



Routine Healthcare Surveillance is Here

Alexander M. Walker MD DrPH

Senior VP Epidemiology

I3 Drug Safety

What Machines Can Do, Machines *Should* Be Doing!

People should think, not tabulate.

Elements of Safety Surveillance

- § Large numbers of users
- § Real-world use
- § Rapid feedback
- § Comprehensive outcome monitoring
- § Ability to dive deeper

Claims Database

- § Claims data extracted from adjudicated physician, facility and pharmacy claims
- § Enrollee and provider demographic tables
- § Size varies: 2 – 40 million “lives”
- § Geographically dispersed
- § Medicaid and Medicare

Research Database

Claims Data

- Member identifier
- Plan
- Gender
- Age
- Dates of Eligibility
- Member identifier
- Prescribing physician
- Drug dispensed (NDC)
- Quantity and date dispensed
- Drug strength
- Days supply
- Dollar amounts
- Member identifier
- Physician or Facility identifier
- Procedures (CPT-4, revenue codes, ICD-9)
- Diagnosis (ICD-9-CM, DRG)
- Admission and discharge dates
- Date and place of service
- Dollar amounts

Administrative Data

Pharmacy Claims Data

Physician and Facility Claims Data

Lab Test Results Data

Consumer Elements

- Member identifier
- Income
- Net Worth
- Education
- Race & Ethnicity
- Life Stage
- Life Style Indicators
- Member identifier
- Lab Test Name
- Result

Machine Readable Dataset

Per-Project Data

Chart Reviews

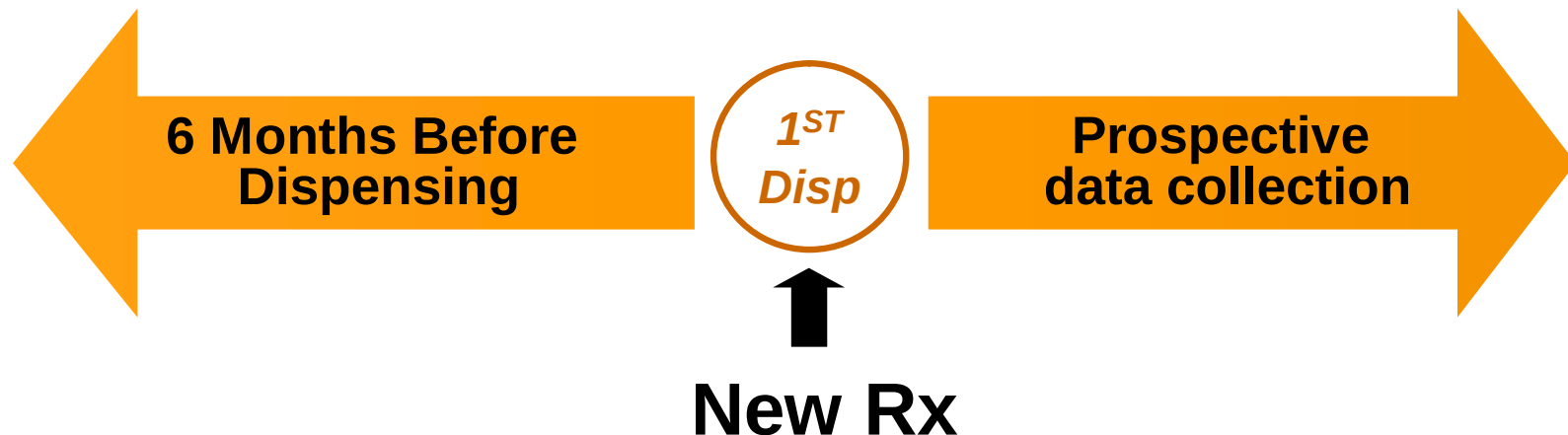
Surveys

Hospital Inpatient

Clinical Measures

Tissue Samples

Data Setup for Quick Retrieval



- Create matched cohorts of New Drug and Market-Leader Drug users
- Tabulate baseline
 - comorbidities
 - drugs
 - procedures
 - demographics
 - healthcare utilization
- Identify clinical outcomes based on claims data
 - outpatient diagnoses
 - inpatient diagnoses
 - drugs
 - procedures
 - healthcare utilization

Drug/Comparator Lookup

Drug/Comparator	Report Access	Data Mining	Drug/Comparator
Aloxi/Zofran		  Rx	Lyrica/Neurontin
Avastin/Non-Drug		  Rx	Namenda/Non-Drug
Boniva/Fosamax		  Rx	Nevanac/Acular
Byetta/Metformin-Glyburide		  Rx	Nevanac/Voltare
Campral/Non-Drug		  Rx	Omacor/Non-Drug
Cialis/Viagra		  Rx	Raptiva/Non-Drug
Crestor/Lipitor		  Rx	Revataz/Kalatra

Reports - Factive/Levaquin

Report Name	View
Demographic Characteristics	
Baseline Diagnoses	
Baseline Procedures	
Baseline Therapeutic Drug Class Dispensings	
Baseline Healthcare Utilization	
Characteristics of Prescribers	
Treatment Patterns	
Primary Inpatient Diagnosis Outcomes	
Outpatient Diagnosis Outcomes	

Report Name	View
Other Diagnosis Outcomes	
Procedure Outcomes	
Therapeutic Drug Class Outcomes	
User Defined Outcomes	
Healthcare Utilization 1-3 months after Initiation	
Healthcare Utilization 4-6 months after Initiation	
Healthcare Utilization 7-9 months after Initiation	
Healthcare Utilization 10-12 months after Initiation	

Demographic Characteristics of Factive/Levaquin (Matched by Propensity Score)

	All Initiators				Matched Initiators			
	Factive (N=9,927)		Levaquin (N=543,236)		Factive (N=9,925)		Levaquin (N=9,925)	
	N	%	N	%	N	%	N	%
Age								
0 - 9	2	0.0	146	0.0	2	0.0	0	0.0
10 - 19	110	1.1	11,105	2.0	110	1.1	112	1.1
20 - 29	832	8.4	50,528	9.3	832	8.4	827	8.3
30 - 39	1,901	19.1	101,735	18.7	1,901	19.2	1,950	19.6
40 - 49	2,785	28.1	137,746	25.4	2,783	28.0	2,756	27.8
50 - 59	2,596	26.2	131,325	24.2	2,596	26.2	2,612	26.3
60 - 64	875	8.8	47,241	8.7	875	8.8	868	8.7
65 +	826	8.3	63,410	11.7	826	8.3	800	8.1
Gender								
Female	5,415	54.5	320,697	59.0	5,414	54.5	5,434	54.8
Male	4,512	45.5	222,539	41.0	4,511	45.5	4,491	45.2
Household Income								
\$0 - \$29,999	1,001	10.1	60,586	11.2	1,001	10.1	1,078	10.9
\$30,000 - \$59,999	2,318	23.4	113,053	20.8	2,317	23.3	2,155	21.7
\$60,000 - \$89,999	2,317	23.3	110,602	20.4	2,317	23.3	2,279	23.0
\$90,000 - \$149,999	1,627	16.4	81,681	15.0	1,627	16.4	1,577	15.9
\$150,000 +	1,103	11.1	55,471	10.2	1,102	11.1	1,115	11.2
Unknown	1,561	15.7	121,843	22.4	1,561	15.7	1,721	17.3
Race/Ethnicity								

Baseline Diagnoses of Factive/Levaquin (Matched by Propensity Score)

Scrollbar Off

Dx Code	Description	All Initiators				Matched Initiators				Unmatched Initiators	
		Factive (N=9,927)		Levaquin (N=543,236)		Factive (N=9,925)		Levaquin (N=9,925)		Factive (N=2)	
		N	%	N	%	N	%	N	%	N	%
466	*Acute bronchitis and bronchiolitis	2,325	23.4	56,382	10.4	2,323	23.4	2,278	23.0	<u>2</u>	100.0
461	*Acute sinusitis	2,141	21.6	72,809	13.4	2,140	21.6	2,087	21.0	<u>1</u>	50.0
401	Essential hypertension	1,969	19.8	116,313	21.4	1,969	19.8	1,980	19.9	0	0.0
272	Disorders of lipid metabolism	1,853	18.7	99,733	18.4	1,853	18.7	1,851	18.6	0	0.0
461	Acute sinusitis	1,768	17.8	69,238	12.7	1,768	17.8	1,610	16.2	0	0.0
786	Symptoms involving respiratory system and other chest symptoms	1,562	15.7	85,340	15.7	1,562	15.7	1,504	15.2	0	0.0
780	General symptoms	1,481	14.9	84,486	15.6	1,480	14.9	1,409	14.2	<u>1</u>	50.0
466	Acute bronchitis and bronchiolitis	1,446	14.6	46,247	8.5	1,444	14.5	1,388	14.0	<u>2</u>	100.0
V72	Special investigations and examinations	1,215	12.2	78,385	14.4	1,215	12.2	1,207	12.2	0	0.0
477	Allergic rhinitis	1,160	11.7	52,133	9.6	1,160	11.7	1,134	11.4	0	0.0

	Matched Initiators					
	Factive (N=9,925)			Levaquin (N=9,925)		
	Mean	Median	IQR	Mean	Median	IQR
Number of People in this Quarter (N, %)	9,914	99.9		9,918	99.9	
Total Costs (\$)	\$1,653	\$423	\$1,143	\$1,955	\$469	\$1,257
Total Patient Costs (\$)	\$242	\$138	\$270	\$254	\$138	\$278
Professional Costs (\$)	\$476	\$100	\$355	\$554	\$116	\$420
Facility Costs (\$)	\$788	\$0	\$174	\$1,012	\$0	\$224
Emergency Room Costs (\$)	\$25	\$0	\$0	\$26	\$0	\$0
Pharmaceutical Costs (\$)	\$365	\$126	\$413	\$364	\$130	\$409
Number of Physician Visits	2.0	1.0	3.0	2.1	1.0	3.0
Number of Hospitalizations	0.0	0.0	0.0	0.0	0.0	0.0
Inpatient Days	0.2	0.0	0.0	0.2	0.0	0.0
Number of Emergency Room Visits	0.2	0.0	0.0	0.2	0.0	0.0
Number of Drugs Dispensed	4.1	3.0	5.0	4.1	3.0	5.0
Number of Unique 3 Digit ICD-9 Diagnosis Codes	4.5	3.0	6.0	4.6	3.0	6.0
Duration of Follow-up	86.7	91.0	0.0	86.3	91.0	0.0

New Events

Description	Matched Initiators				95% Confidence Interval			
	Factive (N=9,925)		Levaquin (N=9,925)					
	N	%	N	%	Relative Risk	Low	High	Score
Allergy, unspecified not elsewhere classified	168	1.7	93	0.9	1.8	1.4	2.3	5
Unspecified adverse effect of drug medicinal and biological substance,	115	1.2	57	0.6	2.0	1.5	2.8	5
Hematuria	158	1.6	237	2.4	0.7	0.5	0.8	-4
Unspecified urticaria	70	0.7	31	0.3	2.3	1.5	3.5	4
Unspecified chronic bronchitis	58	0.6	<u>23</u>	0.2	2.5	1.5	4.2	4
Malaise and fatigue	908	9.1	771	7.8	1.2	1.1	1.3	3
Dyspnea and respiratory abnormalities	811	8.2	679	6.8	1.2	1.1	1.3	3
Unspecified asthma	770	7.8	647	6.5	1.2	1.1	1.3	3

Data Mining

Data Mining - Outpatient Diagnosis of Factive/Levaquin (All Initiators)

Attribute			Outcome		Factive		Levaquin		Re
Type ▾	Code ▾	Description ▾	Dx ▾	Description ▾	Events ▾	N ▾	Events ▾	N ▾	Val ▾
Days since first dispensing	8 to 29 days		995	Certain adverse effects not elsewhere classified	99	9,846	<u>19</u>	9,831	5.2
Days since first dispensing	8 to 29 days		708	Urticaria	38	9,846	<u>4</u>	9,831	9.5
Days since first dispensing	8 to 29 days		782	Symptoms involving skin and other integumentary tissue	82	9,846	35	9,831	2.3
Days since first dispensing	8 to 29 days		719	Other and unspecified disorders of joint	50	9,846	88	9,831	0.6
Days since first dispensing	8 to 29 days		692	Contact dermatitis and other eczema	75	9,846	37	9,831	2.0

New Frontiers in Data Integration

§ Already in production

- Consumer data
- Laboratory results
- Routine pregnancy surveillance

§ Pilot phase

- Inpatient linkage
- Real-time raw claims stream for rapid cycle reporting
- UnitedHealthcare oncology supplementary data
- 6-monthly patient status updates for all cancer patients

A general purpose medical data warehouse built on a health-insurance transactions platform.

Altogether Feasible

- § Private sector – internally funded
- § Prototype up and running in six months
- § V2.0 the following year
- § Maximum of 12 developers at any one time
- § Already large enough to be scalable to any data set size

This is not the “last word” in automated prescription surveillance. We and others have many ideas on how to go forward. It is a demonstration that the principal obstacles ARE NOT technology.



Thank You!

www.i3drugsafety.com

