



***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 2 years.
- Available (free) online from WHO.
- Searchable by conditions, codes, major categories.
- Printable codebook.
- Broad range of codes for ocular conditions.

* *International Statistical Classification of Diseases and Related Health Problems, WHO, 2006*

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, (-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

<i>Disorder by Location / Type</i>	<i>Drugs,etc. (n = 367)</i>	<i>Procs. (n = 149)</i>	<i>Devs. (n = 139)</i>
Glaucoma	31.1%	18.8%	2.2%
Retina, choroid	11.4	34.9	5.8
Refractive error	2.2	12.8	51.1
Lens	12.3	6.0	16.5
Conjunctiva	12.0	4.7	0.7
Cornea	10.9	4.7	2.2
Others	19.2	18.8	21.6

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 bibliography tags, e.g., *Controlled Clinical Trials*, 1991.
- IRB databases.
- Etc.

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