Coding of Clinical Trials and Systematic Reviews in the Cochrane Library Using International Standards

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U.S. Cochrane Eyes and Vision Group (CEVG@US)

**CEVG**
- One of 51 Cochrane Review Groups.
- Headquarters in London, UK.
- Collaborates with ophthalmologists, optometrists, and other vision researchers to conduct systematic reviews of preventive and therapeutic interventions for ocular diseases and conditions.

**CEVG@US**
- Headquarters in Baltimore, Maryland.
- U.S. arm of the Cochrane Eyes and Vision Group.
- Receives support through 7-year contract with the National Eye Institute, NIH.
- Provides training in Cochrane activities and methods to interested researchers.
- Handsearches U.S. vision science literature.
Long-Term Goal

*Develop coding schema to facilitate retrieval of and reporting regarding contents of Cochrane Library:*

- Systematic reviews
- Protocols for systematic reviews
- CENTRAL (≈ 500,000 titles), i.e., publications eligible for inclusion in Cochrane systematic reviews
CENTRAL Entries

- Published articles from controlled clinical trials identified in MEDLINE and EMBASE.
- Published articles from clinical trials identified by handsearching journals.
- Conference abstracts of presentations from clinical trials identified by handsearching proceedings, programs.
CEVG Specialized Register

- Contained within CENTRAL.
- Focused on clinical trials in eyes and vision.
- ≈ 10,000 citations entered.
- Record format: citation with or without abstract.
CEVG Coding Efforts

- MeSH headings added to conference abstracts in CEVG specialized register.
- Arbitrary coding schema applied to systematic reviews by CEVG editor (ophthalmologist).
Goals of CEVG Pilot Study

• Identify and apply coding schemas for:
  ▪ Ocular health and medical conditions
  ▪ Interventions evaluated in trials

• Desired properties of coding schemas:
  ▪ International recognition and implementation
  ▪ Wide availability
  ▪ Pertinent to clinicians
  ▪ Applicable to other health, medical areas
Pilot Study: Phase I

• Two members of U.S. CEVG team:
  ▪ Ophthalmologist / epidemiologist
  ▪ Clinical trialist / ophthalmic epidemiologist

• Searched for potential schemas, priority given to those available online.

• Applied candidate schemas to CEVG (Cochrane) systematic reviews.

• Evaluated reproducibility; formulated coding conventions.
Pilot Study: Phase II

- Selected 10% sample of entries in CEVG specialized register.
- Applied proposed coding schemas to sample (n = 981).
- Evaluated reproducibility of coding among first 100 entries.
- Created database of codes to facilitate summary of entries based on codes.
ICD-10* for Conditions

**Disadvantage:** ICD-9 still being used in U.S.

**Advantages:**
- ICD-10 adopted elsewhere in world; to be adopted in U.S. in \( \approx 2 \) years.
- Available (free) online from WHO.
- Searchable by conditions, codes, major categories.
- Printable codebook.
- Broad range of codes for ocular conditions.

ICHI* for Interventions?

**Advantages**
- Beta-test version available free from WHO.
- Currently downloadable; expected to be online when finalized.
- Searchable by interventions and codes.

**Disadvantages**
- Focused on surgery, in-hospital procedures.
- Limited number of codes for ocular procedures.
- Single code for “pharmacotherapy”!

*International Classification for Health Interventions, (β-test version), WHO, 2004*
Approach to Coding Random Sample of Specialized Register

Ocular conditions:
• ICD-10

Interventions:
• ICHI used for applicable procedures, primarily surgery.
• Adapted codes from ICD-10, Chapter XX, intended to code adverse effects of “drugs, medicaments and biological substances”.
• Also adapted codes from ICD-10 to code devices into broad categories.
CEVG Register Sample:
265 of 981 (27%) Not Codable

- Inadequate information provided in title (and abstract when available): 8.5%
- Normal subjects and eyes only: 8.7%
- Not an RCT or CCT: 4.4%
- Normals compared to those with ocular condition of interest: 2.4%
- Trial conducted for non-ocular conditions; ocular side effects reported: 1.6%
- Trial conducted in surgery patients; reason for surgery not given: 1.4%
CEVG Register Sample

76.3% (716 of 981) Codable

- Primary interventions (accounted singly for 91.5% of codable entries in sample):
  - Drugs, medicaments, biologics – 51.3%
  - Procedures – 20.8%
  - Devices – 19.4%

- Others:
  - Combinations of above – 3.5%
  - Anesthesia – 3.6%
  - Other – 1.4%
## ICD-10 Categories by Single Interventions

<table>
<thead>
<tr>
<th>Disorder by Location / Type</th>
<th>Drugs,etc. (n = 367)</th>
<th>Procs. (n = 149)</th>
<th>Devs. (n = 139)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glaucoma</td>
<td>31.1%</td>
<td>18.8%</td>
<td>2.2%</td>
</tr>
<tr>
<td>Retina, choroid</td>
<td>11.4</td>
<td>34.9</td>
<td>5.8</td>
</tr>
<tr>
<td>Refractive error</td>
<td>2.2</td>
<td>12.8</td>
<td>51.1</td>
</tr>
<tr>
<td>Lens</td>
<td>12.3</td>
<td>6.0</td>
<td>16.5</td>
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<tr>
<td>Conjunctiva</td>
<td>12.0</td>
<td>4.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Cornea</td>
<td>10.9</td>
<td>4.7</td>
<td>2.2</td>
</tr>
<tr>
<td>Others</td>
<td>19.2</td>
<td>18.8</td>
<td>21.6</td>
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</table>
Advantages of Pilot Study Approach

• Made use of internationally available (from WHO) coding schemas.
• Schemas applicable to a wide range of health and medical conditions and interventions.
• Searchable codebooks.
• ICD-10 very satisfactory for conditions.
• Adaptation of ICD-10, Chap. XX, satisfactory for coding drugs, etc.
• Identified some entries in CEVG register to be examined in more detail (e.g. full articles).
Disadvantages of Pilot Study Approach

**Major Disadvantage:**
Hybrid approach to coding interventions less than ideal.

- Other schemas too vague or too detailed.
- Still seeking better schema for coding devices and procedures in eyes-and-vision trials.
- However, better schema for eyes and vision may not be better for coding other health and medical conditions.
Recommendations to CEVG

• Re-evaluate sample of entries coded so far (primarily by one person).
• Use ICD-10 to code conditions.
• Use hybrid approach to code interventions, as used in pilot study, until better schema identified and evaluated.
• Continue to seek a broadly applicable schema for coding interventions
Other Potential Applications

• Registers of clinical trials.
• Specialized bibliotraphy tags, e.g., *Controlled Clinical Trials*, 1991.
• IRB databases.
• Etc.
# Acknowledgements

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<tr>
<th>U.S. CEVG Team</th>
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