
Improved Tools for MedDRA Coding in DataFax

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Overview

- What is MedDRA
- A brief history of DataFax MedDRA tools at SCHARP
- Three Issues recently addressed
 - Speed
 - Synonyms
 - Re-coding

What is MedDRA?

- Medical Dictionary for Regulatory Activities
- Most often used to categorize Adverse Events
- 6 levels ranging from the specific to the general

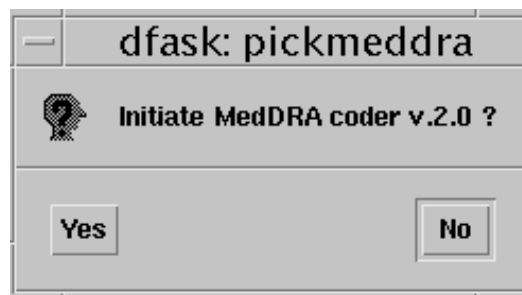
8 Years of MedDRA in DataFax

- Betty Carr and Scott Horton first demonstrated the MedDRA Coding System at DFUG 2000
http://www.datafax.com/UserGroup/2000/presentations/Carr_Horton.pdf
- Betty updated the presentation at DFUG 2005
<http://www.datafax.com/UserGroup/2005/presentations/carr.pdf>

In case you haven't seen the tool
before ...

Here's a quick peak!

Tab into a MedDRA field and the
system asks ...

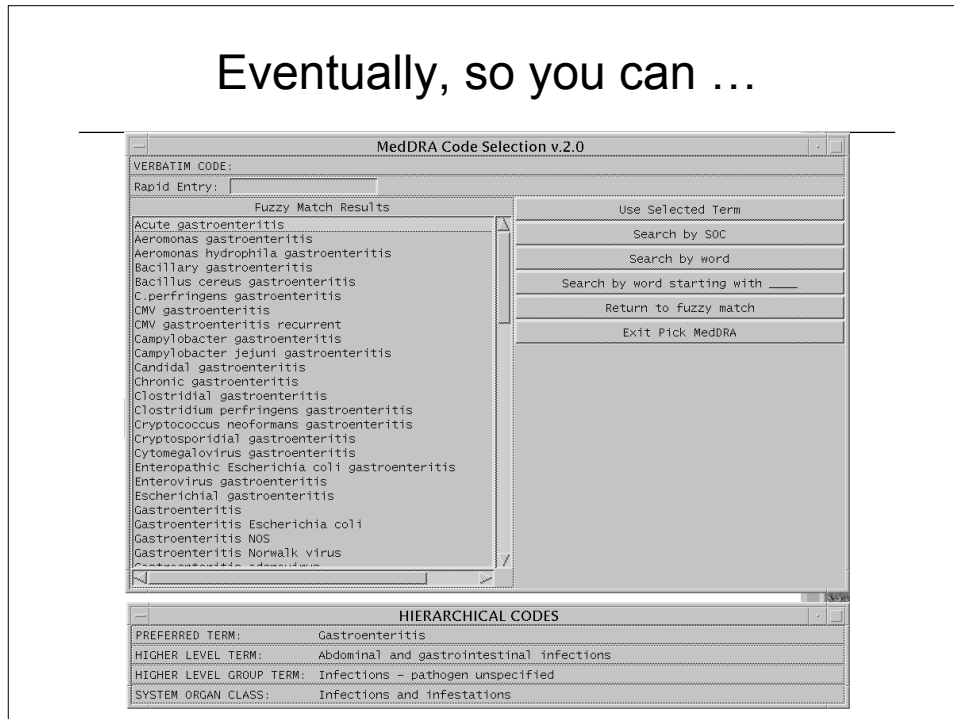


If you say yes ...

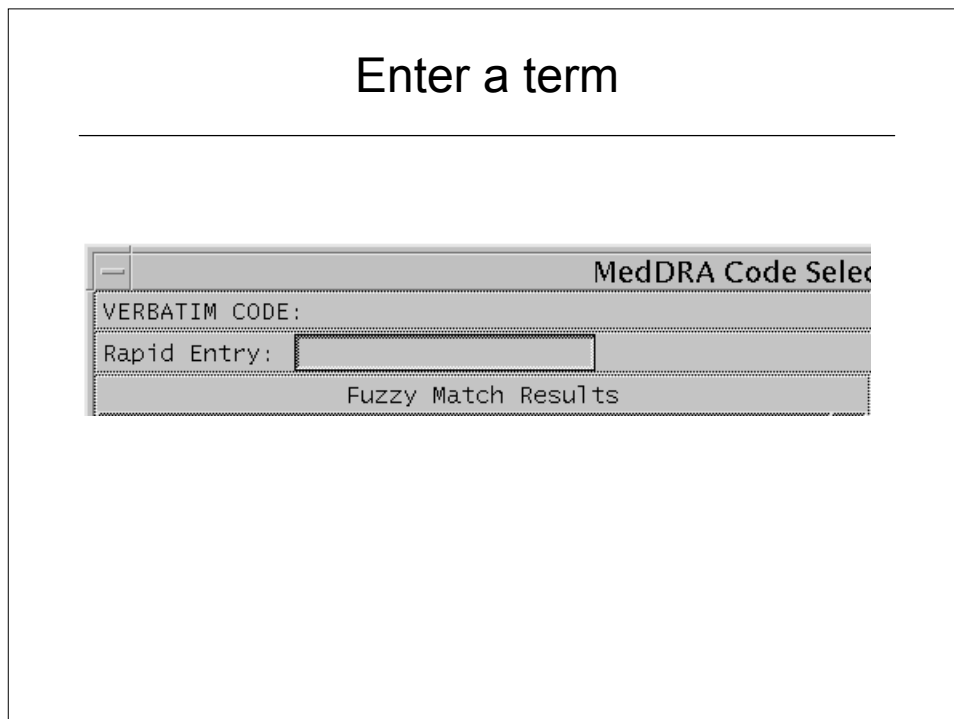
And have patience

The coder opens

Eventually, so you can ...



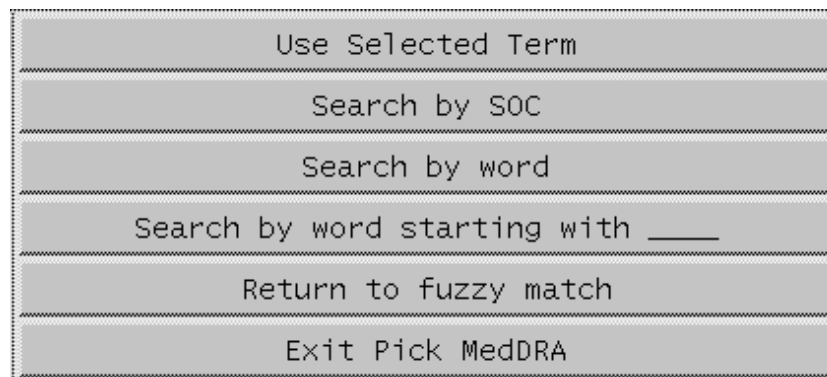
Enter a term



Scroll through Fuzzy Matches to select at term




Or, search for terms by ...



Once a term is selected, you can review its' mapping

HIERARCHICAL CODES	
PREFERRED TERM:	Gastroenteritis
HIGHER LEVEL TERM:	Abdominal and gastrointestinal infections
HIGHER LEVEL GROUP TERM:	Infections - pathogen unspecified
SYSTEM ORGAN CLASS:	Infections and infestations

See the MedDRA Version, numeric and record history codes


 HPTN 048 Ext NVF 90 t (090) AE-1 (420) 420

Participant ID
 502004821 - - Infant's Adverse Experience Log
Site Number Participant Number Chk Cohort

Flag/Version EX10.1 MedDRA 10017888\$Gastri
1. Adverse Experience (AE) and infestatic
 gastroenteritis
Record diagnosis if available. Include anat

So, what can we improve?

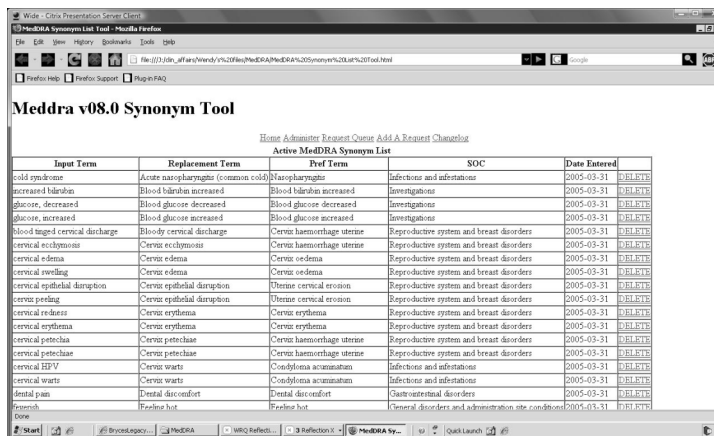
- No support for Synonym Lists
- 20 to 30 seconds of waiting for the tool to open on each and every Adverse Event
- Constant recoding
 - AEs are faxed at least twice
 - The code that automatically selects codes with the Investigator's term exactly matches a "preferred term", wipes out the previously selected code even if nothing but the outcome of the event has changed.

Issue #1 Synonym List Changes

- Who approves?
- What happens when the term that was a synonym is added to the dictionary?

Answer?

- Medical review in ...
- A web-based administration tool



Input Term	Replacement Term	Pref Term	SOC	Date Entered	
cold syndrome	Acute nasopharyngitis (common cold)	Nasopharyngitis	Infectious and infestations	2005-03-31	<input type="checkbox"/>
increased bilirubin	Blood bilirubin increased	Blood bilirubin increased	Investigations	2005-03-31	<input type="checkbox"/>
glucose, decreased	Blood glucose decreased	Blood glucose decreased	Investigations	2005-03-31	<input type="checkbox"/>
glucose, increased	Blood glucose increased	Blood glucose increased	Investigations	2005-03-31	<input type="checkbox"/>
blood-tinged cervical discharge	Bloody cervical discharge	Cervix haemorrhage uterine	Reproductive system and breast disorders	2005-03-31	<input type="checkbox"/>
cervical ectropion	Cervix ectropion	Cervix haemorrhage uterine	Reproductive system and breast disorders	2005-03-31	<input type="checkbox"/>
cervical edema	Cervix edema	Cervix edema	Reproductive system and breast disorders	2005-03-31	<input type="checkbox"/>
cervical swelling	Cervix edema	Cervix edema	Reproductive system and breast disorders	2005-03-31	<input type="checkbox"/>
cervical epithelial disruption	Cervix epithelial disruption	Uterine cervical erosion	Reproductive system and breast disorders	2005-03-31	<input type="checkbox"/>
cervix peeling	Cervix epithelial disruption	Uterine cervical erosion	Reproductive system and breast disorders	2005-03-31	<input type="checkbox"/>
cervical redness	Cervix erythema	Cervix erythema	Reproductive system and breast disorders	2005-03-31	<input type="checkbox"/>
cervical erythema	Cervix erythema	Cervix erythema	Reproductive system and breast disorders	2005-03-31	<input type="checkbox"/>
cervical petechiae	Cervix petechiae	Cervix haemorrhage uterine	Reproductive system and breast disorders	2005-03-31	<input type="checkbox"/>
cervical patches	Cervix petechiae	Cervix haemorrhage uterine	Reproductive system and breast disorders	2005-03-31	<input type="checkbox"/>
cervical HPV	Cervix warts	Condyloma acuminatum	Infectious and infestations	2005-03-31	<input type="checkbox"/>
cervical warts	Cervix warts	Condyloma acuminatum	Infectious and infestations	2005-03-31	<input type="checkbox"/>
dental pain	Dental discomfort	Dental discomfort	Gastrointestinal disorders	2005-03-31	<input type="checkbox"/>
feverish	Febrile hot	Febrile hot	General disorders and administration site conditions	2005-03-31	<input type="checkbox"/>
flu					

Issue #2:

Why can't the coding tool stay open?

- It runs outside datafax and
- Needs to send output directly to a data field
- With multiple users validating records on different workstations, you need a way to tell the system where to send the output.

The Answer

- Use “Sockets” to uniquely identify individual “sessions”
- A single application becomes two
 - The Graphical User Interface, and
 - A “listening” process to communicate between the MedDRA GUI and a specific user’s DataFax Validation tool.

Issue #3: Recoding We need to

- Identify AE records with identical ...
 - Participant (Patient) ID
 - Visit
 - Verbatim
 - Severity
 - Comments
- Allow second pass review to verify accuracy of those fields
- Then promote to highest previously level
 - “4” for records which were only coded
 - “5” for records that have undergone coding review

Practical Limitations

- It takes a long time to read journal files
- Even if you take out data from everything but the AE plates, it can take 10 or 15 seconds to find information about a particular set of keys.
- The “significant” fields are not in the same place in each study.
 - Severity may be field 13 in one study and field 15 in another
 - Comments may be field 30 in one and 33 in another.

The Solution

- Two Perl scripts
 1. Creates an “AE Journal” containing only the last instance of each set of keys for designated AE plates.
 2. Accepts both the field numbers and contents of the significant fields and compares them to the “AE journal”.
- Two “Hidden” fields
 1. Store the output of the second Perl script
 2. Store the highest previously validation level (if the second Perl script returns a “2”; otherwise, store the current validation level.

At Data Entry it looks like this:

*visit code required
(regular or interim).*



iDreturn



prevalid

But wait, there's more!!

- Two Batch Edit Checks
 - One to move designated records from level 3 to 4
 - One to move designated records from level 3 to 5
- Perhaps there could be an X-Prize for a better solution?



How it works at SCHARP

- Perl script #1 runs from cron every hour to update the AE Journal
- A new AE arrives (0 to 2)
 - Perl script #2 finds no match and returns a zero.
 - The current validation level (2) is stored
- Data Review (2 to 3)
 - Perl script #2 returns a “1”.
 - The current validation level (3) is stored.
- Coding (3 to 4)
 - The current validation level (4) is stored.

How it works (cont).

- The record is re-faxed (0 to 2)
 - Perl script #2 verifies matching PTID, Visit, Verbatim, comments and severity and returns a “2”, so ...
 - The value in the previous validation field (“4”) is retained along with the previously chosen term.
- The re-faxed record is reviewed (2 to 3)
 - Perl script #2 verifies matching PTID, Visit, Verbatim, comments and severity and returns a “2”, so ...
 - The value in the previous validation field (“4”) is retained.
- Batch moves the record back to Level 4.

This demonstrates both the current
power and limitations of DataFax

While it is possible to dream of
simpler systems, current tools are
able to accomplish a great deal by
linking to external functions.

And, if you're interested,
we will share

The scripts and some testing
materials are available at
www.DFquality.org