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## ACT now: Accuracy, Completeness, and Transparency in health research reporting

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## REPORTING QUALITY OF RESEARCH STUDIES

**RQRS-001** // Do drug dossiers of pharmaceutical companies provide additional information on study methods compared to journal publications?

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**Background:** Since the introduction of the German Act on the Reform of the Market for Medicinal Products (AMNOG) in 2011, pharmaceutical companies have to submit dossiers for benefit assessments of new drugs. The dossiers contain a tabular description of the relevant randomized controlled trials (RCTs) for the benefit assessment. This description has to adhere to CONSORT (items 2b to 14b including the flowchart, CONSORT 2010), which was originally developed for journal publications. The dossiers including the tabular description of studies are published during the process of drug assessment.

**Objective:** To evaluate to what extent the tabular description in drug dossiers contains relevant additional information on study items according to CONSORT compared to the corresponding journal publications.

**Methods:** The RCTs of 10 drug dossiers were included. Two reviewers independently assessed additional relevant information on study items in the tabular description presented in the dossiers. The assessment was performed for the CONSORT items 2b to 14b including the flowchart. Subitems were counted separately leading to 22 considered points. The information content of the tabular description versus that of journal publications was classified as follows: (1) no new information, (2) partially new information, and (3) completely new information. We calculated the proportion of items for which these categories applied. In the following we show the results for one RCT. We plan to present the full results at the symposium.

**Results:** 27 RCTs and 34 corresponding journal publications were relevant for the overall assessment. Concerning the RCT analysed, for 50% of the items (11/22) the tabular description provided additional information, of which 9% (2/22) reported completely new information and 41% (9/22) reported partially new information. For 50% of the items (11/22) no additional information was provided.

**Limitations:** Our preliminary analysis only covered one RCT; the overall analysis will show whether these preliminary findings are confirmed.

**Conclusions:** Preliminary findings suggest that the compulsory submission of dossiers by pharmaceutical companies for benefit assessments of new drugs makes additional relevant information on study methods publicly available. This may lead to an improved reporting quality of trial data soon after the introduction of new drugs into the market.

## IMPLEMENTATION OF REPORTING GUIDELINES

### IRG-002 // Implementations scheme of the CONSORT guidelines for RCT manuscripts submitted to the American journal of orthodontics and dentofacial orthopedics (AJO-DO)

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The CONSORT and PRISMA guidelines have been adopted by many journals in the biomedical field. Although adoption is widespread the quality of reporting remains suboptimal mainly due to the deficiencies in implementation. At the American Journal of Orthodontics and Dentofacial Orthopedics (AJO-DO) this problem was recognized and in the summer of 2011 it was decided to adopt a new scheme in order to improve reporting quality for RCTs and systematic reviews. According to the scheme all submitted RCTs and systematic reviews are assessed for guideline adherence by the designated associate editor. The associate editor checks the submitted manuscript in detail for guideline compliance making specific comments/suggestions for each checklist item. Subsequently, the manuscript is returned to the authors (revision without review) and when guideline compliance is satisfactory, the peer-reviewing process begins. Alternatively, the manuscript is sent out for peer reviewing and then the comments of the reviewers and the comments of the associate editor regarding guideline compliance are sent to the authors at the same time. This presentation will briefly outline the implementation scheme of the AJO-DO journal for RCTs and with preliminary results since the adoption of the new guideline implementation scheme.

### IRG-003 // Impact of active CONSORT guidelines implementation by journal editors on the reporting of abstracts of randomized trials: an interrupted time-series analysis

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**Objective:** We aimed to investigate the impact of the CONSORT for Abstracts guideline, and different editorial policies to implement the guideline, on the quality of reports of abstracts of randomized trials in high impact journals.

**Methods:** We randomly selected up to 60 primary reports of randomized trials per journal per year from Annals of Internal Medicine (AIM), BMJ, Lancet, JAMA and NEJM in 2006 to 2009, if indexed in PubMed with an electronic abstract. We classified journals in three categories: (1) journals not mentioning CONSORT for Abstracts guidelines in their 'Instructions to Authors' (JAMA and NEJM); (2) journals referring to the CONSORT for Abstracts guidelines in their 'Instructions to Authors' but with no specific policy to implement these guidelines (BMJ) and (3) journals referring to the CONSORT for Abstracts guidelines in their 'Instructions to Authors' with a policy to implement these guidelines (AIM and Lancet). Two authors extracted data independently using the CONSORT for Abstracts checklist. Our primary outcome measure was the mean number of items reported among the nine items reported in fewer than 50% of the abstracts across the five journals in 2006. We performed interrupted time series analysis to assess the impact of the CONSORT for Abstracts guidelines over time.

**Results:** We assessed 955 reports of abstracts of randomized trials. In journals with an active policy to enforce the guidelines (AIM and Lancet) there was an immediate increase in the level of mean number of items reported (increase of 1.50 items;  $p=0.0037$ ). At 23 months post guideline publication, the mean number of items reported per abstract for the primary outcome was 5.41 out of nine items, a 53% increase compared with the expected level estimated on the basis of pre-intervention trends. When focusing on journals with no policy to enforce the guidelines (BMJ, JAMA and NEJM) no increase in the level change or trend change was observed.

**Conclusion:** Our findings show that active implementation of the CONSORT for Abstracts guidelines by journals can lead to improvements in the reporting of abstracts of randomized trials.

#### IRG-004 // Potential Barriers for Journals Attempting to Implement a Reporting Guidelines Policy

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The fundamental value of reporting guidelines lies in their potential to improve reporting standards and increase the transparency of research methods. Although limited, analyses of the utility of guidelines provide tantalizing evidence of their effectiveness, with the possibility of measurable improvements in reporting quality for those journals that implement them. Consequently, it is surprising and disappointing that more journals have not yet adopted reporting standards for authors and reviewers. The primary objective of this work is to speculate as to why commonplace adoption has not yet occurred. Our work also outlines, from the perspective of an editorial office, practical impediments to widespread adoption that reporting guideline developers must take into account when designing, or revising, their guidelines and associated checklists.

To provide insights for these objectives, we report our experiences in devising and then implementing a reporting guidelines policy at the journal Headache. Headache is a mid-sized, citation middle-ranked, medical journal. Using anecdotes and usage statistics, we document logistical and political impediments towards enacting our policies as well as supply data on apparent barriers to the successful application of our policy. We present predictors of a failure to comply with our mandatory demands that a checklist be included with a manuscript submission or an inability to complete a guideline checklist as directed by accompanying instructions.

To conclude, we summarize important practical/logistical steps journals should consider ahead of implementing a reporting guidelines policy while also raising pertinent questions regarding policy enforcement.

#### IRG-005 // Does journal endorsement of reporting guidelines influence the completeness of reporting of health research? A Systematic Review

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**Background:** Considerable waste arises from incomplete and inadequate reporting of research. Reporting guidelines (RGs) emerged to improve the transparency, completeness and thus usefulness of reports of research. They aim to provide authors with a minimum set of items that should be described when preparing reports of their research. To date, over 200 RGs for various types of health research exist and some have garnered uptake in the form of endorsement by journals. With the exception of the CONSORT checklist which has been evaluated elsewhere, the impact of RGs has been largely unclear.

**Objective:** To systematically review the literature evaluating the impact of RG endorsement on the completeness of reported research.

**Methods:** Potential evaluations of 101 pre-identified RGs were sought from three electronic databases (MEDLINE, EMBASE and the Cochrane Methodology Register) and one web citation index (Scopus) and were included if they enabled comparison of completeness of reporting of studies in one of two comparisons: before and after journal endorsement or between endorsing and non-endorsing journals. The main outcome for which data were collected was completeness of reporting, measured by proportion of studies adequately reporting one or multiple items of a RG checklist, as reported within evaluations. Relative risks (RR) and 99% confidence intervals across evaluations were calculated for each checklist item or set of items for each RG, where possible.

**Results:** Five of 101 RGs were evaluated among 8 included evaluations for at least one of the two pre-specified comparisons: the BMJ checklist (n=1), QUOROM (n=3), STARD (n=2) and the CONSORT extensions for both harms (n=1) and herbal interventions (n=1). Five of

eight evaluations had sufficient data to include in meta-analyses. There was no significant difference in completeness of reporting between any of the comparison groups for any checklist items (or sum of items) of the five evaluated RGs. The validity of included evaluations was assessed as 'high'; no studies assessed whether RGs worsened reporting.

**Limitations:** Impact of RGs is difficult to determine; evaluation of journal endorsement is likely a poor surrogate measure of their impact.

**Conclusions:** Further, rigorous evidence is needed to determine the impact of RGs on the completeness of reporting.



## POSTERS

### DEVELOPMENT AND DELIVERY OF EDUCATIONAL AND TRAINING PROGRAMMES ON RIGOROUS RESEARCH REPORTING

DETP-006 // EQUATOR Centre for Journalology

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**Background:** Inaccessible, unusable and biased research reports create billions of dollars of »waste« in health research every year. Exposure to training in academic writing and publication among contributors to, and gatekeepers of, medical literature may play a role in this process, however research is currently lacking. Formal training opportunities for authors, journal editors, and peer reviewers are limited. An independent, academic, research-based training program for academic writing and publishing may be beneficial in establishing a more unified and consistent approach to improving the quality of reporting practices.

**Objective:** Funding is currently being sought to open the first global centre dedicated to the scientific study of academic writing and publishing (i.e. Journalology) – The EQUATOR Centre for Journalology (ECJ). The ECJ will act as a knowledge hub and learning community for contributors to, and users of, the medical literature worldwide. Using an evidence-based approach, we will create innovative educational resources and training programs in journalology, focusing on the promotion of publication ethics and research integrity throughout the research community, and engaging the global public on issues regarding the dissemination of quality science.

**Methods:** The ECJ will provide online and blended learning training courses and resources in journalology for editors, journal and grant peer reviewers, authors, publishers, physicians in training, journalists, and the general public. Users will be able to access a wide variety of training modules, workshops, and learning resources, as well as Webinars and a speaker series through an interactive web portal. The ECJ will offer CME-certified courses, as well as those it will uniquely certify as Continuing Education in Journalology (CEJ). Research at the

ECJ will involve evaluations of change in learners' knowledge, behavioural intentions, and reporting practices. Systematic reviews will also be carried out to examine the effects of peer review in editorial review and the decision-making process of granting agencies.

**Relevance:** The ECJ will increase users' knowledge of best practices in journalology and improve the quality of reported literature. In doing so, the health literature will become more usable by systematic reviewers and clinicians in making important decisions about our population's health.

## REPORTING QUALITY OF RESEARCH STUDIES

### RQRS-001 // Descriptive analysis of timing of clinical trial registration and publication in ICMJE accredited journals

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**Background:** The World Health Organization (WHO) developed the International Clinical Trials Registry Platform (ICTRP) to ensure transparent clinical trial processes from protocol to publication. In 2004, the International Committee of Medical Journal Editors (ICMJE) published a statement supporting prospective registration of trials starting after July 2005. Their updated statement (2007) made prospective registration in a WHO-approved registry a publication prerequisite. Increasingly registries are accepting retrospectively registration. Thus, reporting registration ID numbers does not fulfill the same checks that it had when registries only accepted prospectively registered trials. Now the onus to check registration timing, to align with ICMJE prospective registration mandates, falls on journal editors.

**Objectives:** To determine whether retrospectively registered trials are reported transparently in top medical journals.

**Methods:** We identified five highly cited ICMJE-member journals (New England Journal of Medicine (NEJM) The Lancet, The Journal of the American Medical Association (JAMA), Annals of Internal Medicine, and PlosMed). Journal issues published between October and December 2011 were hand-searched for all randomised controlled trials (RCTs). Data extraction included title, principle investigator, start date, registry number, intervention, primary outcome(s), location, funding source and close-date, and were cross-referenced against registration entries. Descriptive analysis was conducted.

**Results:** We identified 68 RCTs: NEJM (30), The Lancet (19), JAMA (8), Annals of Internal Medicine (6) and PlosMed (5). Twenty-nine of 68 RCTs registered prospectively, and 36 retrospectively. One trial registered in a non-ICMJE/WHO-recognised registry, and two were not registered. Of 29 prospectively registered RCTs, 25 registered after July 2005. Of 36 retrospectively registered, 21 registered after July 2005. Six(20%) prospectively and 7(19%) retrospectively registered RCTs reported different outcomes from those in the registry. Funder data and trial end-dates were reported inconsistently between registry and publication.

**Conclusions:** More than half of the sampled RCTs are retrospectively registered, the majority of which commenced after ICMJE standards were disseminated, showing that prospective registration uptake is poor. The results indicate that journals are accepting publications that have not complied with ICMJE requirements.

### RQRS-002 // The reporting quality of randomised controlled trials in plastic surgery

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**Introduction:** Randomised controlled trials (RCTs) represent the gold standard in evaluating healthcare interventions. However, RCTs can yield biased results if they lack methodological rigour, especially where surgical techniques are involved. Readers need complete, clear and transparent information. The Consolidated Standards of Reporting Trials (CONSORT) statement for non-pharmacological interventions was developed to aid reporting and consists of a 23-item checklist and flow diagram.

**Objective:** To assess the compliance of RCTs in Plastic Surgery with the CONSORT statement.

**Method:** Medline was searched by an information specialist from 1 January 2009 to 30 June 2011 for the MESH heading »Surgery, Plastic« with limitations for English language, human studies and randomised controlled trials. Results were then manually searched for relevant RCTs involving surgical techniques. The papers were scored against the 23 item CONSORT checklist. Secondary scoring was then performed and discrepancies resolved by consensus.

**Results:** 57 papers involving 3,878 patients met the inclusion criteria from a manual search of 254 papers retrieved from Medline. The average CONSORT score was 11.5 out of 23 items (range 5.3-21.0). Compliance was poorest with items related to intervention/comparator details (7%), randomisation implementation (11%) and blinding (26%). There was no link between journal 2010 impact factor and CONSORT score ( $R=0.25$ ). Only 61% declared conflicts of interest, 75% permission from an ethics review committee, 47% declared sources of funding and just 16% stated a trial registry number – deemed mandatory by the International Committee of Medical Journal Editors in 2005.

**Conclusion:** The reporting quality of RCTs in Plastic Surgery is poor and significant work is now needed to address this issue.

### RQRS-003 // Quality of published medical education research studies in Iran: a systematic review

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**Background:** Research evaluating medical education in Iran has increased in recent years, however the quality of reporting of such research has not been comprehensively appraised.

**Objective:** To evaluate the methodological and reporting quality of published articles describing medical education studies conducted in Iran.

**Methods:** We searched for articles evaluating medical education programmes provided to medical students, residents or fellows in Iran. We did not include continuing medical education or faculty development, review articles and reports, and studies considering both medical and nonmedical students. We searched PubMed, the Iranian Scientific Information Database (SID) and three main Iranian medical education journals from March 2003 to March 2008. The Medical Education Research Quality Index (MERSQI) scale, was used to evaluate the completeness of reporting.

**Results:** Ninety-five articles were included in the review of which 16 (16.8%) were experimental studies. Total MERSQI scores ranged between 3.82 and 13.09 with the mean of 8.39 points. Mean domain scores were highest for data analysis (1.85) and lowest for validity (0.61). The most frequently reported item was background (96%) and the least reported was the study limitations (16%).

**Limitations:** It is possible we missed some studies due to poor sensitivity and specificity of the search engine in the Iranian SID, the main electronic database of scientific journals in Iran.

**Conclusions:** Our review suggests that a) the majority of published medical education research describes observational studies; b) the reliability and validity of medical education assessment tools have not been well reported; c) the overall quality of the reporting of research studies in medical education in Iran is poor and d) more robust, rigorous and well reported research studies are needed in the future.

**RQRS-004 // An assessment of the reporting quality of randomised controlled trials relating to anti-arrhythmic agents.**

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**Introduction:** Despite being the gold standard for investigations, RCTs can deliver biased results if methodology is flawed. To assess bias, readers need clear and complete information. The CONSORT statements are intended to improve the reporting of trials. This study is the first to assess the reporting quality of RCTs in cardiology. We assessed the reporting quality of anti-arrhythmic drug trials over the last decade.

**Methods:** Medline and Embase databases were searched for anti-arrhythmic drug trials between 2002 and 2011. Results were searched by two authors and relevant papers selected. Papers were scored according to the 2001 and 2010 CONSORT statements by two reviewers and compared against surrogate markers of paper quality.

**Results:** 694 papers were retrieved from both databases. 59 papers, involving 28,450 patients, met the inclusion criteria. The mean CONSORT 2010 score was 15.4 out of 25 (SD 3.05, range 9-22.5). The least reported items related to abstract content (0%), randomization (6.8%), and protocol referencing (8.5%). There was significant correlation between CONSORT 2001 and 2010 scores ( $R=0.95$ ,  $p<0.001$ ). There was a significant correlation between the CONSORT 2010 score and the annual and 5-year impact factors of the publishing journal ( $R=0.44$  and  $R=0.45$  respectively;  $p<0.001$  for both). No significant correlation was found between the year of publication or number of authors, and 2010 CONSORT score.

**Conclusions:** Although several papers gained high scores, no paper successfully met all criteria laid out in either the CONSORT 2001 or 2010 statements. Correlation between CONSORT 2010 score and impact factor lends support to this as a marker for paper quality. The lack of clarity in reporting found in this study indicates that the application of the CONSORT guidelines remains incomplete within the cardiology literature. Further work is needed collectively by trial groups, funding agencies, authors, and journals to improve reporting.

**RQRS-005 // Assessment of the reporting quality of imaging biomarkers studies: the story of the poor man's relative.**

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**Background:** A key component to accurate assessment of the quality and relevance of research is the complete and transparent reporting. A number of tools for reporting guidelines of tissue and blood biomarkers studies exist (STARD, REMARK, MIAME, BRISQ). Such guidelines for the reporting of imaging biomarkers validation studies do not exist at present. We have used the example of Fluorothymidine, an imaging biomarker of proliferation to assess the reporting quality in these studies.

**Objective:** To assess the quality of reporting of molecular imaging biomarker validation studies.

**Methods:** For the assessment of reporting quality, 27 studies that explored the relationship between FLT PET and Ki-67 were used, having been previously identified from a recent systematic review (1). These original studies included patients with cancer, and investigated the relationship between Ki-67 expression measured by immunohistochemistry and FLT uptake measured with PET scanning. Each of these was published as a full paper in peer-reviewed scientific journals, and were retrieved through a systematic search of the literature. The quality of reporting was evaluated using a modified STARD checklist.

**Results:** Studies were published in 13 different journals between 2003 and 2011. Amongst the poorly reported STARD items were: methods for calculating test reproducibility and quantifying uncertainty (0%), a report of recruitment dates (30%), time interval between index and reference test (33%), use of clinical information (44%) and blinding of the test readers (50%). Only 3/13 of journals have implemented reporting guidelines on their instructions to authors and these were mainly STARD and CONSORT.

**Limitations:** A potential limitation of our study is that we have restricted our search and analysis to only one imaging biomarker. However, this is one of the most well studied molecular imaging biomarkers with 27 original studies, representative of relevant research from various groups around the world and potentially providing an accurate reflection of the reporting quality in the specific research field.

**Conclusions:** Our assessment revealed lack of adequate reporting in most items of the reporting checklist, amongst them critical areas of study design. The development of reporting guidelines in the multidisciplinary field of imaging biomarkers validation studies is essential to enable other researchers to independently validate the findings.

(1) Chalkidou A, Landau DB, Odell EW, Cornelius VR, O'Doherty MJ, Marsden PK. Correlation between Ki-67 immunohistochemistry and 18F-Fluorothymidine uptake in patients with cancer: A systematic review and meta-analysis. *European journal of cancer*. 2012 May 31.

#### RQRS-006 // A PRISMA assessment of the reporting quality of systematic reviews in orthodontics

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**Objectives:** To assess the reporting quality of Cochrane and non-Cochrane systematic reviews (SR) in Orthodontics, and to compare the reporting quality (PRISMA score) with methodological quality (AMSTAR criteria).

**Materials and methods:** Systematic reviews (n=109) published between January 2000 to July 2011 in five leading orthodontic journals were identified and included. The reporting quality of the included reviews was assessed by two authors in accordance with the PRISMA guidelines. Each paper was assigned a cumulative grade based on fulfilment of the applicable

criteria and an overall percentage score was assigned. Descriptive statistics and simple and multiple linear regression analyses were undertaken.

**Results:** The mean overall PRISMA score was 64.1% (95% CI: 62-65%). The quality of reporting was considerably better in reviews published on the Cochrane Database of Systematic Reviews ( $P < .001$ ) than in non-Cochrane reviews. Both multivariable and univariable analysis indicated that journal of publication and number of authors was significantly associated with the PRISMA score. The association between AMSTAR score and modified PRISMA score was also found to be highly statistically significant. Limitations: Orthodontic SRs in journals other than the 5 assessed were not included.

**Conclusion:** Compliance of orthodontic SRs published in orthodontic journals with PRISMA guidelines was deficient in several areas. Fulfilment of PRISMA guidelines was significantly better in orthodontic SRs published in the Cochrane Database of Systematic Reviews.

#### RQRS-007 // Good Clinical Research Practice for Psychotherapy Trials

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Public research funding agencies in Germany requested that psychotherapy trials should be conducted in accordance to ICH-GCP. On this background we systematically analyzed the ICH-GCP-E6 document on its suitability for psychotherapy trials from the perspective of leading scientists and experts in this field. The goal was to provide for a guideline of good clinical practice in psychotherapy trials (GCP-PT).

After a preparatory phase the experts were sent a document where they could rate each item of the ICH-GCP guideline on its applicability to psychotherapy trials and a column where suggestions could be made for modifications. The results were returned to the project centre

in Tuebingen where the ratings and suggestions for modification as well as the initials of the raters were joined into one document.

In the consensus finding phase, the experts discussed the items with divergent ratings and the suggestions for modifications during six face-to-face meetings. Subsequently, the panel discussed which relevant aspects of psychotherapy trials are not addressed in the ICH-GCP guideline and need to be specified by additional items. During the meetings the consented wording of the modifications was documented by the moderator and an assistant.

A final version of the adapted GCP-PT document was created at the project centre and sent to the task group members for revision.

Major issues in the development process were: Psychotherapy as a complex intervention cannot be viewed as analogous to medication; Psychotherapy trials are almost always investigator initiated trials without a »Sponsor« in the strict sense of this term; double blind designs are not possible; adverse events are not yet precisely defined; the stages of development of psychotherapy are different. Important aspects of psychotherapy trials like patient and therapist adherence, therapist competence, requirements of a treatment manual and others are not addressed in ICH-GCP-E6.

The presentation will give an overview over the consensus process and an outline of the resulting CCP-PT document.

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### **RQRS-008 // Validation of the CReDECI checklist for reporting on complex interventions**

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**Background:** The UK Medical Research Council (MRC) provides methodological guidance for researchers on the development and evaluation of complex interventions, and emphasizes comprehensive reporting on the full research process. Recently, we presented a list of criteria for reporting on complex interventions in healthcare (CReDECI) comprising 16 items, divided

into 3 sections: development (n=6 items), feasibility and piloting (n=2), introduction of the intervention and evaluation (n=8) (Moehler Ralph et al. (2012) Int J Nurs Stud 49:40).

**Objective:** To evaluate the applicability of the CReDECI list and to assess the quality of reporting in studies on complex interventions developed according to the MRC framework.

**Methods:** A systematic PubMed search was conducted. Studies on complex interventions in both English and German were included, evaluating an intervention guided by the MRC framework. Titles and abstracts were checked for inclusion independently by two reviewers. For all publications which reported stages prior to the clinical trial, related publications were searched via backward citation tracking. Quality of reporting was assessed independently by two reviewers using CReDECI. Inter-rater agreement and the time needed to complete the list were determined.

**Results:** The search yielded 157 citations; 8 studies could be included. The number of publications belonging to the study ranged from 1 to 6 (mean 3.1). For the criteria referring to development and feasibility / piloting, 6 studies reported on all criteria, 1 study on 7 and 1 study on 3 criteria. For the criteria referring to introduction of the intervention and evaluation, 2 studies reported on 7 criteria, one study on 5 and 5 studies on < 3 criteria. Agreement between the two raters was good. CReDECI application took 30-90 minutes, depending on the number of publications per study.

**Limitations:** A small sample of studies and their related publications were included.

**Conclusions:** The analysed studies demonstrated a high quality of reporting on the development and feasibility/piloting phases, a result contradictory to previous studies. Quality of reporting on the introduction of the intervention and evaluation was low to moderate. There is still room for improvement in reporting on complex interventions. CReDECI has proven its applicability.

### RQRS-009 // Reporting quality of life outcomes in cardiovascular stem cell trials

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**Background:** Bone marrow cardiovascular stem cell (BMcSC) treatment holds great promise as a therapeutic agent for no-option and poor surgical candidates. Consequently, treatment methodologies can have a serious impact on patient quality of life (QOL), though QOL is often measured variably across clinical trials, if at all. It is important that outcomes be measured consistently to ensure that researchers and clinicians can make informed decisions, and clinical trials are using the same units, and measuring those units in the same way (Clarke, 2007).

#### Objectives:

- Describe the timing, frequency intervals and methodology used to measure QOL outcomes in (BMcSC) clinical trials
- Discuss potential solutions for standardising QOL outcomes in these trials.

**Methods:** The study reviewed MEDLINE, Scopus, and Clinical Trials Registries up through September 2010. The search terms used were bone marrow stem cell AND quality of life OR heart OR cardiac AND cardiac AND quality of life OR QOL or Randomised Controlled Trial.

**Results:** Of the 12 BMcSC studies identified, 66% did not measure QOL and only 8% measured QOL at baseline. Of the studies that did measure QOL, there was variability in tools used with 75% reporting use of the Short Form (36) Health Survey and Minnesota Living with Heart Failure Questionnaire, and 25% reporting use of EQ-5D Health Survey. The majority of studies (75%) limited follow up intervals to three months and six months.

**Limitations:** An in-depth systematic review was not conducted and studies were only included if published in the last 10 years.

**Conclusion:** This study found that QOL outcomes are not typically included in BMcSC trials, and when included, the timing/frequency intervals and methodology used to measure QOL

varied across trials. A core outcome set is needed as demonstrated by the lack of standardised QOL measurements.

Reference: Clark, M. (2007) *Trials* 8:39

### RQRS-010 // Gender, age and ethnicity in protease inhibitors trial reporting: evidence of lack of reporting?

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**Background:** Generalisability of results is a prerequisite of a clinical trial; in fact, the results of any research should be applied to a wider, more heterogeneous, patient population, in terms of race, gender, age and other socio-demographic factors. As matter of fact, description of these data is crucial for judging quality of published papers, as stated from all the reporting guidelines checklists.

**Objective:** The aim of this review is to evaluate reporting of age, ethnicity and gender data in phase II and III registrative clinical trial of the protease inhibitors for HIV treatment from 1996 to 2009.

**Methods:** Company-sponsored, phase II or III registrative clinical trials of protease inhibitors enrolling HIV infected adult patients were selected. Papers reporting duplicate patients were excluded. Studies cited in drug labels and medical reviews on the US Food and Drug Administration Approved Drug Products list, for which no publication were available, were retained and information collected from the same source ([www.fda.gov/oashi/aids/virals.html](http://www.fda.gov/oashi/aids/virals.html)).

**Results:** Forty-nine clinical trials were included and data relative to a total of 10224 patients were analyzed. Of the 49 reports, 46 (93.9%) reported data on ethnicity, but in 6 studies ethnicity other than Caucasian were not specified. Overall, the number of study subjects for whom ethnicity was not reported was 1013 (9.9%). Of the 49 reports, 45 (91.8%) reported

data on gender distribution. Overall, the number of study subjects for whom gender was not reported was 994 (9.7%). Forty-three studies reported data on age of patients in terms of mean or median, and one of them reported only the age range.

**Limitations:** One limit of the study is that is based on registrative clinical trial, whose reports may differ from other clinical trials, having to fulfil strict rules from agencies.

**Conclusions:** Poor reporting of specific issues in about 5-10% of papers could impair the feasibility of systematic review and meta-analysis, and limit the generalizability of findings, treatment effects, and side effects.

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#### RQRS-011 // An assessment of reporting quality of abstracts of randomized controlled trials (RCTs) published in leading dental specialty journals

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**Background:** Well-written and detailed RCT abstracts facilitate the initial assessment of a report and aid the retrieval of trials from databases for inclusion in systematic reviews.

**Objective:** The purpose of this study was to investigate the quality of reporting of abstracts of randomized controlled trials (RCTs) published in leading dental specialty journals (with highest impact factor in 2010).

**Methods:** Electronic and supplementary hand searching was undertaken to identify RCTs published in seven dental specialty journals: American Journal of Orthodontics and Dentofacial Orthopedics, British Journal of Oral and Maxillofacial Surgery, Clinical Oral Implants Re-

search, International Journal of Prosthodontics, Journal of Clinical Periodontology, Journal of Endodontics, and Pediatric Dentistry. The quality of abstract reporting was evaluated using a modified CONSORT for abstracts checklist. Descriptive statistics, univariate and multivariate analyses were conducted.

**Results:** A total of 228 RCT abstracts were identified and assessed. The highest percentage of RCTs were published in Journal of Clinical Periodontology (28.5%). Reporting of interventions, objectives and conclusions within abstracts was generally found to be adequate. Inadequately reported items included: title, participants, outcomes, random number generation, numbers randomized and effect size estimate. Randomization restrictions, allocation concealment, blinding, numbers analyzed, confidence intervals, intention-to-treat analysis, harms, registration and funding were rarely described. The mean overall reporting quality score was suboptimal at 62.5% (95% CI: 61.9, 63.0).

**Limitations:** Only seven major specialty journals were included. Conclusions: Abstract reporting in dental specialty journals is suboptimal. Significantly better abstract reporting was noted in certain specialty journals and in multicenter trials.

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#### CPRR-013 // Social and medical influences on becoming a mother: A methodological analysis of UK research

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**Background:** The birth of a first child is an important transition for women and a critical area of maternity policy and practice. Since the late 1970s, research on women's experiences of motherhood has accumulated.

**Objective:** To understand how well this evidence addressed maternity policy and practice, we undertook a systematic review of research on women's perceptions about social and medical

factors influencing their transition to motherhood, including a methodological analysis of UK studies.

**Methods:** Using standard systematic review methods, we identified studies reporting: primary research; in English; published 1975-2009; first-time motherhood; and women's directly described experiences. We extracted sampling and data collection methods information, using framework analysis. Two reviewers assessed, extracted and agreed all information, using custom software.

**Results:** We included 60 UK studies. Most were deficient in reporting even basic standardised information on sample age, ethnicity, education and class. In studies providing information, participants were predominantly white, cohabiting and middle class.

**Limitations:** Conclusions about women's experiences of first-time motherhood have been drawn from incompletely reported samples that are potentially unrepresentative of the currently more diverse UK mothers. It is problematic to generalise findings using such homogeneous research samples.

**Conclusions:** Understanding social/medical influences on women's transition to motherhood is important for appropriate policy and care. Patchy, inconsistent reporting of studies' socio-demographic data makes this difficult. Most studies involved white middle class participants unrepresentative of the population of first-time mothers. Researchers and governing bodies must be aware of these issues and address them in study funding, design, conduct and reporting.

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**CPRR-014 // Conducting international multicenter clinical trials – what the textbooks don't tell you.**

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**Background:** There has been a trend toward international multicenter clinical trials in the medical device industry to help increase recruitment figures and to improve the generalizability of results among other factors. However, working internationally creates its own unique problems which are rarely discussed in the literature.

**Objective:** To elucidate the issues faced by CROs operating internationally to help kick-start a debate on this topic within the scientific community.

**Methods:** A comprehensive literature search was undertaken to see what multicultural issues have already been reported. Long-serving employees at AO Clinical Investigation and Documentation (AOCID) were interviewed for their views of barriers in the conduct of international clinical trials. One of the authors has been compiling appraisal reports for several years from trips to countries interested in conducting clinical research which also served as a primary source of information.

**Results:** The literature available on this topic is very sparse. Dealing with multicultural differences is a skill AOCID has learned over the past decade – particularly as it relates to patients (compliance etc.), regulatory affairs (differing legal frameworks etc.) and surgeons (communication issues etc.). Even countries that are traditional centers for research can pose specific challenges to the conduct of orthopedic trials. A list of countries and issues specific to them has been compiled by AOCID.

**Limitations:** The report is of course a subjective view and may not tally with others' experiences. However, this report should serve as the beginning of a debate on the issue and not the definitive word.

**Conclusions:** CROs conducting international multicenter clinical trials need to develop a range of soft skills to complement their technical knowledge in order to thrive. While skills in literature review, translation, validation and so on are essential, it is being open to, and experienced in, operating in a multicultural milieu that is the key to success.

**CPRR-015 // Reporting of randomized controlled trials that were discontinued – An international multicenter empirical study**

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**Background:** Randomized controlled trials (RCTs) may be discontinued prematurely for reasons including unanticipated adverse effects, apparent benefit, or futility. Others are discontinued early due to slow accrual of participants. Discontinued trials have ethical implications: (i) participants consent on the premise of contributing to new medical knowledge, (ii) limited resources for research are wasted, and (iii) bias might be introduced to meta-analyses if data are not available. Currently little is known about the epidemiology and publication history of discontinued RCTs.

**Objectives and Methods:** The study aims are to 1. determine the prevalence of trial discontinuation for different reasons, 2. identify risk factors for discontinuation of trials due to slow accrual, 3. examine the publication history of discontinued trials. We assemble a multicentre cohort of about 1000 RCT protocols based on protocols approved by 6 research ethics committees in 2000 to 2003 in Switzerland, Germany, and Canada. For all included RCT protocols, we extract data on trial characteristics (e.g. medical field, single- vs multicentre design, length of follow-up) and on planned recruitment (sample size calculations, period, use of pilot data, etc). We determine completion status and publications of trials using information from correspondence between investigators and research ethics committees, surveying investigators, or publications identified through online literature searches.

**Results:** At the EQUATOR Symposium we will present preliminary results regarding: (i) the prevalence of RCTs discontinued for different reasons; (ii) the proportion of discontinued RCTs that were published; and (iii) the association between the different reasons for RCT discontinuation and subsequent publication.

**Conclusions:** Our study will provide insights into the prevalence and reporting of discontinued RCTs. Empirical data on this aspect of reporting may help further emphasize the need for reporting data and lessons learned from discontinued RCTs in order to (i) meet the ethical obligations of RCTs, (ii) prevent early RCT discontinuation due to slow recruitment, (iii) reduce the waste of limited resources, and (iv) prevent potential bias in systematic reviews.

**CPRR-016 // Use of relative and absolute effect measures in reporting health inequalities: a structured review**

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**Background:** Monitoring and reduction of health inequalities are important components of health policies in many countries. To date, no studies have examined the use of absolute and relative effect measures in health inequalities reporting. Choice of absolute or relative measures influences conclusions about whether inequalities are increasing or decreasing over time, which countries, social groups, or health conditions demonstrate the largest inequalities, and whether interventions widen or narrow inequalities. In addition, exclusive use of relative or absolute measures influences patients' and health professionals' interpretation of health information. Reporting guidelines thus recommend using both absolute and relative effect measures whenever possible.

**Objective:** To examine the frequency of reporting absolute and relative effect measures in health inequalities research.

**Methods:** Structured review of 344 articles, published during calendar year 2009, in ten leading medical and public health journals.

**Results:** 40% (138/344) of articles reported an effect measure in the abstract; among these, 88% (122/138) reported only a relative measure, 9% (13/138) reported only an absolute measure, and 2% (3/138) reported both. 75% (258/344) of all articles reported only relative measures in the full text; corresponding absolute measures were incalculable in 46%

(119/258) of these. 18% (61/344) of all articles reported only absolute measures in the full text, and 7% (25/355) reported both absolute and relative measures. These results were consistent across journals, exposures, and outcomes.

**Limitations:** Inclusion of articles from different journals or a different time period, or utilization of a different search strategy, may have produced a different result.

**Conclusions:** Contrary to established recommendations, health inequalities are commonly reported using only relative effect measures, which may influence readers' judgments of the magnitude, direction, significance, and implications of reported health inequalities. Following existing recommendations by reporting both absolute and relative measures will increase transparency, reduce systematic reporting biases, and improve the evidence base for policies aimed at reducing health inequalities.

**Funding:** This work was supported by Canadian Institutes of Health Research Operating Grant #107530.

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### CPRR-017 // Evidence synthesis when clinical trials report early stopping

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**Background:** As reflected in the CONSORT 2010 guidelines, complete and transparent clinical trials reporting requires information about the reasons for early stopping, or truncation. Some researchers have gone further, arguing that early stopping is problematic and that truncated studies should be viewed with scepticism. In previous research we argued that early stopping is not a substantive source of bias and indeed that inclusion of truncated studies in evidence synthesis is essential to avoid bias (1).

**Objective:** In this research we examined the evidence used previously to cast doubt on early stopping. Our objective was to assess the validity of this evidence as a basis for con-

cluding truncated studies are biased. This allows further assessment of whether complete and unbiased evidence synthesis should include the results of truncated studies.

**Methods:** We focused on the approach of comparing truncated studies with non-truncated studies, which is the primary form of evidence that has been used to infer bias in truncated studies. Using theory and simulation, expected treatment effects conditional on truncation were compared with expected treatment effects conditional on non-truncation. The difference between these treatment effects was compared with differences that have been observed empirically in meta-analyses of truncated and non-truncated studies.

**Results:** Conditioning on truncation led to larger treatment effects than conditioning on non-truncation, consistent with empirical observations. The magnitude of the difference was larger for smaller studies, as has also been observed empirically. Simulated meta-analyses involving aggregation of truncated and non-truncated studies led to unbiased estimation of treatment effects, whereas aggregation only of non-truncated studies led to biased estimation.

**Limitations:** Our results are predicated on the use of statistically valid stopping rules for early stopping.

**Conclusions:** Complete and unbiased evidence synthesis requires aggregation of all studies, both truncated and non-truncated. Larger treatment effects are expected in truncated studies due to the statistical conditioning involved in separating truncated and non-truncated studies for comparison. This is analogous to the expected difference between more extreme and less extreme observations in a sample, and does not reflect inherent bias in truncated studies.

Reference: (1) Schou, Manjula, et al., (2011), *Trials*, 12(Suppl 1), A50.

## IMPACT AND CONSEQUENCES OF POOR REPORTING

### ICPR-018 // Reporting and Methodological Quality of Systematic Reviews in the Orthopaedic Literature.

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**Introduction:** Properly designed and conducted systematic reviews can reliably produce valid pooled treatment effect estimates and are an important resource for clinical decision-making. However, few studies have looked at the quality of methodology and reporting in systematic reviews in the orthopaedic literature. The following paper assesses the quality of methodology and reporting of systematic reviews in orthopaedic research.

**Methods:** The top five journals in orthopaedic surgery, as determined by impact factor scores from the 2010 Thompson ISI journal citation reports, were searched by one individual (PK) over the last five years (2006-2010). The journals searched included Osteoarthritis and Cartilage (OC), The Spine Journal (SJ), The Journal of Bone and Joint Surgery (JBJS), The American Journal of Sport Medicine (AJSM), and the Journal of Orthopaedic Research (JOR). Only systematic reviews and meta-analyses were included and assessed separately and independently by two individuals (PK and JG). The reporting quality was assessed using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses' (PRISMA) statement, and the methodological quality using the Assessment of Multiple Systematic Reviews2 (AMSTAR) guidelines both of which are accepted instruments. We calculated the proportions of each item reported within and across journals.

**Results:** Seventy-six systematic reviews and meta-analyses were included. Table I contains the total number of PRISMA items fulfilled or not stratified by journal. Papers from JBJS had the best reporting and JOR papers had the least amount of yes's .. No's ranged from fifty-nine percent (JOR) to twenty-one percent (JBJS). Finally, don't know's ranged from seven percent (SJ) to zero percent (JOR). On average for all journals, papers only reported sixty-eight percent of the PRISMA items.

**Discussion:** Both reporting and methodological quality in the top-five orthopaedic journals was poor with reporting quality being slightly superior. Although there was a wide range of reporting quality and methodological quality scores across the journals, the included articles have room for improvement and therefore the validity of the included articles is less than optimal. The strengths of this study include the use of internationally accepted methodological quality and reporting guidelines. Furthermore, this study looked at the top-five impact journals in orthopaedics, and thus, this should represent the best articles in the field. However, it is possible that there are higher quality papers in other orthopaedic journals. Also, it is possible that the assessment tools used here did not encompass methods specific to orthopaedic systematic reviews. The findings in this paper are similar to other studies.' « The use of PRISMA and AMSTAR guidelines in designing, implementing, and writing systematic reviews is recommended to improve quality of systematic reviews and meta-analyses in orthopaedic journals.

**Significance:** Although doctors and other health professionals may turn to these top-five journals for important information, the reporting and methodological quality of systematic reviews therein is not of the highest possible quality. Strict adherence to reporting and methodologic guidance would improve reporting and methodological quality of these publications.



### ICPR-019 // Methodological Quality of Randomized Control Trials in Recent Orthopaedic Literature

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**Introduction:** Randomized control trials (RCTs) are considered the gold standard in clinical research. Poorly designed and implemented RCTs bias estimates of treatment effects threatening the validity of these designs. However, there has been little investigation of the quality of methodology of RCTs in orthopaedics. The purpose of this study was to assess the quality of methodology in orthopedic related RCTs in the top orthopedic journals.

**Methods:** Investigators determined the top five journals in orthopedic surgery by their impact score from the Thompson ISI citation reports (2010). Two investigators (LC and PK) assessed the quality of all human subject RCTs from The American Journal of Sports Medicine (AJSM), The Journal of Orthopedic Research (JOR), The Journal of Bone and Joint Surgery (JBJS), The Spine Journal (SJ) and Osteoarthritis and Cartilage (OC) from January 2006 to December 2010. Investigators assessed each RCT on ten criteria having empirical evidence for biasing treatment effect estimates when not performed properly (e.g. randomization, group allocation concealment, participant and assessor blinding, withdrawals, statistical analyses). Each criterion was assessed as having proper methodology (Yes), not having proper methodology (No) or having insufficient information to assess (Don't Know, OK).

**Results:** A total of 252 RCTs were reviewed and 232 articles met our inclusion criterion. Overall, American Journal of Sports Medicine fulfilled the highest proportion of methodological quality items, however the proportions varied greatly by journal when referring to individual criteria. Of the ten criteria Osteoarthritis and Cartilage had the largest proportion of Yes ratings in four of the categories (proper analysis, description of withdrawals/compliance, subject blinding, outcome assessor blinding), JBJS was the leader in 3 categories (randomization process, allocation concealment, accounting for clustering), AJSM led in two criterion (baseline characteristics, intervention administration) and JOR had the highest proportion of Yes in one category (outcome assessment). Roughly half of the RCTs lacked description of individuals providing the intervention while less than half (42%) described the statistical analysis used. Less than 1 % of the RCTs accounted for clustering.

**Discussion:** Considering the wide distribution and high impact ratings of these journals, it is evident that the methodology of orthopaedic RCTs has room for improvement. Very few of the studies assessed met all ten criteria for proper methodology. Thus many of these studies likely have biased estimates of treatment effects. In addition, these journals had poor reporting of important methodological aspects ranging from 35% (AJSM) to 54 % (JOR). Though we only extracted data from five orthopaedic journals and thus, this analysis may not represent all orthopaedic literature, we assumed that the top journals would have the highest methodological quality. This research emphasizes the need to improve methodology and reporting of RCTs in orthopaedics to improve their validity and utility for clinical decision making.

**Significance:** Even journals with the highest impact factors are lacking in methodological quality and reporting. Therefore, RCTs in the orthopaedic literature likely have biased estimates of treatment effect. Paying close attention to these criteria in RCTs will improve the validity of RCTs in orthopaedics.

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### ICPR-020 // Conceptualizing the Life Cycle of Healthcare Knowledge

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The concept of healthcare knowledge is multifaceted and involves a wide variety of people in a myriad of roles. To better understand how all of these aspects are connected, we propose a concept map detailing the life cycle of healthcare knowledge.

The Healthcare Knowledge Life Cycle (HKLC) represents the ideal process by which knowledge is organized, managed, and applied in healthcare. It models the journey of healthcare-related knowledge through the research phase, beginning with the development of a research proposal, the conduct of research and reporting of findings. It continues through the application phase, with the uptake of findings into clinical practice and their integration into patient care. The information garnered through this process is then integrated into the body of healthcare knowledge, thus spawning new cycles of the HKLC.

The HKLC concept map incorporates and attempts to classify different factors that may have an impact on the development, implementation, and utilization of healthcare knowledge at various points in the HKLC. This includes »internal« factors which may guide the personal choices and decisions of researchers and clinicians in their work, and »external« factors, which may come in the form of regulations, guidelines or areas of focus. The map also outlines the ways in which knowledge is managed and transformed throughout the HKLC process, from the assimilation of current knowledge into new research proposals, through to the implementation of knowledge in healthcare practices and its integration into the larger body of healthcare knowledge. Various types of training or education are highlighted at various points where learning is critical for maintaining the integrity of healthcare knowledge and ensure that quality is maintained throughout the life cycle.

It is hoped that this concept map will provide a comprehensive and useful tool for discussing the complex web of people and processes that impact how knowledge is created and utilized within the healthcare field. The HKLC may also act as a useful guideline for researchers, practitioners, and decision-makers for taking into account the numerous aspects to consider at critical points during the research process or when applying healthcare knowledge in clinical practice.

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### ICPR-021 // Quality of guidelines for design and conduct of child health clinical trials

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**Background:** Clinical trials in children should be of the highest methodological quality. Inadequate design, conduct and reporting are associated with biased estimates of treatment effects, which may lead to both undertreatment and overtreatment of sick children. In order to conduct scientifically valid research, readily accessible information of appropriate quality should be available on how to design, conduct and report child health clinical trials. Although some methodological guidance exists, its quality and usefulness is uncertain.

**Objective:** To appraise the existing guidance on the design and conduct of child health clinical trials.

**Methods:** We systematically reviewed all current methodological and regulatory literature presenting standards or guidelines for clinical drug trials in children, over the period 1999 – 2009. Information on the development process and recommendations of these guidelines was extracted. Their quality was appraised by a modified version of the Appraisal of Guidelines Research and Evaluation (AGREE) instrument.

**Results:** Of 60 documents found on the internet and 3779 articles found in bibliographic databases, 22 internet guideline documents and 18 scientific publications which contained recommendations for child health clinical trial design and conduct were selected. Process and methods of development of these guidelines were poorly described. Empirical evidence underpinning each of the recommendations was scarce.

**Conclusion:** Methods of the development of guidelines for the design and conduct of child health trials are poorly reported and empirical evidence for the recommendations is lacking. To enhance acceptance and endorsement, these guidelines should be developed using transparent methods with input from end-users and regulators, and engage adequate knowledge translation strategies. Reporting guidelines for guidelines for the design and conduct of randomized clinical trials are needed.

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### ICPR-023 // Individual participant data meta-analysis of prognostic studies: state of the art?

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**Background:** Prognostic factors are associated with the risk of a subsequent outcome in people with a given disease or health condition. Meta-analysis using individual participant data (IPD), where the raw data are synthesised from multiple studies, has been championed as the goldstandard for synthesising prognostic factor studies.

**Objectives:** To assess the feasibility and conduct of IPD meta-analysis of prognostic factor studies.

**Methods:** A systematic review to identify published IPD meta-analyses of prognostic factors studies, followed by detailed assessment of a random sample of 20 articles published from 2006. Six of these 20 articles were from the IMPACT (International Mission for Prognosis and Analysis of Clinical Trials in traumatic brain injury) collaboration, for which additional information was also used from simultaneously published companion papers.

**Results:** Forty-eight published IPD meta-analyses of prognostic factors were identified up to March 2009. Only three were published before 2000 but thereafter a median of four articles exist per year, with traumatic brain injury the most active research field. Availability of IPD offered many advantages, such as checking modelling assumptions; analysing variables on their continuous scale with the possibility of assessing for non-linear relationships; and obtaining results adjusted for other variables. However, researchers also faced many challenges, such as large cost and time required to obtain and clean IPD; unavailable IPD for some studies; different sets of prognostic factors in each study; and variability in study methods of measurement. The IMPACT initiative is a leading example, and had generally strong design, methodological and statistical standards. Elsewhere, standards are not always as high and improvements in the conduct of IPD meta-analyses of prognostic factor studies are often needed; in particular, continuous variables are often categorised without reason; publication bias and availability bias are rarely examined; and important methodological details and summary results are often inadequately reported.

**Limitations:** Only a small number of studies were included. Furthermore, we did not assess the quality of the statistical analyses.

**Conclusions:** IPD meta-analyses of prognostic factors are achievable and offer many advantages, as displayed most expertly by the IMPACT initiative. However such projects face numerous logistical and methodological obstacles, and their conduct and reporting can often be substantially improved.

Reference: Abo-Zaid G; Sauerbrei W; Riley RD (2012): Individual participant data meta-analysis of prognostic factor studies: state of the art? In: *BMC Med Res Methodol* 12 (1): 56.

## ICPR-024 // CONSORT-adherence in bipolar disorders: Implications for the development of the national S3 clinical guideline

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**Background:** Inadequate reporting of clinical trials entails a risk of bias in clinical decision making, therefore authors of evidence-based guidelines – in this case the German evidence and consensus-based S3 guideline for diagnosis and therapy of bipolar disorders have to exclude or downgrade those trials in quality ratings.

**Objective:** This study aimed to identify factors that are associated with CONSORT-adherence and to assess the impact of the quality of reporting on clinical guideline development.

**Methods:** RCTs on pharmacological treatment of bipolar disorders, published between 2000 and 2010 and selected during the process of guideline development by a systematic literature search were included in the analysis. An adapted checklist based on the CONSORT statement (2001) was used to assess the quality of reporting.

**Results:** 134 RCTs were included in this analysis. Of the 72 checklist items 43% were generally reported adequately (reported in  $\geq 75\%$  of all trials) and 25% inadequately (reported in  $< 25\%$  of all trials). Reporting was generally poor for randomization, effect size (reported in 22%), allocation concealment (22%) and NNT (16%). A shift in reporting of methodological and clinical relevant CONSORT items could be found in association to sample size and founding source. In context of the guideline only six RCTs were not downgraded from the highest level of evidence (SIGN 1++; low risk of bias), 21 RCTs were downgraded to 1+ (moderate risk of bias). The remaining were downgraded to 1- (high risk of bias) or even excluded.

**Limitations:** We referred to the CONSORT statement 2001 because of the inclusion of trials published from 2000 to 2010. Future reviews should refer to the CONSORT 2010 statement.

**Conclusion:** Clinical investigators as well as editors and reviewers of journals should be further encouraged to follow publication guidelines. Further research is demanded to investigate whether excluding or downgrading inadequately reported trials from decision making procedures will result in higher quality of clinical guidelines and reliable medical decision making.

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**ICPR-025 // Does use of the CONSORT statement impact the completeness of reporting of randomized controlled trials published in medical journals? A Systematic Review**

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**Background:** The Consolidated Standards of Reporting Trials (CONSORT) Statement is an evidence-based set of items intended to facilitate the completeness, transparency and clarity of reports of randomized clinical trials (RCTs). In 2006, a systematic review examined the effect of CONSORT on the reporting of RCTs in journals that formally endorsed it. Use of CONSORT was found to be associated with improvement in the quality of reporting of RCTs, although the eight included studies were methodologically weak and heterogeneous.

**Objective:** To provide an updated estimate of the impact of CONSORT endorsement on the completeness of reporting of trials since the 2006 systematic review.

**Methods:** Five electronic databases were searched between January 2005 and March 2010, inclusive. Evaluations assessing the completeness of reporting of RCTs based on any items from the 1996 or 2001 CONSORT checklists, four blinding sub-items or a total summary score of any items, were included. The 27 outcomes for which data were collected were: the 22 items of the 2001 CONSORT checklist, four sub-items describing blinding and a 'total summary score' of aggregate items, as reported. Relative Risks (RR) and 99% confidence intervals were calculated to determine effect estimates for each outcome across evaluations.

**Results:** Fifty-three reports describing 50 evaluations (including the original 8) of 16,604 RCTs assessed adherence to at least one of 27 outcomes. Sixty-nine of 81 meta-analyses demonstrated that completeness of reported RCT was better with CONSORT endorsement. Between endorsing and non-endorsing journals, 25 outcomes improved with endorsement, five significantly so. Few evaluations contributed to each meta-analysis, which were largely heterogeneous. No evidence suggested that endorsement worsens the completeness of RCT reports. Validity was assessed as low or unclear for many evaluations.

**Limitations:** The effect of 'endorsement' as an intervention is likely underestimated because journals are not sending a clear message about endorsement to authors submitting manuscripts for publication.

**Conclusions:** Journal endorsement of CONSORT appears to benefit the completeness of RCT reports, however, their reporting remains sub-optimal. More journals should endorse CONSORT and implement stronger policies about authors' adherence to checklist items.

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**DEVELOPMENT OF ROBUST REPORTING GUIDELINES**

**DRRG-026 // Reporting usability to increase confidence in health research**

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Increasingly, electronic devices are being used to collect data directly from research participants. While several advantages can be realized by integrating these data collection methods, the usability of such technologies potentially impacts data quality, data quantity, and the participation of research participants.

Usability focuses on a user's relationship with any item or process. In health research, a user (participant) may interact with computer hardware and data collection software. Compromised usability of hardware or software has the potential to affect the quality and quantity of data

collected, thus altering overall research findings. Low usability may also introduce a non-response bias limiting responses from participants who are challenged by technologies. Usability evaluations can be designed based upon current frameworks such as the U.S. Department of Health and Human Services' Usability Guidelines and the works of Jakob Nielsen. Evaluation may occur at various times during a project allowing for technologies to be altered to increase usability. However, the involvement of researchers with the creation or alteration of technologies can vary widely and variations in evaluation design, timing, and level of technological involvement may pose particular challenges during health research projects. The growing use of electronic devices and the potential for these devices to influence data indicates a need to consider the usability of such technologies in health research projects. An exploration and understanding of variability within usability evaluations provides health researchers with the ability to confront usability problems as they emerge. Additionally, usability evaluations give researchers the perspective to understand and report usability related study limitations. Confidence in data and conclusions is increased by integrating and reporting usability evaluations within applicable health research projects.

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#### **DRRG-027 // Reporting of studies Conducted using Observational Routinely-collected Data [RECORD] initiative**

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**Background:** General guidelines for reporting observational studies (Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)) were published in 2007. However, no reporting guidelines exist for studies based on routinely-collected health data. While the latter studies share many characteristics with traditional observational studies, several issues specific to them are not covered by STROBE.

**Objective:** To develop reporting guidelines for observational studies using routinely-collected health data, as an extension of STROBE.

**Methods:** We will develop reporting guidelines for studies conducted using routinely-collected observational data using the 18-stage EQUATOR Network approach (<http://www.equator-network.org/resource-centre/reporting-guidelines-developers/>). In January 2012 an initial workshop was held at the Primary Care Database Symposium, London UK. Additional meetings and surveys will be held throughout 2012-14 to continue identifying issues specific to REporting on studies Conducted using Observational Routinely-collected Data (RECORD). The RECORD guidelines will supplement existing guidelines for observational studies (STROBE).

**Results:** The initial workshop included > 100 participants from Europe and Canada, and members of the STROBE organizing committee. Participants agreed that reporting of research using routine data sources was often insufficient and highly variable. Potential topics for RECORD guidelines suggested include description of database characteristics, validation of codes and algorithms to identify exposures and outcomes, and record-linkage methodologies. To identify further topics for RECORD guidelines, the working group plans two large international Delphi surveys and face-to-face meetings including expert stakeholders, journal editors, and guideline developers.

**Limitations:** Developing reporting guidelines is an iterative process, and it is recognized that the final guidelines will require updates as a »living document«.

**Conclusions:** Reporting guidelines specific to studies using routinely-collected health data are required. During 2012-14 the RECORD initiative will develop a guidance document, the aim of which is to be published in high-profile biomedical journals. RECORD is intended as an extension of the STROBE statement.



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FREIBURG AT 48 DEGREES NORTH //

### DRRG-028 // Qualitative study reports – checklists and criteria lists and their relation to the quality of the study

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**Background:** Checklists for reporting different types of research studies have become an important tool for researchers and editors of scientific journals. It would be quite appealing to have a consented checklist for reporting qualitative studies.

**Objective:** To discuss problems of a checklist approach, distinguish it from a criteria list approach, and analyze from a theoretical perspective how these approaches relate to the quality of an empirical qualitative study.

**Methods:** Theoretical analysis of different appraisal approaches, informed by the work of the working group »qualitative methods« of the German Network in Health Services Research that was set up to develop standards for good qualitative health services research.

**Results:** Qualitative studies do not represent a special study type, it is rather an umbrella term for very different study types even resorting to different research paradigms. A single checklist cannot capture this spectrum in any reasonable way. Different checklists could be used to guide the report of highly codified methods, a rather limited field of application since qualitative methods are characterized by their openness. However, checklists could help to provide basic information of the study, which might not have direct implications on study quality but improves the ability of the reader to appraise the quality. Criteria lists are different from checklists because they rather ask general questions on different study characteristics. Information gained from these questions can only be interpreted in the context of the whole study. Criteria lists seem to be the most suitable approach to the appraisal of qualitative studies because of their stronger link to quality issues. Still, these lists also are confronted with the problem that qualitative studies might be based on substantially different study approaches and even paradigms. The more general a list becomes, the more it will become a criteria list of good empirical research per se.

**Conclusions:** Checklist can play only a very minimal role in the development of reporting standards for qualitative studies. Criteria lists seem to offer a better approach, but they should be specific enough for the purpose of the study to be able to capture the peculiarities of different qualitative approaches.

### DRRG-029 // Health research reporting guidelines for case reports

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**Background:** A search of PubMed yields more than 1.5 million records. Yet the quality and standardization of published case reports remains uneven (Kaszkin-Bettag 2012, Richason 2009). Therapies used in the real world of healthcare delivery have often not been tested in a clinical trial. Data from case reports hold out the possibility of providing signals of effectiveness and harm in much the same way as a randomized trial.

**Objective:** Develop health research reporting guidelines for case reports to improve the quality, transparency, and completeness of case reports.

**Methods:** We have identified the need for a health research reporting guideline for case reports, reviewed the literature, identified and reviewed the author guidelines from three peer reviewed journal focusing on case reports, and have obtained funding for a case report guidelines initiative, and established an executive committee of David Riley, Gunver Kienle, Joel Gagnier, and David Moher. We will have completed a modified Delphi activity as a pre-meeting activity by the end of September and prepared for a face to face consensus meeting on October 17-18 in North America to review the pre-meeting activity, develop a checklist and flow diagram, and plan post-meeting activity including publication and post-publication activity in 2013.

**Results:** CARE health research reporting guidelines for case reports.

**Limitations:** Data from case reports has historically not provided signals of effectiveness and harm in the same way as a randomized trial. The lack of controls is an obstacle.

**Conclusion:** Standardized, high quality health research reporting guidelines for case reports will strengthen the link between clinical expertise and external evidence, inform clinical trials and other research methods.

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## IMPLEMENTATION OF REPORTING GUIDELINES

**IRG-030 // Reporting Guidelines – Uptake, Impact and Dissemination, Evolution (GUIDE): examining the uptake of the TREND reporting guidelines**

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**Background:** The Transparent Reporting of Evaluations and Non-randomised Designs guidelines (TREND; Des Jarlais, Lyles, Crepaz, & Group, 2004) are an important intervention developed with the aim to improve the quality of reporting of behavioural and public health interventions. However, scoping research indicates that TREND is infrequently cited compared with guidelines such as CONSORT (Begg et al., 1996). Limited uptake of TREND reduces the

potential to improve reporting quality and consequently the evidence base for informed health policy decision making. It is thus important to understand how TREND is currently being used in order to improve strategies to increase dissemination and adherence to the guidelines.

**Objective:** To ascertain how the TREND guideline is »used« by authors and by the journals in which these papers are published.

**Methods:** Published articles that cite TREND were identified through a »cited by« search using Web of Knowledge. Details (e.g. year of publication, how TREND was used) were recorded for all articles. Additional data relating to, for example, study design, was subsequently collected from articles reporting primary research. Lastly, information (e.g. whether TREND was referred to in journals' 'instructions for authors') was retrieved from journals that had published the articles that cited Des Jarlais et al.

**Results:** TREND reporting guidelines have been cited nearly 300 times yet few of these are studies where the guidelines were applied to a primary research study, as intended by the developers of TREND.

Preliminary findings on the impact of TREND on reporting and study quality will be presented.

**Limitations:** It is possible that although authors may adhere to TREND they do not cite the guideline resulting in these papers being unintentionally excluded from our study.

**Conclusions:** These preliminary results suggest that TREND is underutilised by authors and journals. Findings from ongoing investigations into the impact of TREND on reporting and study quality and factors affecting the use of TREND will provide important information on current dissemination strategies and how they might be improved in future.

References:

Begg, C. et al.,(1996). Improving the quality of reporting of randomized controlled trials – The CONSORT statement. JAMA, 276, 637; Des Jarlais, et al., (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. AJPH, 94, 361)

### IRG-031 // Ways to Implementation of Reporting Guidelines in Cardiovascular and Thoracic Surgical Journals in China

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**Background:** Reporting guideline is important but not awarded popularly in China.

**Objective:** To explore a mode to implementation of reporting guideline in journals in China.

**Methods:** Firstly, we collected the reporting guidelines and how to use them by systematic review. Secondly, we identified the problems in using reporting guidelines. Thirdly, we disseminated the reporting guidelines by lecture on annual meeting in academical associations, publication of academical papers on reporting guidelines in editologica periodicals, training the editors by continuing education, training the peer reviewers and authors by author guideline and editing activities, and training the undergraduates and graduates by systematic teaching.

**Results:** We have conducted a systematic review of reporting guidelines for systematic review/meta-analysis of randomized controlled trials. Other systematic reviews of reporting guidelines for primary studies and clinical guidelines in cardiovascular and thoracic surgery are ongoing. The problems in implementation of reporting guidelines are few journals using them and the using method are not correct. We have cooperated with several academical associations to train the authors, peer reviewers, authors and editors.

**Limitations:** This study just began, and just in cardiovascular and thoracic with small sample.

**Conclusion:** PRISMA should be used for systematic review/meta-analysis of randomized controlled trials. Multiple subject discipline cooperation and multilayer training and education may be an effective mode for implementation of reporting guidelines in surgical journals in China.

## INITIATIVES TO IMPROVE THE TRANSPARENCY OF THE RESEARCH LITERATURE

### ITRL-032 // Quality of reporting of controlled diabetes trials in Iran: a systematic review.

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**Background:** Clinicians rely on high quality evidence to enable them to make decisions about their clinical practice.

**Objectives:** For medical intervention studies controlled trials (CTs) are at the top of the hierarchy of evidence. We aimed to evaluate the quality of Controlled Trials in diabetes conducted in Iran and published in both Iranian and non-Iranian journals.

**Methods:** All CTs published in the field of type 1 and type 2 diabetes which were conducted in Iran were evaluated in this systematic review. We searched PUBMED-MEDLINE database, Scopus, Proquest, EBSCO, Science Direct, Web of science, Cochrane Library, Magiran, SID, and IranMedex from 1994 to 2012. Two independent reviewers used pre-defined inclusion and exclusion criteria to identify all eligible articles. Eligible articles were critically appraised, using the CONSORT 2010 statement checklist.

**Results:** Four hundred and fourteen articles (192 in Iranian Journals and 222 in Non-Iranian journals) were screened, 240 papers (128 vs. 110) were included. Eligible articles included Randomized Controlled Trials (92%) and CTs (8%). The most reported item, scientific background, was mentioned in 98% (100% vs. 95%); and the least reported one, interim analyses, appeared in only 1% (1% vs. 0%) of articles. The frequency of reporting other CONSORT items were as follows: inclusion and exclusion criteria, estimation of sample size, blinding were 99% (97% vs. 99%), 19% (12% vs. 33%), and 40% (31% vs. 57%) respectively. Finally, study limitations were reported in 45% of the articles (36% vs. 63%).

**Limitations:** We may have missed some studies due to poor sensitivity and specificity in search results in Iranian databases

**Conclusions:** Our study suggests that the quality of reporting of Controlled Trials in diabetes conducted in Iran seems weak. Reporting completeness assessed by the CONSORT 2010 checklist was lower in Iranian journals than in non-Iranian journals.

### ITRL-033 // Explanation of samples sizes in current biomedical journals: an irrational requirement.

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**Background:** Parallel to the development of applied statistics for medical research have produced a pernicious deviations outside the discipline itself. One is the ritual concerning the use of formulas for calculating the sample size. And this behavior extends under the requirements held by the majority of medical journals that suggest that the detailed disclosure of how it was determined that size should appear in the articles. We considered the conjecture that these requirements have no basis in rationality, and that they are notoriously ignored by the authors, reviewers and editors in the currently published scientific articles.

**Objective:** To discuss the theoretical relevance of current requirements for explanations of the sample sizes employed in published studies, and to assess the extent to which these requirements are currently met by authors and demanded by referees and editors.

**Methods:** A literature review was conducted to gain insight into and critically discuss the possible rationale underlying the requirement of justifying sample sizes. A descriptive bibliometric study was then carried out based on the original studies published in the six journals with the highest impact factor in the field of health in 2009.

**Results:** The few arguments found to support the requirement of a post hoc explanation of

sample sizes are certainly feeble, and on the other hand, there are several reasons why they should not be endorsed. These instructions are neglected in most of the studies published in the current literature with the highest impact factor. In 56% (95%CI: 52-59) of the articles, the sample size used was not substantiated, and only 27% (95%CI: 23-30) met all the requirements contained in the guidelines adhered to by the journals studied.

**Limitations:** The present bibliometric study included only a group of magazines. Although they are among the most influential ones, a further review of more publications would be welcomed.

**Conclusions:** There are no convincing arguments justifying the requirement for an explanation of how the sample size was reached in published articles. There is no sound basis for this requirement, which not only does not promote the transparency of research reports but rather contributes to undermining it.

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#### **ITRL-034 // PROSPERO: the first year of a prospective register of systematic reviews**

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PROSPERO was launched in February 2011 in response to increasing support for the prospective registration of protocols for systematic reviews. PROSPERO was developed in collaboration with an international advisory group and informed by a worldwide consultation to identify the key items for inclusion in the register.

The aims of the register are to help reduce unplanned duplication, to identify and reduce the risk of reporting bias and to encourage transparency in the conduct and reporting of systematic reviews. It is anticipated that this will in time provide an opportunity to improve the quality of systematic reviews and the healthcare decisions that rely on them.

To inform the next stage in the development of PROSPERO, after one year the utility of the database was evaluated. This poster includes a brief outline of the purpose and function of the register, then focuses on the findings of the evaluation. The evaluation provides descriptive information about the 'who, where and what' of registration submissions and the use of the website to register ongoing reviews.

The register has been well received with more than 350 registrations from 33 different countries in the first year. While reviews of interventions form the majority of registrations, diagnostic, prognostic, prevention and service delivery reviews also feature.

A brief on-line survey was emailed to registered users of PROSPERO asking for feedback on the utility of the registration form and process. Overall experience was good or excellent, including navigating the form, relevance of registration fields, support materials and administration turn-round time. Sixty percent of registrants completed the form in 60 minutes or less. In the first year there were over 15,000 visitors and over a million page views.

The next phase in the development of PROSPERO includes the addition of Cochrane protocols; further promotion to encourage registration and use of the database; and stepped expansion of scope for inclusion.

Acknowledgement of funding: The development and ongoing management of PROSPERO is supported by CRD's core work programme which is funded by the National Institute for Health Research, England; the Department of Health, Public Health Agency, Northern Ireland and the National Institute for Social Care and Health Research, Welsh Government.

### ITRL-035 // PROSPERO: an international prospective register of systematic review protocols

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Launched in February 2011, PROSPERO is an international online prospective register of health related systematic reviews, initiated by the UK Centre for Reviews and Dissemination (CRD) and developed in collaboration with an international advisory group. Although protocol development is integral to systematic reviews carried out or funded by many organizations, PROSPERO provides the first opportunity to record information on the systematic review protocol in a free, publicly accessible register. This presentation will describe the establishment of PROSPERO, highlighting its importance in improving transparency and the potential to minimise bias in systematic review.

PROSPERO captures key elements of a systematic review protocol in advance of the main reviewing activity to encourage transparency, provide a safeguard against reporting bias and reduce unplanned duplication of systematic reviews. It offers free registration, with a dedicated web-based interface that is electronically searchable and open to all ([www.crd.york.ac.uk/PROSPERO/](http://www.crd.york.ac.uk/PROSPERO/)).

Registration provides advantages to many stakeholders including researchers, commissioners and funders, guideline developers, methodologists, journal editors and peer reviewers, and is in the interest of patients and the public. Importantly, PROSPERO allows researchers to comply with the 2009 PRISMA statement which advocates registration of systematic review protocols. Following an international Delphi consultation in 2011, registration requires provision of 22 data items with the option to provide details of a further 18.

Prospective registration supports the efficient use of funding and timely updating of systematic reviews, provides a way of helping to identify and reduce the risk of reporting bias, and should in time contribute to improving the quality of reviews and the decisions that rely upon them. Registration offers advantages to many stakeholders in return for modest additional effort from the researchers registering their review. We therefore believe that prospective registration should become standard best practice for those who commission, fund and conduct systematic reviews.

Acknowledgement of funding: The development and ongoing management of PROSPERO is supported by CRD's core work programme which is funded by the National Institute for Health Research, England; the Department of Health, Public Health Agency, Northern Ireland and the National Institute for Social Care and Health Research, Welsh Government.

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### ITRL-036 // Project for a Scientific System Based on Transparency

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**Background:** Current approaches to combat scientific misconduct and ensure good research practices are unsatisfactory. The widely adopted »FFP« definition of misconduct is restrictive in its application and yet too vague to be effective, allowing only the most egregious cases to be tackled, after lengthy and costly investigations. The scientific literature is virtually unprotected from bias, largely because of a lack of common standards of research practice and peer-review, which hampers the independent assessment and replication of findings. A solution to all these problems might be closer than it appears. The EQUATOR network and other initiatives are part of it, but a rethinking of the scientific system is needed.

**Objectives:** This talk will outline the vision of a new approach to managing, teaching and publishing science, centred on ensuring the transparency of research communication.

**Methods:** Scientific misconduct is re-defined as a misrepresentation of the information required to evaluate the validity of a research – at the level appropriate to the context where the research is communicated. Professional societies and initiatives like EQUATOR coordinate their efforts, in order to produce a universal »taxonomy« of research methods. Scientist and students have thus access to univocal guidelines and principles about what they should explain in reporting their research, from general to particular aspects. The primary role of editors and peer reviewers is to ensure that all the required information is given. Authors are held responsible for what they communicate.

**Results:** Efficiency and clarity would increase at all levels of the scientific system. Scientific misconduct and good research would be less ambiguous concepts. In case of suspicions, Research Integrity Officers will have the relatively simple task to establish whether factual information about a study was reported as required. Editors and peer reviewers would avoid subjectivity and bias, by focusing on objective specifications. Teachers and mentors would move away from transmitting »tacit« knowledge and abstract principles, and provide instead concrete standards of communication and responsibility, which would naturally inspire best research practices. Published findings would all be equally amenable to critical assessment and replication attempts.

**Limitations:** Objections, criticisms and the feasibility of these ideas will be discussed

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### ITRL-037 // Narrow agendas in meta-analyses of drug interventions

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**Background:** Systematic reviews and meta-analyses are increasingly used to assess the evidence on specific medical interventions. However, for most medical conditions, many interventions have been tested and ideally one wants to appreciate the relative merits of all of them.

**Objective:** To assess whether published meta-analysis articles address narrow questions on one or a few interventions or examine the wider picture of the evidence where many intervention options may be available.

**Methods:** We evaluated 499 articles published in 2010 that presented at least one meta-analysis of drugs or other biologic agents. We estimated how many articles did not cover all the available comparisons of tested interventions for a given condition (not all-inclusive); focused on specific named agent(s); or focused strictly on comparisons of only one specific active agent versus placebo/no treatment or different doses/schedules.

**Results:** Of 499 eligible meta-analysis articles, 403 (80.8%) were not all-inclusive. In particular, 214 (42.9%) covered only specific named agent(s) and 74 (14.8%) examined only comparisons with one active agent versus placebo/no treatment or different doses/schedules. Only 39 of 499 articles (7.8%) covered all possible indications for the examined agent(s). After adjusting for type of treatment/field, focus on specific named agent(s) was associated with publication in journal venues rather than Cochrane (OR 1.95 [95% CI 1.17–3.26]), industry sponsoring (OR 3.94 [1.66–10.66]), and individual-patient data analyses (OR 6.59 [2.24–19.39]), and was less common in meta-analyses addressing efficacy only rather than both efficacy and harms (OR 0.36 [0.22–0.60]). Individual-patient data analyses almost always (33/34) focused on specific named agent(s).

**Conclusions:** The scope of meta-analysis publications frequently is not broad enough and may be shaped in order to serve particular agents.

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**ITRL-038 // Guidelines for reporting of studies using linked data**

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**Background:** Linkage of records between electronic health databases for research purposes is becoming increasingly important as individual-level electronic information can be combined relatively quickly and inexpensively. Reports of studies based on linked data often lack the information necessary for interpreting validity of results.

The impact of linkage bias can be substantial. Examples in the literature are underestimated mortality rates, biased mortality ratios due to differential linkage by ethnic group, exclusion of vulnerable populations due to poorly-recorded identifiers and erroneous rankings of relative hospital performance due to differing data quality between units.

Such potential biases should be acknowledged and results adjusted accordingly, yet linkage evaluation is rarely reported as linkage and analysis are often performed separately. Linked data-users frequently have limited access to details of linkage processes, and data-providers do not recognise the importance of facilitating linkage evaluation. There is a lack of guidance for researchers on the information required from data providers for appropriate reporting of these studies.

**Methods:** From the privileged position of performing both linkage and analysis, we are developing recommendations by agreeing on elements that should be considered in reports of research based on linked healthcare-data. These recommendations will undergo stakeholder review and a Delphi process and will be included as a key component of the REporting of studies Conducted using Observational Routinely collected Data (RECORD) guidelines.

**Results:** We propose a checklist of items relating to linkage set-up, methods, criteria, results, error assessment and analysis.

**Discussion:** The development and implementation of the linkage guidelines as part of the RECORD initiative will help improve the quality of reporting of linked data research. As linkage is only one element of these observational studies, these guidelines need to be piloted alongside comprehensive recommendations for reporting studies based on routinely-collected data,

to ensure essential details are incorporated in a user-friendly way.

**ITRL-039 // Evolving role of medical writers in the current scenario**

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The detonation of clinical research has opened up new opportunities or enhanced the existing opportunities for qualified skilled professionals. Medical writing, »communicating clinical and scientific data and information to a range of audiences in a wide variety of different formats», is one among such an opportunity. Medical writing has been a part of the industry for a quite long time, but it is only in recent years that the field has really taken off. Medical writers, a most debated role in clinical research, are used by pharmaceutical companies, contract research organizations, business process outsourcing companies, and medical communication agencies to write, edit, and publish research of their interest in reputed regulatory and public platforms. They often improve the effectiveness of medical communications by working closely with study teams, key opinion leaders, and other stake holders to develop clear, concise and scientifically legitimate documents. However, in the current scenario, the role of medical writers is expanding. New regulatory requirements, ethical considerations, writing and publishing guidelines, growing clinical experiences, ever increasing number of clinical trials, advances in the medical and scientific domain, breakthrough of new diseases, and technological advancements are considered to be major contributors in expanding the role of medical writers. It is expected that these dynamic factors will continue to contribute and the scope of medical writing and the role of medical writer will be evolving. Hence, medical writing has become a niche field in clinical research. In this paper all these factors would be explained with more focus on ethical considerations.

**ITRL-040 // AQUILA: assessment of quality in lower limb arthroplasty.**

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**Background:** In the light of both the importance and large numbers of case series and cohort studies (observational studies) in orthopaedic literature as well as the recent disasters with metal on metal arthroplasty, it is remarkable that there is no specialized reporting checklist.

**Objective:** A Delphi approach was used to develop a reporting checklist for case series and cohorts in total hip and total knee arthroplasty with a focus on aseptic loosening.

**Methods:** A web-based Delphi was conducted consisting of two internal rounds and three external rounds in order to achieve expert consensus on items considered relevant for reporting.

**Results:** The internal rounds were used to construct a master list. The first external round was completed by 44 experts involving 17 nationalities on five different continents and included experts with a mean 16 years experience. 35 experts of the initial group completed the second external round and 33 of them completed the third external round. Consensus was reached on an 8-item reporting checklist.

**Limitations:** The possibility that the results were affected by non-responder bias should be considered.

**Conclusions:** A reporting checklist for case series and cohorts in total hip and total knee arthroplasty was successfully created through this Delphi. As a treatment specific extension of STROBE, this checklist should improve the accuracy, completeness and quality of case series and cohorts regarding total hip and total knee arthroplasty

**ITRL-041 // Moving from clinical trial reporting guidelines to guidelines for design and conduct**

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**Background:** Despite the endorsement of the CONSORT statement by many journals the reporting of randomized clinical trials in child health is still insufficient. Additionally, major issues related to the design and conduct of RCTs including children impair interpretation and application of these trials' results. Currently, guidance for the design and conduct of child health randomized clinical trials is developed and published. Contrary to guidance documents issued by regulating agencies, these guidance documents do not have any authority.

**Objective:** To develop methods to appraise these guidance documents, and identify best practices that lead to high quality guidelines.

**Methods, Results:** Our quest for instruments to appraise the quality of guidance documents for design and conduct of trials led us to the AGREE II instrument to appraise clinical practice guidelines and to a paper by David Moher et al. about the development of health research reporting standards.

**Limitations:** These checklists can only be applied partially to guidance documents for the design and conduct of clinical epidemiological studies. Of the 23 items of the AGREE II instrument 9 are deemed not applicable, and the sequence of the steps advised by Moher et al. is considered to be different when developing a guidance document for the design and conduct of clinical epidemiological studies.

**Conclusions:** No standards exist for the development of guidelines for the design and conduct of RCTs including children. We propose to conduct a Delphi procedure to reach consensus with clinical researchers and regulators about a checklist for appraising guidance documents for the design and conduct of clinical epidemiological studies.

References: Brouwers, Melissa, et al., (2010) CMAJ, 182, E839; Moher, David et al., (2010) PLoS Med, 7, e1000217

## DEVELOPMENT AND DELIVERY OF EDUCATIONAL AND TRAINING PROGRAMMES ON RIGOROUS RESEARCH REPORTING

### DETP-042 // From protocol to publication. A study of consistency in the reporting of Danish academic clinical drug trials

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**Background:** Unacknowledged inconsistencies between protocols and publications of clinical trials undermine the validity of the results of the trials. Little is known about inconsistency in the reporting of academic clinical drug trials. Furthermore, the severity of the scientific and clinical impact of inconsistency varies with the nature of the trial objective as either confirmatory or exploratory. The threat is particularly serious to confirmatory trials, which have the potential to change clinical practice. We here present a new approach to the assessment of inconsistency between protocols and publications.

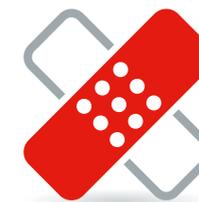
**Objective:** To investigate the prevalence of consistency between protocols and publications of academic clinical drug trials.

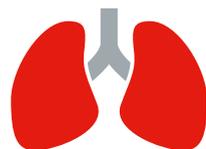
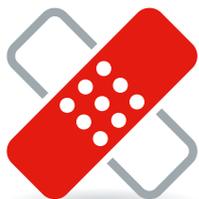
**Methods:** We systematically assessed approved protocols submitted to the Danish Medicines Agency in 1999, 2001 and 2003 and corresponding publications. The primary outcome was the prevalence of overall consistency defined as the absence of inconsistency regarding study type (categorized as either exploratory or confirmatory), primary objective, primary endpoint, and – for confirmatory trials only – hypothesis and sample size calculation. Secondary outcomes were the prevalence of each of the component variables and the number of inconsistencies per trial.

**Results:** A total of 95 protocols and 143 publications were included. Overall consistency was observed in 39% (37/95) of the protocols. Individual rates of inconsistency: primary endpoint 41% (39/95), study type 22% (23/95), primary objective 19% (20/95). Individual rates of inconsistency among trials with both a confirmatory protocol and a confirmatory publication: hypothesis 14% (5/37) and sample size calculation 46% (17/37). At the publication level, inconsistencies were observed in 49% (70/143).

**Limitations:** The assessment of protocols and publications were conducted by a single reviewer. To ensure reproducibility, quality assurance and control measures were utilized.

**Conclusions:** Inconsistencies occurred frequently and, thus, academic clinical drug trials do not seem to be an exception from previously studied cohorts of clinical trials. The reporting of exploratory protocols as confirmatory trials is of special concern, as these publications may directly affect the development of clinical guidelines.



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