VDW EverNDC Data Structure

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1. Overview

This document describes the data dictionary for the EverNDC table.

Each site will create its own EverNDC Table and update it when it updates its VDW Pharmacy table. Each site-specific EverNDC Table will only contain NDCs used at that site during the data period.

For multi-site projects, a local list of NDCs from the lead site rarely captures all NDCs used at all participating HMORN sites. A two-step approach that uses the EverNDC table will help compile a complete list of all NDCs for the studied drugs. The lead analysts of specific projects will first write a distributed program to query the site-specific EverNDC tables. They may use generic names, brand names, AHFS codes (if available), or GPI codes (if available) to identify the NDCs in use at other sites. They will then collate the NDCs identified from all participating sites to compile the final list of NDCs for their study.

Number of dispensings and of members who used each drug during a specific period can be obtained by querying the VDW Pharmacy file using the NDCs identified from the two-step approach.

2. EverNDC Table Data Dictionary

	Definition		Comments
NDC	National Drug Code	Char (11)	This is the HIPAA/CMS/NCPDP standard 5-4-2 configuration (no dashes), see references below.
GENERIC	Generic Name	(105)	It is highly recommended that each site extracts only the generic name (e.g., "fluoxetine", and not "fluoxetine tab" or "fluoxetine tablet")

BRAND	Brand Name	Char (105)	
AHFS1	AHFS Code		Please add two zeros at the end of your codes if they are in the 6-digit format.
AHFS2	AHFS Code	Char (8)	Leave this blank if there are no other AHFS codes
AHFS3	AHFS Code	Char (8)	Leave this blank if there are no other AHFS codes
AHFS4	AHFS Code	Char (8)	Leave this blank if there are no other AHFS codes
AHFS5	AHFS Code	Char (8)	Leave this blank if there are no other AHFS codes
AHFS6	AHFS Code	Char (8)	Leave this blank if there are no other AHFS codes
AHFS7	AHFS Code	Char (8)	Leave this blank if there are no other AHFS codes
GPI	GPI Code	Char (14)	Generic Product Identifier, NOT Generic Price Indicator available in FDB

3. Notes/Updates

- Each record is based on a unique NDC and generic name pair. For example, a generic name with two NDCs, or a NDC with two different generic names should both have two records.
- Some sites may not have AHFS or GPI codes, or both.
- The seven AHFS fields do not imply a hierarchy, include all available AHFS codes assigned to each NDC in the sequence you prefer. [Up to seven AHFS codes are assigned to some NDCs in FDB]

4. References

A. FDA National Drug Code (NDC)

The Drug Listing Act of 1972 requires registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. (See Section 510 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360)). Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for human drugs. FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory which is currently updated semimonthly.

The National Drug Code is a unique 10-digit, 3-segment numeric identifier assigned to each medication listed under Section 510 of the US Federal Food, Drug, and Cosmetic Act. The segments identifies the labeler or vendor, product (within the scope of the labeler), and trade package (of this product).

- NDC codes exist in one of the following groupings of digits into segments: 4-4-2, 5-3-2, or 5-4-1, but all NDC codes have 10 digits.
- Example, 1234-5678-90, 12345-678-90, and 12345-6789-0 could all be entirely different products with the same barcode 1234567890. To prevent any actual ambiguity from impacting the marketplace, ambiguity checks are part of the new electronic listing process.
- The first segment, the labeler code, is 4 or 5 digits long and assigned by the Food and Drug Administration (FDA) upon submission of a Labeler Code Request. A labeler is any firm that manufactures, repacks or distributes a drug product.
- The second segment, the product code, is 3 or 4 digits long and identifies a specific strength, dosage form, and formulation for a particular firm.

• The third segment, the package code, is 1 or 2 digits long and identifies package forms and sizes. In very exceptional cases, product and package segments may have contained characters other than digits.

However, HIPAA wanted to avoid any confusion and in response, National Council for Prescription Drug Programs (NCPDP) and Centers for Medicare and Medicaid Services (CMS) created an 11-digit NDC derivative, which pads the labeler, product, or package code segments of the NDC with leading zeroes wherever they are needed to result in a fixed length 5-4-2 configuration (but always written without dashes). The 11-digit NDC format cannot be transformed back into the 10-digit standard format without the help of the product listing database.

Converting NDCs from 10-digits to 11-digits: 10-digit Format on Package

FDA NDC Format	10 -digit Format Example	11-digit Format	Format	Actual 10 -digit	11-digit Conversion of Example
4-4-2	9999-9999-99	5-4-2	0 9999-9999- 99	0002-7597-01 Zyprexa® 10mg vial	0 0002-7597-01
5-3-2	99999-999-99	5-4-2	99999 -0 999- 99	50242-040-62 Xolair® 150mg vial	50242- 0 040-62
5-4-1	99999-9999-9	5-4-2	99999-9999- 0 9	60575-4112-1 Synagis® 50mg vial	60575-4112- 0 1

B. American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification System ©

The AHFS Pharmacologic-Therapeutic Classification was developed and is maintained by the American Society of Health-System Pharmacists (ASHP). ASHP is the national professional association that represents pharmacists who practice in inpatient, outpatient, home-care, and long-term-care settings. ASHP has a long history of fostering evidence-based medication use as well as patient medication safety.

Originally published by ASHP in the inaugural edition of the American Hospital Formulary Service (AHFS; now AHFS Drug Information), the Classification has been the foundation for organizing drug formularies in institutional, governmental, and other settings since 1959. The AHFS Pharmacologic-Therapeutic classification originated as an adaptation of the drug classification used to organize the University of Michigan's Hospital Formulary of Selected Drugs. The principal change reflected in the 1959 adaptation was the incorporation of a hierarchical numeric structure to the alpha description of the drug classes and subclasses. The AHFS classification allows the grouping of drugs with similar pharmacologic, therapeutic, and/or chemical characteristics in a 4-tier hierarchy. There are 31 classifications in the first tier, 185 in the second tier, 256 in the third tier, and 94 in the fourth tier. (See link for tier details.)

Sample Expansion to the Fourth Tier

Some classes, like 16:00 and 60:00, only have a first tier, but others continue down the hierarchy with more granularity the further they go.

Compare the class for celecoxib (28:08.04.08) with aspirin (28:08.04.24)

AHFS Class Number	AHFS Class Description
28:00.00.00	Central Nervous System Agents
28:08.00.00	Analgesics and Antipyretics
28:08.04.00	Nonsteroidal Anti-inflammatory Agents
28:08.04.08	Cyclooxygenase-2 (COX-2) Inhibitors
28:08.08.24	Salicylates

C. Medi-SpanTM Generic Product Identifier (GPI)

A series of 14 characters defined by Medi-Span™ that consists of a hierarchy of seven subsets, each providing increasingly more specific information about drug products; encompassing drug group, class, sub-class, name, name extension and dosage. In addition, GPIs provide categories of brandname and generic drugs in like-therapeutic classes. (See below example.) Products assigned the same code should be pharmaceutically equivalent regarding active ingredients, dose form, route of administration, and strength. The same drug may be classified in multiple therapeutic classes.

While Medi-Span[™] incorporates the American Hospital Formulary Service (AHFS) (1994), a classification system based on the pharmacological uses of drugs, Medi-Span[™] also groups drugs with comparable compounds in the same therapeutic class and allows the same drug to be classified into multiple therapeutic classes.

Medi-spanTM Classification System - Example of an Antidepressant

GPI	Coding	Example
58-	Drug Group	Antidepressants
58-20-	Drug Class	Tricyclic Agents
58-20-00-	Drug Sub-Class	
58-20-00-60	Drug Name	Nortiptyline
58-20-00-60-10	Drug Name Extentsion	Hydochloride

58-20-00-60-10-01 Dosage Form

10mg

D. Master Drug Data Base v2.5 (MDDB®)

DELIVERS TIMELY DRUG DESCRIPTIVE AND PRICING DATA

When you make and sell prescription products, you need ready access to the latest drug information and pricing. Updated daily, MDDB® provides the very latest pricing and descriptive information on name brand, generic, prescription and OTC medications, including herbals. The industry's leading comprehensive drug file, MDDB®, provides timely and accurate information that supports multiple application needs.

E. First Databank (FDB)

First DataBank, Inc. (FDB), provides context-relevant, integrated drug database products. The firm creates and maintains widely used drug database products, software for drug database integration, and drug reference products.

5. Future direction

6. Contact information

Please contact the VDW Pharmacy working group for questions and suggestions.

V3.1 EverNDC Specification

The V3.1 EverNDC specification was approved for implementation at the mid-year VIG meeting in November 2012.

The target date for implementation of the V3.1 EverNDC specification is found on the VIG Calendar page.

*New Field

Additional Comments:

OBSOLETE_DT AND REINSTATED_DT: These variable will help explain the data when there are gaps in use of an NDC or to know when an NDC/Drug combination has been retired and the NDC is reused.

Variable name	Variable Definition	Values	Comments

NDC	National Drug Code	Char (11)	This is the HIPAA/CMS/NCPDP standard 5-4-2 configuration (no dashes), see references below. Must be present, this is the primary key, duplicates okay if NDC was retired and reused.
*NDC_FDA	FDA National Drug Code	Char(12)	Original FDA 4-4-2, 5-3-2, or 5-4-1 format, including hyphens. This can be useful, since NDC can be padded with zeros. The 11-digit NDC format cannot be transformed back into the 10-digit NDC_FDA standard format without the help of the product listing database.
GENERIC	Generic Name	Char (105)	It is highly recommended that each site extracts only the generic name (e.g., "fluoxetine", and not "fluoxetine tab" or "fluoxetine tablet"). All UPPER CASE.
BRAND	Brand Name	Char (105)	All UPPER CASE.
AHFS1	AHFS Code	Char (8)	Please add two zeros at the end of your codes if they are in the 6-digit format.
AHFS2	AHFS Code	Char (8)	Leave this blank if there are no other AHFS codes
AHFS3	AHFS Code	Char (8)	Leave this blank if there are no other AHFS codes
AHFS4	AHFS Code	Char (8)	Leave this blank if there are no other AHFS codes
AHFS5	AHFS Code	Char (8)	Leave this blank if there are no other AHFS codes
AHFS6	AHFS Code	Char (8)	Leave this blank if there are no other AHFS codes
AHFS7	AHFS Code	Char (8)	Leave this blank if there are no other AHFS codes
GPI	GPI Code	Char (14)	Generic Product Identifier, NOT Generic Price Indicator available in FDB
*UNIT_OF_MEASURE	Unit of Measure	Char(site specific)	Raw from source data. All UPPER CASE. Can contain values like :2000, U/4ML, GM/15ML, %/5GM, -500IU, -400 UNIT

*STRENGTH	Drug Strength	Char(site specific)	Raw from source data. All UPPER CASE. Can contain values like: 99.99%, 9G, 9MCG/0.3ML, 9MG-0.4MG, 9MG-200MCG, DRUG_STRENGTH_NO, 9000 UNIT, 900B CELL, 900MCG/30, 900MCG/5ML, 900MG-60MG
*DOSAGE_FORM	Dosage Form	Char(site specific)	Raw from source data. All UPPER CASE. Can contain values like: VIAL, VIAL PORT, VIALNEB, WAFER, WAFR, WAX,SOLN RECON, SOLN SEQ, SOLN(GRAM),SOLR, SOLUTION, SPACER, SPIRIT, SPONGE
*OBSOLETE_DT	Obsolete Date	NUM(4)	Date NDC was made obsolete, only if different NDC/Generic combination. Many NDCs have obsolete dates, but come back out with same NDC/Generic combination.
*REINSTATED_DT	Reinstated Date	NUM(4)	In the remote possiblity a NDC/Generic combination was made obsolete and Populate if a NDC was made obsolete and there was a gap in time before the same was reinstated.

V3.1 EverNDC Implementation Status by Site

Site Data Managers: please update with the following statuses.

- Not started
- Started
- Verification program results submitted
- Addressing issues (uncovered by program)
- Completed

Feel free to add additional comments and clarifications.

Site	Status	Date of last status update
EIRH	An EverNDC file is not currently needed. We don't have a	n RX file. 2/28/2013
Fallon	QA Results Submitted	2/27/2013

Group Health	QA Results Submitted	4/9/2013
Geisinger	QA Results Submitted	2/26/2013
Henry Ford	Verification program results submitted	2/19/2013
Health Partners	s Verification program results submitted	2/15/2013
Harvard Pilgrin	n QA Results Submitted	09/24/2013
KPCO	Completed. Note that Obsolete and reinstate date fields will be null at KPCO.	7/22/2013
KPGA	Fields have been added.	5/28/2013
КРН	Completed	6/1/2013
KPMA	Completed	4/9/2013
KPNC	Verification program results submitted	5/17/13
KPNW	Completed	2/25/13
KPSC	Not started, plan to work on this in the next few weeks	4/11/13
Marshfield	Completed	4/11/13
SWH		
PAMFRI	Completed	4/9/13

Related content RX EverNDC V3 QA Feb 2013

Comments (22)

Krajenta, Rick Nov 04, 2010 08:07 AM

I would like to see some text references to AHFS code hierarchy and/or secondary data tables to be companion tables. Some are available from AHFS. Below is copied from their web site. Secondary Data Tables

Additional mapping tables are available to relate AHFS Classification codes to NDC and/or RxNorm Saylor, Gwyn Nov 22, 2010 02:00 PM

KPCO can create this file as specified.

Hitz, Paul Nov 22, 2011 03:21 PM

Marshfield can implement this specification.

Ross, Tyler Aug 28, 2012 02:45 PM

Can we make the NDC_FDA length 12 and suggest that people put dashes in if they know it?

Is NDC required to be non-null?

Krajenta, Rick Aug 28, 2012 04:02 PM

If an NDC is reused it is more likely to be assigned to a different drug formulation than the original. This seems like reinstate date should be effective(in use) date. This will provide date ranges when each NDC = specific drug. I see the potential to mis-ID NDCs if generic name searches don't limit by date.

Pardee, Roy Sep 11, 2012 09:35 AM

Agree that an active_date -> inactive_date would be easier to understand conceptually. Like Rick says--if an NDC is reincarnated, won't it be for a completely different drug?

That said, I'm not at all sure GH has a good source for these dates.

Bachman, Don Aug 29, 2012 12:01 PM

GPI codes are proprietary to Medispan and must be licensed. While there isn't a concern about VDW programs using GPI codes to select drugs, we need to determine whether we can share the EverNDC tables (containing GPI) with other health plans.

Pardee, Roy Sep 11, 2012 09:37 AM

Don, do you mean entire EverNDC tables, or are you also concerned about extracts (e.g., all records meeting a query intended to pull up NDCs for statins)?

The AHFS var poses the same issue, doesn't it?

Bachman, Don Aug 29, 2012 12:10 PM

I don't know if sites have obsolete and reinstated dates available in their source data. If most sites don't, perhaps we can create a separate table containing (NDC, obsolete_dt, reinstated_dt) from a central source (say UMLS, Multum, etc.) and store it in the VDW macro library (just like the format library). A macro could be used to determine which NDC codes have been made obsolete and reinstated. If sites can't get these fields populated with their source data, then these variables could be useless, or worse, misleading (obsolete date is missing in the VDW when there really is an actual obsolete date).

Bachman, Don Aug 29, 2012 12:49 PM

Perhaps we can have another central source that has AWP (average wholesale price)? NDC, start date, end date and AWP. I want to be clear that I am not pushing for sites to populate this variable but to collect it from a central source and make it available in the macro library.

Pardee, Roy Sep 11, 2012 09:42 AM

I like this idea & wonder if the UMLS has goodies that will make our lives simpler in general. In particular, I have the impression that RxNorm's RxCUI identifier might be a good supplemental identifier to NDC, collapsing across e.g., otherwise-identical formulations produced by different companies.

Bachman, Don Aug 29, 2012 12:25 PM

Programmers using this data probably would prefer the most common values standardized across sites. It would be more efficient to use this data.

In the Vitals table, there are raw and standardized variables for height and weight. Does it make

sense to do the same for these 3 variables (create standardized variables as well)? If I had to choose between raw and standardized values, I would recommend keeping the raw values (as per the current specs). It might be good to get input from the Vitals team on this decision.

Pardee, Roy Sep 11, 2012 09:44 AM

FWIW, my preference would be to keep a single set of vars, unstandardized to start. Then once they're implemented, do a round of freqs to see what the potential is for standardizing & then publish lists of valid values (QA would tolerate some small %age of invalid values). IMHO having 2 sets of vars is too cumbersome.

Bachman, Don Aug 29, 2012 12:28 PM

Should we force generic name and brand name to be in upper case to ease text searches? What about units (???), strength and dosage form?

Pardee, Roy Sep 11, 2012 09:45 AM

Yes! Case on all text vars should be standardized.

Bachman, Don Aug 29, 2012 12:40 PM

I have always been a bit uncomfortable with removing the dashes from the 13 digit NDC code values to create 11 digit NDC code values as the dashes can be in different places. I'm not saying this is wrong or in error. Is there a scenario where 2 different 13 digit codes (dashes in different places) convert to the same 11 digit code? Maybe or maybe not? I don't know. It's possible that some sites don't have 13 digit NDC codes in their source data, but do we know this for sure?

I realize that we have already committed to using 11 digit NDC codes and that "ship has sailed". However, if we had the 11 and the 13 values in the EverNDC, we could determine whether this (conversion of 13 digits to 11 digits) is a problem or not.

Bachman, Don Aug 29, 2012 02:14 PM

The good news is that each case where one NDC links to multiple internal codes, the generic names for the internal codes are vitually identical. The internal product number has been used since 1986 and I don't believe they are being re-used. What I am saying is that I don't believe NDC codes have been reused for substantially different drugs at KPNW. Here's the code I used to determine this.

```
proc sort data=internal_rx_lookup_table(keep=prod_nr ndc_nr gen_name prod_name where= (ndc_nr is not null)) out=ndc;
```

```
by ndc_nr prod_nr;
run;

data dups;
set ndc;
by ndc_nr prod_nr;
if first.ndc_nr=0 or last.ndc_nr=0;
run;

proc print data=dups;
by ndc_nr;
id ndc_nr;
var prod_nr gen_name prod_name;
format gen_name prod_name $30.;
run;
```

Cleveland, Catherine Sep 05, 2012 05:38 PM

KPNW can implement the spec, but the obsolete_dt and reinstated_dt variables will most likely be null.

Folck, Bruce Sep 05, 2012 07:03 PM

I don't know if KPNC can populate the new NDC field; we'll need to research it more, to see if we can identify the format of the source NDC, and whether the source NDC format is consistent across all meds or if it varies. We are already including unit, strength and dosage form/"route." We can

probably fill in an obsolete_dt because we are able to identify discontinued medications with reasonable certainty. But I do not know about the reinstated_dt.

Pardee, Roy Sep 11, 2012 09:49 AM

GH can implement everything w/the possible exception of NDC_FDA and the obsolete/reinstated dates.

Graham, Jove Oct 01, 2012 02:56 PM

Geisinger (GHS) should not have a problem adding NDC_FDA, unit, strength or dosage_form from available EPIC/Clarity sources. We still do not have access to the AHFS codes in our local warehouse but have submitted a request to see if we can get them. Will need some guidance from others on how to populate "obsolete_dt / reinstated_dt" as this isn't something we've done and seems like it should have a non-site-specific solution.

zhouz Feb 05, 2013 05:38 PM

New columns that can be implemented at Marshfield Clinic: UNIT_OF_MEASURE, STRENGTH, DOSAGE_FORM.

New columns that cannot be supported by Marshfield Clinic: NDC_FDA, OBSOLETE_DT, REINSTATED_DT.