

Additional file 4 : The Evaluation of the Quality of the Empirical Studies Included in the Review

	Is it clear whose perspective is offered?	Are the data collection and analysis methods clearly described?	Were questions for data collection open or closed? Was the analysis grounded in the data or framed externally?
Albersheim 2010 [40]	Yes, practicing neonatologists in Canada	Yes, semi-structured interviews and comments on scenarios Yes, thematic analysis of interviews and quantitative analysis of responses to scenarios	Open and closed questions. Externally framed analysis
Allmark 2006 [47]	Yes, parents who gave consent to the TOBY trial and clinicians who sought it, in UK	Yes, semi-structured interviews Yes, framework analysis	Open questions Flexibly framed analysis
Ballard 2004 [46]	Yes, parents of newborns enrolled to the NEOPAIN study in Kentucky, USA	Yes, open ended questions. Yes, questions translated into a closed Likert score and analysed quantitatively	Open questions Externally framed analysis
Ballard 2011 [51]	Yes, parents of newborns enrolled to a specific phase II study in the Neonatal Intensive Care Unit at the University of Kentucky, USA	Yes, open ended questions asked during a controlled trial comparing standard consent with enhanced consent. Yes, questions translated into a closed Likert score and analysed quantitatively	Open questions Externally framed analysis
Brinchmann 2002 [36]	Yes, parents who had experienced one or more life-and-death decisions relating to their critically ill and/or premature infant, in Norway	Yes, in-depth interviews Yes, thematic analysis discussed in the light of theories of ethics	Open questions Emergent themes framed by theories of ethics
Burgess 2003 [25]	Yes, parents who agreed, and those who refused, to enrol their newborns into trials in a NICU in a tertiary care referral centre, Canada	Yes, questionnaire with Likert scale and 3 open questions Yes, quantitative analysis	Closed and open questions Externally framed analysis
Culbert 2005 [53]	Yes, parents who had received obstetrical or neonatal care at a tertiary perinatal centre, Denmark	Yes, mailed questionnaire with Likert scale Yes, quantitative analysis	Closed questions Externally framed analysis

De Leeuw 2000 [61]	Yes, Physicians and nurses in 143 NICUs across Europe	Yes, self-administered Questionnaire Yes, quantitative analysis	Closed questions Externally framed analysis
Garel 2004 [62]	Yes, obstetricians and midwives in three tertiary-care maternity units, France	Yes, semi-structured interviews Yes, content analysis	Open questions Analysis grounded in the data
Garel 2011 [44]	Yes, physicians and nurses in three NICUs, France	Yes, semi-structured interviews Yes, content analysis	Open questions Analysis grounded in the data
Hayman 2001 [16]	Yes, parents who consented or declined to participate in a study of SIDS, New Zealand	Yes, questionnaire Yes, quantitative analysis	Closed questions Externally framed analysis
Hoehn 2005 [17]	Yes, parents of neonates having cardiothoracic surgery, a Children's Hospital, Philadelphia, USA	Yes, Semi-structured qualitative interviews Yes, thematic analysis of spontaneously offered reasons for or against research participation	Open and closed questions Themes emergent from the data
Hoehn 2009 [32]	Yes, parents of neonates with critical congenital heart disease, who had made decisions either for or against research participation before their neonate's cardiothoracic surgery, Chicago, USA	Yes, semi-structured interview Yes, thematic analysis	Open and closed Themes emergent from the data
Hulst 2005 [31]	Yes, parents or legal representatives of children (pre-term neonates to 18 years) in ICU who were approached for consent to enrol their child in a nutritional assessment study, The Netherlands	No Yes, quantitative analysis	Closed questions Externally framed analysis
Jollye 2009 [18]	Yes, parents who had chosen or declined to participate in clinical trials, England	Yes, semi-structured interviews Yes, thematic analysis	Open questions Themes emergent from the data
Kavanaugh 2005 [37]	Yes, mothers hospitalised for risk of pre-term birth; their partners, physicians and nurses, USA	Yes, serial interviews with parents; single interviews with each clinician. Yes, analysed in line with Ottawa Decision Support Framework	Open questions Externally framed analysis
Korotchikova 2010 [29]	Yes, parents of healthy full-term newborn babies on the postnatal wards in a University	Yes, observation of presence/ absence partner	Open questions Externally framed analysis

	Maternity Hospital, Ireland	Yes, quantitative analysis according to four principles of the consent process	
Maayan-Metzger 2008 [19]	Yes, mothers of healthy term newborns and mothers of stable growing preterm infants with no active disease who had given birth at a large tertiary hospital, Israel	Yes, questionnaire with Likert scale Yes, quantitative	Closed questions Externally framed analysis
Mason 2000 [34]	Yes, parents who had been asked for consent to neonatal trials and neonatologists seeking consent, in Europe	Yes, semi-structured interviews Yes, quantitative analysis according to four principles of the consent process	Open questions Externally framed analysis
McHaffie 2001 [38]	Yes, doctors and nurses working in six large neonatal intensive care units (NICUs) throughout Scotland	Yes, in-depth, face-to-face interviews with semi-structured schedules Unclear, 'Data were entered onto a computer under predetermined variable names, with scope for unlimited values to accommodate the full range of qualitative responses'	Open questions Analysis unclear
Morley 2005 [20]	Yes, parents of premature babies in the neonatal intensive care unit, Australia	Yes, questionnaire with multiple choice answers or Likert scale Yes, quantitative	Closed questions Externally framed analysis
Nathan 2010 [59]	Yes, parents of neonates undergoing cardiac surgery who had made decisions about research participation before their neonate's surgery, USA	Yes, MacArthur competence assessment tool for clinical research (MacCAT-CR), specifically testing the components of understanding, appreciation, reasoning and choice Yes, quantitative	Unclear whether questions open or closed Externally framed analysis
Paulmichl 2011 [43]	Yes, clinicians involved in various dilemmas of neonatology (nurses, obstetricians, neuro-paediatricians and neonatologists, midwives and other health professionals such as	Yes, a questionnaire for professionals; for parents, similar questions asked in interviews no more than 30 minutes long	Some open, some closed Content analysis and descriptive statistics for analysing answers to questions

	clinical psychologists and physical therapists); and parents of preterm and term infants treated in NICU		Unclear to what extent analysis externally framed
Rogers 1998 [55]	Yes, mothers of low birth weight infants eligible for an RCT of primary care follow-up, Texas, USA	Yes, structured interviews Yes, RCT of conventional or modified consent procedure	Closed and open questions Pre-set outcomes
Saigal 1999 [63]	Yes, mothers of infants who weighed less than 1500 g at birth, Ontario, Canada	Yes, standardized interviews using the Standard Gamble technique to elicit preferences for 5 pediatric hypothetical health states with varying disabilities Yes, quantitative	Closed questions Externally framed analysis
Schmidt 1999 [57]	Yes, premature infants were eligible for enrollment in a placebo-controlled trial of antithrombin therapy, a university medical centre, Canada	Yes, physical health status of newborns with parents who consented or refused Yes, quantitative analysis	No questions Externally framed analysis
Sharma 2011 [64]	Yes, women with at least one prior Caesarean in the last 18 months who were eligible to undergo a trial of labour for a subsequent pregnancy, Oregon, USA.	Yes, 45 minutes using a computerized evidence-based decision aid based Yes, quantitative comparison of two decision aid models	Closed questions Externally framed analysis
Simon 2006 [60]	Yes, parents of children eligible for RCTs of leukemia treatments, Maryland, USA.	Yes, observed & recorded informed consent sessions, and interviews Yes, quantitative analysis of references to altruism related to RCT participation	Open and closed questions Externally framed analysis
Singhal 2002 [26]	Yes, parents of newborn babies in NICU, in a large tertiary referral center and teaching hospital, Canada	Yes, questionnaire with graded responses and five research scenarios	Closed questions Externally framed analysis
Singhal 2004 [41]	Yes, doctors and nurses in a large tertiary care center in western Canada	Yes, questionnaire with 20 scaled items and five case scenarios	Closed questions Externally framed analysis
Snowdon 1997 [48]	Yes, parents of critically ill newborns who	Yes, in-depth interviews at 47-140 weeks after birth	Open questions Emergent themes

	consented to enrolling in ECMO trial, UK.	Yes, thematic analysis with Atlas-ti	
Snowdon 1998 [33]	Yes, parents whose baby had participated in ECMO trial, and they had received trial results, UK	Yes, in-depth interviews Yes, thematic analysis with Atlas-ti	Open questions Emergent themes
Snowdon 2004 [42]	Yes, neonatologists and neonatal pathologists associated with five UK trials	Yes, semi-structured interviews Yes, thematic analysis with Atlas-ti	Open questions Emergent themes
Snowdon 2004 [39]	Yes, bereaved parents from five UK neonatal units	Yes, in-depth interviews Yes, thematic analysis with Atlas-ti	Open questions Emergent themes
Snowdon 2006 [28]	Yes, parents of babies, most associated with the neonatal trials; some parents refused consent, some babies died, UK	Yes, in-depth interviews Yes, thematic analysis with Atlas-ti	Open questions Emergent themes
Stenson 2004 [35]	Yes, parents of sick newborns enrolled in a randomised trial in the early neonatal period, Scotland	Yes, a short questionnaire using Likert scales Yes, quantitative analysis	Closed and open questions Externally framed analysis
Ward 2009 [27]	Yes, in NICU, in USA, mid-Atlantic hospitals	Yes, in-depth interviews; Yes, qualitative content analysis	Open questions, themes developed from the data
Zupancic 1997 [21]	Yes, parents who had recently given or declined consent to one of three controlled trials in the NICU, Canada	Yes, questionnaire using Likert scales Yes, quantitative analysis	Closed questions Externally framed analysis