RTI HEALTH SOLUTIONS®

ISSUE PANEL IP1

The United Kingdom's National Institute for Health and Clinical Excellence

NEW DEVELOPMENTS

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Panel Members

Moderator

Stephen Beard, MSc

Head of Health Economics, RTI Health Solutions, Manchester, UK

Panelists

Carole Longson, PhD

Director, NICE, Centre for Health Technology Evaluation, London, UK

Matt D Stevenson, PhD

Technical Director, University of Sheffield, School of Health and Related Research Technology Assessment Group (ScHARR-TAG), Sheffield, UK

Sorrel Wolowacz, PhD

Senior Health Economist, RTI Health Solutions, Manchester, UK

Overview

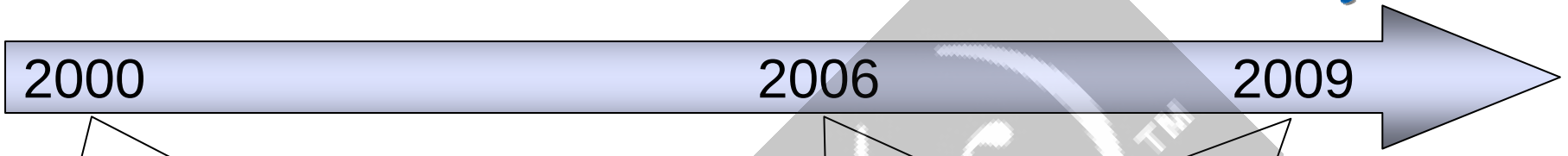
1. **Recent developments at NICE**	**Carole Longson** NICE
2. **The Evidence Review Group Perspective**	**Matt Stevenson** ScHARR-TAG
3. **Recommendations for Research Planning**	**Sorrel Wolowacz** RTI Health Solutions
4. **Open Session for Audience Questions, Discussion, and Debate**	**Open Session**

Issue Panel IP1

RECOMMENDATIONS FOR RESEARCH PLANNING

Sorrel Wolowacz, PhD

RTI Health Solutions' Experience in NICE Submissions



First full round of technology appraisals
Hip prostheses

First STA submission
Docetaxel for early breast cancer

New STA template
Ongoing submission

Strategic Support
• Research planning • Submission strategy • Appraisal consultations, committee meetings appeals

Systematic Reviews
• Clinical evidence • Economic evaluations • Utility weights / HRQL • Resource use / costs

Data Synthesis
• Meta-analyses • Indirect and mixed treatment comparisons

Models
• Cost utility • Budget impact

Submission Preparation
• Technical writing • Professional document production • Full or partial submissions

RTI(h)(s)

Recent Developments Impacting Research Planning

- Recent developments
  - Updated methods guide, June 2008 (supported by briefing papers)
  - Updated STA template, October 2009
  - Expanded process (expected end: October 2009)
  - PPRS Rapid Reviews
- Impact on research requirements
  - No fundamental changes
  - More explicit guidance to encourage “standardisation”

Recent Developments Impacting Research Planning

- Stronger steer towards utility estimates based on EQ-5D measured in Trials or by TTO
  - Careful consideration of inclusion of EQ-5D in pivotal trials
  - Careful consideration of timing of assessments and selection of analyses
- Greater emphasis on systematic review for published utility and resource use and cost estimates
  - Formalisation of searches, study inclusion, and selection of data
- Possibility of inclusion of cost-savings to government departments other than NHS and/or PSS
  - Requires prior agreement
  - High-quality estimates needed

STA Research Planning: Key Research Requirements

	Research Requirement	Main Purpose
1	Data describing current practice	Identification of relevant comparators
2	Systematic review of clinical evidence	Identification of all relevant efficacy and safety evidence for the intervention being appraised and its comparators
3	Meta-analysis and/or indirect and/or mixed treatment comparison (if appropriate)	Synthesis of all relevant clinical evidence for the intervention being appraised and its comparators
4	Systematic review of relevant economic evaluations	Identification of all relevant economic evaluations of the intervention being appraised
5	Economic evaluation	Estimation of cost-utility ratios in accordance with the NICE Reference Case
6	Systematic review of published utility estimates and HRQL studies	Identification of all relevant utility estimates, justification of selected values, and characterisation of uncertainty
7	Systematic review of resource use and cost estimates	Identification of all relevant resource use and cost estimates, justification of selected values, and characterisation of uncertainty
8	Evidence of association between intermediate and final outcomes	Support for estimates of final outcomes (if estimated from intermediate outcomes)
9	Budget and population health-impact analysis	Estimation of the impact of a positive recommendation on NHS budgets

Key Research Requirements

Research Requirement		Main Purpose
1 Data describing current practice in England and Wales		Identification of relevant comparators
Recommendations		
Timing	Early, update prior to submission	Needed to identify comparators to include in systematic review of clinical evidence and economic model
Issues	Relevance	Needed to reflect current practice in the population of interest
	Level of detail	Detailed information, for example, about dosing may be important (e.g., in cancer chemotherapy, efficacy may vary by dose and number of cycles)

Key Research Requirements

Research Requirement		Main Purpose
2 Systematic review of clinical evidence		Identification of all relevant efficacy and safety evidence for the intervention being appraised and its comparators
Recommendations		
Timing	Early, especially if a large evidence base is anticipated	Quality assessment and data abstraction can be time-consuming if a large number of trials are identified
	Update prior to submission to ensure recent data are included	Data are needed before meta-analysis or indirect treatment comparison can begin
Issues	Searches must be performed for the intervention being appraised as well as for the comparators	The main purpose is to demonstrate to the ERG and appraisal committee that all relevant evidence for the intervention and comparators have been identified
	Searches, study inclusion, and quality assessment must be performed to a prespecified protocol and fully documented	NICE define a systematic review as "research that summarises the evidence on a clearly formulated question according to a predefined protocol"
		The systematic review will be validated by the ERG
	Study selection criteria should be fully justified with respect to the decision problem	Example: date or language limits on searches or study inclusion, number of participants, type of study (randomised, non-randomised, observational)

Key Research Requirements

Research Requirement	Main Purpose
3 Meta-analysis and/or indirect and/or mixed treatment comparison (if appropriate)	Synthesis of all relevant clinical evidence for the intervention being appraised and its comparators

Recommendations

Timing	Mid-phase activity	Results usually required for the economic model; analyses may be sophisticated and time-consuming
Issues	Collaboration between researchers	Close collaboration between researchers performing data extraction, meta-analysis, and modelling is crucial
	Comprehensiveness of analyses	Prepare for requests for additional analyses from NICE if potentially relevant analyses are not submitted
	Appropriate selection of methods	Careful consideration of the available data, the known or putative treatment-effect modifiers, and the needs of the economic analysis are required

Key Research Requirements

Research Requirement		Main Purpose
4 Systematic review of relevant economic evaluations		Identification of all relevant economic evaluations of the intervention being appraised
Recommendations		
Timing	Early, update prior to submission	Often helpful in design of model structure and identification of some parameter estimates Needs to be up to date at time of submission

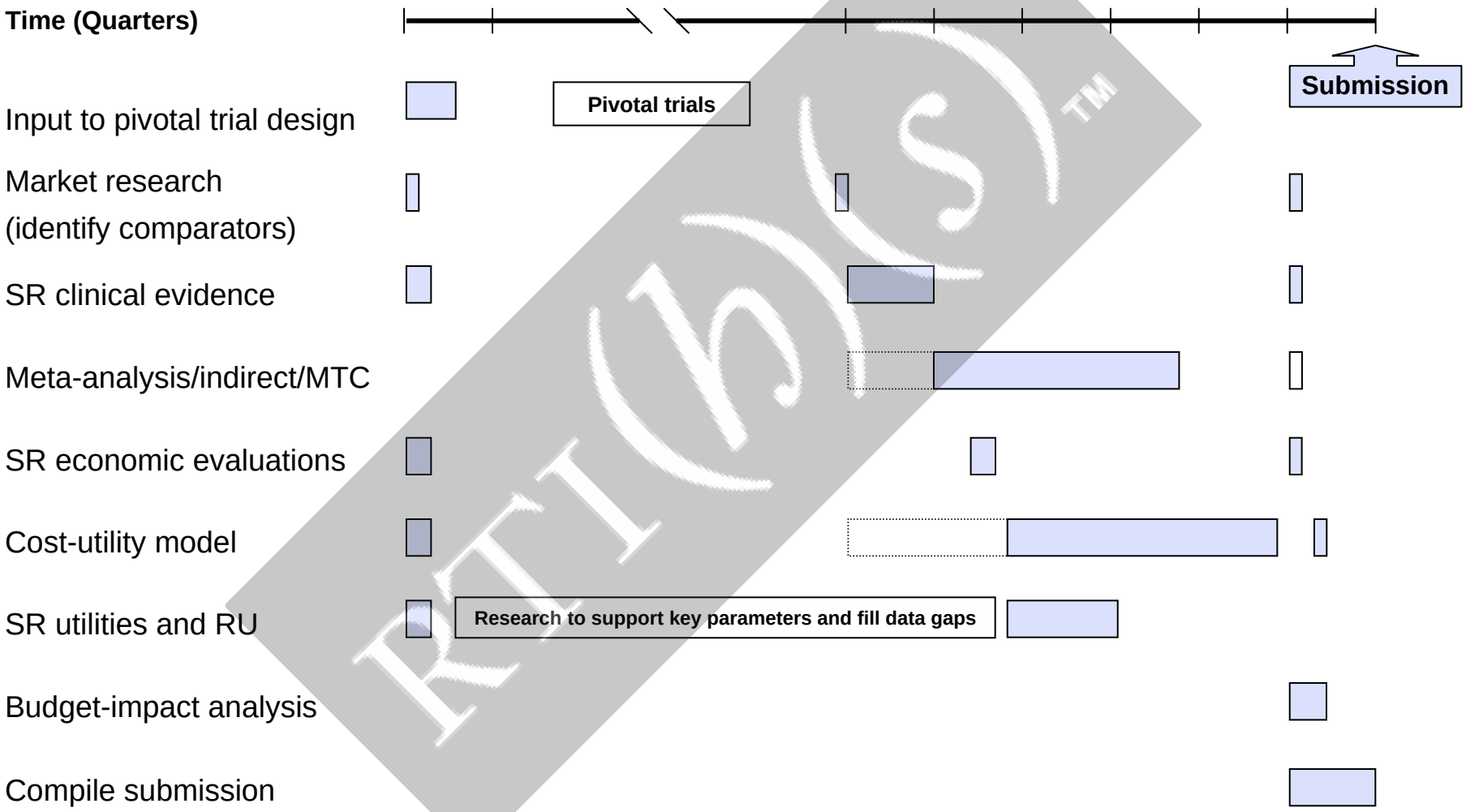
Key Research Requirements

Research Requirement		Main Purpose
5 Economic evaluation		Estimation of cost-utility ratios in accordance with the NICE Reference Case
Recommendations		
Timing	Mid- to late-phase activity (Early-phase models also are recommended to inform research planning for data collection supporting key model parameters)	Model-specification stage is best performed in parallel with systematic review of clinical evidence and statistical analysis plan for meta-analysis and/or MTC to ensure best use of available data Finalisation usually occurs shortly before submission, when the confirmed price is available
Issues	Research planning for key parameter estimates	Identify key drivers of cost-utility estimates and plan to ensure availability of high-quality data
	Pre-existing global models	Global HE/MA functions give full consideration to NICE Reference Case and fully involve UK affiliates in development of global models
	Should conform as far as possible to the NICE Reference Case	*Guide to the Methods of Technology Appraisal*, June 2008 (N1618)

Key Research Requirements

Research Requirement		Main Purpose
6 and 7	Systematic review of published utility and RU estimates	Identification of all relevant utility and RU estimates
Recommendations		
Timing	Mid-phase activity (Early work recommended to inform research planning for data collection supporting key model parameters)	In parallel with model-specification and early-model development
Issues	Selection and synthesis of alternative estimates	Briefing papers (*PharmacoEconomics* 2008;26(9)) and good published examples (e.g., Peasgood et al., *Osteoporosis Int*. 2009;20:853-868) In general, national cost estimates and public listings are most appropriate (e.g., NHS reference costs, MIMS); payment by Results Tariff may provide more specific costs in some cases
	Potentially substantial piece of work	Pragmatic approach is appropriate

Research Schematic: Key Submission Requirements



Open Discussion Session

Moderator

Stephen Beard, MSc

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