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Annual Cochrane Skin Group (CSG) Meeting 17 - 18 March 2015 (Dresden)

Attendees List

Name	Professional background	Country
Alam, Murad	Dermatologist	USA
Apfelbacher, Christian	Methodologist	Germany
Barbaric, Jelena	General Practitioner	Croatia
Bauer, Andrea	Dermatologist	Germany
Chalmers, Joanne	Methodologist	UK
Chosidow, Olivier	Dermatologist	France
Deckert, Stefanie	Methodologist	Germany
Delamere, Finola	Managing Editor	UK
Doney, Elizabeth	Trials Search Co-ordinator Librarian	UK
Eleftheriadou, Viktoria	Medical trainee	UK
Grainge, Matthew	Methodologist	UK
Johannsen, Lena	Methodologist	Germany
Kottner, Jan	Methodologist	Germany
Le Cleach, Laurence	Dermatologist	France
Mayer, Anke	Trial research manager	Germany
Pinart, Mariona	Biologist	Spain
Prescott, Laura	Editorial Assistant	UK
Prinsen, Cecilia A.C.	Clinical Epidemiologist, Methodologist	The Netherlands
Ratib, Sonja	Methodologist	UK
Schlager, Justin	Medical student	Germany
Schmitt, Jochen	Dermatologist	Germany
Sharma, Maulina	Dermatologist	UK
Thomas, Kim	Methodologist	UK
Weberschock, Tobias	Dermatologist	Germany
Weller, Karsten	Dermatologist	Germany
Werner, Ricardo	Dermatologist	Germany
Wild, Thomas	Surgeon	Germany
Wilkes, Sally	Methodologist	UK
Williams, Hywel	Dermatologist	UK

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Background:

The failure to rigorously translate research knowledge into clinical practice constitutes a major challenge for evidence-based healthcare.¹ The Cochrane Collaboration plays a critical role in summarising and translating research knowledge into clinical practice by identifying, synthesising and critically appraising clinical trials and by making research evidence accessible on a global level. The *choice of adequate outcome measures* in clinical trials is essential to make trial results meaningful. The failure to assess the outcome domains most important to patients (e.g. quality of life, disease severity) and the continued use of outcome measurement instruments with unclear validity and reliability are frequent and constitute important barriers towards evidence-based medicine.² The second barrier for evidence-based clinical decision making is the *use of many different outcome measures* in clinical trials. This is true for the field of dermatology as well (e.g. ³⁻⁵). Generally, the lack of standardisation of outcome measurement instruments across trials for specific skin conditions makes it almost impossible to meta-analyse studies.

The development of *core outcome sets (COS)* is a powerful strategy to overcome problems related to the use of different, non- or partly validated outcome measures in dermatology trials. A COS is an agreed minimum set of outcomes that should be measured and reported in all clinical trials of a specific disease or trial population.⁶ A core outcome set does not mean that only the COS should be measured, but simply that the COS should be measured and reported in all future trials of that particular (skin) disease. Outcomes additional to the COS can be measured as required for the specific research question. The Core Outcome Measures in Effectiveness Trials (COMET) initiative (www.comet-initiative.org), launched in 2010, summarises and supports the development, reporting and application of COS for all medical topics (condition or intervention specific). The Harmonising Outcome Measures for Eczema (HOME) initiative (www.homeforeczema.org) set out to develop a COS for eczema trials in 2011 and developed a roadmap to guide the process of core outcome domain and core outcome measurement selection.⁷ Recently, other COS initiatives for specific dermatological diseases, such as acne (<http://sites.psu.edu/acnecoreoutcomes/>) and vitiligo,⁴ have been initiated. A platform for COS initiatives in dermatology is needed to support and integrate the different initiatives, to further develop methodological approaches and recommendations, and to set a quality standard for COS development and application in dermatology. Such a platform would also enable exchanges of common experiences and methodological approaches and would therefore generate synergies between different initiatives in the context of COS development and application.

In response to the described challenges in evidence-based dermatology, the *Cochrane Skin Group has established the Core Outcome Set Initiative (CSG-COUSIN)*. CSG-COUSIN is a working group within the international Cochrane Skin Group and was initiated by Professor Jochen Schmitt (JS) and Professor Hywel C. Williams (HW) in 2014 and supported by the editors of the Cochrane Skin Group.

CSG-COUSIN is a research group that is open for everyone with an interest in outcomes research and evidence-based dermatology and with enthusiasm to develop and implement COS in dermatology.

The kick-off meeting of CSG-COUSIN was held on March 17th and 18th 2015 in Dresden, Germany as the exclusive theme of the Annual Cochrane Skin Group Meeting. The first meeting day was dedicated to introduce and discuss the CSG-COUSIN initiative and to discuss current efforts in COS

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development in dermatology. The second day focused on current CSG reviews and methodological challenges with specific consideration of outcome assessment.

Tuesday 17th March 2015 (12pm – 5pm)

Focus on core outcome sets & the Cochrane Skin Group

Welcome

HW, JS, and Stefanie Deckert (SD) opened the meeting by welcoming the group to Dresden. HW then asked everyone to introduce themselves. The attendees represented a broad mix of different stakeholder groups, professions, skills and perspectives relevant for the development and application of COS.

Introduction to Cochrane Skin Group - Finola Delamere

Finola Delamere (FD) gave an introduction to the Cochrane Collaboration by showing a concise overview of the rationale, the structure, and the aims of the Cochrane Collaboration. FD highlighted a selection of dermatology reviews and emphasised the situation of varying outcomes in trials and often reported high risk of bias. Finally, the impact of some Skin Group reviews used in guidelines in UK, USA, Canada and by WHO were listed (e.g. topical treatments for chronic plaque psoriasis).

There were no questions or further discussion points.

Why harmonise outcome measures? - Hywel Williams

HW described the need for a COS in eczema trials and presented the HOME initiative. HW explained the HOME roadmap⁷ and how it might be applied by other groups developing core outcomes for the other skin diseases. He referred to other COS initiatives in the field of dermatology listed on the Core Outcome Measures in Effectiveness Trials (COMET) initiative website (<http://www.comet-initiative.org/>):

- Vitiligo
- Acne
- Incontinence-dermatitis
- Vulval skin diseases
- Cutaneous leishmaniasis
- Appearance of Facial Aging

He referred to further COS and methodological initiatives in other medical fields such as the Outcome Measures in Rheumatology (OMERACT) (<http://www.omeract.org/>) and the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) group (<http://www.cosmin.nl/>), which have already developed guidance, methodological approaches or recommendations for the selection of outcome measurement instruments for e.g. outcomes

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included in a COS. Finally, he summarised the philosophy of the HOME initiative that could be adopted as part of CSG-COUSIN:

- Working hard together to help patients
- Respecting all stakeholder viewpoints
- Creating a common language and a minimum set for all clinical trials
- A COS might be different for clinical trials and routine care
- Outcome measures need to pass the test of truth, discrimination and feasibility
- Covering the key domains of skin disease, to allow for comparison of something meaningful not just measurable, and striving to erase selective reporting bias
- Putting prejudices and allegiances aside in order to achieve the greater good for patient care
- Evidence-based and evidence-generating
- Pragmatic – to inform clinical decision-making
- To have fun
- With very little money

Discussion

It was discussed whether the focus of CSG-COUSIN (i.e. including measurement properties) can be integrated into the philosophy of the Cochrane Collaboration. HW said that the traditional topic of the Cochrane Collaboration is defined as the evaluation of the benefits and harms of treatments. However, in order to be able to compare treatment effects, comparable, valid, reliable, and sensitive to change outcome measurement instruments are necessary. Outcomes for diagnostic test accuracy (DTA) reviews were mentioned, but it was decided that these would fall within the remit of the Cochrane Methods Groups.

The CSG Core Outcome Set Initiative (CSG-COUSIN) - Jochen Schmitt

JS illustrated the mission and global aims of CSG-COUSIN:

Mission:

To support and guide the development and implementation of COSs in dermatology in order to improve and standardise outcome measurement in clinical trials to make trial evidence more useful for clinical decision making.

Aims:

- To develop standardised, evidence-based and consensus-derived disease specific COS in dermatology, using adequate instruments, for inclusion in all clinical trials to enable meta-analysis
- To apply and further develop the HOME roadmap
- To provide methodological input and guidance material for COS developers and Cochrane reviewers
- To collect and disseminate dermatology core outcome sets

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The key points and results from the presentations are summarised below. The presentation by SD highlighted the necessity of COS in the wide field of dermatological diseases, whilst the other presenters demonstrated a variety of different methods, experiences and challenges in current COS development procedures.

- Cecilia Prinsen (CP) and SD: melanoma outcome domains,
- Christian Apfelbacher (CA): eczema and quality of life (QoL) outcome measures
- Victoria Eleftheriadou (VE): the use of an e-Delphi in the development of a vitiligo specific COS, and
- Alam Murad (AM): prioritisation areas for future COS development in skin surgery

All slides are available on the Cochrane Skin Group website (<http://skin.cochrane.org/de/csg-annual-meeting-2015>).

Overview of outcome measures in CSG reviews - Stefanie Deckert

Based on the published review by Smith et al. 2015,⁸ SD presented results of a systematic overview of all 64 CSG reviews (comprising 1566 trials) published until January 2015 to 1) identify the variety of outcome measures used, 2) to systematically compare predefined outcome measures in CSG reviews and reporting of these outcomes in underlying trials in CSG reviews, and 3) to identify disease categories that might benefit from COS development. For this overview, all predefined primary and secondary outcomes described in the methods section of each review were extracted and subsequently compared with all outcomes reported in the results section of each review. A total of 402 outcomes were predefined in these CSG reviews, and of these, 33% of these outcomes (n= 133) were not reported in at least one of the trials included in these reviews. The remaining 67% of these outcomes were reported in at least one component trial of the included reviews. SD concluded that all skin disease categories (i.e. chronic inflammatory diseases, infectious diseases, skin cancer, autoimmune disease, allergological diseases, benign tumors, and others) would critically benefit from COS development and application.

Whole group discussion regarding core outcome sets in skin disease in general

Discussion-points

- One main **barrier in developing a COS** is the lack of funding. Without funding a lot of free time and enthusiasm is necessary. The full COS development process needs several years.
- **Who should be included in COS development?** All stakeholders should be involved – patients, clinicians, methodologists, guideline developers, editors, and possibly also pharmaceutical industry, regulators, and other decision makers.
- **How to select outcome measures for a COS:** As described in the HOME roadmap, core outcome *domains* (“what to measure”) need to be decided first. The second step is to define valid, reliable, responsive and feasible *outcome measurement instruments* (“how to measure”) to measure these core outcome domains. Domains should be relevant for patients and interpretable for clinicians and other decision makers. Domains can reflect the effectiveness and efficacy of a therapy but could also measure safety, benefit, and harms of

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an intervention. It is recommended that domains (e.g. quality of life) should be defined and selected in the first instance and followed by sub-domains such as physical functioning.⁹

- **Implications for practice:** It is a challenge to translate research results to individual clinical situations. There are currently no recommendations provided regarding how a COS for clinical research should be implemented in routine care/ clinical practice, or quality assurance. Requirements of a COS for routine practice are an important goal but beyond the scope of CSG-COUSIN at the first stage of its work.
- One problem is the **missing comparability** between the outcomes of reviews and trials. Meta-analysis is difficult without COS, thus limiting the ability to make evidence-based recommendations.

Developing a core outcome set for (stage IV) melanoma trials (PART 1) – Cecilia Prinsen

CP presented a proposed project for the development of a multi-disciplinary, consensus-based COS for melanoma clinical trials and the instruments to measure them. In addition she explained in more detail individual steps which should be applied when developing a COS, including scoping and assessing applicability, identifying and engaging relevant stakeholders, planning the conduct of a Delphi study, followed by the identification of outcome measurement instruments (OMIs) through the systematic reviewing of the quality of studies and quality of the measurement properties. In this context she introduced the COSMIN checklist,¹⁰ a standardised tool for the critical appraisal of methodological studies evaluating the measurement properties (such as validity, reliability and responsiveness) of outcome measurement instruments.

Developing a core outcome set for (stage IV) melanoma trials (PART 2) – Stefanie Deckert

SD summarised the results of a recently conducted systematic review. The two main objectives were to systematically assess how the reported outcome domains were defined and which outcome measurement instruments have been used to measure the reported outcome domains. The number of outcomes reported in included studies ranged from 2 to 8 (median: 4). Most reported outcomes were safety, overall and progression-free survival. In the vast majority of the studies included, outcomes were not clearly stated and defined. It should be discussed whether a COS for melanoma in general or a stage-specific COS is necessary. For the reported outcome measures, the COSMIN checklist, which is originally developed for patient-reported outcome measures (PROMs), would not be applicable for the outcomes reported in stage IV melanoma studies. This project will be embedded within CSG-COUSIN if it is funded (*post meeting note*: CP et al. applied for funding with PCORI but the proposal was rejected after the second round). SD raised the question of whether CSG-COUSIN needs a methods group to develop further required methodological approaches in COS development.

Discussion

COSMIN was developed for PROMs and not specifically for other outcome measures (e.g. performance-based measures, clinical-based measures, or laboratory measures). But given the lack of other standardised checklists to appraise the quality of studies which evaluated measurement properties, COSMIN is currently used in a modified or adapted version.

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Quality of life as a core-domain for eczema trials – Christian Apfelbacher

Christian Apfelbacher (CA) presented the results of a systematic review showing which quality of life (QoL) measures have been used in eczema trials. A total of 14 outcome measures were identified that assess QoL of eczema in adults including five generic, nine skin disease specific, and two eczema specific measures. CA concluded that eczema-specific outcome measures for QoL are only rarely used (proxy-reported by carers and adults) or do not exist (self-reported by children). Poor-quality instruments were used, and there was low comparability.

Discussion

Reasons for using selected QoL instruments are not clearly explained in the literature. In some studies authors described the ease of use, general recommendation, wide application, and costs as reasons why a particular QoL measure was used.

Developing a core outcome set for vitiligo clinical trials - Viktoria Eleftheriadou

Viktoria Eleftheriadou (VE) presented the ongoing work on development of a COS for vitiligo, including a systematic review of outcome measures used in published trial⁴ and an international e-Delphi consensus exercise.¹¹ The systematic review demonstrated that many different outcomes and measurements have been used in published vitiligo RCTs.⁴ The subsequent e-Delphi consensus study,¹¹ included 101 participants (patients, clinicians, and researchers) from 24 countries. Consensus was reached over the essential and recommended core outcome domains for vitiligo. Essential items are repigmentation, side effects and harms of treatment, and maintenance of gained repigmentation. Recommended items are cosmetic acceptability of the results, quality of life, cessation of spread of vitiligo, tolerability/burden of treatment. Now the next step is the identification of a unified scale to measure % repigmentation and the characteristics of repigmentation, and to select the best instruments to measure the identified core domains.

Discussion

Once again, the involvement of patients was discussed. It was generally agreed, that the consideration of the patient's perspectives and experiences are important and necessary to define and select patient-relevant outcomes. But in a next step it should be clarified "how we can best involve patients?" Because it can be difficult to communicate the concepts involved in an e-Delphi to patients, different possibilities were discussed such as handbooks for patients in plain language, a pre-selection of the outcome domains conducted by patients or a veto for patients and commensurate group-sizes of patient representatives. Furthermore the applied methods of the e-Delphi as described by VE were critically discussed in terms of cut-offs of voting results (e.g. What proportion can be considered as agreement? Can results of different groups be pooled?). All agreed that the work was a significant step forward for international consensus of key domains for vitiligo.

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Prioritising areas for future COS development in skin surgery - Murad Alam

First MA presented regarding the need for COSs in skin surgery. He introduced the initiative *Measuring Priority Outcome Variables in Dermatology Surgery (IMPROVED)* which aims “to standardise measurement of changes in the physical appearance and functions of the skin” associated with cutaneous surgical procedures. IMPROVED consists of experts from different subspecialties of dermatology (e.g. medical dermatologists, dermatologic surgeons, methodologists) who selected as the object of their first COS *assessment of appearance*. Work on this COS was begun in October 2013 and is still ongoing. MA closed his presentation with questions and discussion points and received helpful advice from the group.

Discussion

Because IMPROVED is based in the USA, the first recommendation was that the initiative should be expanded to be global/international. Consideration should also be given to the potential importance of ethnic group differences given the particular salience of such differences in matters pertaining to physical appearance. It was suggested that the primary aim of the COS should be more precisely defined: cosmetic plastic surgery to address photodamage or aging, or return to health (e.g. following extirpation of tumour). Additionally, it was suggested that regardless of the context, the realm of physical appearance could be narrowed, perhaps just to facial physical appearance. Once the conditions of interest had been clarified, then the domains could be defined. MA concurred and expressed an intention to divide the work on the proposed COS into two parts, one focusing on recovery from skin cancer surgery, and one on facial appearance associated with photoaging and chronological aging.

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Wednesday 18th March 2015 (9am – 12pm)

Focus on core outcome sets & the Cochrane Skin Group

Recap, action points, and closure of the 1st day and open the discussion about the prioritisation survey – Hywel Williams

HW summarised the presentations of the first meeting day and gave an overview of the main discussion points. He highlighted that lack of COS is a major obstacle for evidence-based dermatology. Due to the multi-professional skills and methods which are necessary when developing a COS, there are various opportunities for all attendees to be involved.

Main discussion points from Day 1 summarised by HW were:

- The use of the Delphi Technique and the associated different Delphi Methods (online surveys, face to face meetings) were criticised by Jan Kottner (JK). He mentioned that results of Delphi techniques may not be reproducible (cf. computer vs. paper and pencil version vs. face to face meetings). The methodological validation of Delphi outcomes generated by different Delphi methods has not been readily explored. The whole group agreed that optimised methods for patient involvement in the consensus process are needed including how to engage patients, in which way should we include patients, and do we need a manual for patients similar to the one used by OMERACT? In this context it became clear that more methodological work in COS development is necessary so that JS proposed to develop a CSG-COUSIN methods group. CP and JK expressed interest to participate in this methods group.
- JS suggested that CSG-COUSIN will use the HOME roadmap⁷ as a general approach for COS development and will provide more methodological details/recommendations which will be useful for other COS initiatives. Through the application of the HOME roadmap in different COS development projects it may be further developed and adapted in an iterative process.
- Communication and knowledge transfer with other COS initiatives and Cochrane Groups are important.

Further discussion points were:

- Matthew Grainge (MG) asked if a registration for COS is needed. The whole group discussed pros and cons. CSG-COUSIN should provide an overview of all already existing COS initiatives in dermatology and should also present concrete recommendations for domains and measurement instruments to avoid parallel working groups on the same topic.
- Tobias Weberschock (TW) recommended that guideline developers should be involved in the COS development process because there are synergies in creating both processes (i.e. guidelines and COS). JS mentioned that there is a danger because of the different aims of guideline developers in different countries and COS developers (e.g., quality indicators and feasibility are guideline priorities, not systematic review priorities) and proposed that they should only be alerted of the project. Thomas Wild (ThW) added that guidelines were different from reality. However, TW argued that it is the different perspectives that benefit the discussion and that his vision is guideline developers making suggestions, not creating the COS, and sharing their facilities. HW agreed we could use their ideas and skills. TW added

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that guideline groups can help/add additional aspects. The group agreed that they should be invited to the Delphi groups because they play an important role in evidence-based medicine. This also creates a trajectory from development of COS straight through to guideline developers. JK said that we needed to consider outcomes relevant to, for example, trialists, guideline developers, and statisticians, so it would be wise to include all of these people. HW said we should think of guideline developers as part of the formative group. Maulina Sharma (MS) pointed out that it was also important to have an independent person present.

- Kim Thomas (KT) asked what COUSIN could provide for other groups. Could it be a core methodological support group, providing help to other spin-offs? JS proposed that CSG-COUSIN should develop further methodological guidance to ensure the quality of the COS development process, e.g. by providing resources (methodological recommendations and advices, technical support for reviewers (e.g. data management for critical appraisals)), and peer review procedures by e.g. reviewing of study protocols
- JS highlighted the need to find an approachable and feasible way to contribute to the main work of the Cochrane Skin Group, i.e. conduct of systematic reviews (review of protocols concerning outcomes), guidance for reviewers how to identify COS and how to judge if identified COS is adequate, i.e. of high quality

Some of the attendees are especially interested in the following topics and would like to be involved as an active player within CSG-COUSIN:

- Thomas Wild: COS for wound healing
- Mariona Pinart: COS for eczema
- Cecilia Prinsen and Jan Kottner: Methodological work group
- Cecilia Prinsen, Stefanie Deckert, Jochen Schmitt: COS for melanoma (depending on funding)
- Karsten Weller and Maulina Sharma: COS for urticaria
- Andrea Bauer and Christian Apfelbacher: COS for hand eczema

The group of attendees highlighted the importance of COS development for the validity and utilisation of RCTs and systematic reviews.

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Improving the quality of our Skin Group Reviews

Review – the submitted Cochrane review ‘Topical treatments for scalp psoriasis’ – Justin Schlager

Justin Schlager (JuS) presented his Cochrane systematic review, including discussion of the methods used and difficulties encountered. The results showed that steroid/vitamin D-combination was only of small additional benefit over corticosteroid monotherapy for scalp psoriasis and both treatments did not differ in the risk of causing adverse effects. The review included studies with a mix of efficacy outcomes, which used different measurement tools. Only 3 studies were found to assess QoL, there was no evidence for most topical treatments, outcomes were mainly short-term, and their quality was variable.

Discussion

HW commented that the review revealed some interesting findings and it was a pity that there was not more evidence on older treatments. JS wondered if the reason for the unexpected findings was that the trials were from a different time period. JuS said that all recent trials assessed topical corticosteroids. TW asked what kind of adverse effects were reported. JuS stated that the review authors did not look for the sort of adverse events, since this was not described as an outcome in the review protocol. However, he ensured that the most frequent adverse events for each topical treatment would be addressed with the published version of the review.

Review – the recently completed Cochrane review ‘H1-antihistamines for chronic spontaneous urticaria’ – Maulina Sharma

MS talked about her experience writing her published Cochrane review.¹² She spoke of why they undertook the review and what they hoped to achieve, summarising the inclusion criteria used, the results, and bias/quality issues. She discussed about the challenges faced when doing a large Cochrane systematic review and useful tips to overcome potential barriers. The review found that H1-antihistamines at standard doses are better than placebo. However, the reported outcomes were not comparable, and under half of the comparisons provided outcome data for meta-analysis. Again, many studies did not address QoL. MS presented a number of outcome-related implications for practice, including advocating standardised outcome scores and wider use of standardised and validated QoL scores.

Discussion

HW and TW asked for clarification on some clinical aspects of the presentation, with TW asking about differences in efficacy, on which MS commented that at standard doses of treatment, several antihistamines were effective when compared with placebo. The results had been from a few studies or, in some cases, from single-study estimates. The quality of the evidence was affected by the small number of studies in each comparison and the small sample size for many of the outcomes. No single H1-antihistamine stood out as most effective. Timing of outcome assessment as well as outcome measures varied in studies with only few studies directly reporting the pre-specified review outcomes, again highlighting the need for COS. Some clinical discussion on the subject area followed. Regarding first-generation ('sedating') and second-generation ('non-sedating') antihistamines, the

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review did not carry out subgroup analyses on the basis that included studies with relevant outcome data were too few to allow meaningful comparisons.

In the review update, conducting network meta-analysis and use of indirect comparisons may be possible if there were additional studies with more robust data and connections (e.g. drug- drug comparisons) to provide a much better analysis

Excluding small studies from a systematic review or meta-analysis – Matthew Grainge

Matthew Grainge (MG) began his presentation asking if it was ever acceptable to exclude studies on the basis of low sample size. Most of the audience said no, with comments about not excluding any kind of evidence, about the decision being topic-dependent, challenging the theory that it's problematic to exclude, and the fact that many small studies address questions of relevance to patient care versus big pharmaceutical-driven trials. MG said that there may be pragmatic reasons for excluding small studies, such as saving time assessing poor-quality trials. MG talked about 2 case studies where trials would be excluded based on their size, then summarised reasons not to exclude. MG explained how he surveyed the Cochrane Statistical Methods Group about whether there were occasions when it was acceptable to exclude studies from a Cochrane review or meta-analysis and revealed that all voters were against excluding small studies. MG gave the following reasons why small studies could be excluded: small negative studies are less likely to be published, the (false?) assumption that sample size reflects poor study quality, and practicality. However, the strong consensus from the survey was that the first 2 of these are best addressed by excluding small studies in a sensitivity analysis. MG ended his presentation by sharing some tips for dealing with this problem and possible areas of future research.

Discussion

The question of orphan diseases was raised, which MG countered was exactly why we can't have a general rule. JC asked if reviewers distinguish between small RCTs and pilot studies. JS questioned what makes RCTs better. There was a suggestion to exclude small studies from meta-analysis and sensitivity analysis, rather than from reviews per se.

End of meeting discussion

- JS shared relief that there was a shared vision of why COSs were needed
- All attendees explained what they got out of the meeting, and there were a number of offers of help from the audience
- The next steps were decided upon
- It was agreed that there needed to be patient involvement at the next meeting
- The issue of whether the focus should be on effectiveness or safety, or both, was raised
- HW and JS agreed that the meeting had been valuable and was important, as the subject is a core principle, not just an interesting topic

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Brief summary of action points

HW defined further important steps of CSG-COUSIN (how we progress discussion into action):

- Clarify the aims
- Clarify how may we go forward
- Define achievable short, medium, and long term objectives (use a 3 year time frame)
- Provide a framework which describes the strategic aims of the meeting and how these can be achieved (share it and all participants should be invited for commentaries) and a short meeting report published in a journal
- Form a methodology support group and develop tools to support people
- Undertake some methods work, e.g., assess Delphi and look at patient involvement
- Formalise processes
- Be careful in the use of the Cochrane Logo (COS is only one part) and ensure that COUSIN is seen as a subset of Cochrane work
- Prepare a CSG-COUSIN logo and website
- Involvement with industry should be done with caution
- Retain strong ties with OMERACT, COSMIN, COMET, and HOME
- Think about funding (PhD Students; programmes)

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