

An Enterprise Approach to Managing Recalled or Discontinued Medications

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Paul Kleeberg, M.D.
Medical Director, CDS
paul@allina.com

Do you want to spend the next hour in this room?

- Outline
 - Setting the stage
 - Background on Allina
 - Why you should think about this
 - Our experience with Vioxx
 - Lessons from doing a “dry run”
- Audience
 - Epic customers who have not yet had to pull a medication from their system.
- Disclaimer
 - This is high level and not a technical talk
 - We are still running Fall04

Allina Hospitals & Clinics

Allina Hospitals & Clinics



- Largest health system in Minnesota
- Revenue: \$3.5 billion gross/ \$2 billion net
- Diverse organizational entities
 - 4 metro hospitals
 - 7 regional hospitals (30 to 80 beds)
 - Allina Medical Clinics (AMC) - 42 clinic locations with 700+ employed providers, 23 hospital-based clinics
- 1,700+ staffed beds
- More than 22,500 employees

Current Implementation Statistics

- Implementation complete in 5 hospital facilities
 - 2 regional (New Ulm Medical Center, Buffalo Hospital)
 - 3 metro (Abbott Northwestern, Mercy and Unity Hospitals)
- Practice Management implemented in all clinics (65 total)
- EpicCare Ambulatory implementation to be complete in June 2007.
- Active Excellian users as of September 1 = 12,816
- Patient records as of September 1 = 4,210,000

Let's set the stage...

- The Situation
 - A major drug is recalled (Vioxx)
 - A frequently ordered medication is no longer produced (Nasacort)
 - There is a new contraindication (Paxil and teens).
- The Impact
 - The medication is on your order sets.
 - It is in your SmartSets.
 - It comes up on your preference lists
 - It is mentioned on your web site
 - You have out patients who are taking it
- How do you approach this in an organized way?

Benefits of an Electronic Medical Record

- No longer a paper search
 - Paper order sets
 - Outpatient charts
- Now you can enlist the help of a computer
- But finding the content in your EMR is not nearly as easy as finding content with Google.



So what's the big deal?

- Our implementation was in silos
- Our performance with Vioxx was not as smooth as we had expected and more challenging than when we had Logician.
- The pharmacy team was aware of the issue and was able to address it on the inpatient side
- No one was on point to address the issue on the ambulatory side
- We wanted to have a coordinated approach going forward.



A dry run...

- Lente and Ultralente
 - Production was to stop 12/31/05
 - Patients who were stable on these meds would need time to adjust
 - Used both inpatient and outpatient
 - Discovered in Fall which gave us lead time to implement
- We decided to use Lente and Ultralente to get our process down.
- We felt it was better to be prepared now than scrambling later
- It was more complex than we thought



Our first challenge was to be on the lookout for change

- Assign a responsible party
 - Possible sources:
 - The pharmacy community
 - Listservs
 - FDA Medwatch
- <http://www.fda.gov/medwatch/>
- A web page
 - An RSS feed
 - A listserv list.

The screenshot shows the MedWatch website interface. At the top, it says 'U.S. Food and Drug Administration' and 'Department of Health and Human Services'. Below that is a navigation bar with links like 'FDA Home Page', 'About MedWatch', 'Contact MedWatch', and 'MedWatch Partners'. The main heading is 'The FDA Safety Information and Adverse Event Reporting Program'. There's a search bar on the right. Below the navigation, there are sections for 'Stay Informed' with links to XML and RSS feeds, and 'What's New' with several recall notices. There are also images for 'Safety Information' and 'Medical Product Reporting'.

Our second step was to determine a plan of action

- Determine the urgency
 - Vioxx vs. Nasacort vs. Lipitor
- Whom does it affect?
 - Inpatient
 - Ambulatory
 - ED
- What teams are involved?



Next it was time to begin...

- Gather information to attach to the ERX file
 - Identify alternatives
 - Create a message
 - Identify Web Links
- Identify where the item appears
 - Order sets
 - SmartSets
 - Preference Lists
 - Web site
 - Formularies
- Communicate, communicate, communicate.

Creating the Alternative Alert

- We created a document which gave information about the issue
- We used that to create the text for the alert
- Select alternative medications for the alert
 - If there are many, select the top 3 or 4
- Identified links for the alert
 - FDA document
 - Manufacturer document
- Do not disable ordering for ambulatory
 - Patient calls for a refill
 - Meds placed historically

Alternative Alert: Inpatient can have a hard stop

Alternative Selection

ROFECOXIB 50 MG TAB

On Sept. 30, 2004, the FDA and Merck announced a voluntary withdrawal of rofecoxib (VIOXX) from the market. Refer to the weblink to the right.

Please select an alternative COX-2 listed below, or click "Cancel Filling Process" to go back to order entry.

Web Links

FDA Press Release 09.30.2004
Allina COX II advisory 10.28.2004

Alternative	Dose	Route	Frequency	End Date	Class	Cost
CELECOXIB 100 MG CAP [29743]						
CELECOXIB 200 MG CAP [254]						
CELECOXIB 400 MG CAP [52288]						

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Alternative Alert: Ambulatory must have a soft stop

Alternative Selection

INSULIN ZINC EXTENDED HUMAN 100 UNIT/ML SUSP, SUB-Q INJ

Eli Lilly and Company has stopped manufacturing Humulin® U Ultralente® due to declining usage of this insulin over the years. The current stock of this insulin will become unavailable at pharmacies sometime around December 31, 2005. As a result, you should consider ordering a different form of insulin. The buttons below do the following:

- Accept Alternative: Select from the listed comparable insulin to replace the Humulin U
- Continue with Current Order: Continue with Humulin U order. Choose this option if you are routing the encounter to a provider (i.e Refill Encounter).
- Cancel Filing Process: Return to Order Entry to select a different medication

Web Links

Eli Lilly and Company
FDA

Alternative	Sig	Disp	Refill	End Date	Class	Cost
LANTUS 100 UNIT/ML SUB-Q [9763]						
INSULIN GLARGINE 100 UNIT/ML SUB...						

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Physicians and Other Providers

- We notified them early
- We let them know in advance that there will be a system response
- Give them detailed information once the plan was in place
- Involved them in all direct-to-patient communication make on their behalf
- Provide instructions on how to use the letter and other tools created in the system

What we told the physicians:

- How we were going to help them identify which of their patients were affected
- How to let us know what action they would want us to take on their behalf
- About the letter and how to use it
- About the alert and what to expect
- That they can still order the med in ambulatory if they choose
- About the action taken on SmartSets, preference lists, order sets
- About action taken on patient education materials
- About changes on the web site
- That the call center was informed
- ...and we asked for feedback

Hospital Pharmacists

- Coordinated the medication change in their own facility
- Were coordinated by the pharmacy team
- Managed the local formularies and preference list changes
- Need to be aware of the process



Recall Letter

- Utilized content from the “master document” and the alternative alert
- Ran it past content editors for readability
- Used it for
 - Letters activity
 - MyChart Communication
 - Consider using on the Web
- Sent a copy to providers, triage nurses and the call center
- Planned to remove it when no longer needed



Patients with Med on Their Active Med List

- This was not easy
- Pre Reporting Workbench:
 - Created a clarity report that could search by location and medication
 - Gave detailed instructions as to how to run the report to the clinics
 - A “Clinical Care Improvement Facilitator” at each clinic ran the report
 - Providers identify patients to be contacted.
 - Clinic could contact on provider’ s behalf
- Using Reporting Workbench

Removing the Medication from Order Sets and SmartSets

- A time consuming process
- Identify the order sets and SmartSets
 - Identify the ERX for each formulation of the medication
 - Perform a chronicles search
 - Identifying the SmartSets and order sets
- Get utilization information
- Starting with the most frequently used:
 - Is an alternative required?
 - Is the alternative on the formulary?
 - Does the change require review by the content experts?
 - Make the change

Can be tracked with a custom data base

- Medication Database
 - Used to build initial medication files
 - Can copy an FDB or custom record easily
- Order Set Database
 - Partial extract of 6 different chronicle reports; Order set, restriction, section, medication, comment and admin instructions.

Get utilization information

- A chronicles report
- Report needs to be created



SmartSet Usage by Name and Location

For Contact Dates: 8/23/2005 to 8/23/2006

Double Click on SmartSet for Drill Down

Run Date & Time: 8/23/06 & 2:53 pm

SmartSet	# of Patients	
25707	FLU SHOT - AMB	22095
25593	PHYSICAL THERAPY TREATMENT VISIT OV - PT	20888
21007	PRENATAL EXAM ROUTINE OV - OBGYN	18034
22208	PACEMAKER ICD EVALUATION - CARDIO	7418
26005	NURSE VISIT - INJECTIONS	6633
22462	OFFICE VISIT MCA DOWNTOWN - CARDIO	6473
26007	CHIRO OV - CHIRO	6408
21002	ANNUAL ADULT EXAM - OBGYN	6272
26001	NURSE VISIT - ALLERGY	5806
26004	NURSE VISIT - IMMUNIZATIONS	5783
22465	OUTSIDE ORDERS MCA MOBILE - CARDIO	5576
28007	JOINT INJECTION - ORTHO	5285
20000	ERRONEOUS ENCOUNTER - OPENED IN ERROR	4726
25591	PHYSICAL THERAPY EVALUATION OV - PT	4703
25541	PREVENTATIVE MEDICINE ORDERS/ DX/ MEDS - IM W/ R	4022
22460	AUDIOLOGY OV - AUDIO	2982
22461	OFFICE VISIT MCA SATELLITES ONLY - CARDIO	2952
20030	HEALTH MAINTENANCE HISTORICAL ORDERS	2638
27314	EAR NOSE THROAT OV - ENT	2604
22468	NURSE VISIT - OCC MED	2603
27316	ALLERGY OV - ALLERGY	2232
26008	PREOP OV - AMB	2017
20630	SPEECH EVALUATION OV - SLP	1917
22469	EMPLOYER DIRECT OV - OCC MED	1694
22484	WCC OV 7-12 YR - PEDS	1533
25600	ERRONEOUS ENCOUNTER - NO SHOW	1521
26013	PEDORTHIC OV - PEDORTH	1499
26601	PHYSICAL FEMALE ADULT - FP	1484
22657	(IA) WELL CHILD EXAM 2 MO - PEDS	1437
22656	(IA) WELL CHILD EXAM BIRTH - 2 WKS - PEDS	1416
25601	ERRONEOUS ENCOUNTER - CANCELLATION	1328
22658	(IA) WELL CHILD EXAM 1 MO - PEDS	1324



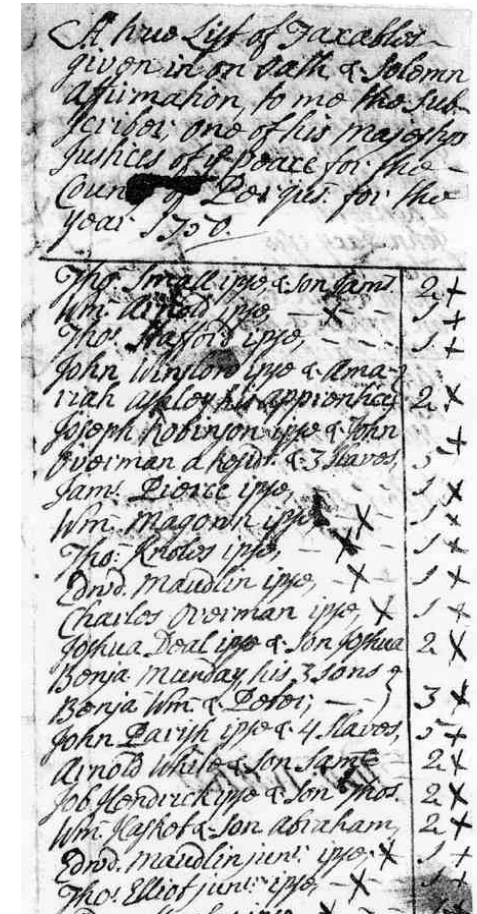
We notified our clinical experts

- Make them aware of the changes
- Gave them with alternatives for approval
- Asked them to sign off on the change



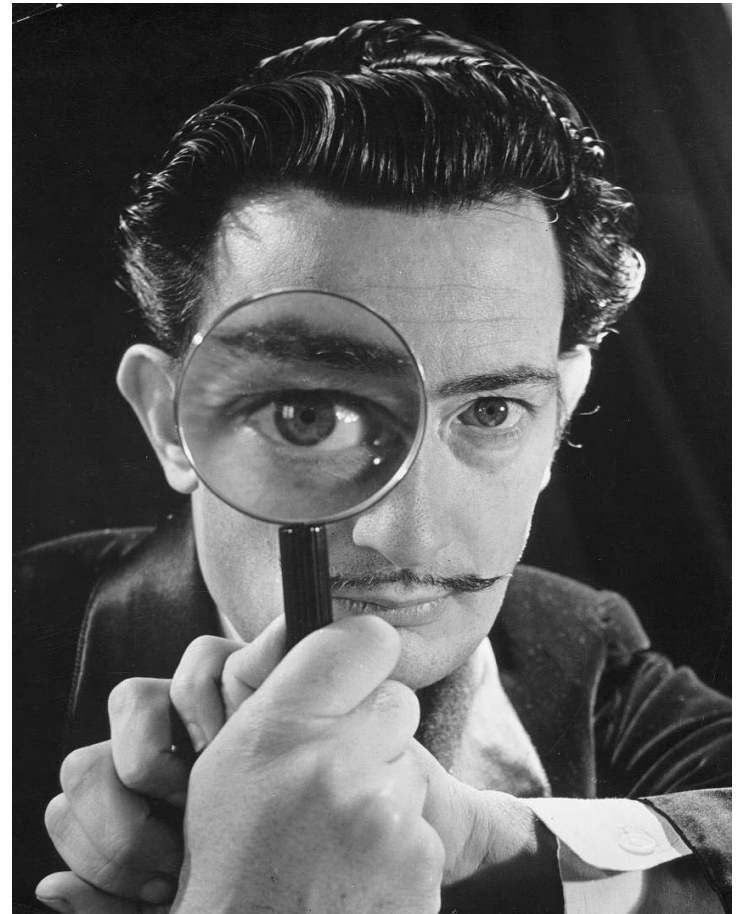
Formularies and Preference Lists

- Process different for Inpatient ambulatory
- Inpatient
 - Preference lists are locally controlled
 - One per hospital
 - Adding pediatric to prevent rounding errors
 - Formularies are local for now
- Ambulatory
 - Preference lists are specialty specific and system wide
 - Formularies are not used



Check the information in Patient Education Materials

- Vioxx in treatments for arthritis
- Estrogen and heart disease



- Locally hosted content:
 - Medical director note placed on medication page
- Remotely hosted material requires update by vendor
- Corporate material
 - Search web pages for relevant content
 - Contact owners and advise of change



Warning in local content

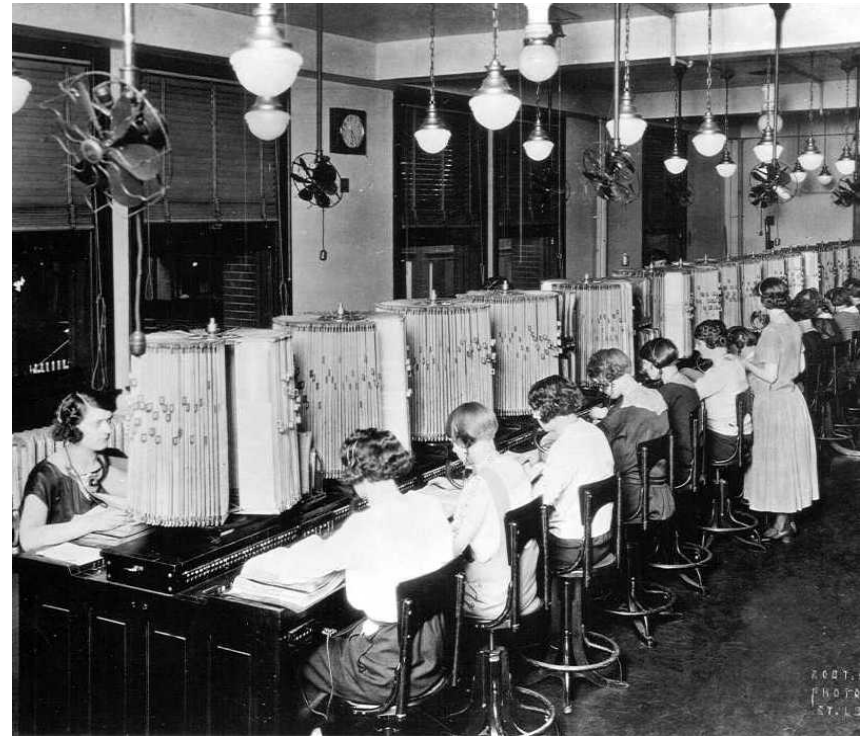
Medical director's note: On Sept. 30, 2004, the maker of Vioxx® (rofecoxib) announced a voluntary worldwide withdrawal of the arthritis and acute pain medication. Merck & Co., Inc. took the drug off the market due to three years of data from the APPROVe (Adenomatous Polyp Prevention on Vioxx) trial. The now-ended study showed an increased risk of heart attack and stroke after 18 months of treatment with Vioxx.

There are many alternatives to Vioxx. If you take Vioxx, consult your health care provider about the best substitute medication for you.

For more information, read Arthritis Drug Vioxx Pulled from Market (<http://www.medformation.com/ac/healthday.nsf/2b1a0abda1fbdd5e86256def0057659f/6f82ad323f18b85f86256f200016808e?OpenDocument>) or visit the United States Food and Drug Administration's Vioxx information page (<http://www.fda.gov/cder/drug/infopage/vioxx/vioxxQA.htm>).

We kept the Call Center in the loop

- Our call center schedules appointments and does nurse triage
- Told them of the process before everything was final
- We gave them:
 - An early draft of the letter being sent to the providers
 - A copy of the changed information on the web site
 - A draft of the patient letter
- Gave them time to create a message for patients



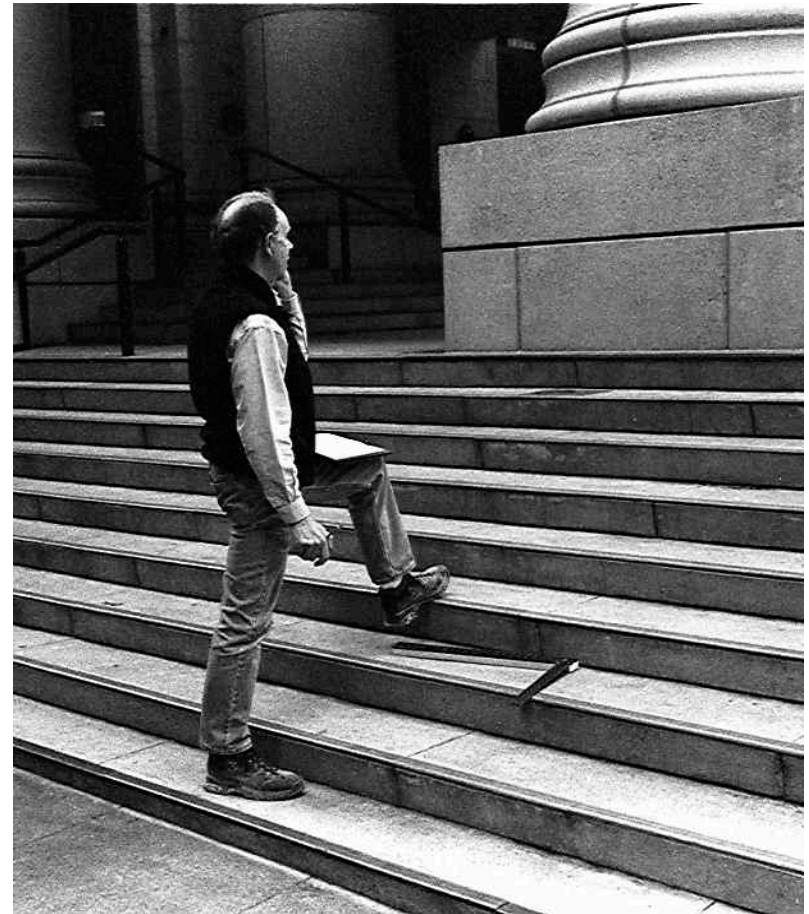
Retail Pharmacies

- Another point of contact for patients
- Can be a source of information for you
 - They see the scripts your provider's write
 - They can notify you of med issues
- Should be aware of the process



What are the steps required to be prepared?

- Have a process in place
- Identify responsible parties
- Identify the sources of this information
- Create a decision hierarchy
- Identify the environments that could be affected
- Rehearse your process with a minor recall
- Document it so you know what to do when the time comes.



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