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Registration of experimental studies and systematic reviews

Alison Booth
Overview of presentation

- Principles and practice of registration
- Barriers and facilitators to registration
- Development and evaluation of utility of PROSPERO
- The future
Principles of registration

- Availability of evidence to inform health care decisions
- Avoidance of publication bias and selective reporting bias
- Requirement of The Declaration of Helsinki
- Avoid unnecessary duplication
- Identify gaps in research
- Facilitate recruitment
- Promoting collaboration
- Early identification of potential problems

WHO ICTRP: www.who.int/ictrp/en/
Practice of registration

- Accessible to the public at no charge
- Accept registrations from anyone (unduplicated, eligible and complete)
- Managed by a not-for-profit organisation
- Validate entries (within scope and complete)
- Electronically searchable
- Provide a unique identification number for each record
- Require provision of a minimum data set
- Permanent entries

ICMJE criteria for clinical trial registers: www.icmje.org/update_june07.html
Publication bias and selective reporting of outcomes

**In animal studies**

**In clinical trials**

**In systematic reviews**
How registration can help

• Records key planned features of the research
  • randomisation/inclusion criteria
  • primary and secondary outcomes and measures

• Allows comparison of published results with what was planned in the corresponding registration record
  • readers can judge whether any discrepancies are likely to have introduced bias

• Registration should allow amendments and maintain audit trail (not unreasonable to make changes, but need to know why)
Avoiding unintended duplication

• Research can be invasive/time consuming and costly
• Often duplicate or very similar studies are undertaken
• Unintended duplication is economically wasteful

• Registration should allow those planning research to check whether there are any studies already in the ‘pipeline’ that address their topic of interest

• They can then decide whether or not to proceed
Practical barriers to registration

• Availability of a registry

• Process for process sake
  • no legal or ethical imperative: ? value to registrant

• Safeguarding privacy
  • focus/topic of investigation
  • researchers carrying out the investigation

• Timing
  • too soon – lots of amendments
  • too late – fails to fulfil purpose of registration

• Costs
  • time, effort and money
Benefits of registration

- Researchers
- Commissioners and funders
- Guideline developers
- Journal editors and peer reviewers
- Methodologists
- The public
Prospective registration of systematic review protocols

- Importance increasingly recognised
- PRISMA 2009 advocated registration
- No open access facility to formally register systematic review protocols
  - Cochrane and Campbell Collaboration protocol registration limited to their own organisations
Development of PROSPERO

- CRD initiated development of PROSPERO in 2010
- International Advisory Group
- Minimum dataset agreed by international consultation
  - 22 required fields
  - 18 optional fields

Lancet 2011;377(9760):108-109
Inclusion/exclusion and timing

- Ongoing systematic reviews that have a health related outcome in the broadest sense
  - Systematic reviews of reviews
  - Reviews of methodological issues with an outcome that can be used in health care practice
- Scoping reviews – excluded as are not systematic reviews
  - Reviews of animal studies – excluded as outcomes not of direct relevance in health care practice
- Registered before screening against eligibility criteria commences (currently accepted as long as they have not progressed beyond the completion of data extraction)
PROSPERO launched February 2011

- Web based
- Free to register, free to search
- Users create and **update** their own records
- Record content is responsibility of review author
- Administrators check for “sense” **not** peer review
- An audit trail of amendments is maintained
- Registration record indexed by the PROSPERO team
- As many administration tasks as possible are automated
- Minimum data set
One year evaluation of utility

- Based on 232 responses from users (response rate 22%)
  - 80% found registration fields relevant to their review
  - 99% found joining and navigation was easy/very easy
  - 96% found turn round time was good/excellent
  - 80% found supporting materials helpful/very helpful
- 99% rated their overall experience of registering with PROSPERO as good or excellent
- 79% completed the registration form in 60 minutes or less
- Conclusion: registration of systematic review protocols is feasible and not overly burdensome for those registering their reviews

*Booth et al. Systematic Reviews 2013;2:4*
Criticisms of the dataset

• ‘Form bias towards reviews that involve statistical data analysis rather than narrative or qualitative reviews’

• ‘Some leaders assert that systematic reviews are exploratory in nature and should not have pre-determined primary outcomes’

• Legitimate reasons why data extraction, risk of bias (quality) assessment and data analysis all started but not completed
Cumulative totals for new registrations
March 2013: PROSPERO contains details of 1260 reviews being carried out in 57 different countries.
The future

• Improve functionality of form and search interface
• Expand the scope to include all systematic reviews for which there is a health related outcome in the broadest sense
• Continue to encourage registration and use of the database
• Work on a programme of methodological research

• Potentially help support development of satellites (*X-3 or Miranda?*)

• With the right support and flexible pragmatic approach - setting up a register is possible
Welcome to PROSPERO
International prospective register of systematic reviews

PROSPERO latest news
Over 1000 records available as PROSPERO takes on a new look.
Scope for eligibility has been expanded to include:
- Systematic reviews of reviews
- Systematic reviews of methodological issues as long as they contain at least one outcome of direct patient or clinical relevance
Full details of eligibility can be found under 'inclusion criteria'.

Latest new and updated records
- Total hip replacement and surface replacement for the treatment of pain and disability resulting from end stage arthritis of the hip: review of technology appraisal guidance 2 and 44
- Systematic review on the incidence of bisphosphonate related osteonecrosis of the jaw in children diagnosed with osteogenesis imperfecta
- Levosimendan for low cardiac output syndromes: a systematic review with meta-analysis and trial sequential analysis
- The effectiveness of exercise for soft tissue injuries of the shoulder: a systematic review of the literature by the OPTIMA Collaboration
- Endocrine-disrupting chemicals, diabetes risk, and diabetes-related metabolic traits,

Page last updated: 21 January, 2013

www.crd.york.ac.uk/PROSPERO