Overview of outcome measures in Cochrane Skin Group reviews

Stefanie Deckert, Jochen Schmitt, and the Cochrane Skin Group

Background – Selected citations from CSG Reviews

<ins>Napkin dermatitis:</ins>
"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)

<ins>Nail psoriasis:</ins>
„Because there is no consensus on core outcome measures for nail psoriasis, we included all possible outcomes." (de Vries et al. 2013)

<ins>Female pattern hair loss:</ins>
"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)

<ins>Atopic eczema (in children):</ins>
"The following outcomes, influenced by the HOME work, were of interest to us as measured by participant, carer […]." (Ersser et al. 2014)

<ins>Metastatic malignant melanoma</ins>:
"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

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

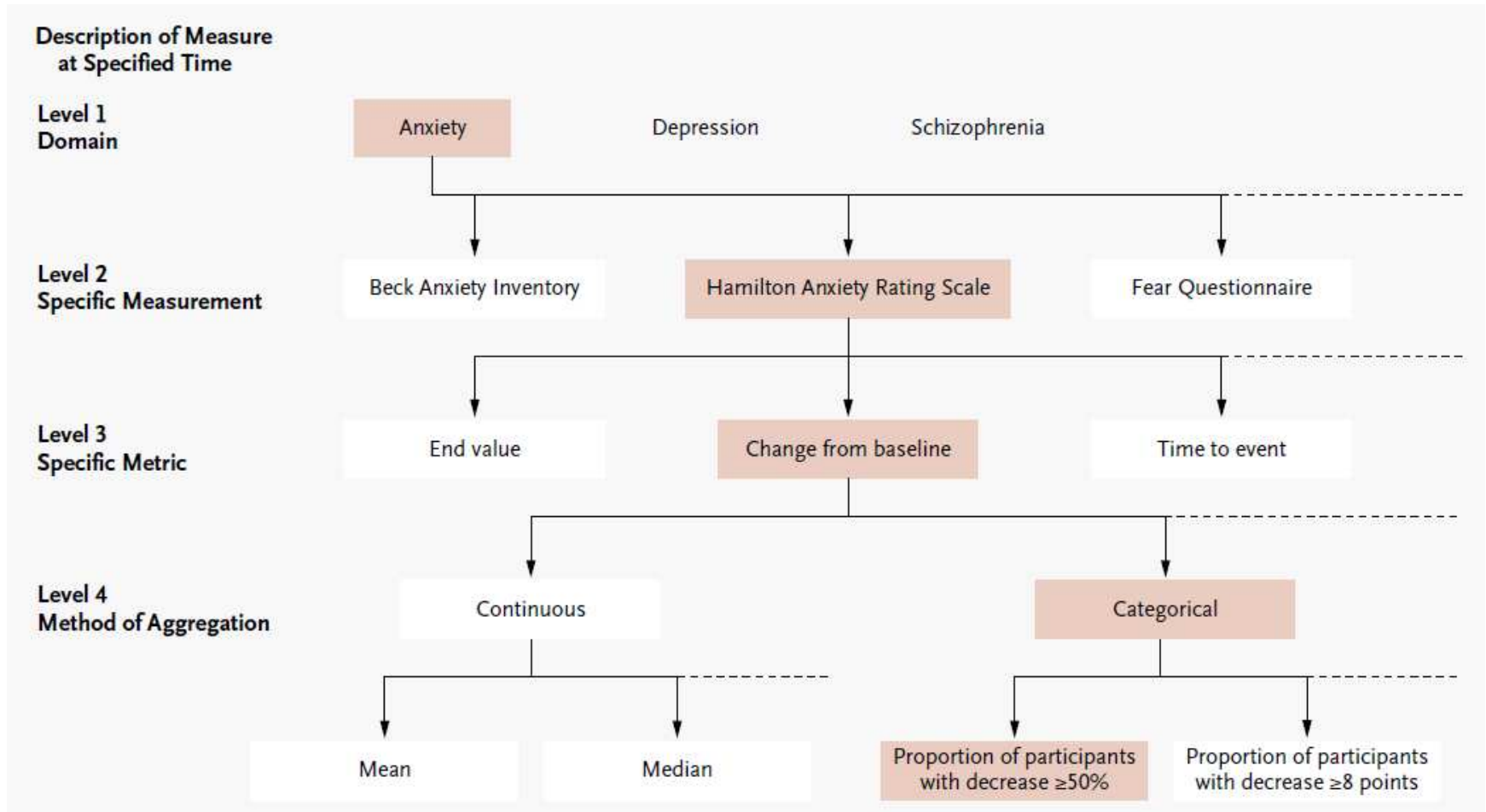- **Measurement** of the same outcome **in a variety of ways**

Background – Selective reporting of outcomes

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

Zarin et al. 2011

5

Chalmers & Glasziou 2009

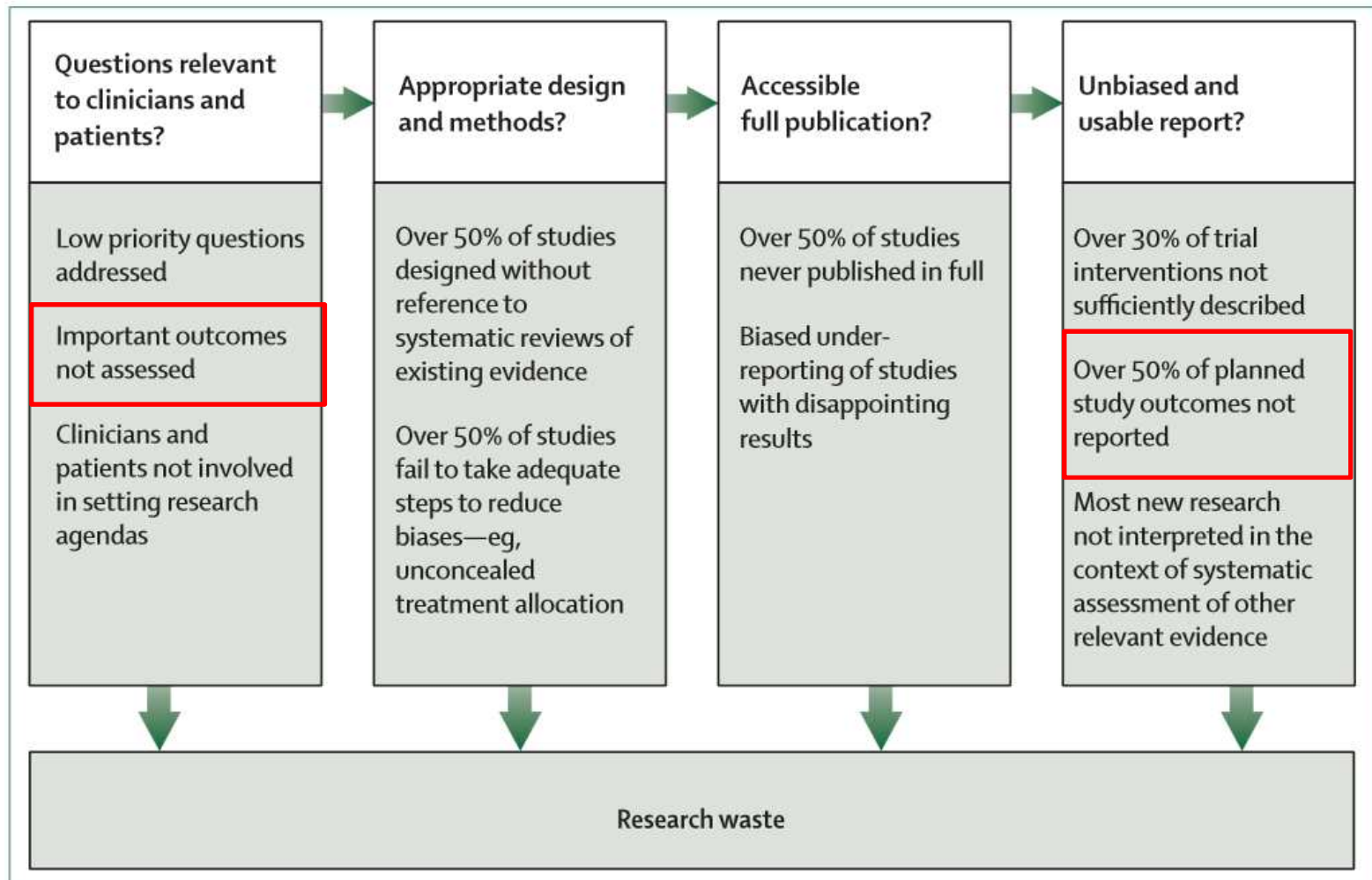**3)** **Selective reporting of outcomes** (Kirkham et al. 2010)

– The selective reporting of a specific outcome

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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

Background – Survey of outcomes in Cochrane Reviews

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.

9

Background – Survey of outcomes in Cochrane Reviews

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Journal of Clinical Epidemiology ■ (2014) ■

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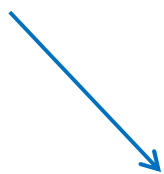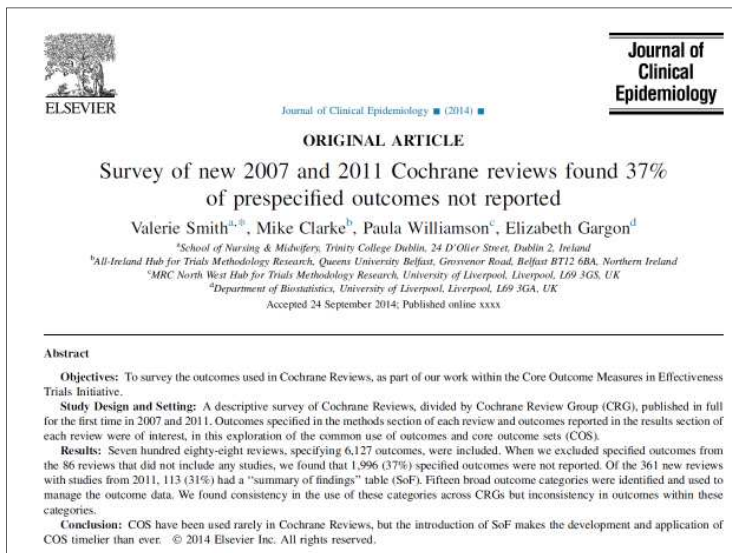Accepted 24 September 2014; Published online xxxx

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Categories of outcomes that were specified in ≥ 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)

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

- 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

Study base

Number of reviews
n=69

Exclusion of reviews without included studies (n=3)

Exclusion of reviews because of missing differentiation between primary and secondary outcome (n=2)

Final included reviews

n=64 reviews
(n=1566 trials)
published between
2000 and 2015

Total no. of outcomes = 449
Median no. of outcomes across
all reviews = 6
(range 1 - 19)

Number of reviews by diseases

| Chronic inflammatory skin disease **n=23** | Infectious disease **n=12** | Skin Cancer **n=11** | Autoimmune disease **n=6** | Allergologic disease **n=5** | Others **n=6** | Benign tumors **n=1** |

13

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 *reviews* which predefined this outcome	Number of reviews in which at least one underlying *trial* 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 *reviews* which predefined this outcome	Number of reviews in which at least one underlying *trial* 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 *reviews* which predefined this outcome	Number of reviews in which at least one underlying *trial* 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 *reviews* which predefined this outcome	Number of reviews in which at least one underlying *trial* 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:

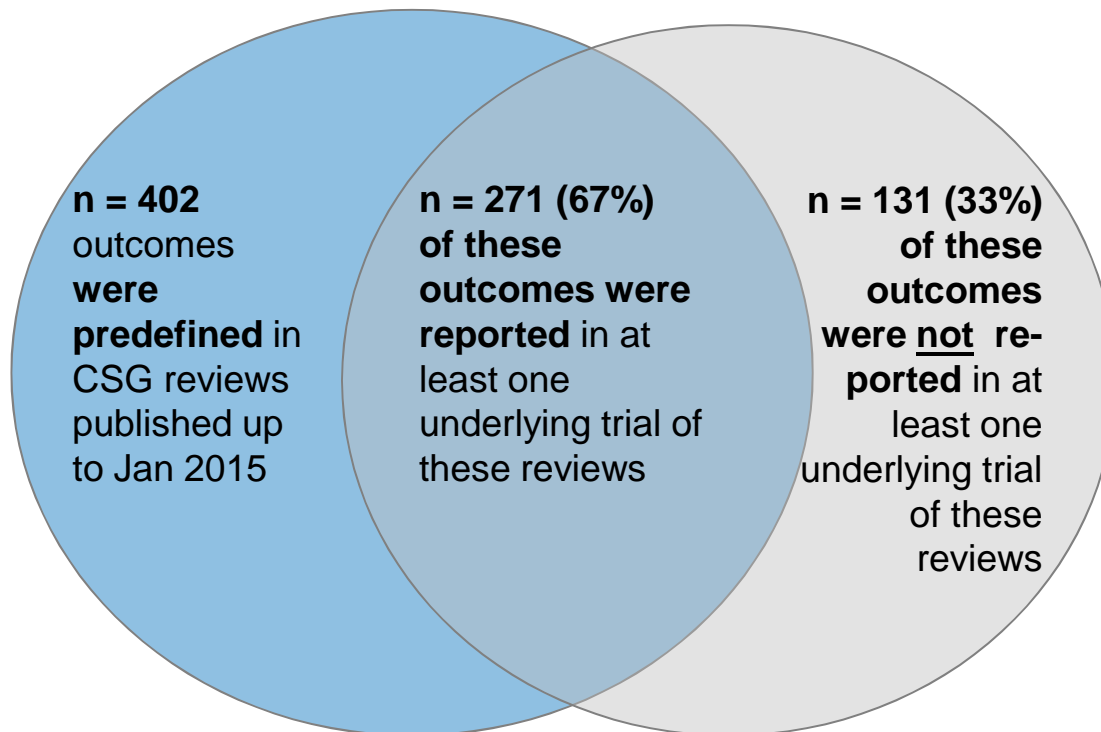| Outcomes	Number of *reviews* which predefined this outcome	Number of reviews in which at least one underlying *trial* reported this outcomes
Adverse events	4	3
Quality of life	4	2
Symptoms	3	2

Discussion

▌ 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

n = 402 outcomes **were predefined** in CSG reviews published up to Jan 2015

n = 271 (67%) **of these outcomes were reported** in at least one underlying trial of these reviews

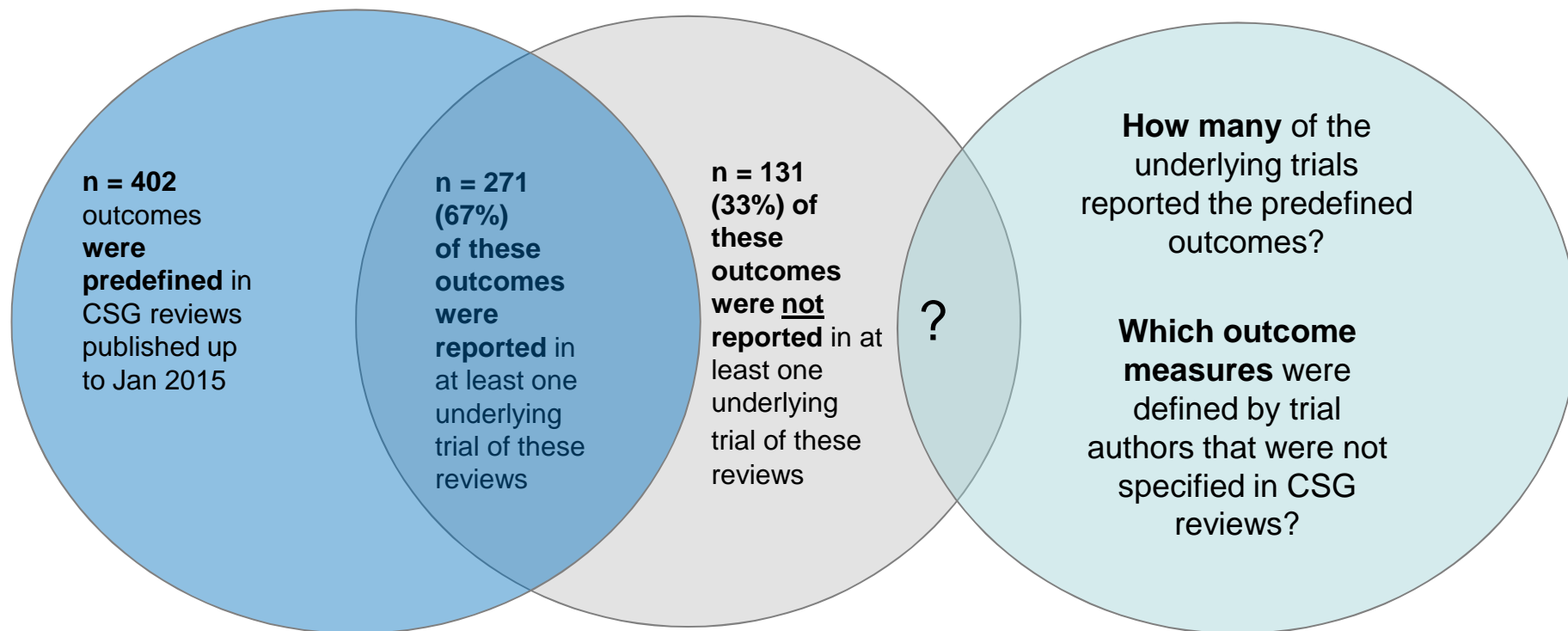n = 131 (33%) of these outcomes were <u>not</u> reported in at least one underlying trial of these reviews

Discussion

▌ 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**

n = 402 outcomes **were predefined** in CSG reviews published up to Jan 2015

n = 271 (67%) of these outcomes were reported in at least one underlying trial of these reviews

n = 131 (33%) of these outcomes were <u>not</u> reported in at least one underlying trial of these reviews

?

How many of the underlying trials reported the predefined outcomes?

Which outcome measures were defined by trial authors that were not specified in CSG reviews?

Many thanks!