Parallel Discussion Session E: Using qualitative methods to select and develop outcomes for randomised controlled trials *(Bridget Young, University of Liverpool)*

Qualitative research and the selection of outcomes for RCTs

Enhancing the development and selection of the outcomes or endpoints for usein RCTs is crucial if research is to influence practice and policy in healthcare. Outcomes need to be relevant to patients and other stakeholderswho makehealthcare decisions. Awareness of the value of qualitative research in the development of patient-reported outcome instruments, such as health-related quality of life scales, has grown in recent decades.[1] However, there is less awareness of the potential contribution that qualitative research can make in the development of core outcome sets(COS), which are agreed standardized collections of outcomes to be measured and reported in all clinical trials for a specific health condition.[2]

Core outcome sets and why they are needed

Inconsistencies between RCTs (within the same clinical condition) in how outcomesare measuredand reported make it difficult to interpret, synthesise and use the results of RCTs. The use of COS is advocated to allowdirect comparisons of the effects of different interventions and to minimise bias in outcome reporting.[3]Evidence indicates that patients prioritise outcomes which other stakeholders overlook or consider less important[4] (see example overleaf of how parents and clinicians ranked different core outcomes in paediatric asthma) and the involvement of patients/carersalongside other stakeholders such as clinicians and researchers in the development of COS is important to ensure that the outcomes selected are meaningful. An important part of the process of COS development is to seek consensus among stakeholders about what outcomes to measure.[5]While researchers have occasionally used qualitative methods such as interviews and focus groups in the process of COS development, their use has been less frequent than quantitative methods such as Delphi surveys.[6]

Questions for group discussion

1. What can qualitative research uniquely contribute to COS development?
2. How can qualitative methods contribute to the development of COS (e.g. in what circumstances, at what point in the course of COS development, how should the qualitative findings be fed into the final consensus process)?
3. What are the potential difficulties in using qualitative methods in COS development?
4. Would specific guidance on using qualitative research in COS development be helpful? If so, what would this guidance include? If not, what resources would help researchers using qualitative methods to develop COS?

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[1] Lasch et al (2010) *Qual Life Res* 19:1087-1096

[2] Using a COS does not mean a particular RCT is restricted only the outcomes in a COS, rather these are the *core* outcomes with the implication that researchers can use other outcomes.

[3] Williamson et al (2012) *Trials* 13:132

[4] E.g. Arnold et al (2008) *Patient Educ Counsel* 73:114-120

[5] Questions about what to measure are usually addressed first, with questions about how and when to measure particular outcomes coming later.

[6] Delphi is a structured process or survey method which utilises a series of questionnaires to gather a group's opinions in ways that aim to overcome the limitations of traditional face-to-face meetings (due to group dynamics such as a few individuals dominating discussion and others being reticent to voice an opinion). See Goodman 1987 *J of Adv Nurs*12:729-734.

Preschool children: the importance of each outcome listed in the phase 2 questionnaire, as scored by clinicians and parents

	Clinicians ($n = 43$)			Parents ($n = 23$)		
Outcome	**Clinician rank**	**Median (IQR)**	**Number (%) scoring outcome in top 3**	**Parent rank**	**Median (IQR)**	**Number (%) scoring outcome in top 3**
Nocturnal symptoms	1	4 (3, 4)	19 (44)	1=	4 (4, 4)	10 (43)
Exacerbations	2	4 (3, 4)	15 (35)	3	4 (4, 4)	7 (30)
Quality of life	3	3 (3, 4)	13 (30)	4	4 (3, 4)	5 (22)
Daytime symptoms	4	4 (3, 4)	11 (26)	10	4 (3, 4)	3 (13)
Death	5	4 (2, 4)	10 (23)	1=	4 (4, 4)	10 (43)
Hospital admission	6	4 (3, 4)	9 (21)	7	4 (4, 4)	4 (17)
Parent/child global assessment of control	7	4 (3, 4)	9 (21)	11	4 (3, 4)	3 (13)
Impact of asthma on the family	8	4 (3, 4)	8 (19)	16	4 (3, 4)	1 (4)
Use of reliever	9	3 (3, 4)	8 (19)	8	4 (3, 4)	4 (17)
Normal activities	10	4 (3, 4)	5 (12)	14	4 (3, 4)	2 (9)
Long-term AE	11	4 (3, 4)	7 (16)	13	4 (4, 4)	2 (9)
School attendance	12	3 (3, 4)	5 (12)	6	4 (3, 4)	5 (22)
Activity or exercise	13	3 (3, 4)	4 (9)	12	3 (2, 4)	3 (13)
GP/A + E attendance	14	4 (3, 4)	4 (9)	15	4 (3, 4)	2 (9)
Growth	15	3 (3, 4)	3 (7)	9	4 (3, 4)	3 (13)
Health-related problems when older	16	3 (2, 4)	0	5	4 (4, 4)	5 (22)
Short-term AE	17	3 (2, 3)	0	17	3 (3, 4)	0

Sinha *et al. Trials* 2012 **13**:103 doi:10.1186/1745-6215-13-103

Sinha et al (2012) Development of a core outcome set for clinical trials in childhood asthma: a survey of clinicians, parents and young people. *Trials 13:103*