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# Overview of outcome measures in Cochrane Skin Group reviews

Stefanie Deckert, Jochen Schmitt, and the Cochrane Skin Group

Annual Cochrane Skin Group Meeting 2015

Dresden, 17th March

# Background – Selected citations from CSG Reviews

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## **Napkin dermatitis:**

*“Due to the poor reporting of methodology and results of the studies, no quantitative data was available for analysis (or meta-analysis) in this review.”* (Baer et al. 2006)

## **Nail psoriasis:**

*„Because there is no consensus on core outcome measures for nail psoriasis, we included all possible outcomes.“* (de Vries et al. 2013)

## **Female pattern hair loss:**

*“The use of proprietary severity scales and non-standardised scales significantly hampered our ability to combine study results for a meta-analysis.”* (van Zuuren et al. 2012)

## **Atopic eczema (in children):**

*“The following outcomes, influenced by the HOME work, were of interest to us as measured by participant, carer [...].”* (Ersser et al. 2014)

## **Metastatic malignant melanoma:**

*“Despite the importance of evaluating quality of life, there was no available data to perform the meta-analysis in this systematic review. Only three studies reported data about quality of life, all with different methods.”* (Sasse et al. 2007)

# Background – Choice of outcome measures

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- 1) **Choice of outcome measures** (needs to be relevant to patients, clinicians, and regulators) (Kirkham et al. 2013)
- 2) **Inconsistent choice of outcome measures** (many meta-analysis are unable to include data from all the relevant underlying trials) (Kirkham et al. 2013)



- **Heterogeneity in the outcomes measured** in included trials
- **Measurement of the same outcome in a variety of ways**

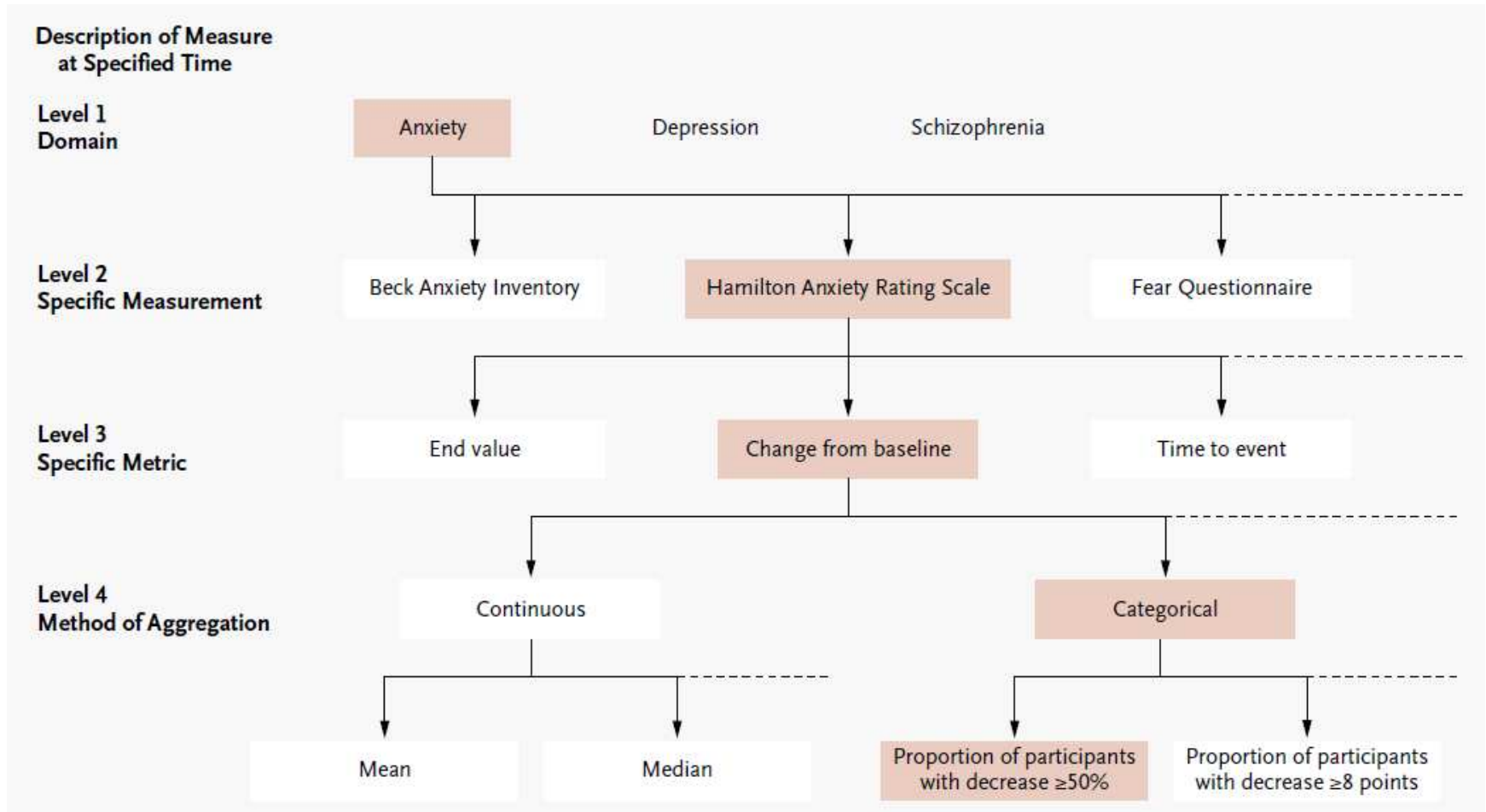
# Background – Selective reporting of outcomes

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## 3) **Selective reporting of outcomes** (Kirkham et al. 2010)

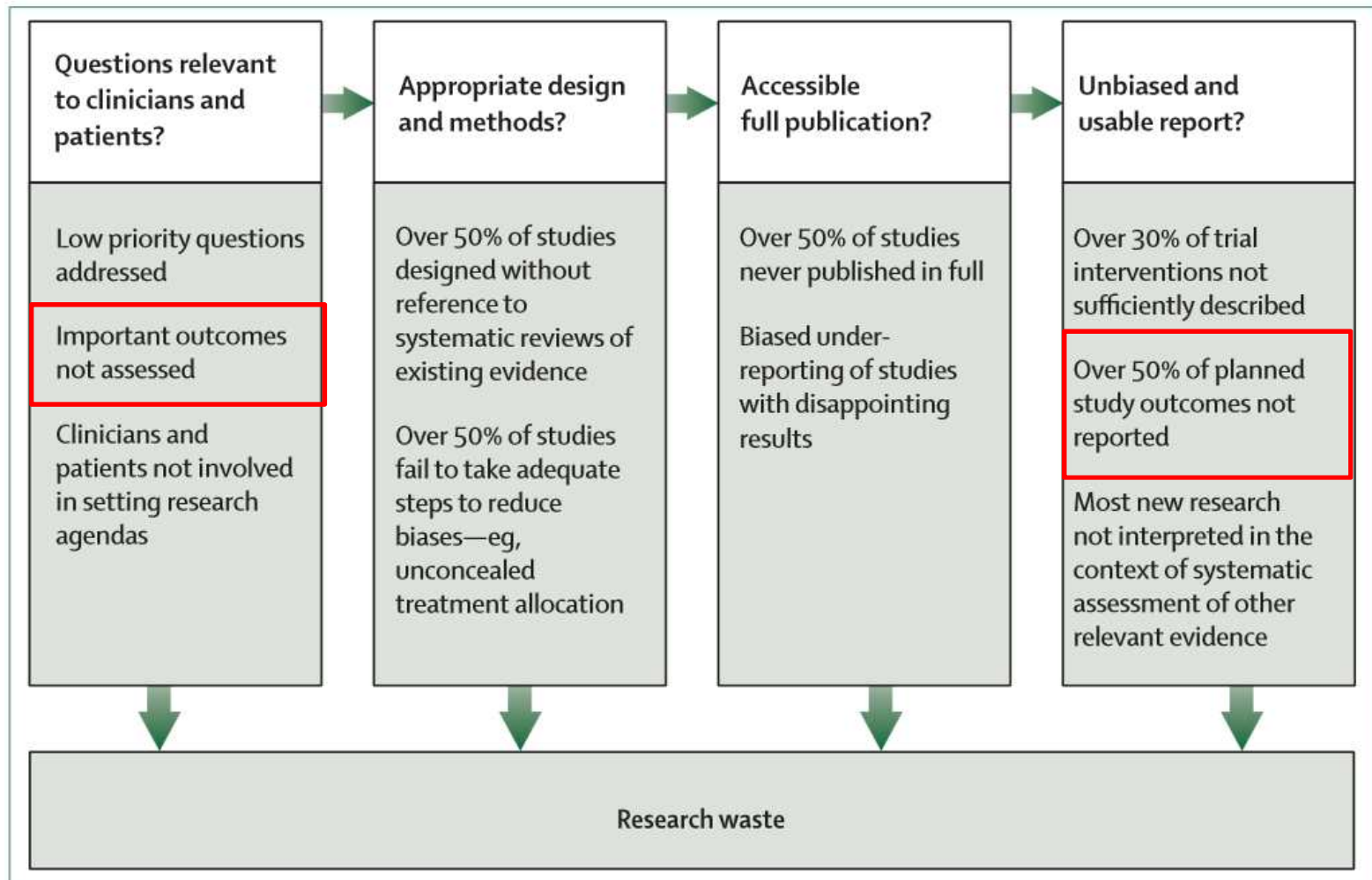
- The selective reporting of a specific outcome
- Incomplete reporting of a specific outcome
- The selective reporting of some of the set of study outcomes

# Background - An example of the four levels of specification in reporting outcome measures



Zarin et al. 2011

# Background – Avoidable research waste



# Background – Selective reporting of outcomes

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## 3) **Selective reporting of outcomes** (Kirkham et al. 2010)

- The selective reporting of a specific outcome
- Incomplete reporting of a specific outcome
- The selective reporting of some of the set of study outcomes



**One solution** to overcome problems related to the difficulty of outcome variation and outcome reporting bias in systematic reviews is to develop **Core Outcome Sets**.

# Background – Existing Core Outcome Sets in Dermatology

The image displays two overlapping website screenshots. The top screenshot is the COMET Initiative website, featuring a navigation menu with 'Home', 'About COMET', 'Search', 'Events', 'Resources', 'Links', and 'Contact'. A sidebar on the left lists categories like 'Overview', 'Background', 'Aims and objectives', and 'Research projects'. The main content area shows a red header for 'HOME' and a sub-header 'Harmonising Outcome Measures for Eczema'. The bottom screenshot is the Acne Core Outcomes Research Network website, with a prominent orange and red graphic header for 'Acne Core Outcomes Research Network'. It includes a navigation menu with 'Home', 'Project Aims', 'Meet the Teams', 'Publications', 'For Professionals', 'For Study Subjects', and 'Contact'. The main content area features a section titled 'Project Aims' with text describing the group's long-term objective and a list of stages.

**COMET INITIATIVE**  
Core Outcome Measures in Effectiveness Trials

Home About COMET Search Events Resources Links Contact COMET V Meeting

Overview

The West trial mak cons Bris and

HOME  
Harmonising Outcome Measures for Eczema

Home  
About  
Core outcomes for eczema trials  
Meetings and Events  
Publications  
Resources  
Contact  
Links

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Harmonising Outcome Measures for Eczema (HOME)

"Developing a consensus set of core outcomes for eczema for inclusion in clinical trials."

The HOME initiative is an international effort for researchers, clinicians, patients and regulators to agree a core of outcomes for atopic eczema clinical trials

Participation in HOME is open to all researchers and clinicians with an interest in outcomes for atopic eczema clinical trials. If you are interested please [contact us](#).

About HOME

**Acne Core Outcomes Research Network**  
An International Organization to Develop Standardized Acne Outcome Measures

Home Project Aims Meet the Teams Publications For Professionals For Study Subjects Contact

**Project Aims**

The **long-term objective** of the ACORN group is to use a team-based approach to develop a tool box of validated instruments to measure acne outcomes that are important to patients, clinicians and researchers for use in ALL clinical trials and which are also suitable for use in everyday clinical practice.

The **long-term objective** will be reached via a series of key stages:

- i) identification of items/constructs of interest using *at least* a Delphi exercise and one or more systematic reviews

ACORN News & Events  
ACORN Newsletter  
American Academy of Dermatology  
World Congress of Dermatology  
American DermatoEpidemiology

Dermatology News  
Dermatologists identify first-line treatments and procedures that may not need to be used in everyday clinical practice  
How to remove acne from the face



# Background – Survey of outcomes in Cochrane Reviews



Journal of Clinical Epidemiology ■ (2014) ■

**Journal of  
Clinical  
Epidemiology**

## ORIGINAL ARTICLE

### Survey of new 2007 and 2011 Cochrane reviews found 37% of prespecified outcomes not reported

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#### Abstract

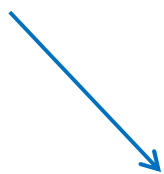
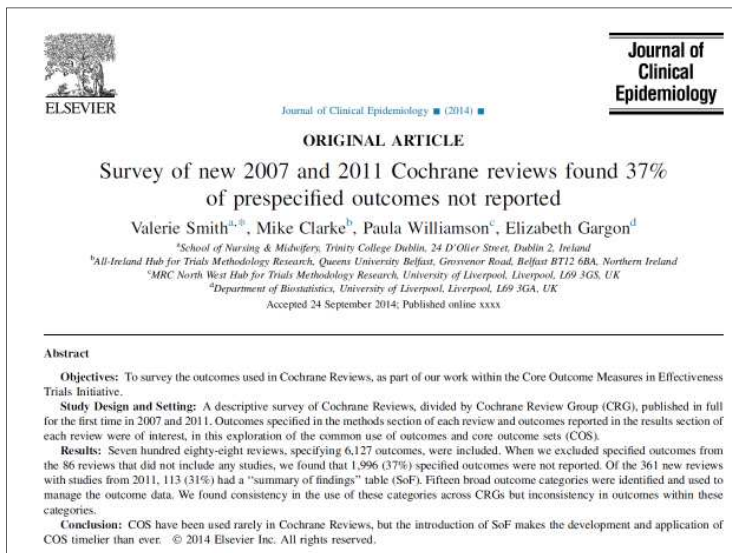
**Objectives:** To survey the outcomes used in Cochrane Reviews, as part of our work within the Core Outcome Measures in Effectiveness Trials Initiative.

**Study Design and Setting:** A descriptive survey of Cochrane Reviews, divided by Cochrane Review Group (CRG), published in full for the first time in 2007 and 2011. Outcomes specified in the methods section of each review and outcomes reported in the results section of each review were of interest, in this exploration of the common use of outcomes and core outcome sets (COS).

**Results:** Seven hundred eighty-eight reviews, specifying 6,127 outcomes, were included. When we excluded specified outcomes from the 86 reviews that did not include any studies, we found that 1,996 (37%) specified outcomes were not reported. Of the 361 new reviews with studies from 2011, 113 (31%) had a “summary of findings” table (SoF). Fifteen broad outcome categories were identified and used to manage the outcome data. We found consistency in the use of these categories across CRGs but inconsistency in outcomes within these categories.

**Conclusion:** COS have been used rarely in Cochrane Reviews, but the introduction of SoF makes the development and application of COS timelier than ever. © 2014 Elsevier Inc. All rights reserved.

# Background – Survey of outcomes in Cochrane Reviews



Categories of outcomes that were specified in  $\geq 50\%$  of new reviews from the **Skin Group**

Outcomes	No of reviews (%) 2007	No of reviews (%) 2011
Adverse events/ effects	4 (67)	3 (100)
Improvement	3 (50)	2 (67)
Itch	3 (50)	---
Quality of life (generic)	4 (50)	---

# Aim of the overview (according to Smith et al. 2014)

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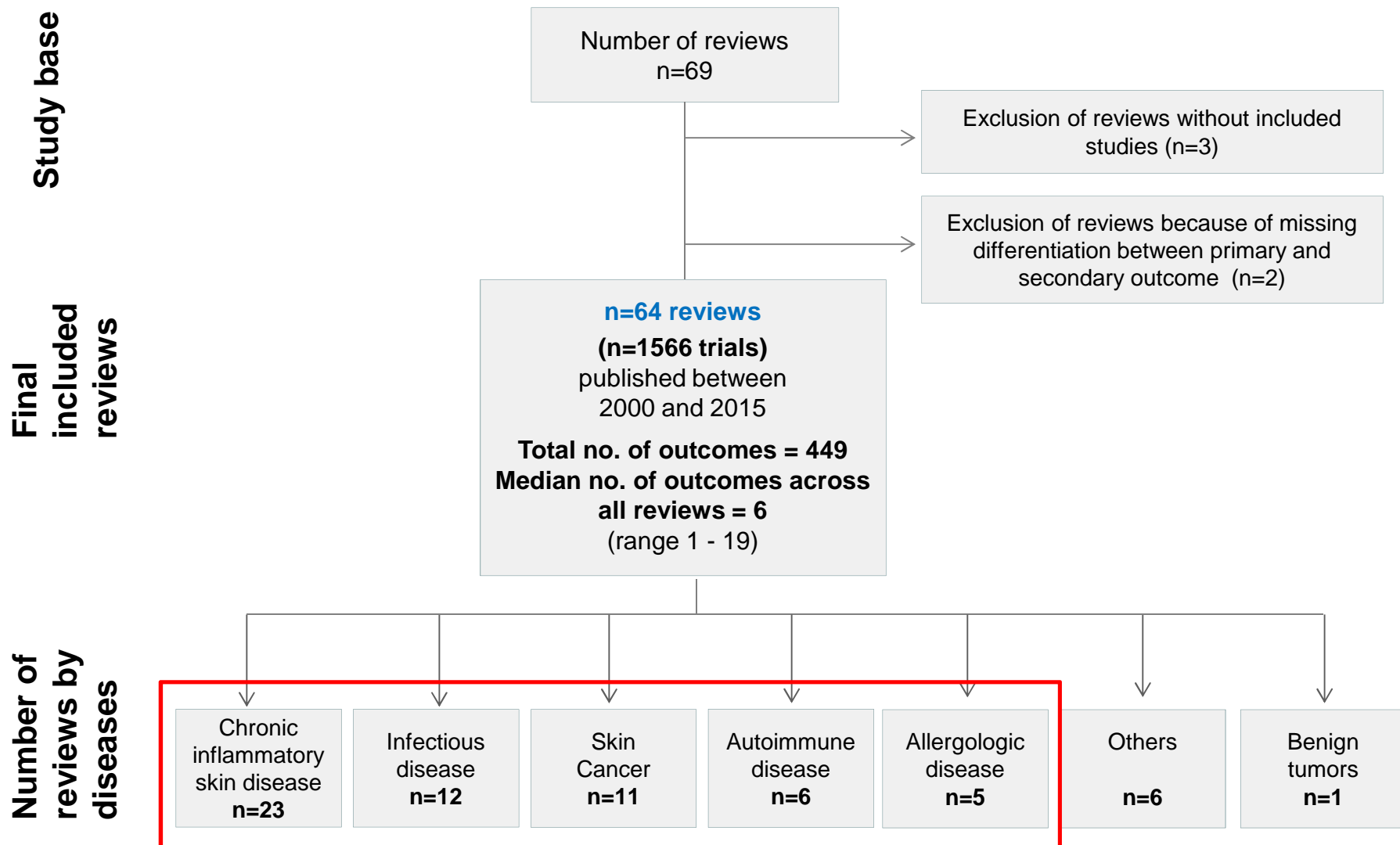
- 1) To identify the **variety of outcome measures** used in CSG reviews
- 2) To systematically **compare predefined outcome measures** in CSG reviews and **reporting of these outcomes in underlying trials**
- 3) To **identify disease categories** that might benefit from COS development

# Methods

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- Overview of **all CSG Reviews published up to January 2015**
- Reviews that did not identify any randomised controlled trials and/or did not differentiate between primary and secondary outcomes were not assessed further
- **Extraction of all predefined primary and secondary outcomes** described in the methods section of each **review**
- **Comparison of all predefined review outcomes in the methods section** of each review and **outcomes reported in the results section** of each review (by using Archie output)

# Results – in general



# Results - Chronic inflammatory disease (n=23 reviews; n = 561 underlying trials)

- Median number of predefined outcomes across all reviews = 7 (range 4 – 19)
- Total number of outcomes predefined in these reviews = 172
  - n = 54 (31%) predefined review outcomes were not reported in at least one underlying trial of these reviews
- Categories of outcomes that were specified in at least 50% of the reviews:

Outcomes	Number of <i>reviews</i> which predefined this outcome	Number of reviews in which at least one underlying <i>trial</i> reported this outcome
Severity	22	18
Quality of life	19	11
Adverse events	16	14

# Results – Skin Cancer (n=11 reviews; n = 202 underlying trials)

- Median number of predefined outcomes across all reviews = 7 (range 1 – 11)
- Total number of outcomes predefined in these reviews = 73
  - n = 16 (22%) predefined review outcomes were not reported in at least one underlying trial of these reviews
- Categories of outcomes that were specified in at least 50% of the reviews:

Outcomes	Number of <i>reviews</i> which predefined this outcome	Number of reviews in which at least one underlying <i>trial</i> reported this outcome
Mortality/Survival	7	7
Adverse events/effects	7	7
Quality of life	6	3

# Results – Infectious disease (n=12 reviews; n = 529 underlying trials)

- Median number of predefined outcomes across all reviews = 6 (range 4 – 12)
- Total number of outcomes predefined in these reviews = 83
  - n = 28 (34%) predefined review outcomes were not reported in at least one underlying trial of these reviews
- Categories of outcomes that were specified in at least 50% of the reviews:

Outcomes	Number of <i>reviews</i> which predefined this outcome	Number of reviews in which at least one underlying <i>trial</i> reported this outcome
Adverse events	11	3
Quality of life	9	1
Cure	8	8



# Results – Autoimmune disease (n=6 reviews; n = 99 underlying trials)

- Median number of predefined outcomes across all reviews = 7 (range 5 – 10)
- Total number of outcomes predefined in these reviews = 42
  - n = 18 (43%) predefined review outcomes were not reported in at least one underlying trial of these reviews
- Categories of outcomes that were specified in at least 50% of the reviews:

Outcomes	Number of <i>reviews</i> which predefined this outcome	Number of reviews in which at least one underlying <i>trial</i> reported this outcome
Adverse event	6	1
Quality of life	5	2
Remission	3	2
Mortality	3	2

# Results – Allergologic disease (n = 5 reviews; n = 89 underlying trials)

- Median number of predefined outcomes across all reviews = 6 (range 5 – 8)
- Total number of outcomes predefined in these reviews = 32
  - n = 15 (47%) predefined review outcomes were not reported in at least one underlying trial of these reviews
- Categories of outcomes that were specified in at least 50% of the reviews:

Outcomes	Number of reviews which predefined this outcome	Number of reviews in which at least one underlying trial reported this outcomes
Adverse events	4	3
Quality of life	4	2
Symptoms	3	2

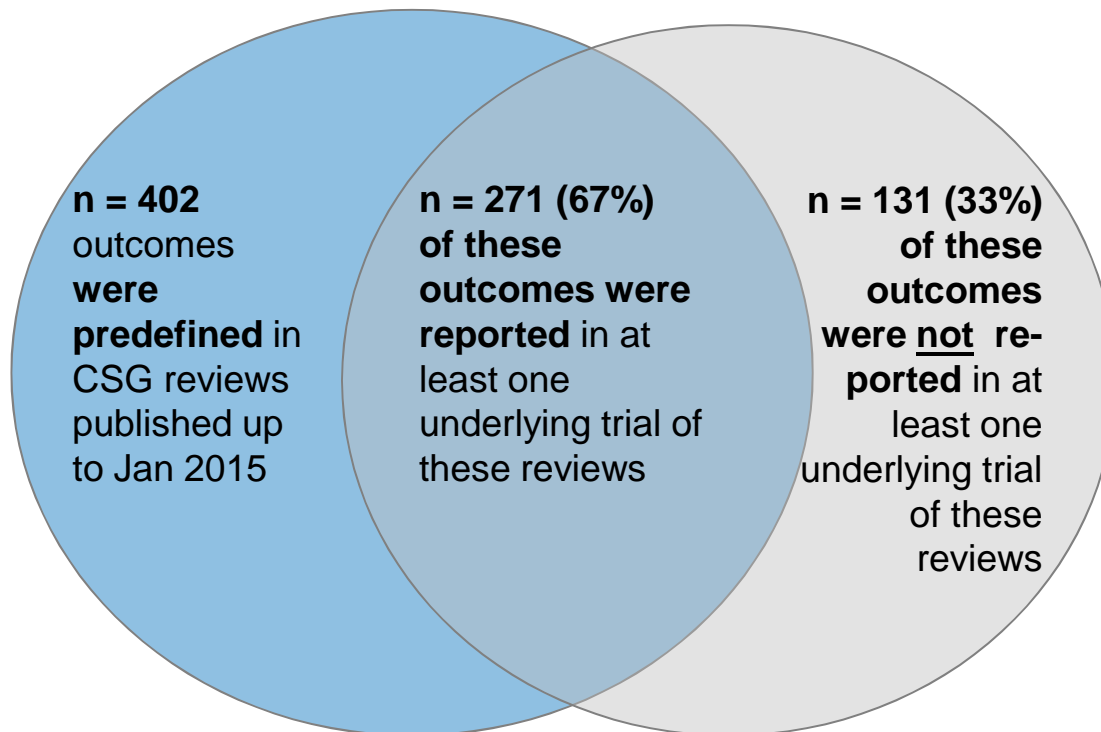
# Discussion

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- Even though quality of life and adverse events were reported for all disease categories in at least 50% of the reviews, there is a wide variation in outcomes reported in CSG reviews

# Discussion

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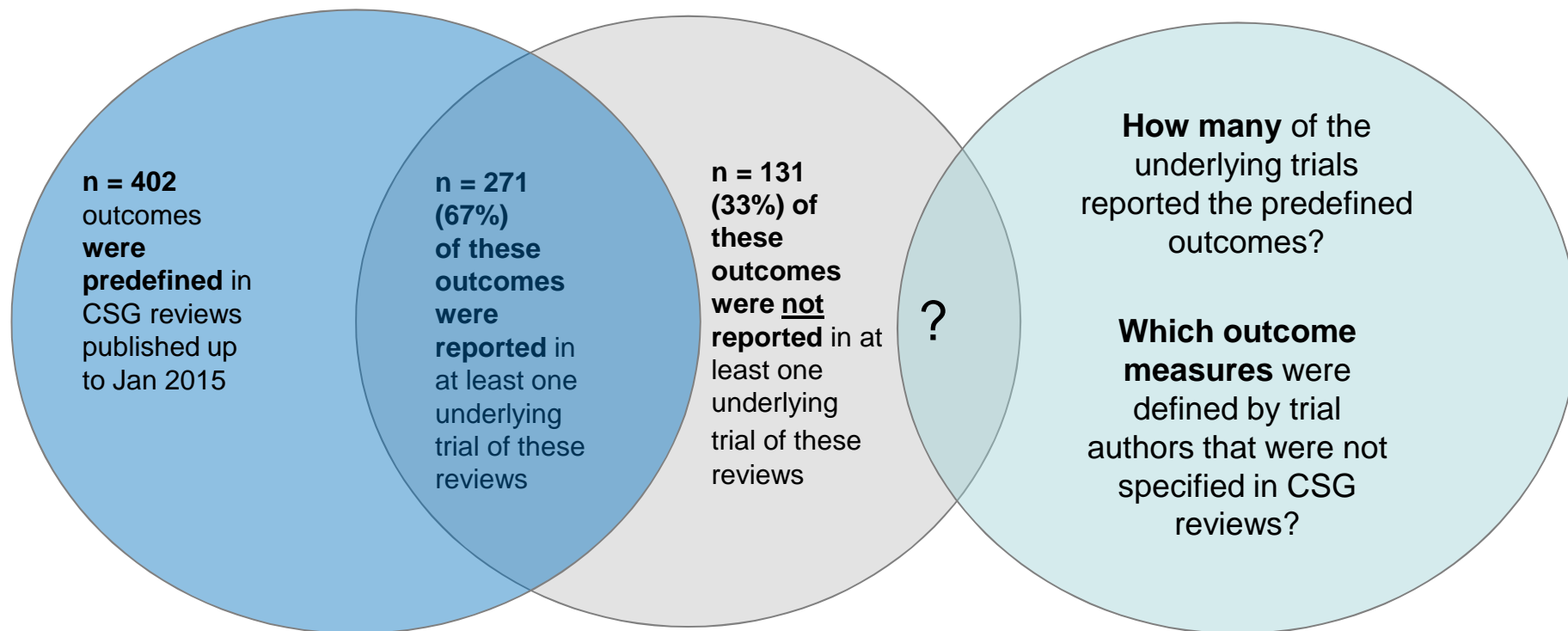


# Discussion

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- Even though quality of life and adverse events were reported in at least 50% of the reviews in all disease categories, there is a wide variation in outcomes reported in CSG reviews
- Avoidable research waste = avoidable waste of research money
- Which outcomes should be specified in a review/trial?
- A greater consideration of outcome selection may be required by review planning
- All disease categories might benefit from COS development → we need to select specific dermatological diseases

# Discussion – further questions





**Many thanks!**