

What is a Core Outcomes Set and why does this matter?

James Webbe, Neena Modi and Chris Gale
On behalf of the COIN Steering Group



Core Outcomes
In Neonatology

Contents

Outcomes in neonatal research

- Causing problems for researchers
- Causing problems for healthcare professionals
- Causing problems for parents

Core outcomes sets

- What they are
- An example: OMERACT

COIN Project

- Core outcomes for neonatal research
 - Applications beyond research
-

Outcomes in neonatal research

Systematic Cochrane Reviews in Neonatology: A Critical Appraisal

Christiane Willhelm ^{a,*†}, Wolfgang Girisch ^a, Sven Gottschling ^b,
Stefan Gräber ^c, Holger Wahl ^d, Sascha Meyer ^{a,d,*†}

^aUniversity of Saarland, Medical School, Saarbrücken, Germany

^bDepartment of Paediatric Palliative Care, University Children's Hospital of Saarland, Saarbrücken, Germany

^cDepartment of Biostatistics and Epidemiology, University Hospital of Saarland, Saarbrücken, Germany

^dDepartment of Paediatrics and Neonatology, University Children's Hospital of Saarland, Saarbrücken, Germany

Received Jun 27, 2012; received in revised form Aug 30, 2012; accepted Mar 5, 2013

Key Words

Cochrane reviews;
evidence-based
medicine;
meta-analysis;
neonatology

Background: There is a lack of up-to-date, systematic reviews that critically assess the role and potential limitations of evidence-based medicine (EBM) and systematic reviews in neonatology.

Methods: We performed a systematic literature review of all Cochrane reviews published between 1996 and 2010 by the Cochrane Neonatal Review Group (CNRG). *Main outcome parameter:* assessment of the percentage of reviews that concluded that a certain intervention provides a benefit, the percentage of reviews that concluded that no benefit was seen, and the percentage of studies that concluded that the current level of evidence is inconclusive.

Results: In total, 262 reviews were assessed, most of which included exclusively preterm infants (146/262). The majority of reviews assessed pharmacological interventions (145/262); other important fields included nutritional (46/262), and ventilatory issues (27/262). In 42/262 reviews, a clear recommendation in favor of a specific intervention was given, whereas 98/262 reviews concluded that certain interventions should not be performed. However, the largest proportion of reviews was inconclusive (122/262) and did not issue specific recommendations.

The proportion of inconclusive reviews increased from 30% (1996–2000), to 50% (2001–2005), and finally to 58% for the years 2006–2010. Common reasons for inconclusive reviews were the small number of patients (105), insufficient data (94), insufficient methodological quality (87), and heterogeneity of studies (69).

Outcomes in neonatal research

Outcomes in neonatal research have been criticised by parents:

- Selected by researchers
- Correlate poorly with long term difficulties/functioning
- Artificially divide continuous outcomes
- May not have a clear relationship with quality of life

(Janvier et al 2016)

Core outcomes sets

A “Core Outcomes Set” is an agreed minimum set of outcomes or outcome measures

Improve research outcomes:

- Ensure important outcomes universally reported
 - Ensure results can be combined in meta-analyses
 - Reduces selective outcome reporting/interpretation
-

Examples of core outcomes sets

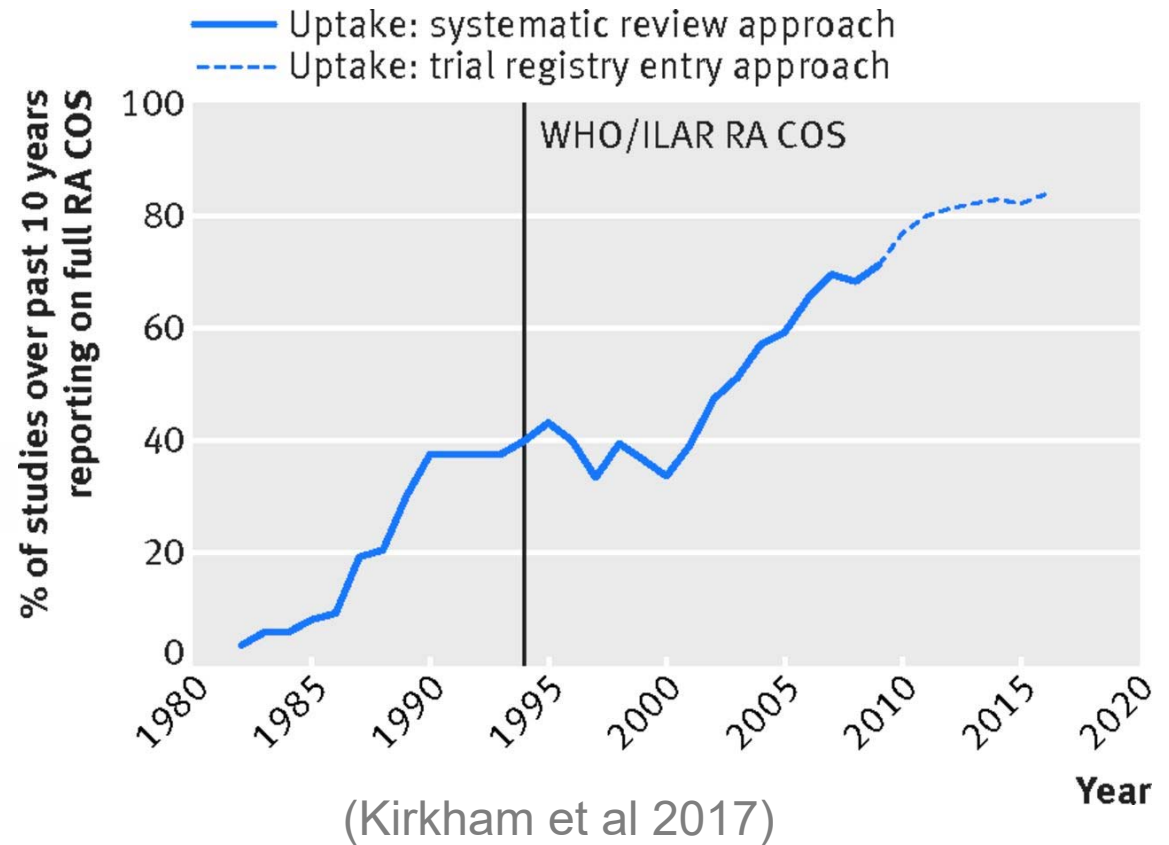
WHO/ILAR core endpoints for symptom modifying antirheumatic drugs in rheumatoid arthritis clinical trials

1. Pain
2. Patient global assessment
3. Physical disability
4. Swollen joints
5. Tender joints
6. Acute phase reactants
7. Physician global assessment

In studies of 1 or more years' duration

8. Radiographs of joints
-

Examples of core outcomes sets

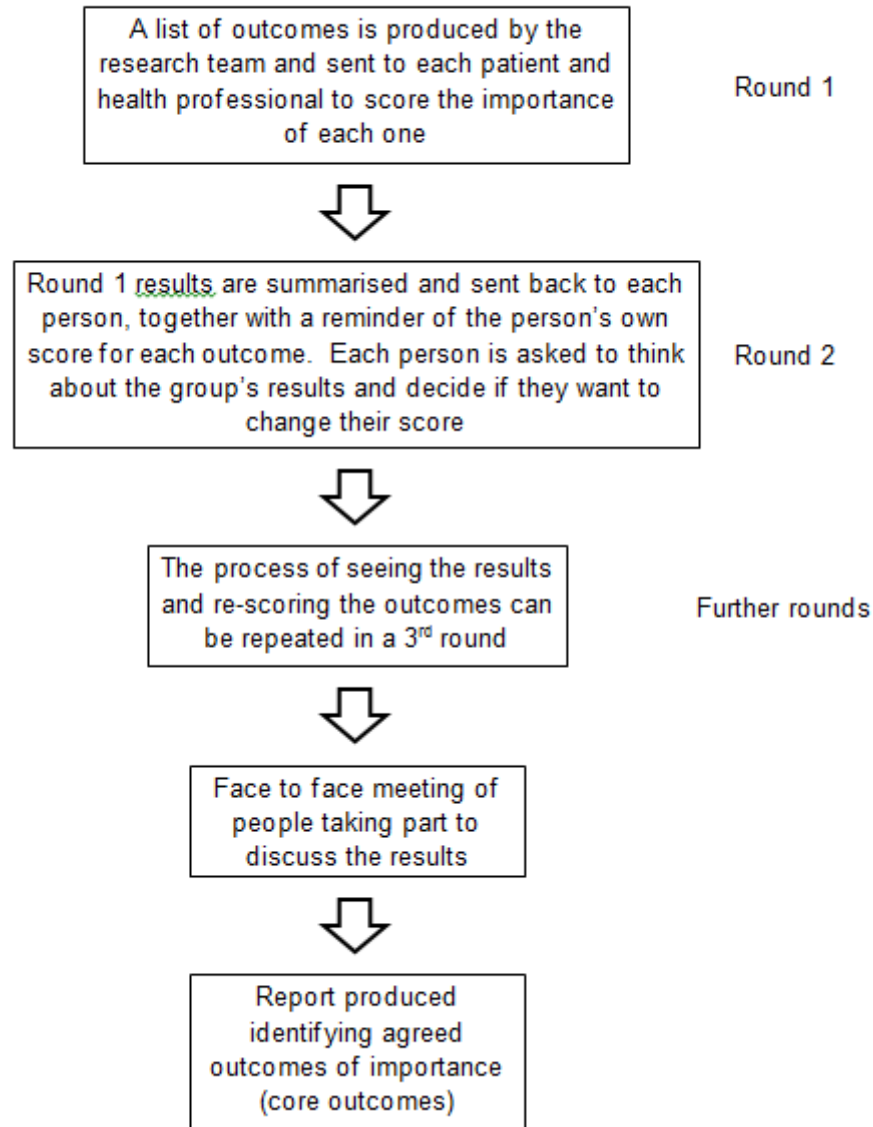


Core Outcomes in Neonatology

Aim: Develop a core outcomes set for neonatal medicine



The Delphi Process



Methods

Neonatal outcomes identified by systematic reviews of quantitative and qualitative research

Four stakeholder groups recruited to complete Delphi survey

- Former neonatal patients and parents
- Nurses and therapists
- Doctors
- Neonatal researchers

Consensus meeting

NEUROLOGICAL - relating to the brain and nerves

Please do not use the browser's back button.

You have answered: 37 out of 104 outcomes

Page 5 of 24

All of these outcomes are important, we want you to identify the small number that are SO IMPORTANT they should be measured in every neonatal research study.

DID YOU KNOW?: Nerves can conduct signals at up to 275mph!

If you feel unable to comment based on your experience, please select 'unable to score'. If you would like clarification on a variable, please hold your cursor over the variable and a text box will be displayed with additional information or definitions where available.

Outcome	Not important			Important but not critical			Critical			Unable to score
	1	2	3	4	5	6	7	8	9	
Neurological										
Retinopathy of Prematurity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Brain injury on imaging	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Blood flow in cerebral vessels	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cerebral oxygenation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Seizures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sleep disorders (after discharge home)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Neurological symptoms (unspecified)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
ElectroEncephaloGram (EEG) abnormalities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please note: You will only be able to save/move to the next page if you have answered ALL the questions on this page.

Save and Exit

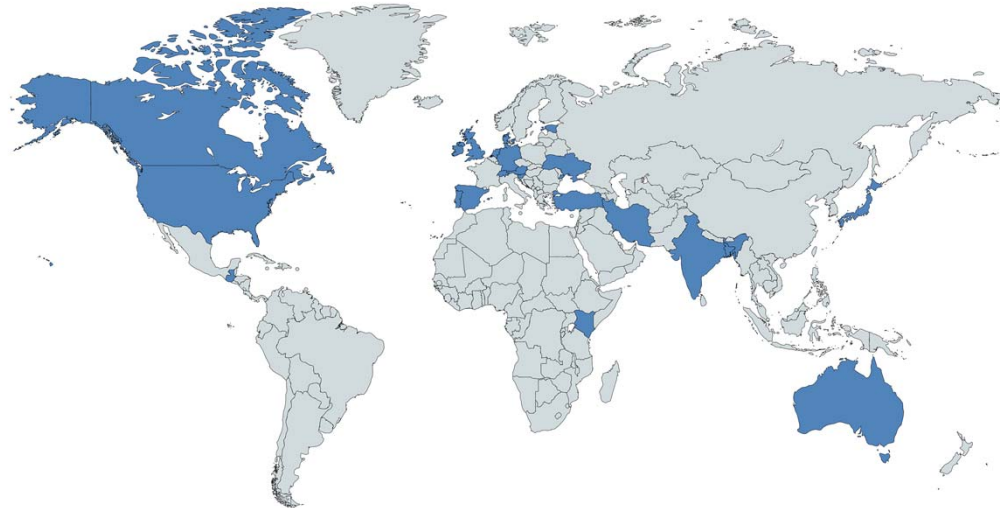
Goto Page 5 Or Next Page

Results: Participants

414 respondents in first round

- 244 former neonatal patients and parents
- 53 nurses and therapists
- 83 doctors
- 34 neonatal researchers

25 countries



Created with mapchart.net ©

Results: Participants

	Round 1		Round 2		Round 3	
	Started	Completed	Started	Completed	Started	Completed
Parents and former patients	244	111	84	61	61	53
Doctors	83	74	71	62	67	59
Neonatal nurses and allied professionals	53	44	39	38	34	33
Neonatal researchers	34	31	29	26	29	28
Total	414	260	223	187	191	173

Results: Round 3

Patients and parents	Nurses and therapists	Doctors	Researchers
Survival	Survival	Survival	Survival
Necrotising enterocolitis (NEC)	Necrotising enterocolitis (NEC)	Necrotising enterocolitis (NEC)	Necrotising enterocolitis (NEC)
Sepsis	Harm due to medical treatment	Sepsis	Sepsis
Brain injury on imaging	Sepsis	Brain injury on imaging	Visual impairment or blindness
Harm due to medical treatment	Brain injury on imaging	Hearing impairment or deafness	Hearing impairment or deafness
Parental bonding with their baby	Quality of life	Retinopathy of prematurity	General cognitive ability
Pain	Visual impairment	General cognitive ability	Quality of life
Suffering	Pain	Harm due to medical treatment	Brain injury on imaging
Parental involvement	Suffering	Ability to walk	Breastfeeding
Retinopathy of prematurity	Parental bonding with their baby	General gross motor ability	General gross motor ability
Quality of life	Retinopathy of prematurity	Quality of life	Retinopathy of prematurity
General fine motor ability	Ability to walk	Visual impairment or blindness	Ability to walk
Team working by professionals	Parental involvement	General communication ability	Need for surgical operations
Visual impairment	General gross motor ability	Breastfeeding	Harm due to medical treatment
Seizures	General cognitive ability	Effective communication	Pain

Consensus meeting

Face-to-face meeting of stakeholders from all groups
16 participants

Discussed Delphi results and
reviewed the core outcome set



Final Core Outcome Set

Survival

Sepsis

Necrotising enterocolitis

Brain injury on imaging

General gross motor ability

General cognitive ability

Quality of life

Adverse events

Visual impairment or blindness

Hearing impairment or deafness

Retinopathy of prematurity (*preterm only*)

Chronic lung disease/bronchopulmonary dysplasia (*preterm only*)

COIN: Beyond research

Audit, benchmarking and quality improvement also need important outcomes

Incorporating the core outcomes set into the NNRD will ensure high quality outcome data is captured at population level

This data will have multiple uses:

- Clinical trials
 - Observational research
 - Audit
 - Benchmarking
 - Quality improvement
-

Summary

Core outcomes sets can standardise research outcomes and reduce research waste

These outcomes:

- Are important to all groups
- Will facilitate meta-analysis if measured in a standardised manner
- Could be adopted for audit, benchmarking and quality improvement

We have identified a neonatal core outcomes set with input from former patients, parents, nurses, doctors and researchers

Imperial College
London

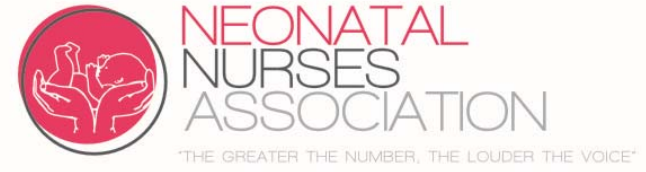
Chelsea and Westminster Hospital 
NHS Foundation Trust

Acknowledgements

COIN Project Participants

PhD supervisors

Section of Neonatal Medicine



CROWN
CORE OUTCOMES IN
WOMEN'S AND NEWBORN HEALTH



Bliss
for babies born
premature or sick

