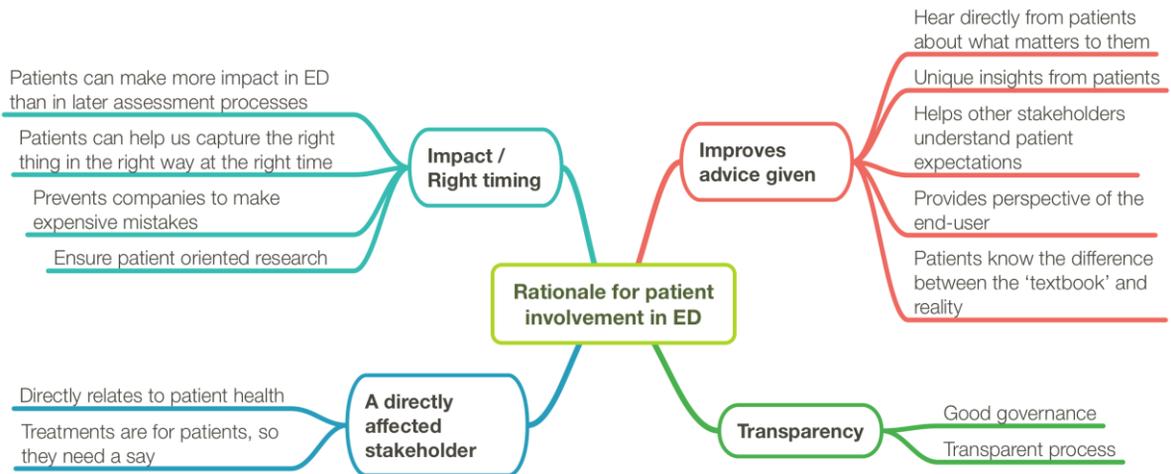
Chair HTAi Patient & Citizen Involvement in HTA Interest Group

PARADIGM workshop on ED

- On 19th October 2018, eleven representatives from HTA bodies came together to discuss patient involvement in Early Dialogues, the current challenges in implementing patient involvement and the potential solutions (agencies from UK, Canada, Norway, Sweden, Spain, Italy, France and EUnetHTA)

The rationale for involving patients and/or advocates in the early dialogue process	The current challenges of initiating a patient involvement process in ED	The current experience of involving patients and the challenges that have been identified so far	The resources or tools that would be useful in solving the identified challenges
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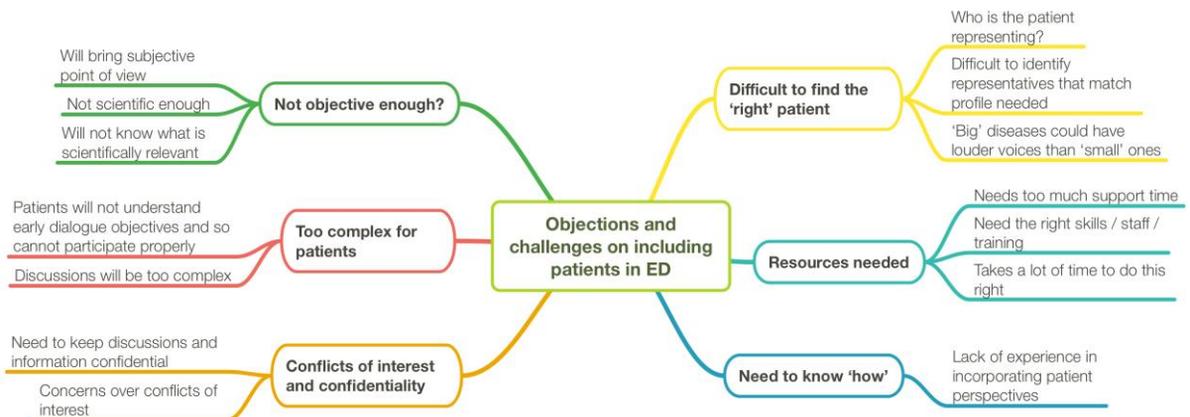
Agencies attending were very supportive of patient involvement in ED



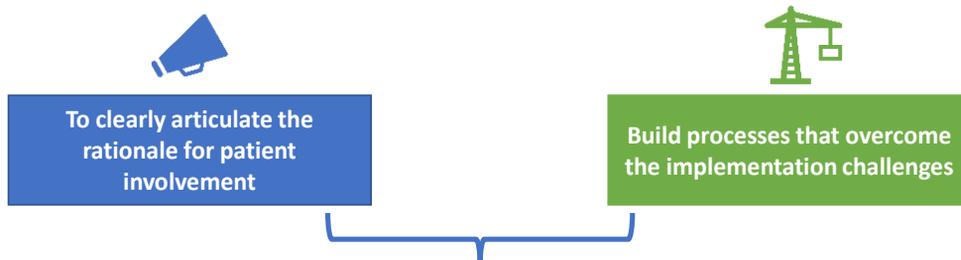
But they hear a lot of objections and there are implementation challenges

Objections often heard

Challenges in implementation



So to make patient involvement in Early Dialogues a reality we need...



Create consistency and predictability across patient involvement in ED processes

Have a menu of methodologies and approaches that could be applied

Set a baseline standard of patient involvement in Early Dialogues

Areas of immediate need

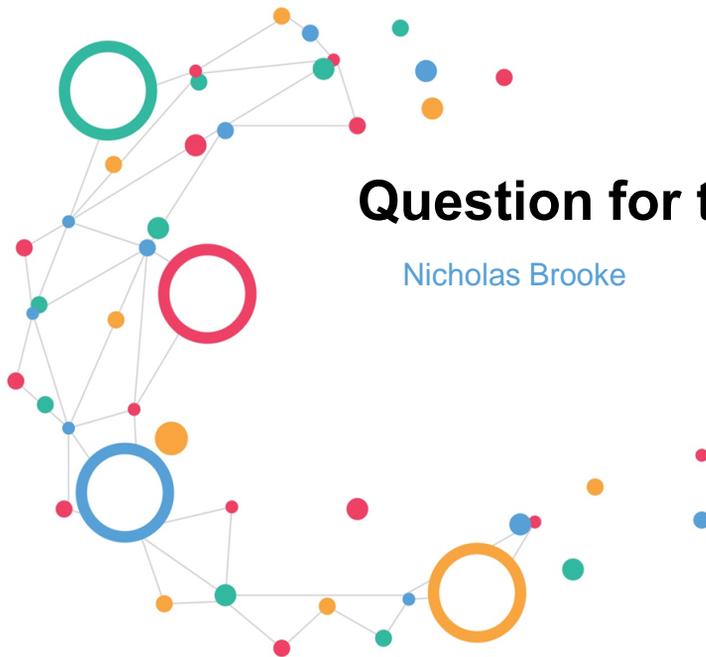
Standard, generic tools that can be shared across HTA bodies...

	<p>Patient finding and recruitment</p>	<ul style="list-style-type: none"> • Patient finding case studies • Patient consent process • Patient capability criteria • Patient guidance and ethical guidance
	<p>Guidance and standards on patient interviews</p>	<ul style="list-style-type: none"> • Standard interview templates and guidance, adaptable for each ED • Guidance on skills needed for the interviewer
	<p>Minimum standards framework</p>	<ul style="list-style-type: none"> • Framework of methods with guidance • Guidance for patients • Guidance for chairs • How to meet the needs of vulnerable groups

If any of you have examples of tools and resources in these areas (not necessarily for HTA or ED), then please share them if possible (nb@neilbertelsen.com)

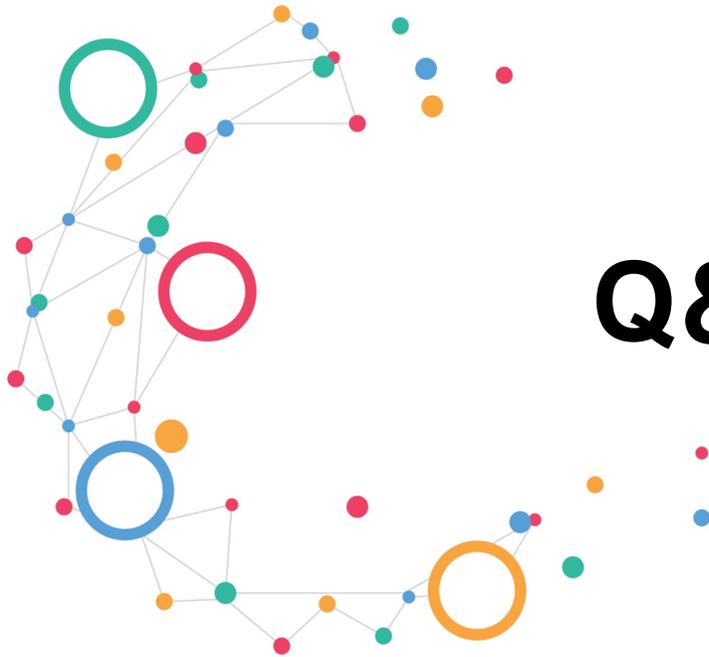
Thank you

Neil Bertelsen



Question for the audience...

Nicholas Brooke



Q&A

