

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

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On behalf of the COIN Steering Group



Core Outcomes  
In Neonatology

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# Outcomes in neonatal research

## Systematic Cochrane Reviews in Neonatology: A Critical Appraisal

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### 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)

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## 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

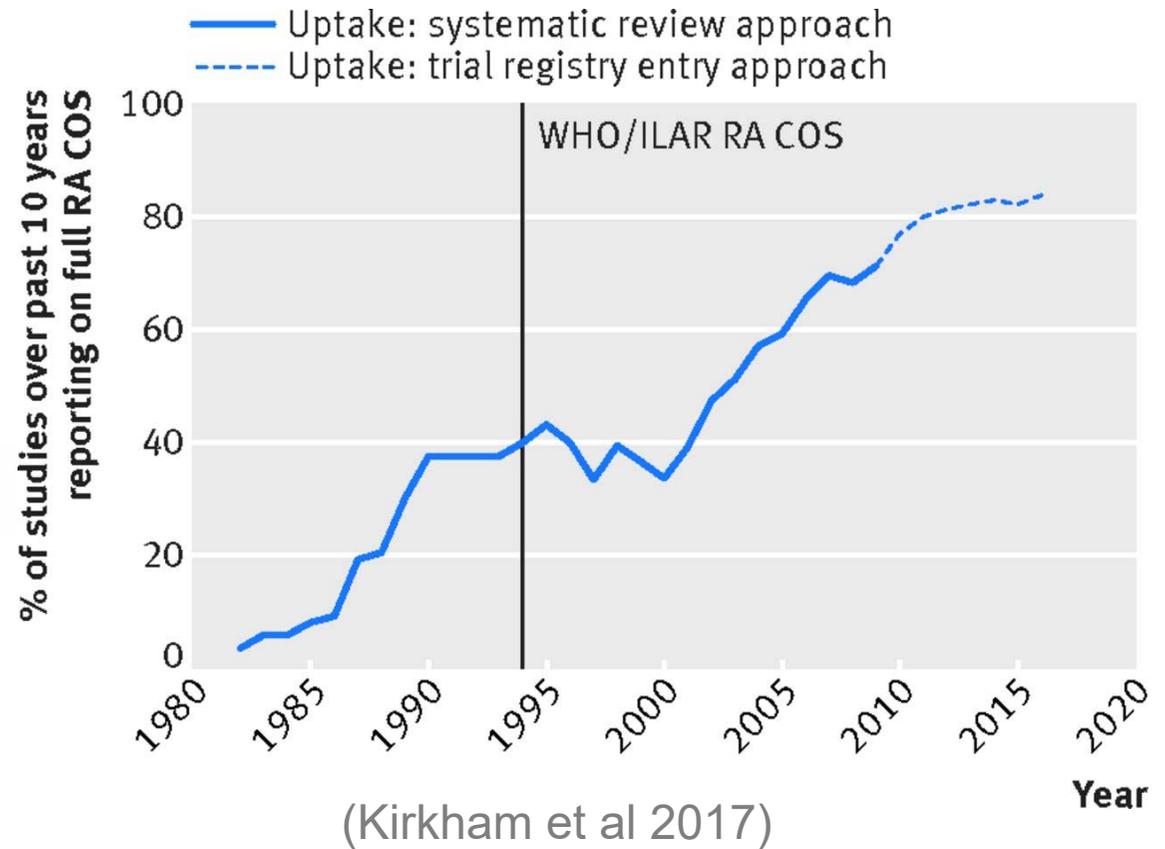
WHO/ILAR core endpoints for symptom modifying antirheumatic drugs in rheumatoid arthritis clinical trials

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

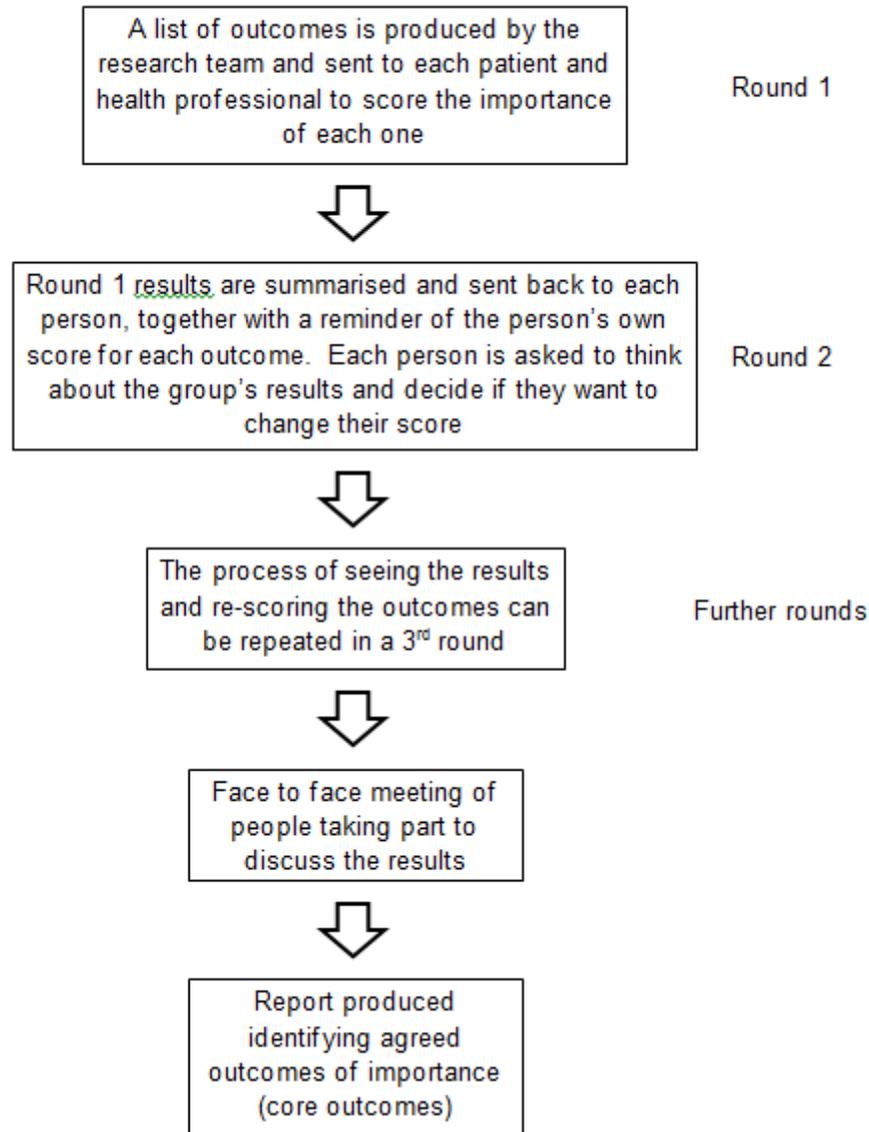


## Core Outcomes in Neonatology

**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

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NEUROLOGICAL - relating to the brain and nerves

Please do not use the browser's back button.

You have answered: 37 out of 104 outcomes

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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	
<b>Neurological</b>										
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.

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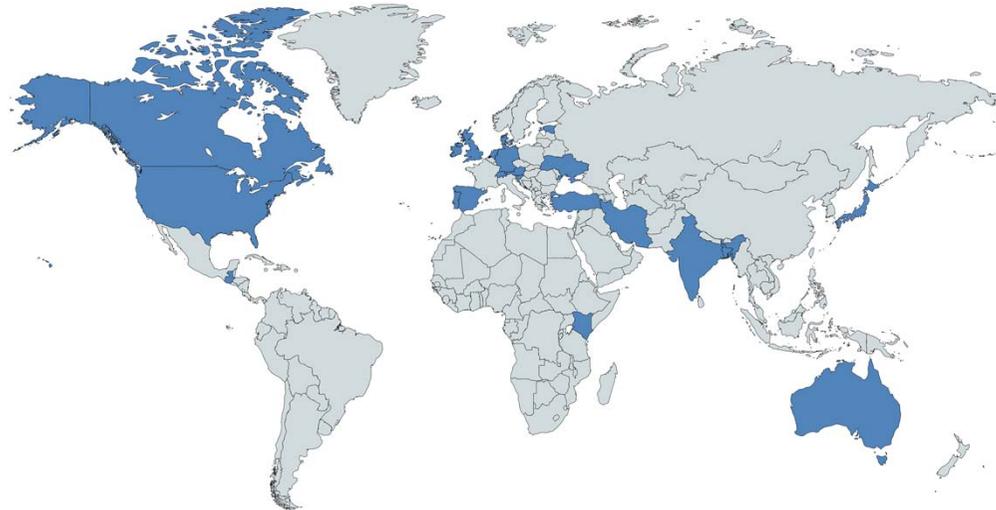
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## Results: Participants

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
<b>Total</b>	<b>414</b>	<b>260</b>	<b>223</b>	<b>187</b>	<b>191</b>	<b>173</b>

## Results: Round 3

<b>Patients and parents</b>	<b>Nurses and therapists</b>	<b>Doctors</b>	<b>Researchers</b>
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*)

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## 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

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COIN Project Participants

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Section of Neonatal Medicine



**CROWN**  
CORE OUTCOMES IN  
WOMEN'S AND NEWBORN HEALTH



**Bliss**  
for babies born  
premature or sick

