Terminologies for recording of ADR:s
Adverse reaction terms

- Dizziness
- SOB
- feeling hot
- dyspnoea
- lightheadedness
- breath shortness
- evidence of VEBS on ECG
Concepts

• Terminology
  – collection of accepted terms

• Thesaurus
  – relationships included

• Dictionary
  – with definitions
Major thesauri for coding of ADR information

- WHO-ART
  - WHO Adverse Reaction Terminology
- MedDRA
  - Medical Dictionary for Regulatory Activities
WHO-ART

• Developed for the WHO Drug Monitoring Programme
  - since 1968
  - for adverse reaction monitoring
  - used also by pharmaceutical companies
    • also for use in clinical trials
WHO-ART hierarchy

Content December 2001

Body organ

Grouping of PT

Principle terms for coding

Synonyms to PT

System Organ Class 32

High Level Term 180

Preferred Term 1930

Included Term 2758
WHO-ART

• **System Organ classes**
  - Skin and appendages disorders
    • 0100
  - Musculoskeletal disorders
    • 0200
  - etc.
    • ...
  - Secondary terms
    • 2000
  - Poison specific terms
    • 2100
WHO-ART

Heart rate & rhythm disorders SOC

Tachycardia HLT

- Palpitation PT
  - Heart pounding IT
  - Heart fluttering IT
- Tachycardia PT
  - Pulse rate increased IT
  - Sinus tachycardia IT
WHO-ART Translations

Through the Record Number System

Record Number 0027

RASH
English

ERUPTION
French

HAUTAUSCHLAG
German

RASH CUTANEO
Italian

ERUPCION CUTANEA
Spanish

ERUPCAO CUTANEA
Portuguese
WHO-ART - File Layout

- Record No: 0364
- Seq. No: 001
- High Level term link: 0363
- System Organ Class: 0800
- Text: Acidosis lactic
WHO-ART

Availability

- Computer files
- Diskette or FTP
- Paper print
- English
- French
- German
- Italian
- Portuguese
- Spanish
WHO-ART
Definitions

• Preferred term
• APNOEA
• Definition
  • Cessation of airflow at the nose and mouth for at least 10 sec.
• Basic requirement
  • Demonstration according to the definition
• Reference
  • CIOMS; Harmonizing the use of adverse-drug-reaction terms, Geneva, 1996
WHO-ART

Critical Terms

• Critical terms are a subset of adverse reaction terms referring to, or possibly being indicative of, serious disease states, which have been regarded as particularly important to monitor.
Use of WHO-ART

Example

SUMATRIPTAN

<table>
<thead>
<tr>
<th></th>
<th>AUS</th>
<th>DEN</th>
<th>NET</th>
<th>SWE</th>
</tr>
</thead>
</table>

Cardiovascular disorders

- Hypertension      5   1   3
- Oedema            2
- Pallor            4
- Syncope           2   3

Heart rate and rhythm disorders

- Arrhythmia         3
- Palpitation        5   6   5   3
- Tachycardia        5
ICD-ART

- WHOART will be put in XML format
- ICD-WHOART bridge will be created
- Possible to find corresponding and related terms in the three terminologies
- Possible to pool datasets
- Possible to perform advanced querying in literature
- Possible to add other terminologies
MedDRA
Medical Dictionary for Regulatory Activities

• For all areas relevant to drug regulation
  - clinical studies (pre- and post marketing)
  - spontaneous ADR:s
  - regulatory submissions
  - product information

• For all medical information e.g.:
  - symptoms
  - signs
  - diseases
  - diagnoses
  - investigations
  - procedures
  - medical/social/family history
MedDRA structure

System Organ Class
26

High Level Group Term
332

High Level Term
1683

Preferred Term
15709

Lowest Level Term
55638
Drug Classification

• Consistency
• Structure
  - to allow easy and flexible data retrieval and analysis
• Groupings
  - Chemical
  - Indication
• Hierarchical
  - to allow different levels of precision
• Up to date
WHO Drug Dictionary

• Source of international drug names
• Includes all drugs reported to the WHO Drug Monitoring Programme
WHO Drug Dictionary

Contents

- information on:
  - Active substances
  - Pharmaceutical form and strength
  - Manufacturers and license holders
  - ATC classification
  - Reference sources
  - Drug record numbers
WHO Drug Dictionary

- Proprietary drug names
  - single-ingredient drugs
  - multiple-ingredient drugs
- Generic drug names
WHO Drug Dictionary

Contents

• March 2002:
  • 44 500 proprietary drug names
  • 28 400 single-ingredient drugs
  • 16 100 multiple-ingredient drugs
  • 9 200 chemical substances
  • 2 500 drug names added yearly
### WHO Drug Dictionary

- Example illustrating the record number system

<table>
<thead>
<tr>
<th>Drug name</th>
<th>Drecno</th>
<th>Seq1</th>
<th>Seq2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amantadine</td>
<td>559</td>
<td>01</td>
<td>001</td>
</tr>
<tr>
<td>Amantadine HCl</td>
<td>559</td>
<td>02</td>
<td>001</td>
</tr>
<tr>
<td>Virofral</td>
<td>559</td>
<td>02</td>
<td>002</td>
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<tr>
<td>Symmetrel</td>
<td>559</td>
<td>02</td>
<td>003</td>
</tr>
<tr>
<td>Amantadine sulfate</td>
<td>559</td>
<td>03</td>
<td>001</td>
</tr>
<tr>
<td>PK-Merz</td>
<td>559</td>
<td>03</td>
<td>002</td>
</tr>
<tr>
<td>Contentron</td>
<td>559</td>
<td>03</td>
<td>003</td>
</tr>
</tbody>
</table>
WHO Drug Dictionary

**Preferred** name for single ingredient drug

<table>
<thead>
<tr>
<th>Nonproprietary names (Designation = N)</th>
<th>Source of reference:</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>INN name</td>
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<tr>
<td></td>
<td>Martindale</td>
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<td>Negwer</td>
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<td>USAN</td>
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<td></td>
<td>Merck Index</td>
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</table>
WHO Drug Dictionary ATC System

- Anatomical-Therapeutic-Chemical
- Hierarchical structure
- Continuously revised and updated
- Guidelines for coding available
- International applicability
- Adopted by WHO
ATC Classification system

A  Alimentary tract and metabolism
B  Blood and blood forming organs
C  Cardiovascular system
D  Dermatologicals
G  Genito-urinary system & sex hormones
H  Systemic hormonal preparations, excl. sex hormones
J  General antiinfectives, systemic
L  Antineoplastics and immunosuppressants
M  Musculo-skeletal system
N  Central nervous system
P  Anti-parasitic products
R  Respiratory system
S  Sensory system
V  Various
ATC Structure

N - Central Nervous System
  Anatomical Main Group

  05 - Psycholeptics
    Therapeutic Subgroup

    B - Tranquillizers
      Pharmacological Subgroup

      A - Benzodiazepines
        Chem/Ther/Pharm Subgroup

        01 - Diazepam
          Chemical Substance

        04 - Oxazepam
          Chemical Substance

N05BA 01 - Diazepam
N05BA 04 - Oxazepam
<table>
<thead>
<tr>
<th>Drug name</th>
<th>Des</th>
<th>Drecno</th>
<th>Seq1</th>
<th>Seq2</th>
<th>Code</th>
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</thead>
<tbody>
<tr>
<td>Atropine</td>
<td>N</td>
<td>28</td>
<td>01</td>
<td>001</td>
<td>A03BA</td>
</tr>
<tr>
<td>Atropinol</td>
<td>T</td>
<td>28</td>
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<td>002</td>
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<tr>
<td>Atropine sulfate</td>
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<td>02</td>
<td>001</td>
<td>A03BA</td>
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<tr>
<td>Isopto-Atropin</td>
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<td>28</td>
<td>02</td>
<td>002</td>
<td>S01FA</td>
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<tr>
<td>Barbitropin</td>
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<td>324</td>
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<tr>
<td>Atropine sulf.</td>
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<td>A03CB</td>
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<tr>
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<td>324</td>
<td>01</td>
<td>003</td>
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</tr>
</tbody>
</table>
WHO Drug Dictionary
The use of ATC codes for searches

ACE Inhibitors  vasculitis  C09A
Antihistamines  cardiac effects  R06
Oral contraceptives  venous thromboembolism  G03A
NSAID's  GI bleedings  M01A
Cephalosporins  respiratory insufficiency  J01DA
Quinolones  haemolytic anaemia  J01M
Herbal ATC System

- Selective herbal searches
- Retrieval of summary data
- Group comparison searches
WHO Drug Dictionary

• Versions available

• Drug Dictionary files
  - sequential copy of the relational data base
  - ASCII text file
  - available on CD
  - complete data base or quarterly updates

• Searchable through Web-search
The summer residence of Carl von Linné