The WHO Drug Dictionary Types and Formats and Loading Considerations in TMS

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Acknowledgements and Introductions

- Many thanks to the OCUG for opportunity to present a tutorial related to the WHODrug Dictionary Types and Formats.
- Many thanks to Anders Hansson and Daniel von Sydow of the World Health Organization, Uppsala Monitoring Centre.
- Many thanks to the audience members for attending.





Agenda

- Part I: Overview, Content and Usefulness of the WHODrug Dictionary Types
 - WHODD
 - WHODDE
 - WHOHD
 - Combined Files of WHODDE and WHOHD
- Part II: Overview of the WHODrug Formats
 - B1/B2 Format and C Format
 - Uses of C Format
 - Differences between B2 and C Format
- Part III: Loading and Updating the B2 and C Formats into TMS
 - The ATC Derivation Problem and Options in TMS
 - C Format Loading Considerations in TMS
 - Update Considerations for B2 Drug Code





Part I: Overview, Content and Usefulness of the WHODrug Dictionaries





WHO Drug Dictionary History

- WHO Drug is a dictionary of known medicines maintained by the World Health Organization since 1968.
- It contains lists of all known manufactured drugs in every country that was ever reported to WHO.
- WHODrug identifies Generic Drugs (Preferred Terms) and non-Generic Drugs
- The dictionary also associates a drug with an Anatomical-Therapeutic Chemical (ATC) Classification; that is, the parts and systems of the human body where this drug might have an effect.
- The dictionary has changed structure (formats) three times in its history, the most recent in 2002 with the introduction of the C Format, which provides a unique MP_ID and associates
 EVERY Drug to an ATC code

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WHODrug Dictionary History (2)

- Until 2002 there was only one format
- Until 2005 there was only one type
- Historical data is often coded with
 - dictionary type: WHO Drug Dictionary
 - dictionary format: B-2





WHODrug Dictionary Types

- The WHO Drug Dictionary, WHO Drug Dictionary Enhanced, and WHO Herbal Dictionary are different products; the difference between them are the content.
 - WHO-HD contains herbal products only
 - WHO-DD is the same WHODrug dictionary which has existed previously
 - WHO-DDE contains the same types of products as the WHO-DD but with the addition of a large number of new drugs from IMS Health.
 - WHO-Combined contains the content of WHO-DDE and WHO-HD without overlaps in data.
- All three dictionaries are provided in the three different FORMATS - C, B-1 and B-2. Therefore loading considerations for WHODD are also valid for WHODDE and WHOHD.
- There are a few minor differences in the use of a few fields between WHODD and WHOHD.



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WHO Drug Dictionary

- The WHO Drug Dictionary contains medicinal data that has been reported from National Centers
- In order to populate the dictionary with all products in all countries the UMC entered a collaboration with IMS Health
- Increased the number of names with 300% (B-2 entries)





WHO Drug Dictionary Enhanced

- Collaboration with IMS required a new agreement with the subscribers
- WHO Drug Dictionary Enhanced was produced as a separate dictionary type
- Subscribers that have not upgraded can still use WHO Drug Dictionary – without the IMS data
- New customers get WHO Drug Dictionary Enhanced





WHO DDE - Uses

- More names increased chance of finding a 'direct hit'.
 - Less manual work
- Reduced need for taking chances and "googleing" – higher quality of data.
- Non-unique names may have "siblings" only in WHO Drug Dictionary Enhanced





WHO DDE - maintenance

- The WHO DDE grew dramatically during 2005-6.
- It continues to grow with data from IMS new launches and new formulations
- Modified formulations are also reported from IMS
- Other sources of data are also entered into WHO DDE





WHOHD Content

- The WHO Herbal Dictionary contains all products that only include ingredients of natural origin.
- Products that contain a combination of conventional substances and herbals will be included in the WHO Drug Dictionary and the WHO Drug Dictionary Enhanced.
- All entries in the WHO Herbal Dictionary are coded with the Herbal ATC classification.







WHO Herbal Dictionary

- A need for special classification of herbal products botanic instead of chemical.
- The Drug Code identifies plants and parts of plants instead of molecules and salts
- 'CAS number' (substance ID) identifies plants etc
- Herbal ATC contains additional groups





WHO Herbal Dictionary - Uses

The 'chemical environment' contains also the herbal remedies the patients take.

Trade names for herbal products can be found.





Combined dictionaries

- WHO Herbal Dictionary is distributed seamlessly integrated with WHO Drug Dictionary and WHO Drug Dictionary Enhanced
- All files contain a mix of herbals and conventional products
- ATC files contain a mix of ATC and HATC
- No overlaps!



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Part II: Overview of the WHODrug Formats





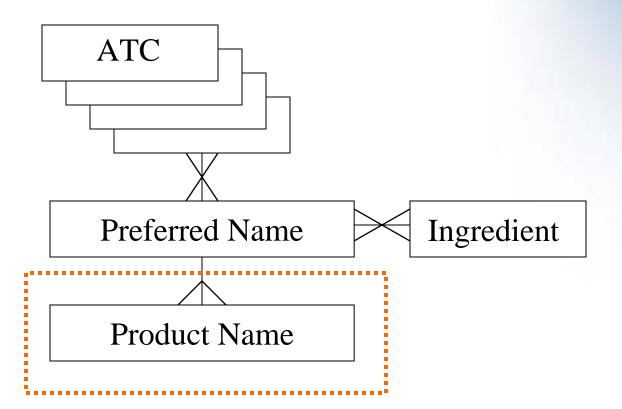
Dictionary Formats

- The WHO Drug Dictionaries are available in different formats
- The formats are data-files, with pre-defined data-fields and relationships between the tables
- The data-files are loaded into the TMS





WHODrug Dictionary the B-2 Format







B-2 - files

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ING.txt Text Document 2 308 KB	MAN.txt Text Doc 1KB		Text Document	X	TableTotals.xls Microsoft Excel-kalkylblad 17 KB

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DD table

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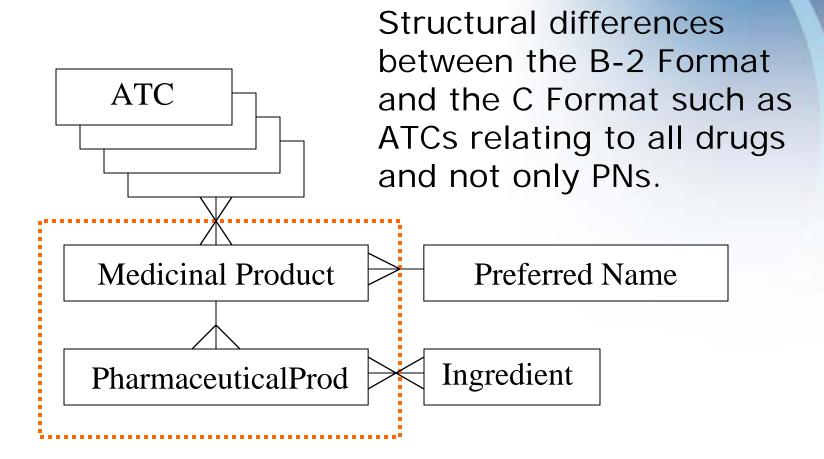
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These entries are identif	fied by text	ts in italic in	n the Notes	ponding text can be found in the Subsidiary Files. column. E.g <i>DDSOURCE.SOURCE_CODE</i> . is the field where the corresponding code can be
MAIN FILES				
MAIN FILES	Field	No of positions	Position in record	Notes
MAIN FILES DRUG DICTIONARY				Notes
				Notes Alphanumeric with leading zeroes
DRUG DICTIONARY	(DD)	positions	in record	
DRUG DICTIONARY Drug Record Number	(DD)	positions 6	in record 1 - 6	Alphanumeric with leading zeroes
DRUG DICTIONARY Drug Record Number Sequence Number 1	(DD) 1 2	positions 6 2	in record 1 - 6 7 - 8	Alphanumeric with leading zeroes Alphanumeric with leading zeroes
DRUG DICTIONARY Drug Record Number Sequence Number 1 Sequence Number 2	(DD) 1 2 3	positions 6 2 3	in record 1 - 6 7 - 8 9 - 11	Alphanumeric with leading zeroes Alphanumeric with leading zeroes Alphanumeric with leading zeroes Each Drug Code (Drecno, seq1, seq2) is assigned
DRUG DICTIONARY Drug Record Number Sequence Number 1 Sequence Number 2 Check Digit	(DD) 1 2 3 4	positions 6 2 3 1	in record 1 - 6 7 - 8 9 - 11 12	Alphanumeric with leading zeroes Alphanumeric with leading zeroes Alphanumeric with leading zeroes Each Drug Code (Drecno, seq1, seq2) is assigned a check digit A one letter code classifying the type of a Drug





WHODrug Dictionary C Format



Authors: Anders Hansson, Daniel von Sydow, Sunil G. Singh
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Overview of the C Format

- The C Format dictionary is a dictionary of **Medicinal Products**
- Medicinal Product
 - A unique combination of
 - Name
 - Name Specifier
 - Market Authorisation Holder
 - Country
 - Substance and Strength (Ingredients and Units)
 - Dosage form •
 - Drug Code •





C - files

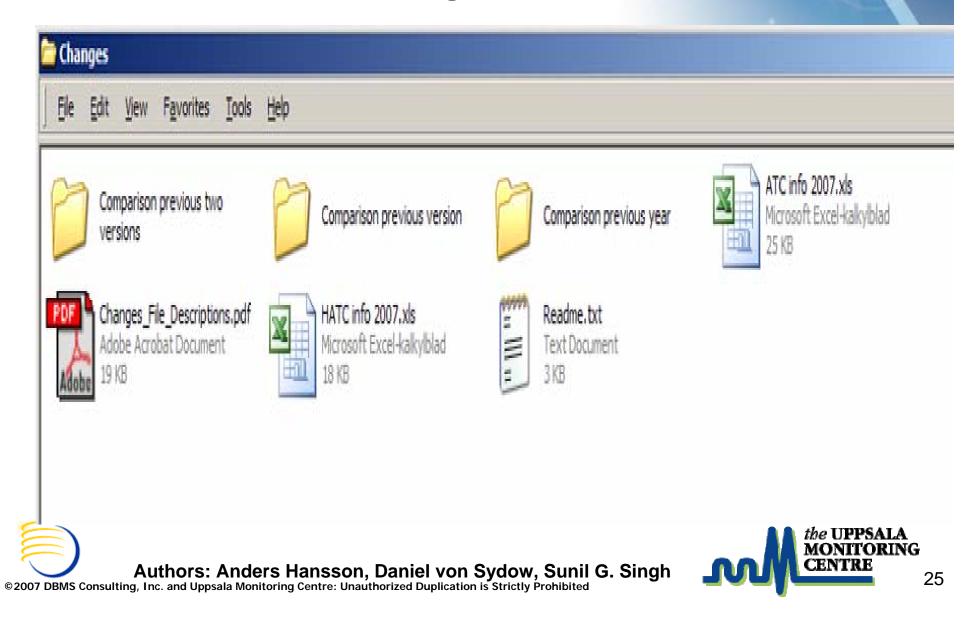
Changes	200 m	ATC.txt Text Document 162 KB	₩u 11	CCode.txt Text Document 22 KB	PDF	Format_C-File_Descriptions.pd Adobe Acrobat Document 25 KB
Format_C-File_Diagram .pdf Adobe Acrobat Document 460 KB	5555 11 11 11	ING.txt Text Document 140 518 KB	₩ II	MP.txt Text Doci 368 681 KB	=	DRG.txt Fext Document 3 515 KB
PF.txt Text Document 19 KB		PP.txt Text Document 59 202 KB	***	PRG.txt Text Document 1 KB	**************************************	PRT.txt Text Document 1 KB
README.txt Text Document 2 KB	19999 	SRCE.txt Text Document 36 KB	**************************************	STR.txt Text Document 1 563 KB	₩	SUN.txt Text Document 1 732 KB
TableTotals.xls Microsoft Excel-kalkylblad 17 KB		ThG.txt Text Document 48 822 KB	£11 III 11	UNIT.txt Text Document 3 KB		UNIT-L.txt Text Document 5 KB
UNIT-X.txt Text Document 3 KB						

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Changes files

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Why two formats?

- The B-2 format (previously known as the A format) has been in use over 20 years
- The C format was introduced in 2002
- The additional features in the C format is useful to:
 - Code with higher precision
 - Understand the difference between drugs with similar drug names



B and C Formats

- The B format is a dictionary of product names
 - Unique identifier Drug Code (B-2)
- The C format is a dictionary of medicinal products. Each drug name can appear many times – e.g. in different forms and countries
 - Unique identifier Medicinal Product ID
 - Drug Code is also included





B-1 and B-2

- The B format is available in two versions B-1 and B-2.
 - In B-1 a name and a drug code can be repeated
 - In B-2 the name and the drug code is unique
- B-2 is the most commonly used dictionary format – B-1 is used by some companies as a reference





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B-2 view

User: ddeemmoo	Organisation: DEMO	Version June 1,		Dictionary: WHODDE	Fri, Sep 15, 2006 GMT: 14:48
Search page	ATC tree	Condensed	Result	Product page	
Product Name		Dru	iq Code		Ingredient(s)
Product Name			i <u>q Code</u> 20001004		<u>Ingredient(s)</u> Paracetamol
		000			A CONTRACTOR OF





	the second s	and the second		1			<u>Ω</u> €
User: ddeemmoo	Organ DEMO	isation:		ersion: ine 1, 2006	Dictionary: WHODDE		Fri, Sep 15, 2006 GMT: 14:49
Search page	ATC tr	ee	Condensed	Result	Product pac	<u>ie</u>	
<u>MP_id</u>	Drug Code 00020001004	Product Name Alvedon	<u>Name</u> specifier	Pharmaceutical Form SUPPOSITORIES, PAEDIATRIC	<u>Strength</u> Unspecified	<u>Country</u> United Kingdom	MAH Novex pharma
		Name		SUPPOSITORIES,		United	
and the second se	00020001004	Alvedon		Unspecified	Unspecified	and the second se	Novex pharma
188672	00020001004					Kinguoin	
188672 4765	00020001004	Alvedon		Unspecified	Unspecified		Draco ab
			Forte	Unspecified Unspecified	Unspecified Unspecified	Sweden	Draco ab Astra pharmaceutical products, inc.
4765	00020001004	Alvedon	Forte			Sweden Sweden	Astra pharmaceutical
4765	00020001004	Alvedon Alvedon	Forte	Unspecified	Unspecified	Sweden Sweden Philippines	Astra pharmaceutical products, inc. Multicare pharm
4765 4967 807830	00020001004	Alvedon Alvedon Alvedon	Forte	Unspecified TABLETS	Unspecified Unspecified	Sweden Sweden Philippines Philippines	Astra pharmaceutical products, inc. Multicare pharm



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ICH compatible C format

- The International Conference of Harmonisation (ICH) is in the process of producing guidelines for medicinal product information.
- A number of fields were added in 2005 added, and some field lengths were expanded





Sequence 3 and 4

- Information about Pharmaceutical Form and Strength have been added to the Medicinal Product table
 - Sequence Number 3 Pharmaceutical Form
 - Sequence Number 4 Strength
- Facilitates the use of the C format, all relevant information is available in the same table





Use of Sequence 3 and 4

 With the additional fields all important datafields can be accessed in the Medicinal Product table
 – a 'one table' dictionary can be created.

MP_ld	Drug Name	Name Specifier	Drug Code	MaHolder	Country	Form	Strength	Ingredient
59142	Seresta	Forte Tabletten	000409 01 005	AHP AG	Switzerland	Tablets	50 Milligram	Oxazepam
59138	Seresta	Tabletten	000409 01 005	AHP AG	Switzerland	Tablets	15 Milligram	Oxazepam





Information levels

	Drug Code	Name	Name specifier	Country	MAH	Form	Strength
1	X	X					
2	X	X	(X)				
3	X	X	(X)	X			
4	X	X	(X)	X	X		
5	X	X	(X)	X	X	X	
6	X	X	(X)	X	X	X	X

C format – information levels

MP_ld	Drug Name	Name Specifier	Drug Code	MaHolder	Country	Form	Strength	Ingredient
59142	Seresta	Forte Tabletten	000409 01 005	AHP AG	Switzerland	Tablets	50 Milligram	Oxazepam
59138	Seresta	Tabletten	000409 01 005	AHP AG	Switzerland	Tablets	15 Milligram	Oxazepam
59139	Seresta	Tabletten	000409 01 005	AHP AG	Switzerland	Tablets		Oxazepam
59140	Seresta		000409 01 005	AHP AG	Switzerland			Oxazepam
405769	Seresta		000409 01 005	Biodim	France	Tablets		Oxazepam
405770	Seresta		000409 01 005	Biodim	France			Oxazepam
8477	Seresta		000409 01 005	Wyeth	Netherlands			Oxazepam
59141	Seresta		000409 01 005					Oxazepam





Non-unique names

- Some drug names can mean many things the names can be used in different countries or forms with different active ingredients
- In the B-2 format the Drug Record number and Sequence number 1 is added to the drug name – to make it unique
- In the C format entries have additional data fields





Non-unique name, B-2 format

ACTRON ACTRON ACTRON ACTRON ACTRON /00020001/ /00109201/ /00321701/ /00391201/





Non-unique name, C format

Drug Name	Name Specifier	Drug Code	MaHolder	Country	Ingredients
Actron		003912 01 026	Bayer	France	Acetylsalicylic acid Caffeine Paracetamol
Actron		001092 01 461	Bayer	Mexico	Ibuprofen
Actron		003217 01 053	Bayer	United States	Ketoprofen
Actron		000200 01 158	Bayer	Spain	Paracetamol
Actron	/Old form/	007271 01 001	Miles Martin	Spain	Acetylsalicylic acid Caffeine Citric acid Paracetamol Sodium bicarbonate





Content Differences Between B-2 and C: Name WHO Drug Dictionary B-2 Format

- Distributed for over 20 years
 - It is a dictionary of drug names, where a name can be searched and translated to coded information.
 - It consists of mainly active ingredients, drug codes (which represents active ingredients and salts/esters) and Anatomical Therapeutic Chemical Classification.
 - The drug name appears only once
 - A drug name is added the dictionary at the first occurrence of the name.
 - **Please Note:** The B-2 Format was made completely country independent in the March 1, version 2005.





Content Differences Between B-2 and C: Country WHO Drug Dictionary C Format

- The C Format allows for country specific information
 - It is possible to see which drug names appear in a specific country.
 - This information is especially relevant for certain types of products; where the same product names are marketed in different countries with different sets of ingredients.
 - In the B-2 Format the coder will not be able to determine which version of the drug is used in a certain country, but this information is available in the C Format.





Content Differences Between B-2 and C: **Dosage Form and Strength**

- The C Format contains more information than the B-2 Format; dosage form and strength. The UMC has put more focus on populating the dosage form information than the strength information for two reasons:
 - The dosage form information is relevant to the analysis of clinical data.
 - Types of reaction may vary depending on the type of administration; local versus systemic effects, and there could be different types of reactions to a sustained release tablet compared to a regular tablet.
 - Inadequate dosage forms may explain adverse reactions; Esophagus Ulcer caused by capsules that weren't swallowed properly.
 - Sometimes the same trade name is available in different dosage forms, with different ingredients.
 - The suppository could contain additional ingredients, or different salts of the substance salts

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October 2007 Content Differences Between B-

2 and C: Drug Code

- In the B-2 Format, the Drug Code, unique system code, describes the active ingredient(s), the salt/ester and the product name.
 - The code is very useful for analysis, but it causes the following problems for data management:
 - The Drug code is affected when a product formulation is changed; one of the active ingredients is replaced by another, or a different salt of a substance is used.
 - The Drug code is affected when corrections are made; if a drug has been included in the dictionary with an incorrect salt or substance and later corrected.
 - The Drug code is affected when the name changes for various reasons. This means that the system has neither a code nor a text that is completely stable. (although these changes are exceptions and are not very common).



OCUG 2007 Atlanta, GA Tutorial Session: WHODrug Formats and Loading in TMS October 2007 Content Differences Between B-2 and C: ATC Coding with B-2

- Both the B-2 Format and the C Format contain ATC classification.
- WHO Drug Dictionary B-2 Format
 - All products are coded with the same ATC codes as its preferred name (an active ingredient or unique combination of active ingredients).
 - For example, all products containing Acetyl Salicylic acid will be coded with the following ATC codes:
- A01AD IOCAL ORAL TREATMENT B01AC PLATELET AGGREGATION ANALGESICS AND ANTIPYRETICS NO2BA © 2007 DBMS Consulting, Inc. and Uppsala Monitoring Centre: Unauthorized Duplication is Strictly Prohibited

Content Differences Between B-2 and C: ATC Coding with C

WHO Drug Dictionary C Format

- A specific product is coded with the ATC code that reflects the most common use of the product.
- For example, an Acetyl Salicylic acid product used mainly as a painkiller would be coded with the N02BA code.





OCUG 2 Partanta GA Julorial Session: WHODrug Formats and Loading in MS Updating Control of Control the B2 and C Formats into TMS



Deriving ATC Codes from WHODrug in TMS to OC

- Since TMS requires a Single Derivable Path to derive dictionary terms to an External System (such as AERS or OC), Drug Names with Multiple ATCs can NOT send ALL possible ATCs to OC.
- This problem occurs regardless of WHODrug Dictionary Format. In B2 Format, it occurs for Preferred Name (Generic) Drugs only, but in C Format, it occurs for ALL Drugs.
- 4 Common options for dealing with this situation in TMS follow





Loading ATC codes in Type B2 and Type C

- Option 1: Concatenating ATC codes as level detail of Preferred Name or Drug Name.
 - Since the Drug Name is always derivable, the entire set of ATC codes becomes a concatenated string, which is a Level Detail Attribute of the Drug Name or Preferred Term.
 - This requires parsing of the concatenated ATC Codes within OC by Derivation Procedures, or within SAS.





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Loading ATC codes in Type B2 and Type C (2)

- Option 2: Create a Primary link to the ATC codes based on some programmatic rule defined by the business users or with a "MULTIPLE" flag
 - Could be based on common occurrences of ATCs, known indications, or even alphabetical order although this is not recommended
- In addition also set a "MULTIPLE" ATC or Level Detail which would indicate to an OC Data Manager that multiple ATCs were possible and therefore, High-Level Reclassification might be necessary. Without this MULTIPLE indicator, a strong knowledge of ATC classifications would be required at the OC level to know whether or not multiple ATCs were possible.





Loading ATC codes in Type B2 and Type C (2)

- Option 3: Load Separate Drug and ATC Dictionaries.
 - Loading Drug Names into a first dictionary and ATCs into a second dictionary
 - The 2nd ATC Dictionary would have a classification level as the concatenation of the Preferred Drug Name and ATC code
 - A derivation procedure populates the VT level of this 2nd ATC dictionary from the classified Preferred Drug name (from the first dictionary) concatenated with Indication or Route for coding in the 2nd dictionary.
 - This requiring two Batch Validations, which is sometimes called a "split" WHODrug dictionary solution.





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Loading ATC codes in Type B2 and Type C (3)

 Option 4: Do not derive ATC codes and create a custom view for retrieving all ATC codes into SAS.





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View of TMS, WHODrug B2 without a PL (Option 1) and WHODrug Split Dictionary (Option 3)

C-S WHODrug Type B2, No Primary Link 🛮 ATC Group Level Ġ-ATC1 . ⊖----€ATC2 .⊖----€АТСЗ -----(ATC4 ⊖-:…:Preferred Name Synonym ⊖-:--:Drug Constituents └─;····Source of Drug 🔀 Verbatim Term Classification Level -Preferred Name ←Svnonvm ⊖-:--:Drug Constituents └─:····Source of Drug -}---Source of Drug -----Manufacturers <u>-^{MT}</u>∈Verbatim Term

👒 Split WHO ATC Type C Dictionary. O-Anatomic Therapeutic Classification ⊖–⊶–∈Unique Drug ATC <u>└─^ỵT</sub>∈Verbatim Term</u> 👒 Split WHODrug Type C -Preferred Term 🔶 Unique Drug <u>₩</u>T∈Verbatim Term Ə∹⊷⊜Ingredientsi ⊖-j…iSubstances. -fend Source -⊡Source on Sydow, Sunil G. Singh ation is Strictly Prohibited

Loading the C Format into TMS

- Explain challenges to loading the WHO Drug the C Format in TMS 4.5.
- Identify the key decision points that must be addressed before loading.
- Provide suggestions for possible loading and configuration options.





Differences in the WHODrug C Format Affecting TMS The Drug names themselves are **not** unique in the C

- The Drug names themselves are **not** unique in the C Format.
- ATC codes are now associated to every Drug Name in the C Format.
- A Pharmaceutical Product level, which contains the Pharmaceutical Form (PF), was introduced in the C Format.
- All ingredients and their amounts were introduced in the C Format.
- The Medicinal Product ID (MP ID), which represents 7 drug attributes, now uniquely identifies a drug
 - (Drug Name, Name Specifier, Country, Manufacturer, All Ingredients w/ Strengths and Units, Pharmaceutical Form Drug Code (DrgRecNum+Seq1+Seq2))



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Loading Considerations

- Since the drug name is not unique in the C Format, the drug name alone can not be loaded as the Classification level in TMS. Therefore, the drug names must be made unique somehow.
- In making drug names unique in the C Format, the TMS built-in automatic matching would potentially be diminished. Some considerations have to be made for preserving TMS auto encoder efficiency.
 - There should be an entry with only the Name as he Classification Term and Drug Code as the DICT_CONTENT_CODE.
 - Sometimes there are two different Drug Codes (sets of ingredients) for the same Name. In these cases, the TMS coder needs to view the higher levels of the dictionary to find the difference between the entries it could be country or pharmaceutical form. An the UPPSALA



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Loading Considerations (2)

- Considerations to preserve TMS auto encoder efficiency
 - In the March 1 2005 version of the in B-2 Format, the /.../ was added to all names that appeared with more than one drug code including Preferred name entries XXXXX01001. Approximately 14% of the names needed the additional /.../ code in order to make them unique. The reason why the /.../ code is added is that there is AT LEAST one more entry with the same name but different drug codes. That means that at most 7% of the names are "non-unique".
 - In the June 2005 version of the in B-2 Format, the preferred name entries are left without the /.../ code in order to make autoencoding possible.





Loading Choices

- Option 1: Use the Medicinal Product ID itself to make the Drug Names unique in the classification level.
- Option 2: Use the logical expansion of the Medicinal Product ID to make the Drug Names unique in the classification level and possibly populate a VTA Level with Drug Names only.
- Option 3: Add an additional level to store the Drug Names only as part of a Classification Group in the TMS WHODrug structure.





Option 1 : Medicinal Product ID at Classification Level

Advantages

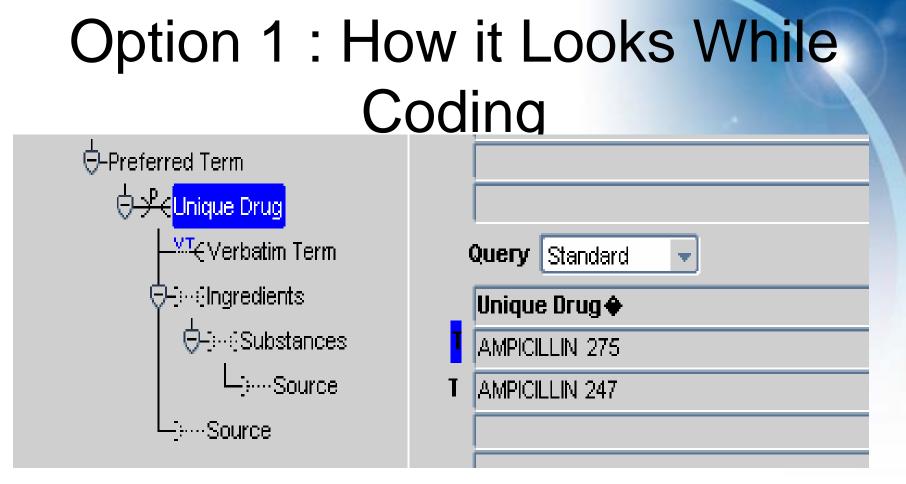
• Easy to load.

Disadvantages

- Auto encoding would not be possible.
- Coders would not have information needed to select correct VTA.
- Another suggestion is to add the MP_ID to only non-unique drug terms. However, this still leaves many terms (10,000+) which will not auto encode, and therefore, are less likely to be used.







DrugName MP_ID





Option 2 : Use the Logical Expansion of the MP ID

Advantages

 Information is available for coders to select appropriate VTA.

Disadvantages

- Nothing auto encodes.
- Load script is more complicated and takes longer.
- Field length may require > CHAR 300.





Option 2 : Auto Encoding Implications

- Load Verbatim Term Assignments (VTAs).
- This also allows coders to use the filter buttons in TMS Omission Management to choose the VTA Level and only code on the Drug Names if desired.
- Problem Over 10,000 drug names are not unique.
- Do you have to manually code all 10,000+?
 - Yes and No !



Option 2 : Manually Code All **Duplicate Drug Names**

Advantages

- Control of the codes you can select certain drugs from specific countries, or manufacturers, or ingredients, etc.
- You could reload same VTAs, once they are selected to new versions of the dictionary.

Disadvantages

- As each version is released, you will need to repeat this exercise
- How long will it take your team to code 10,000+ terms?
- Some of these terms you will never see in a study, but you will spend a lot of time on them initially.





Option 2 : Or, Don't do it Load only the Unique Drug Names as verbatim

- terms.
- Code the others as they are encountered as verbatim terms.

Advantages

- Over 40,000 will be able to have VTAs loaded.
- You only spend time on those you need.

Disadvantages

- You may give up consistency in decision making if this is done over time.
- Many of the most common drugs encountered are in this group.
- You need to repeat this with each new version of the dictionary.





Option 2 : Or, Do it Systematically

Advantages

- Same script can be used for each new version of the dictionary.
- Logic can be applied that is consistent across all term choices.
- The script will run faster than your team can do the work!





Option 2 : Or, Do it Systematically (cont)

Disadvantages

- Decisions still need to be made on the logic to be used.
- Some terms will not have VTAs because the same drug name by different. countries/manufacturers are really different

drugs.

- TMS loading Script development is complex and will take some time to run!
- Additional code must be added into the TMS loading script to take into account PF and strength.





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Which Drugs Should Have VTAs?

- Drugs having the same DrgRecNum and Seq1 and can have a VTA selected.
- The same DrgRecNum and Seq 1 mean the drug is the same drug with the same Preferred term and the same ingredients.
- Please Note: WHODrug will continue to support the DrgRecNum and Seq numbers (see the document titled <u>The New C Format</u>: New Features that accompanies each version of the dictionary).





Reason for Multiple Drug Record Numbers

- A strategic decision by a manufacturer to change the active ingredients to improve the product over time, but keep the same Drug Name due to market share and brand recognition.
- The lack of availability of some active ingredients in some countries or geographies, including cases where the raw materials are not available or are banned by a country for human use or import.





Reason for Multiple Drug Record Numbers (2)

- The purchase or acquisition of one company or brand by another combined with a strategic decision to keep the same brand recognition and market share purposes, but to also change or improve the drug which might change the active ingredients.
- The lack of enforcement of intellectual property rights or patents in some countries, where the same Drug Name is used illegally and manufactured with completely different ingredients. WHO-UMC is still obligated to report the creation and use of these drugs.







Same Drug Name in Different Countries

Benadryl in Italy

0 110101104 10111								
Verbatim Term								
Ģ-∺⊡Ingredients								
-								
L. Source	Query Standa	ird 🗨						
L_:Source	Unique Drug	٠		Level	Medicinalpro	oc Sequence_ke		
	T BENADRYL W	ARNER LAMBERT CONSUMER HEAI	LTH IRL	UNIQUE	DF 52370	00647601002		
					DF 51457	00000402049		
					DF 52616	00945501004		
	T BENADRYL W	ARNER LAMBERT ESP		UNIQUE	OF 51459	00000402051		
	T BENADRYL W	ARNER LAMBERT GBR		UNIQUE	DF 52615	00945501003		
	T DENADRITE VV			UNIQUE	OF 51462	00000402054		
	BENADRYL WARNER LAMBERT ITA				DF 52393	00673901009		
T DENADRYL WARDER LAMBERT THA				UNIQUE		00000402050		
				না ১				
						_		
	Relation	Term			Appr? Alt Code	Туре		
	_T Strong	SODIUM CITRATE 38 84982				Dictionary "		
	T Strong	MENTHOL 38 84983				Dictionary ⁻		
	T Strong	DIPHENHYDRAMINE HYDROCH	ILORIDE 38 84984			Dictionary 1		
	_T Strong	AMMONIUM CHLORIDE 38 849	85			Dictionary		
	T Strong	MARTINDALE - THE COMPLETE	E DRUG REFERENC			Dictionary 1		





Same Drug Name in Different Countries (2)

Benadryl in the United Kingdom

Image: Drug
Image: Substances Image: Substances Image: Source Image: Standard Image: Standard Image: Standard I
Image: Substances Image: Standard Image: Standard <t< td=""></t<>
Limitation Medicinalprox Sequence_I Unique Drug Image: Consumer Healthing Medicinalprox Sequence_I I BENADRYL WARNER LAMBERT CONSUMER HEALTHING UNIQUEDF 52370 00647601002 I BENADRYL WARNER LAMBERT CONSUMER HEALTHING UNIQUEDF 51457 00000402049 I BENADRYL WARNER LAMBERT DNK UNIQUEDF 52616 00945501004
Limitation Medicinalprox Sequence_I Unique Drug Image: Consumer Healthing Medicinalprox Sequence_I I BENADRYL WARNER LAMBERT CONSUMER HEALTHING UNIQUEDF 52370 00647601002 I BENADRYL WARNER LAMBERT CONSUMER HEALTHING UNIQUEDF 51457 00000402049 I BENADRYL WARNER LAMBERT DNK UNIQUEDF 52616 00945501004
T BENADRYL WARNER LAMBERT CONSUMER HEALTH IRL UNIQUEDF 52370 00647601002 T BENADRYL WARNER LAMBERT CONSUMER HEALTH USA UNIQUEDF 51457 00000402049 T BENADRYL WARNER LAMBERT DNK UNIQUEDF 52616 00945501004
T BENADRYL WARNER LAMBERT CONSUMER HEALTH USA UNIQUEDF 51457 00000402049 T BENADRYL WARNER LAMBERT DNK UNIQUEDF 52616 00945501004
T BENADRYL WARNER LAMBERT DNK UNIQUEDF 52616 00945501004
T BENADRY'L WARNER LAMBERT ESP UNIQUEDF 51459 00000402051
BENADRYL WARNER LAMBERT GBR UNIQUEDF 52615 00945501003
T BENADRYL WARNER LAMBERT HKC UNIQUEDF 51462 00000402054
T BENADRYL WARNER LAMBERT ITA UNIQUEDF 52393 00673901009
T BENADRYL WARNER LAMBERT THA UNIQUEDF 51458 00000402050
Relation Term RGIb? Appr? Alt Code Type
T Strong ACRIVASTINE 38 85279 ✓ ✓ Dictionar
T Strong MARTINDALE - THE COMPLETE DRUG REFERENC V Dictionar





Changes in the Drug **Robitussin AC**

- Preferred Term - Cunique Drug - Substances - Source	Query Standard							
- Source	Unique Drug 🔶			Level		Iproc Sequenc		SubType
	T ROBITUSSIN A-C	/OLD FORM/ ROBINS A.H. COMPANY, II	NCORPORA	UNIQUEDF	11947	00074201	1001	Company
Entered in 2002	T ROBITUSSIN AC P	ROBINS A.H. COMPANY, INCORPORATE	ED USA COD	UNIQUEDF	35354	00693301	1008	Company
	T ROBITUSSIN AC V	WHITEHALL-ROBINS INC. CAN CODEINE	PHOSPHAT	UNIQUEDF	11948	00074201	1002	Company
					1			
					,			
	Relation	Term		Level		Code	RGlb'	? Appr? A
	T Strong	CODEINE PHOSPHATE 38 51900		INGWH003	Q4-ING	51900		
	T Strong	GUAIFENESIN 38 51 901		INGWH003	Q4-ING	51901		
	T Strong	AMERICAN DRUG INDEX		INGMHOD	04-SRCE	010		



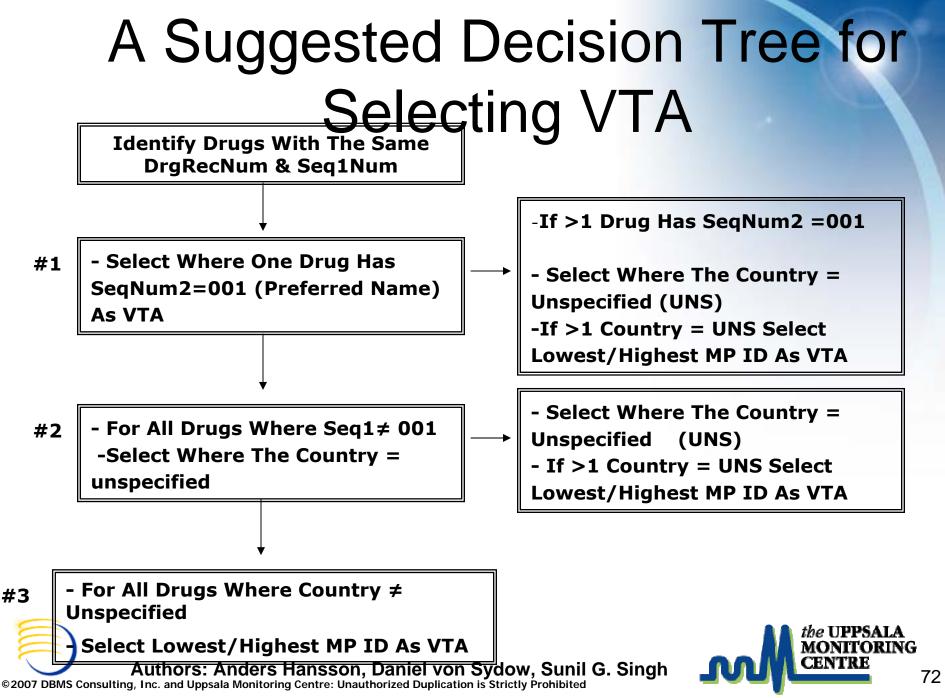


Changes in the Drug (2) Robitussin AC

⊖-Dictionaries	Query Standar	d 💌		-		
Ingenix_WHOATC_03Q4	Unique Brug 4		Level	Medicinalpro	Sequence_k	e Su
॑ - ℅ Ingenix_WHODrug_03Q4	ROBITUSSIN A-	C /OLD FORM/ ROBINS A.H. COMPANY, INCORPOR		11947	00074201001	C
-Preferred Term	T ROBITUSSIN A	CROBING A.H. COMPANY, INCORPORATED USA C		35354	00693301008	C
ં 	T ROBITUSSIN AC	WHITEHALL-ROBINS INC. CAN CODEINE PHOSPH	A1 UNIQUEDF	11948	00074201002	: C
– – Substances						
Li-Source						
L. Source						
	Relation	Term	Level	Cod		9lb?
Entered in 1985	_T Strong	CODEINE PHOSPHATE 38 13807	INGWH003	3Q4-ING 138	07 🔽	
	T Strong	GUAIFENESIN 38 13808	INGWH003	3Q4-ING 138	08 🔽 🔽	
	_T Strong	PHENIRAMINE MALEATE 38 13809	INGWH003	3Q4-ING 138	09 🔽	
	_ T Strong	AMERICAN DRUG INDEX	INGWH003	3Q4-SRCE 010		
	T Strong	ROBITUSSIN A-C	INGWHO03	3Q4-VT		







Dictionary Updates and Reducing Data Scope One consideration is whether or not all of the Drug

- One consideration is whether or not all of the Drug data should be loaded. Why not parse all of the Drug Names only and simple load these Drug Names?
 - Not Loading the MP_ID or loss of the MP_ID will make updating this dictionary very difficult. This is because the default TMS APIs for updating the dictionary, TMS_LOAD_DICTIONARY.MigrateRelations and TMS_LOAD_DICTIONARY.MigrateTerms expect a unique DICT_CONTENT_CODE in the dictionary which comes from the vendor which can be compared with queries against the vendor source data to determine what DICT_CONTENT_CODEs to insert/update/delete.
 Additionally, during the dictionary load process, it is not required to specify a DICT_CONTENT_CODE nor is

uniqueness enforced! But during update calls using the

TMS_LOAD_DICTIONARY API, it is a de facto expectersion.



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Dictionary Updates and

- Reducing Data Scope (2)
 This means not having the MP_ID for all of the WHODrug source data will make updating very difficult. Calls to TMS_USER_MT_DICTIONARY for updating, inserting and deleting terms will have to be made on a separate basis, without the benefit of the TMS migration APIs.
- Additionally, if only part of the drug data is loaded (a reduction in the data scope), it may be possible to make a validation argument that the dictionary loaded in TMS was not actually a representation of the WHO-UMCs WHODrug dictionary, but a customized dictionary which is a proprietary to a single organization, which may introduce some additional validation requirements.





Loading and Update Considerations for B2 Format

- Since the Drug Recnum + Sequence 1 have been added to the B2 format for Drug Names which have multiple Drug Record Numbers, some Drug Names which previously autocoded do not currently autocode.
- While this represents a small percentage of Drug Names in quantitative terms, these drugs are the most commonly used and therefore occur the most frequently





Why does Aspirin No Longer Autocode?

- Consider the drug aspirin in the WHODD or WHODDE B2 format dictionary:
 - In the case of WHODD, the single occurrence of aspirin appears with a drug record number appended, to indicate that other drug record numbers are possible
 - In the case of WHODDE, multiple occurrences of aspirin exist with different drug record numbers





Possible Solutions

- Use a similar algorithm for WHODrug Type C format loading for B2.
 - Requires establishing domain VTA rules for each of the multiple sets of Drug Recnums
 - Drug Names could be defaulted based on country or Preferred Name derivation
 - Create Global VTAs where a single drug exists with a Drug Code appended if the WHODD Type is being used.
- If the goal of coding is ONLY to derive Preferred Names and NOT ATCs, then it is possible to create a Global VTA if all the Preferred Names are the same, even if the Drug Recnums are different
- Possible enhancements to TMS to allow "single" VTA coding (formerly called VTI functionality), which is similar to HLC at the VT coding level instead
- Derive a specific match based on Site/Investigator/Patient location or country, and use this in a derived question or Search Object.





Questions?

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