VAi2: Reducing Adverse Drug Events

Marta Render, M.D.

Chief, VA Inpatient Evaluation Center, Department of Veterans Affairs

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VAi2: Industry Innovation Competition

"We identify, fund, and test new ideas from VA employees, academia, and the private sector. Our focus is on improving access, quality, performance, and cost. At the end of the day, progress in these areas greatly enhances the VA's ability to serve Veterans in the 21st Century."

- VAi2 gives Veterans Affairs a structured way to identify, fund, and test creative new solutions that advance the services we provide
- The Industry Innovation Competition is your invitation to participate in the process
- We've identified 6 key areas that are opportunities for significant advancement
- We ask for your best ideas on making significant improvements in these 6 areas
- Proposals should provide a clear benefit that can be demonstrated via prototype or field test within about 1 year

Broad Agency Announcement Process

- Issued under FAR 35.016 and 6.102(d)(2)(i)
- Does not commit the Government to make an award or pay proposal preparation costs
- Open until September 30, 2010
- Government available to commence evaluations beginning July 6, 2010
- Proposals must be valid for at least 90 days
- Proposals will be evaluated on their own merit according to the criteria stated in the BAA, not against other proposals

Broad Agency Announcement Process

Proposal Preparation Instructions

- Quality is more important than quantity of information
  - Technical volume is limited to 50 pages
  - Charts, diagrams and similar representations count towards the page limit
  - Hyperlinks are not allowed

Instructions, Continued:

- Firm Fixed Price (FFP) contracts preferred
- Offerors must be registered in the Central Contractor Registry (CCR)
- Proposals must be submitted electronically to vai2baa@va.gov

Adverse Drug Event

"Adverse Drug Events (ADE) cost lives and money and VA is interested in finding solutions to help identify and prevent ADEs before they occur."

- VA defines an adverse drug event (ADE) as an injury resulting from the use of a drug. It can include both preventable and non-preventable events (often known as adverse drug reactions).
- The literature has little data to contribute about the frequency of ADEs, particularly in outpatient settings, but some estimates put total costs in the billions without even mentioning psychological and physicals costs to patients.
- VA is already a leader in ADE prevention, particularly in in-patient settings using EMR alerts, safe formulary drugs, and evidence-based prescribing criteria.

Adverse Drug Event

Prescribing → *Transcribing* → *Dispensing* → *Administering*

Tools in Use:

- Electronic medical record
- Formulary Committee
- Bar code medication administration

Limitations:

- Order checks occur at time order entered
- Involve drug:drug interaction no drug: lab interaction
- Some new failures

Adverse Drug Event

Gaps in VA ADE Prevention

- Inability to pro-actively identify patients whose status has changed, increasing their risk for ADE
- Resource intensive and non-timely reporting systems prevent proactive prevention / reduction of injury from ADE
- Current alerts are only generated based on an action (e.g. new prescription) and not on new patient data (e.g. declining renal function).
- "Alert overload" often results in inaction.

Gaps, continued:

- Inability to detect trends. Current ADE alerts only activate at hard cutoff values rather than based on negative trends.
- Little system to screen for ADEs in nursing home and out patient setting.
- Resources do not exist for efficient full review of medication at each patient encounter.

Adverse Drug Event

How important are the gaps?

- Methods: Apply a "trigger tool" developed by Claussen and Bates, which makes rules for risk of ADE using laboratory and pharmacy data making
  - Example High gentamycin level injures kidneys(GENT + CR), Motrin causes kidney injury (NSAID + Cr)

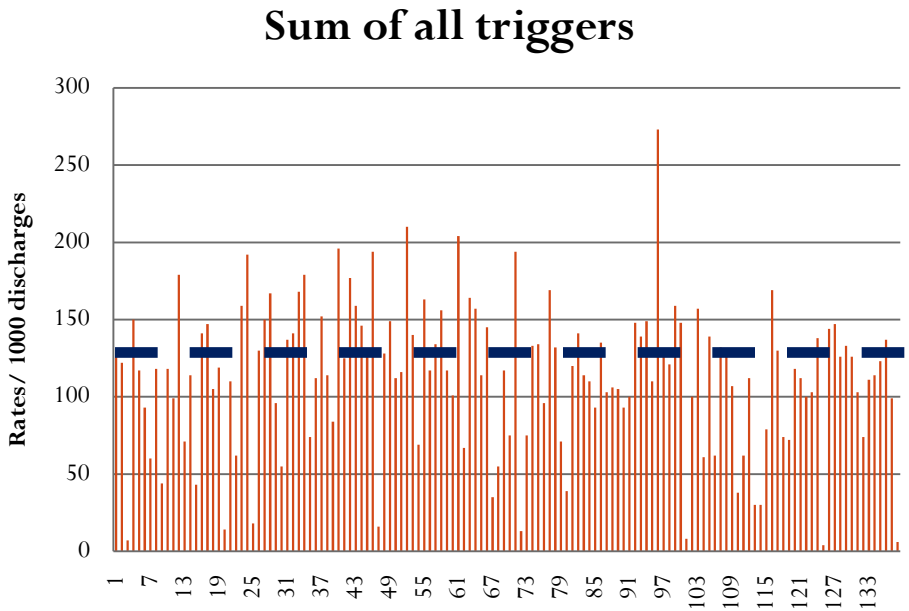
Importance, continued:

- IPEC applied 33 of the triggers to 2009 Inpatient labs and physician orders for medications
- Determined rates of ADE triggers in VA inpatients/ Hosp
- Caveats – didn't determine if the drug had been stopped

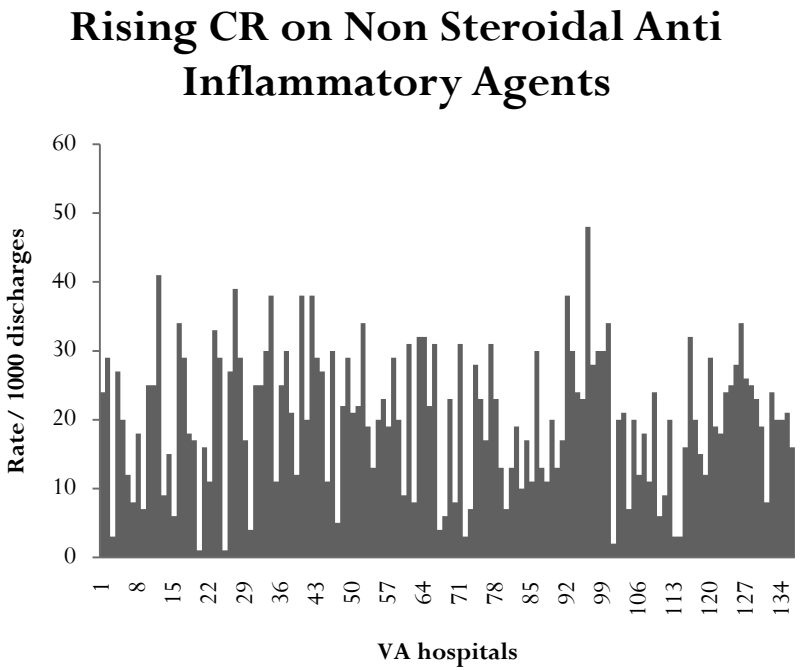
Adverse Drug Event: Trigger Tool

RULE	TITLE		RULETEXT
981	ADE - LOW K AND DIGOXIN	SUPER HIGH	If patient is on (DIGOXIN, DIGITOXIN, DIGOXIN CAPSULE) (prn orders excluded) (scale orders excluded) & the prior POTASSIUM result during the last 3 days is < 3.2 [initial date: 5/1/00]
985	PTT	High	If any of the last 2 PTT results during the last 1 days is > 100 and the patient is on HEPARIN (route=IV) [initial date: 9/10/00]
986	INR	High	****MODIFIED 6/8/2001**** If a patient is on WARFARIN SODIUM and the prior INR result is >4. [Used PT from 9/10/2000 to 6/7/2001; Used INR from 6/8/2001 to present]
1001	ADE - AMIODARONE & DIGOXIN	High	Patient is on AMIODARONE and DIGOXIN. [Initial date:3/22/2001]
1015	ADE - RAPIDLY ACCELERATING INR	High	INR has increased > 2 over last 24 hours. [Initial date:6/20/2001]
1027	ADE - ADULT HYPOKALEMIA	High	If any of the last POTASSIUM levels during the last 1 day < 2.8 [Initial date:7/5/2001]
1029	ADE - RISING CR/ACE INHIBITORS	High	***MODIFIED 11/16/2001 ***If patient is on CAPTOPRIL, LISINOPRIL, ENALPRIL, OR ENALAPRILAT & Any of last 1 CREATININE results within last 1 days are > 1.5 & CREATININE has RISEN 1.0 since previous result over last 99 days.[Initial date:8/9/2001][Cre result incr to 1.0 on 11/16/01]
1030	ADE - RISING CR/AMINO-GLYCOSIDES	High	*****MODIFIED 11/16/2001*****If patient is on TOBRAMYCIN, AMIKACIN, or GENTAMICIN & Any of last 1 CREATININE results within last 1 days are > 1.5 3.5< & CREATININE has RISEN .5 since previous result over last 99 days.[Initial date:8/9/2001, [Tobra Ophth Oint eliminated 11/16/2001]
1031	ADE - RISING CR/ NSAIDS	High	*****MODIFIED 11/16/2001***** If patient is on ACETYLSALICYLIC ACID, BUFFERED ASPIRIRN, ASPIRIN ENTEREIC COATED, CELECOXIB, DICLOFENAC, IBUPROFEN, INDOMETHACIN, KETOROLAC, NABUMETONE, NAPROXEN, PIROXICAM, ROFECOXIB, SALSALATE, SULINDAC, or TOLMETIN & Any of last 1 CREATININE results within last 1 days are > 1.5 & CREATININE has RISEN .5 since previous result over last 99 days.[Initial date:8/9/2001,[ASA, ECASA, BUFF ASA deleted 11/16/2001]
1034	ADE - RISING CR/ ANTIVIRALS	High	If patient is on ACYCLOVIR or PENTAMIDINE & Any of last 1 CREATININE results within last 1 days are > 1.5 & CREATININE has RISEN .5 since previous result over last 99 days.[Initial date:8/9/2001]
1035	ADE - RISING CR/ ANTIFUNGALS	High	If patient is on AMPHOTERICIN, FOSCARNET, FLUCONAZOLE, or ITRACONAZOLE & Any of last 1 CREATININE results within last 1 days are > 1.5 & CREATININE has RISEN .5 since previous result over last 99 days. [Initial date:8/9/2001]
1036	ADE -RISING CR/ IMMUNE SUPPRESSANTS	High	If patient is on CYCLOSPORINE (SANDIMMUNE), NEORAL, or TACROLIMUS & Any of last 1 CREATININE results within last 1 days are > 1.5 & CREATININE has RISEN .5 since previous result over last 99 days. [Initial date:8/9/2001]
1037	ADE - RISING CR/ VANCOMYCIN	High	If patient is on VANCOMYCIN & Any of last 1 CREATININE results within last 1 days are > 1.5 & CREATININE has RISEN .5 since previous result over last 99 days.[Initial date:8/9/2001]
1038	ADE - RISING CR/ ANTINEO-PLASTICS	Low	If patient is on CARBOPLATIN, CISPLATIN, or IFOSFAMIDE & Any of last 1 CREATININE results within last 1 days are > 1.5 & CREATININE has RISEN .5 since previous result over last 99 days.[Initial date:8/9/2001]

Results: Modified ADE Trigger Tool



National Rate range from 7 to 226



ADE: Nightly Reporting Tool Pilot

Results:

- 13 sites ran crude reports for 3 triggers nightly for 4 weeks
  - Toxic phenobarb level
  - INR > 4
  - Platelets < 50,000 on heparin
- Results of triggers and actions were collected weekly using web based tool.

Results:

- 4.8 triggers/ mo/ hospitals
- 13/63 triggers for lowplatelets on heparin, 50/65 for INR > 4.0
- 30% of triggers resulted in action, 73% potentially life threatening.

Extrapolation nationally with 3/ 74 triggers:

- Prevention /injury reduction in 8700 triggers
- 1800 life threatening

Adverse Drug Event

Possible Solutions

VA is interested in solutions to the gaps identified on the previous slide. Functionality may include:

- Fully integrate with VA EMR to allow identification of risk for patients from all kinds of patient data (particularly laboratory)
- Adaptable to all care settings
- Ability to roll up nationally both triggers and actions for metrics and national trend analysis
- Continuous monitoring of "at risk" patients

Functionality, continued:

- The ability for the system to auto-generate reports based on pre-set preferences.
- Ability for the system to generate specific decision support for users (amiodarone raises the dig level 2 fold NOT amiodarone and dig have an interaction)
- Allow easy review/ action on "triggers"
- Allow for easy updating of "triggers"
- The ability to track and identify trends in patient information beyond simple cutoffs for metrics.

Questions and Answers

- Answers to questions will be posted at www.fedbizopps.com