#### The Kaiser Permanente Approach for Implementing Quality, Outcomes Based Prescription Drug Use

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#### What is Clinical Decision-Support?

#### A systematic approach that "Makes it Easier to Do the Right Thing"

And makes it "harder" to do the "wrong" thing

## Stratification of Patients by Risk: Cox 2 Example

- How does the prescribing MD decide when it is most appropriate to use a Cox-2 NSAID?
- Who are the high risk patients for NSAID induced GI bleeding that may benefit from a Cox 2 drug?

#### **ARAMIS DATA**



Am College Rheum, Annual Meeting; 11/9/98, Abstract #256.

#### GI Event Rate per 100 patient years of NSAID Exposure





Risk Level (*e*SCORE)

PCP Area : ORC

PCP Clinic : SAN

PCP Dept:PC



Patient's data from KP databases			
SAID GI Risk SCORE	12		
itient's GI Risk Level	2		
arfarin Rx within last 6 mths.	No		
IF (by registry)	No		
N (by registry)	No		
of KP Hospitalized GI Bleed / Ulcer $^{*}$	No		

OUTPATIENT treated GI bleeds / ulcers are NOT nsidered in this tool. The KP GI Risk SCORE and Risk Level based on the findings from the ARAMIS data base rospective data on > 11,000 patients with arthritis) by Dr. ogh and colleagues at Stanford University, which did not dude outpatient treated GI bleeds/ulcers.

Patient's NSAID History			
Drug	Rx's in PIMS ?		
Ibuprofen(Motrin)	No		
Naproxen (Anaprox, Naprosyn)	No		
Sulindac (Clinoril)	No		
Nabumetone (Relafen)	No		
Etodolac (Lodine)	No		
Salsalate (Disalcid)	No		
Choline Magnesium Trisalicylate (Trilisate)	No		
Rofecoxib (Vioxx)	No		
Celecoxib (Celebrex)	No		
Valdecoxib (Bextra)	No		
APAP History			
Acetaminophen with Codeine	No		
Acetaminophen with Hydrocodone	No		

Recommended alternatives *	Recommended Normal ADULT dose
IBUPROFEN	600-800 mg TID
NAPROXEN	375-500 mg BID
SULINDAC	150-200 mg BID

Total Score	Treatment Recommendation
atient's GI Risk Level 1&2 (< 15 points)	<ul> <li>Ibuprofen (Motrin) 600-800 mg TID</li> <li>Naproxen (Naprosyn) 375-500 mg BID</li> <li>Sulindac (Clinoril) 150-200 mg BID</li> <li>Alternatives: Any NSAID from Risk Level 3 (see below)</li> </ul>
atient's GI Risk Level 3 (16-20 points)	<ul> <li>Nabumetone (Relafen) 500 mg 1-2 tabs BID</li> <li>Etodolac (Lodine) 300-400 mg BID - TID</li> <li>Salsalate (Disalcid) 500-750 mg 2 tabs BID</li> </ul>
atient's GI Risk Level 4 (> 20 points)	<ul> <li>Acetaminophen (APAP) or APAP w/ codeine or APAP w/ hydrocodone</li> <li>Nabumetone (Relafen) 500 mg 1-2 tabs BID with Omeprazole 20 mg daily</li> <li>Etodolac (Lodine) 300-400 mg BID - TID with Omeprazole 20 mg daily</li> <li>Salsalate (Disalcid) 500-750 mg tabs BID with Omeprazole 20 mg daily</li> </ul>

OX-2's are NOT indicated for patients with an NSAID GI Risk SCORE of 20 points or less (Risk Levels 1&2 or 3).

OX-2's and NSAIDS are not recommended for patients on warfarin/lovenox or for patients with a history of hospitalized GI bleed.

#### **NSAID GI Risk Strategizer**



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#### \*COX-2 inhibitors:

- Are NO better than NSAIDs at relieving pain and inflammation
- Cause adverse renal, HTN, and CHF effects similar to NSAIDs
- Have similar rates of dyspepsia and nausea as NSAIDs
- Do NOT eliminate the risk of GI bleeding. ALL beneficial effects appear to be lost with low-dose aspirin use

For more information, visit the pharmacy website at: pharmacy.kp.org

#### **NSAID GI Risk SCORE Card**

To determine your patient's SCORE (Standardized Calculator of Risk for Events), enter the points in the right-hand column corresponding to the appropriate answer. The total of the points is the patient's SCORE.

			POINTS		
1.	Patient's age i 46 – 50 51 – 55 56 – 60 61 – 65	n years? 8 points 9 points 10 points 12 points	66 – 70       13 points         71 – 75       14 points         76 – 80       16 points         81 – 85       17 points         >85       18 points		
2.	2. Current health status as rated by the patient? Very Well0 points Poor3 points Well1 point Very Poor4 points Fair2 points				
3.	Does patient h <b>No</b>	ave <i>rheumatoid art</i> 0 points	<i>hritis</i> ? Yes2 points		
4.       Use of oral prednisone or other oral steroids in past year?         0 mo       0 points       7-10 mo       4 points         1-3 mo       1 point       11-12 mo       5 points         4-6 mo       3 points       3 points       5 points					
5.	Hospitalized fo	or a GI bleed or an u 0 points	ulcer?( <i>If "Yes", skip #6)</i> Yes8 points		
6.	Has patient ha <b>No</b>	d GI side effects w 0 points	nen taking NSAIDS? Yes2 points		
		Total	SCORE (add all points):		
Total SCORE         TREATMENT RECOMMENDATIONS:           First consider non-pharmacological therapy, acetaminophen (Tylenol®), or narcotics (e.g., Tylenol® w/ Codeine, Vicodin®)					
	RISK         LEVELS 1 & 2         ≤ 15 points         Lowest Risk Patients <ul> <li>OTC Ibuprofen (Advil<sup>®</sup>) 200 mg 2 tabs TID-QID</li> <li>OTC Naproxen (Aleve<sup>®</sup>) 220 mg BID-TID</li> <li>Ibuprofen (Motrin<sup>®</sup>) 600-800 mg TID-QID</li> <li>Naproxen (Naprosyn<sup>®</sup>/Anaprox<sup>®</sup>) 375-500 mg BID</li> <li>Sulindac (Clinoril<sup>®</sup>) 150-200 mg BID</li> <li>Alternatives: Any NSAID from Risk Level 3 (see below)</li> </ul>				
RI 16	RISK LEVEL 3       • Nabumetone (Relafen <sup>®</sup> ) 500 mg 1-2 tabs BID         • Etodolac (Lodine <sup>®</sup> ) 300-400 mg BID-TID         • Salsalate (Disalcid <sup>®</sup> ) 500-750 mg 2 tabs BID				
RI > Highe	RISK LEVEL 4       • NF-Rofecoxib (Vioxx <sup>®</sup> ) Start with12.5 mg 1-2 tabs QD (for patients without CHF, HTN, or peripheral edema)         • NF-Celecoxib (Celebrex <sup>®</sup> ) 100 mg 1-2 times daily         • Misoprostol (Cytotex <sup>®</sup> ) or Pantoprazole (Protonix <sup>®</sup> ) plus         Average or Low GI Toxicity NSAID				
NF=	Non-Formulary	ulary ©2000 KPMCP, Southern California Region			

For more information, visit the pharmacy website at: pharmacy.kp.org





**COX-2** Utilization Trend











#### Isotretinoin Risk Management

- KP MedSmart Program designed to meet or exceed the Roche SMART Program
- KP MedSmart linked the dispensing of isotretinoin to a required negative pregnancy test result using KP systems
- Registry created of female patients to track compliance with pregnancy testing and isotretinoin prescribing and dispensing.

### KP MedSMART Program

- Approved policies and procedures
- Easy to use by patients and MDs
- 98.5% patients had documented negative pregnancy test results prior to dispensing
- No patients with a positive pregnancy test received isotretinoin
- Flexibility via product labeling vs subpart H drug requirements of iPledge Program

#### KP MedSMART Results

- Rate of actual pregnancies while on isotretinoin not reduced in the cohort through intensive management of pregnancy testing status
- Failure of patient to adhere to all risk management requirements related to becoming pregnant while on isotretinoin

## Integrated Delivery System Viewpoint

- Establish clinical standards with flexibility on procedures/systems to meet or exceed the standard
- Data collection necessary
- Reporting to providers as part of a quality management process (track and trend results)
- Regulatory changes may be needed.

#### References

- Cheetham TC, Levy G, Spence M. Predicting the risk of gastrointestinal bleeding due to nonsteroidal antiinflammatory drugs: NSAID electronic assessment of risk. J Rheumatol 2003; 30:2241-4
- Cheetham TC, Wagner RA, Chiu G, Day JM, Yoshinaga MA, Wong L A risk management program aimed at preventing fetal exposure to isotretinoin: retrospective cohort study. J Am Acad Dermatol 2006; 55:442-8

### Appendix on Change Management

# **Quality Prescribing Process**

- Pharmacy and Therapeutics Committee for oversight and management
- Physician leaders & champions with pharmacist collaboration
- Focus on appropriate evidence-based drug use for targeted drugs
  - secondary benefit of cost savings
- Support evidence-based medicine with systematic decisionsupport, practice tools, credible data, education, etc.
- Monitoring and Feedback -- Invest in good data

## **Strategies/Tactics**

- Physician Champions & Leadership
  - **Physician Initiative** not Pharmacy Initiative
  - Pharmacist support/collaboration
  - Peer oversight
- Secure the Evidence-Base
- Decision-Support and Practice Support Tools ("Make it easy to do the right thing")
- Education
  - clinicians & patients
- Performance Reporting & Feedback

#### **Thoughts on Change Management/Diffusion Theory**

- All Diffusion is about Change
  - Build on Diffusion Theory
  - Barriers are part of change management
- Define the change
  - Build on small successes
- The key roles of sponsorship, change agent and champion
- Understand your environment
  - Past successes/failures will haunt you
- Communicate, communicate, communicate
  - Be honest, don't sugar coat it...

#### **Rules for Disseminating Innovations in Health Care**

- Find sound innovations
- Find and support innovators
- Invest in early adoptors
- Make early adopter activity observable
- Trust and enable "Reinvention"
- Create slack for change
- Lead by example

## **Rationale & Opportunities**

- Effective medications get better outcomes
- Safer drugs avoid complications & liability
- Generic drugs are safe and effective
- "Me too" drugs present cost saving opportunities
- Prescribe appropriate to condition
- MD's must make the clinical decisions
- Support appropriate, evidence-based clinical decision making, including outcomes informed prescribing

## Other Decision-Support & Practice Tools

- Pharmacist interventions/consultations
- Rx starter packs
- Pre-printed Rx Pads (OTC)
- Patient/member tools
- Member mailings (e.g. allergy rx)
- Rx conversion protocols
- Care/case management
- Tool Kits (best practices)

## **Automated Database for Tracking, Reporting, & Tools**

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PHARMACY RECRUITMENT	COX-2 RX SCORECARD	COX-2 TOOL UTILIZATION MEMORY	
PROVIDER CLEAN-UP	ELDERCARE QUESTIONNAIRE	CUSTOM DRILLDOWN MEMA	

MIM

NEW PPI RXS

MIM EARLY ADOPTER.

NEW SSRI RXS MEW I

PEER COMPARISON PRODUCT VARIANCE TRACK RX v1.001

MIGRAINE

MY PANEL NEW

PPI RXS SCREENING MEMA

RENAL POPULATION MGMT

## Performance Reporting & Feedback

- Computerized data tracking and reporting
- Executive scorecards
- Facility, department, MD specific reports
- Targeted MD specific reports (Abx, GI drugs)
- Outlier communications
- Peer MD 1-on-1 contact/feedback/discussions

# **Aggressive, Saturation Education**

- Paycheck messages
- Videoconferences (CD-ROM, tapes)
- Academic detailing; Hosted dinners (GI)
- Point-Counterpoint Posters/Flyers
- CME presentations
- Publications
- Email communications
- And more

# **Keys to Successful Diffusion**

#### • Sponsorship

- Oversight, coordination
- Use a change management strategy

#### • Develop <u>with</u> clinicians & users

- Tools, applications, & training/implementation plans
- Solid evidence base
- Local Teams w/Strong Clinical (PMG) Leaders/ Champions
- Understand business & clinical processes
  - Re-design process as needed
  - Minimize disruption to work flow
- Multiple approaches/redundancy

## **Keys to Successful Diffusion**

- Strong analytic support and credible data
- Keep application & tools simple, easy to use & flexible
- Validate & pilot before roll out
- Planned training & implementation
  - Training & implementation tools
- Communication Plan
- Accessible support, help, consultation



## Appendix References

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