

SWAN Drug Group (SDG) Longitudinal Created Variables

Baseline through Visit 15

ARCHIVED DATASET 2019

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DOCUMENTATION FOR THE SWAN DRUG GROUP DATASET

Who is included in the public use dataset:

This dataset contains 37 SWAN Drug Groups (SDG) created from the SWAN longitudinal medication dataset. The purpose of this dataset is to allow investigators to use medication groups as covariates in analyses. The SDGs are based on the lowa Drug Information Service (IDIS) system but they have been modified by the SWAN Pharmacoepidemiology Committee. They do not include all drugs mentioned by participants in SWAN if the drugs were used infrequently and/or not in a frequently used drug group. If you are considering using the drugs as exposures or outcomes, you must review the medications included in the SDG, as some of the groupings are broad and may include drugs that you do not expect. While some drugs have multiple indications, we have only included each drug in one SDG. You can tailor the SWAN Drug Groups to your purpose.

Difference between previous releases of the SDG dataset (nialsdg2018):

- the dataset was updated up to Visit 15
- Additional OTC drugs were reviewed and those that met the criteria for select non-rx were included
- Added SDG 37 –Parasympatholytic Agents

Created variables:

RX: The medications included in this dataset have to be one of the following:

- 1) an identifiable prescription (Rx) medication,
- 2) a medication that is over the counter (OTC) and that has been determined to be important to SWAN (select non-rx, see table below),
- 3) medications that are currently OTC that were prescription at the start of SWAN
- 4) medications that are OTC Hormone/Herbal medications used to treat menopause symptoms.
- 5) medications that meet the criteria for both select non-rx and OTC hormone

Select Non-Rx medications included in the dataset (RX = 2, Select non-Rx)

Generic Name	Common Brand Name Examples
Acetaminophen	Tylenol, Anacin-3
Antacids & Absorbents	
Aspirin	Bufferin, Ecotrin, Ascriptin, Aspir-Low,
	Anacin
Calcium	
Calcium Carbonate	Tums, Caltrate
Calcium Citrate	Citracal
Chondroitin	
Cimetidine	Tagamet
Coenzyme Q10	
Famotidine	Pepcid AC, Fluxid, Mylanta AR
Glucosamine	
Ibuprofen	Advil, Motrin, Nuprin
Insulin	Novolin, Humulin
Lansoprazole	Prevacid OTC
Naproxen	Aleve, Naprosyn, Anaprox
Nizatidine	Axid AR
NSAID	
Omeprazole	Prilosec
Ranitidine	Zantac
Vitamin D	
Vitamin D2	
Vitamin D3	

Medications that were once prescription but are not currently (RX = 3, Rx to non-Rx)

A complete list of Rx to non-Rx is available on the Consumer Healthcare Products Association website https://www.chpa.org/SwitchPP.aspx and choosing the option Switch List. ("Ingredients & Dosages Transferred From RX-to-OTC Status (or New OTC Approvals) by the Food and Drug Administration Since 1975")

OTC Herbal medications included in the dataset (RX = 4, OTC Hormone/Herbal)

Select herbal preparations are included because such products are used to treat menopause-related symptoms. OTC medications containing the active ingredients below are flagged and included in the database

Generic Name
Black Cohosh
Black Currant Seed Oil
Borage
Chaste Tree
Chasteberry
Dong Quai
Estrogen
Evening Primrose Oil
Flaxseed
Flaxseed Oil
Phytoestrogens
Progesterone
Pregnenolone
Red Clover
Soy
Soy Isoflavones
Soy Supplements
St John's Wort
Wild Yam

Medications removed from SDG

- Pentosan Polysulfate
- Phytosterol
- Beta-Sitosterol
- Taurine
- Licorice, Deglycyrrhizinized
- Glutathione
- Lactic Acid
- Citric Acid
- Lecithin & Soyalecithin
- Gaba
- Phosphatidylcholine
- Bromfenac
- Nepafenac
- Buprenorphine
- Dipyrone
- Felbinac
- Palmidrol
- Rimexolone
- Selegiline
- Sibutramine
- Magnesium Sulfate
- Alpha-Lipoic Acid
- Timolol
- Cannabis
- Regenesis
- Paricalcitol

Inhaled medications removed from SDG

- Nicotine
- Pentamidine
- Zanamivir

Additional information:

Drug Reformulations

- Over the course of data collection in SWAN, multiple products were reformulated by manufacturers. The
 largest group affected by these changes has been cough and cold preparations. Many changes are
 related to the FDA request in November 2000 that drug manufacturers remove Phenylpropanolamine
 from their products. (Similar reformulations accompanied regulations on Pseudoephedrine.)
- Frequently, the brand name remained the same but the product was reformulated with different generic
 ingredients. It is not always possible to differentiate the formulation based only on brand name. In those
 instances, the original generic ingredients were assigned.

THE IDIS DATABASE

- The IDIS (Iowa Drug Information Service) database was a subscription service developed by the University of Iowa, which was discontinued in 2014.
- A detailed list of IDIS drug names and categories is available for reference and explanation in the file idis_dictionary.xlsx.

LISTING OF CREATED VARIABLES IN THE DATASET

Variable	Label	Code
ARCHID	Participant ID	
VISIT	Study visit	'00' = Baseline to '13' = Visit 13
RACE	Race/Ethnicity	1= Black 2= Chinese/Chinese American 3= Japanese/Japanese American 4= White Non-Hispanic 5= Hispanic
SITE	Study site	11= Detroit, MI 12= Boston, MA 13= Chicago, IL 14= Oakland, CA 15= Los Angeles, CA 16= Newark, NJ 17= Pittsburgh, PA
RX	Prescription type	1= RX, 2 = Select non-RX 3 = RX to non-RX 4 = OTC Hormone/ Herbal 5 = Select non-RX & OTC Hormone
SDG1	Generic Med 1 SDG	Grouped 1 - 34
SDG2	Generic Med 2 SDG	Grouped 1 - 34
SDG3	Generic Med 3 SDG	Grouped 1 - 34
SDG4	Generic Med 4 SDG	Grouped 1 - 34
SDG5	Generic Med 5 SDG	Grouped 1 - 34
SDG6	Generic Med 6 SDG	Grouped 1 - 34

Detailed information on Created SDGs.

Please remember that IDIS codes by ingredient. Therefore, combination medications will have more than one generic name and SDG per pill.

SDG 1: Alpha Blocker: Some agents may not be typically used for blood pressure lowering. Yohimbine was added.

SDG 2: Beta Blocker: Sotalol is listed here but is typically used as an antiarrhythmic

SDG 3: Calcium Channel Blocker

SDG 4: ACE Inhibitor

SDG 5: Angiotensin Receptor Blocker

SDG 6: Diuretic: This drug category mixes loop and non-loop diuretics, and drugs such as thiazide and polythiazide.

SDG 7: Anti-Hypertension - Other such as hydralazine,methyldopa, brimonidine solution, clonidine, minoxidil, and reserpine

SDG 8: Anti-Coagulant: This drug category includes older and newer oral anti-coagulants (NOACs).

SDG 9: Anti-Lipemic: This drug category includes statin and non-statin lipid lowering agents. Niacin was added to this group as a select OTC.

SDG 10: Anti-Arrhythmic: This includes digoxin which is often used as an inotrope.

SDG 11: Vasodilator-Nitrate

SDG 12: Platelet Inhibitor: This drug category includes several drugs but most of the use relates to aspirin. Aspirin was included if it was taken alone, but not if it was part of cold or other preparation

SDG 13: Analgesic: Removed bromfenac and nepafenac (ophthalmic solutions), buprenorphine (opioid addiction treatment), and dipyrone, felbinac, and palmidrol (not available in the US).

Created 4 Subgroups

13a - Opioid

13b - NSAID

13c - Migraine

13d - Acetaminophen

SDG 14: Anti-Gout

SDG 15: Glucocorticoid:

15 - Glucocorticoids – unspecified (route of administration not asked)

15a - Glucocorticoids-Oral

15b - Glucocorticoids-Topical/skin

15c - Glucocorticoids-Injection

15d - Glucocorticoids-Inhaled

SDG 16: Antibiotic

SDG 17: Estrogen: Genistein added from anti-neoplastics

SDG 18: Progesterone: Megestrol added from anti-neoplastics

SDG 19: Other Endocrinological Preparation such as Parathyroid hormones, Pituitary hormones, Thyroid Agents and Antagonists

SDG 20: Selective Estrogen Receptor Modulator (SERM): Tamoxifen, Toremifene, and Clomiphene added.

SDG 21: Anti-ulcer and Antacid such as Proton Pump Inhibitors, H2 Antagonists, aluminum hydroxide, and antacids.

SDG 22: Anticonvulsant: Phenobarbital is listed in this category even though it is an ingredient in cough medicines.

SDG 23: Axiolytic

SDG 24 Antidepressant

24a - Antidepressant-TCA

24b - Antidepressant-SSRI - Bupropion added

24c - Antidepressant-SNRI

24d - Antidepressant- Other

SDG 25: Antipsychotic

SDG 26: Antihistamine- Hydroxyzine added

SDG 27: Anti-neoplastic

27a - Anti-neoplastic (Bevacizumab, Trastuzumab)

27b - Anti-neoplastic with hormonal action (Fulvestrant, anastrozole, Exemestane, Letrozole).

27c - GnRH receptor Analogue (Leuprolide, Nafarelin, Goserelin)

SDG 28 Hypoglycemic- Created 8 Subgroups

28a - Metformin

28b - Sulfonylurea

28c - Meglitinide

28d - Thiazolidinedione

28e - DPP-IV Inhibitor

28f - Incretin

28g - Insulin

28h - Hypoglycemic-other

28i - Diabetic Agent-other

SDG 29: Leukotriene Receptor Antagonist

SDG 30: Anti-Osteoporosis

SDG 31: Non-steroidal Respiratory Inhaler

SDG 32: Gonadotropin

SDG 33: Androgen

SDG 34: OTC Hormone/Herbal - These are non RX. NOTE: Estrogen/Progesterone may be found in both RX and non RX categories.

SDG 35: Janus Kinase (JAKS) Inhibitor

SDG 36: Unknown

SDG 37: Parasympatholytic Agent

NOTE: Calcium and Vitamin D supplements can be found in the Longitudinal Vitamin D/Calcium dataset

DATA COLLECTION FORMS

Questions B1-B20 shown below (the **a** columns), and B26-B28 are taken from the **Visit 10 Interview** for creating the following variables GENERIC_NAME, IDIS_CATEGORY, SDG1-SDG5, and RX. These same questions have been asked at baseline and all follow-up visits up to visit 10.

ASK RESPONDENT TO GATHER PRESCRIPTION MEDICATIONS SO THEY ARE WITHIN REACH. REMEMBER, DO NOT READ OUT LOUD ANY SCRIPT IN CAPITAL LETTERS.

REFER TO THE "MEDICATION REFERENCE LIST" AS PER PROTOCOL.

I would like to begin the interview by asking you some questions about prescribed and over- the-counter (OTC) medications.

I will start by asking about any pills or medicines, including patches, suppositories, injections, creams and ointments which are <u>prescribed</u> by your doctor or other health care provider, that you have taken <u>since your last study visit</u>.

b.

What is the

name of the

medication?

#MEDNAME

IF YES TO ANY, RECORD MEDICATION NAME IN THE SPACES PROVIDED

PRESCRIPTION DRUGS

IF YES

c. INTERVIEWER

VERIFIED

MEDICATION

CHECK:

Have you been

the last month?

taking it at least two

times per week for

			inst mond		FROM CONTAIN LABEL?	ER
	Since your last study visit] ,	NO	YES	NO	YES
B1.	Have you taken any medication, pills or other	<u> </u>	. 1	2	1	2
	medicine to thin your blood (anticoagulants)?	-	. 1	2	1	2
	'ANTICOAGULANT'					
B2.	Anything for your heart or heart beat, including		. 1	2	1	2
	pills or patches? 'HEART'	<u>:</u>	. 1	2	1	2
В3.	Any medications for	<u>.</u>	. 1	2	1	2
	cholesterol or fats in your blood? 'CHOLESTEROL'	<u>:</u>	. 1	2	1	2
B4.	Blood pressure pills? 'BLOOD PRESSURE'	· 	. 1	2	1	2
	BLOOD PRESSURE	<u> </u>	. 1	2	1	2

What is the name of the medication? #MEDNAME

b. Have you been taking it at least two times per week for the last month?

c. INTERVIEWER
CHECK:
MEDICATION
VERIFIED
FROM
CONTAINER
LABEL?

Since your last study visit, have you taken....

		, , , ,	NO	YES	NO	YES
B5.	Diuretics for water retention?		1	2	1	2
	'DIURETICS'	<u>:</u>	1	2	1	2
B6.	Thyroid pills? 'THYROID'	<u>:</u>	1	2	1	2
	mrkob	:	1	2	1	2
B7.	Insulin or pills for sugar in your blood?	:	1	2	1	2
	'INSULIN'	<u>.</u>	1	2	1	2
B8.	Any medications for a nervous condition such	· <u>·</u>	1	2	1	2
	as tranquilizers, sedatives, sleeping pills, or anti-depression medication? 'NERVOUS CONDITION'	:	1	2	1	2
B9.	Steroid pills such as Prednisone, or cortisone?	·	1	2	1	2
	'STEROIDS'	<u>:</u>	1	2	1	2
B10	Prescribed medication for arthritis?	·	1	2	1	2
	'ARTHRITIS'	<u>:</u>	1	2	1	2
B11	. Fertility medications to help you get pregnant	<u>:</u>	1	2	1	2
	(such as Pergonal, Clomid, Fertinex, Gonal- F, Follistim or Repronex)?	<u>:</u>	1	2	1	2

What is the name of the medication? #MEDNAME

b. Have you been taking it during the past month?

c. INTERVIEWER
CHECK:
MEDICATION
VERIFIED
FROM
CONTAINER
LABEL?

HORMONE QUESTIONS B12-17:

Since your last study visit, have you taken....

	NO	YES	NO	YES	NO	YES
B12.Birth Control pills? 'BIRTH	1 (B13)	2	1	2	1	2
CONTROL'	1	2_	1	2	1	2

B12.d For your most recent use, what was the <u>primary</u> reason for taking birth control pills?

TO PREVENT PREGNANCY	1
TO HELP CONTROL PRE-MENSTRUAL SYMPTOMS	2
TO HELP CONTROL MENOPAUSAL SYMPTOMS	3
TO CONTROL OTHER SYMPTOMS	4
TO REGULATE PERIODS	5
TO PREVENT OSTEOPOROSIS	6
TO REDUCE BLEEDING	7
OTHER	8
(SPECIFY)	
DON'T KNOW	8

	NO	YES	NO	YES	NO	YES
B13. Estrogen pills	1 (B14)	2	1	2	1	2
(such as Premarin, Estrace, Ogen, etc)?	1	2	1	2	1	2

'ESTROGEN PILLS'

B13.d IF YES: Does/Did your prescription have you take estrogen daily or on and off on a monthly cycle? [IF MORE THAN ONE MENTIONED, RECORD THE MORE RECENT AT 1.]

EVERY DAY1	EVERY DAY1
OFF AND ON2	OFF AND ON2
DON'T KNOW8	DON'T KNOW8

V	ince your last study isit, have you aken	NO	YES	NO	YES	NO	YES
B14.E	strogen by injection	1	2	. 1	2	1	2
Е	r patch (such as straderm)?'ESTROGEN NJECTION OR PATCH'	1	2	 . 1	2	1	2
B15.	Combination estrogen/	1	2	 1	2	1	2
	progestin (such as COMB ESTROGEN/PROGE	1	2_	1	2	1	2

- a. What is the name of the medication? #MEDNAME
- b. Have you been taking it during the past month?
- c. INTERVIEWER
 CHECK:
 MEDICATION
 VERIFIED FROM
 CONTAINER
 LABEL?

Since your last study visit, have you taken...

		NO	YES	NO	YES	NO	YES
B16.	Progestin pills	1	2	1	2	1	2
	(such as Provera)? 'PROGESTIN'	1	2	1	2	1	2

B16.d IF YES: Does/Did your prescription have you take progestin daily or on and off on a monthly cycle? [IF MORE THAN ONE MENTIONED, RECORD THE MORE RECENT AT 1.]

EVERY DAY1	EVERY DAY1
OFF AND ON2	OFF AND ON2
DON'T KNOW -8	DON'T KNOW -8

- a. What is the name of the medication? #MEDNAME
- b. Have you been taking it during the past month?
- c. INTERVIEWER
 CHECK:
 MEDICATION
 VERIFIED FROM
 CONTAINER
 LABEL?

Since your last study visit, have you taken...

		NO	YES	NO	YES	NO	YES
B17.	Any other prescription	1	2	1	2	1	2
	hormones that I haven't asked you	1	2	1	2	1	2
	about, for example vaginal rings (such	1	2	1	2	1	2
	as Femring), progestin injections (such as Depo- Provera), estrogen/testosteron e	1	2	- 1	2	1	2
	combinations (such as Estratest), or vaginal creams? 'OTHER RX						

HORMONE'

Since your last study visit, have you taken...

	NO	YES		NO	YES	
B18. IV (into the vein) medication to prevent or treat osteoporosis (brittle or thinning bones; such as IV bisphosphonates)?	1	2	B18a. If yes, have you taken it in the last year?	1	2	

- a. What is the name of the medication?
 #MEDNAME
- b. Have you
 been taking
 it at least
 two times
 per week for
 the last
 month?
- c. Have you been taking it once a week for the last month?
- d. Have you been taking it once a month?
- INTERVIEWER CHECK: MEDICATION VERIFIED FROM CONTAINER LABEL?

Since your last study visit, have you taken...

	NO	YES	S	NO	YES	NO	YES	NO	YES	NO	YES
B19. Non IV medications to prevent or treat osteoporosis;	1	2		1 (c)	2 (e)	1 (d)	2 (e)	1	2	1	2
(brittle or thinning bones; such as Fosamax, Didronel, Evista, Miacalcin, Rocaltrol, Actonel, Forteo (PTH))?	1	2 IS'		1 (c)	2 (e)	1 (d)	2 (e)	1	2	1	2

- a. What is the name of the medication? #MEDNAME
- b. Have you been taking it at least two times per week for the last month?
- c INTERVIEWER
 . CHECK:
 MEDICATION
 VERIFIED FROM
 CONTAINER
 LABEL?

Since your last study visit....

	YES	NO	YES	NO	YES
B20. Are there any other prescription pills or	2	1	2	1	2
medications	2	1	2	1	2
that you have taken, that I haven't asked you about?	2	1	2	1	2
(PLEASE LIST.)	2	1	2	1	2
'OTHER RX MED'	2	1	2	1	2
	2	1	2	1	2
	2	1	2	1	2
	2	1	2	1	2
	2	1	2	1	2
	2	1	2	1	2
	2	1	2	1	2
	2	1	2	1	2
	2	1	2	1	2
	2	1	2	1	2
	2	. 1	2	1	2

Now I would like to ask you about over-the-counter medications, non-prescription, that you have taken regularly at least 2 times per week for a month or more, since your last study visit.

IF YES TO ANY, RECORD MEDICATION NAME IN THE SPACES PROVIDED Since your last study visit, have you taken			a.	What is the name of the medication? #MEDNAME	b. Have you been it at least two per week for to month?		wo times
nave you canenum	NO	YES				NO	YES
B26. Any over-the-counter medications	1	2_			_	1	2
for pain including headaches and arthritis?	1	2_			_	1	2
B27. Anything for problems sleeping?	1	2 _			_	1	2
'OTC SLEEP'	1	2			_	1	2

IF YES TO ANY, RECORD MEDICATION NAME IN THE SPACES PROVIDED a. What is the name of the b. medication?
#MEDNAME

Have you been taking it at least two times per week for the last month?

Since your last study visit...

		NO	YES	NO	YES
B28.	228. Have you taken any other over-the-	1	2	_ 1	2
	counter pills or other	1	2	1	2
	medications (including liquids or	1	2	_ 1	2
	ointments or aspirin) that I haven't asked	1	2	_ 1	2
	you about? (PLEASE LIST.)	1	2	_ 1	2
	'OTC OTHER'	1	2	_ 1	2
		1	2	_ 1	2
		1	2	_ 1	2
		1	2	1	2
		1	2	_ 1	2
		1	2	_ 1	2
		1	2	_ 1	2
		1	2	_ 1	2
		1	2	_ 1	2
		1	2	1	2

Visit 12-13 SWAN RX/selected Non-Rx Medication Data Collection Sheet

C. Record all prescription and selected non-Rx medications (including pills, dermal patches, eye drops, creams, salves, and injections) that were a) administered only **once or twice a year** and used **since your last study visit** ("YES" to B23) or b) used in the previous **three months** ("YES" to B24). **Record the complete medication name exactly as written on the container label.**

#	Medication Details					<u>Dose – Quantity</u> many times taken/time	<u>Dose – Duration</u> (for how long)		
Medication Name	Route	Dosage Form	Strength	Streng th Unit	#	unit) Time Unit	#	Time Unit	
#MEDNAME		_	_			D W M Y NA Other, specify:		D W M Y O NA	
						Collect	at time of blo	od draw	
RX Status:	PRN?		Verified by container?		ntly using cation?	Taken within 24 hours of blood draw?			
1 Written Rx 2 OTC/self 3 OTC/doctor 4 Other8 Unknown	No 1 Yes 2	No Yes	1 2	No Yes New since inte	2	No1 Yes2 No Blood Draw3			

^{*} Note: The medication details assist in providing more information for assigning the SWAN drug group.

Visits 12-13 Over-the-Counter (OTC)/VITAMIN/Dietary SUPPLEMENT (Non Prescription) Products Data Collection Sheet

D. Record all other OTC/vitamin/supplement products (including pills, patches, eye drops, creams, salves) that were used in the previous <u>three</u> <u>months</u> ("YES" to B24). Record the complete medication name exactly as written on the container.

#		0.	TC/Vitamin/Supple	ment			
Product Name	Route	Dosage Form	Strength†	Strength Unit†	Number taken in previous 24 hours?		Verified by container?
#MEDNAME		_	_	_	_	No Yes	1 2

^{*} Note: The product details assist in providing more information for assigning the SWAN drug group.

Visit 15 SWAN RX/selected Non-Rx Medication Data Collection Sheet

C. Record all prescription and selected non-Rx medications (including supplements, vitamins, pain medications, or sleep aids) that were administered in the previous <u>three months</u> ("YES" to Q. B23 AND/OR Q. B24). Record the complete medication name exactly as written on the container label.

#		Media	cation Details	RX Status?	PRN?
Medication Name#MEDNAME	Route*	Strength	Strength Unit	Written Rx	No 1 Yes 2
				Collect at time of bl	ood draw
Method of verification?		Currently using	medication?	Taken within 24 hours of b	lood draw?
Medication container		NoYes Yes New since intervie	2	No	

SECTION D. Over-the-Counter (OTC)/VITAMIN/Dietary SUPPLEMENT (Non Prescription) Products Data Collection Sheet

USE PAGE 7 TO ASSIST WITH ROUTE CODES

D. Record all other OTC/vitamin/supplement products (including pills, patches, eye drops, creams, salves) that were used in the previous <u>three</u> <u>months</u> ("YES" to Q. B23 AND/OR Q. B24) Record the complete medication name exactly as written on the container.

#					
Product Name	Route*	Strength†	Strength Unit	Method of verification?	Currently using OTC/Vitamin/Supplement?
				Medication container1	OT GIVITAIIIIII GAPPIOIII CIIC
				Personal list	No1
#MEDNAME				Pharmacy/health center provider printout 3	Yes2
				Phone follow-up4	
				Email follow-up5	
				Not verified 6	
					I .