# Smart ePrescribing (eRx):

## Some Lessons from the Department of Veterans Affairs

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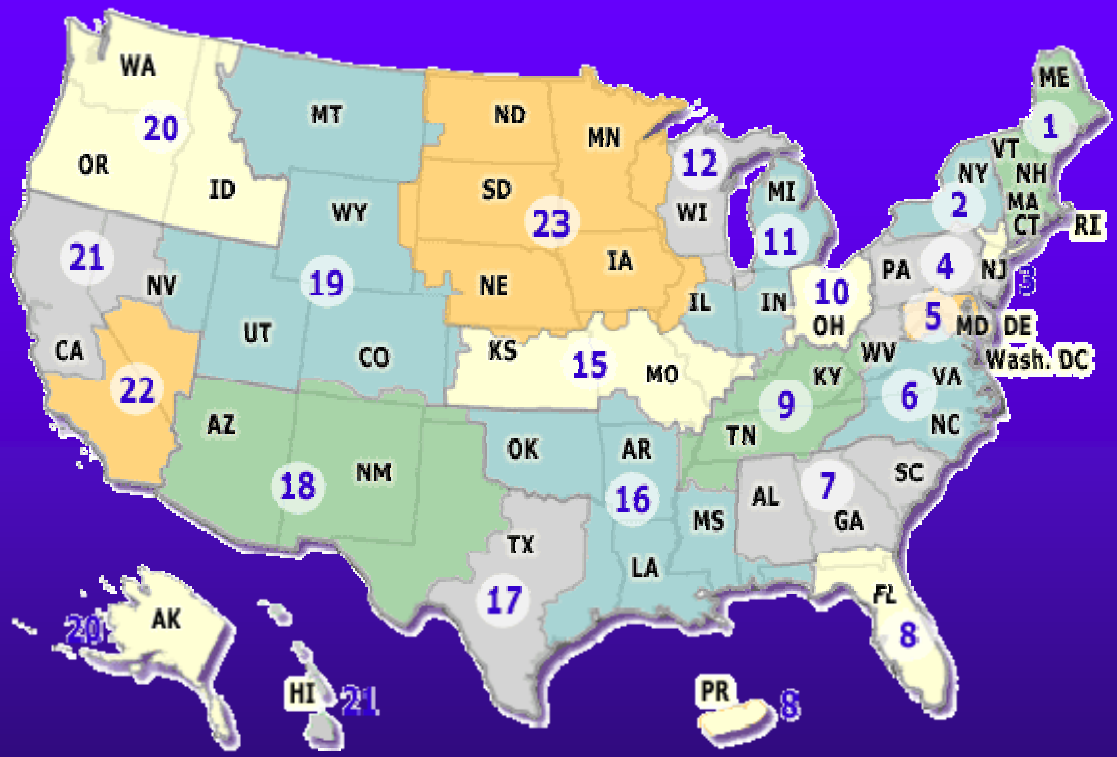
*VA Greater Los Angeles Healthcare System*
*Co-Director, VA Center for Medication Safety*

*Department of Veteran Affairs has about 150 medical facilities, over 800 outpatient clinics and 135 nursing homes in 21 geographic regions*
*7 million enrollees (> 4 million in health care system)*



# VA Greater Los Angeles Healthcare System


# Closed Ordering

- VA maintains a list of drugs with closed ordering on its intranet website:
  - Drug
  - Company
  - Requirement (e.g., FDA or MFG)
  - Drug on Formulary
  - Process of PBM web site link
  - Company/pharmaceutical website

# Current List

- Includes
  - Accutane (Isotretinoin)
  - Clozaril (Clozapine)*
  - Revlimid (lenalomide)
  - Thalomid (Thalidomide)
  - Tikosyn (Dofetilide)
  - Tracleer (Bosentan)
  - Tysabri (Natalizumab)
  - Xyrem (Sodium Oxybate)

# Example

- Thalomid (Thalidomide)
  - Company: Celgene Pharmaceuticals
  - Special Handling: Closed Ordering & Distribution System
  - Requirement: FDA Required –Safety
  - VANF: No
  - Rx by physicians and pharmacists registered in S.T.E.P.S program

# VA Clozapine Program

- Caremark originally had exclusive rights for distribution from Sandoz
  - Physician and pharmacy registration necessary
- VA received authorized vendor status
- Developed outpatient program
- Tracks blood counts weekly, bi-weekly or monthly (includes wbc and absolute neutrophils):
  - Looks for progressive drop over 3 blood draws (→ agranulocytosis)
- VA is the only program that prevents Rx from being dispensed without appropriate white count
- Proactive vs. retrospective assessment (registry)
- Limitation: program misses eosinophil elevation

Gratefully acknowledge: Gary Ripper, Jeff Ramirez

# Clozapine Program

**Department of Veterans Affairs**
**Veterans Health Administration**
**Washington, DC 20420**

**VHA DIRECTIVE 99-035**

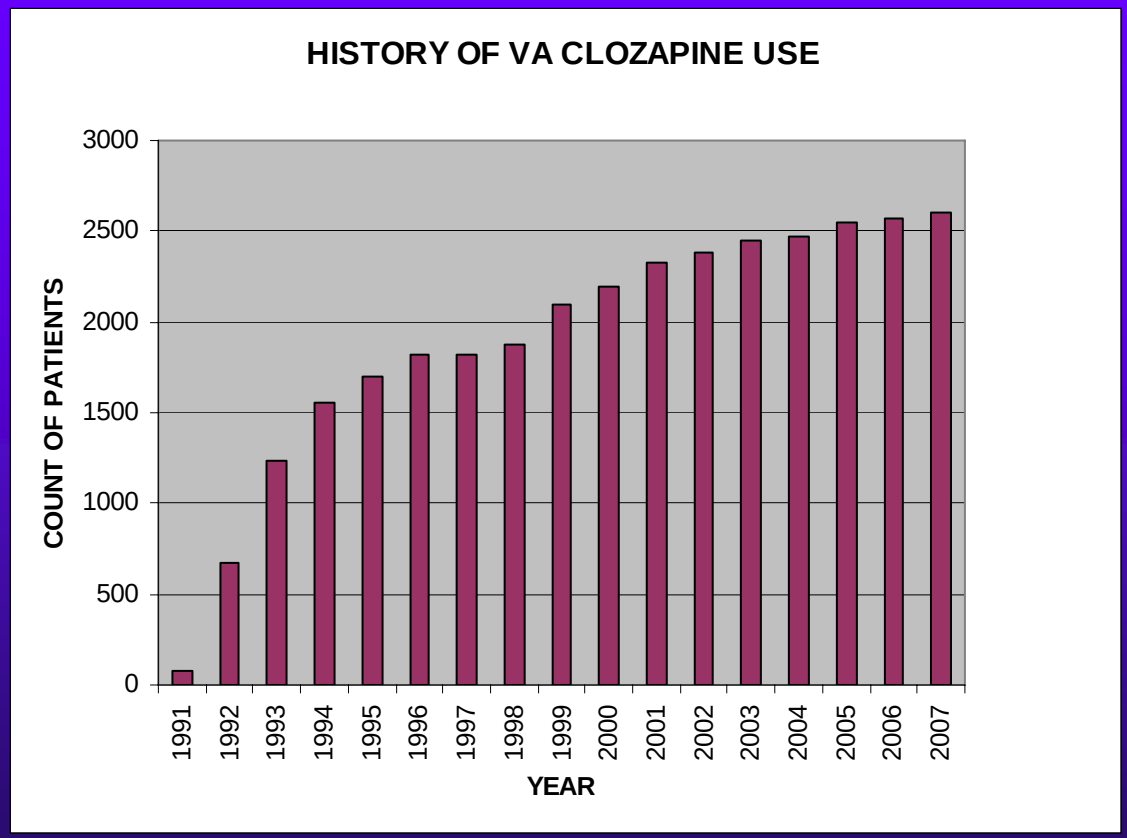
**July 29, 1999**

**CLOZAPINE PATIENT MANAGEMENT PROTOCOL (CPMP)**

a. The Department of Veterans Affairs (VA) National Clozapine Coordinating Center (NCCC) will prepare a list of active clozapine patients whose records in the VA database meet the FDA criteria for white blood count (WBC) testing every-other-week. In order to qualify, a clozapine patient must have a WBC sample drawn and tested once each week for at least 6 months. All of these samples must produce "acceptable" results (WBC count > 3000 per cubic millimeter ($mm^{3)}$ and absolute neutrophil count (ANC) > $1500/mm^3$). Qualification will be made electronically, based on data available at the NCCC, and separate lists will be prepared for each active clozapine site.

(1) Do Not, Under Any Circumstances, Permit a Prescription for Clozapine to be Based on a White Blood Cell Count More than 6 Days Old. Overrides of the current Pharmacy computer safety interlocks for this purpose are not acceptable. The Chief of Psychiatry or the designated Chief of the Clozapine Treatment Team may authorize an override only when administrative problems prevent an acceptable WBC count (< 6 days old) from being entered into the laboratory computer. Each override must be fully documented by the pharmacist coding the override. Full justification must be provided to the NCCC at any time. The FDA and Novartis Pharmaceuticals are also following such information.

# Clozapine Use




Gary Ripper, VA National Clozapine Coordinating Center

# Processes

- Program stops dispensing at point of Rx if does not meet parameters.
- Overall, data aggregated by electronic means (less than 50%) and fax (about 45%)
- VA is generally meets 95% compliance with FDA requirements for a single week.
  - January (2007) initial compliance at 88%.

# Evidence-Based Practices

Evidence and Prescribing

# New Molecular Entities

- National Monograph (review)
  - VA PBM
- Develop evidence-based criteria
- Implementation
  - Regional Committees (VISN)
  - Local Pharmacy & Therapeutics Committees
    - Prior authorization
    - Non-formulary request

# Monograph: Example



National PBM Drug Monograph
**Lenalidomide (Revlimid®)**
July 2006
VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel

**Executive Summary:**

**Efficacy**:

- Lenalidomide is an analogue of thalidomide. It is an immunomodulatory drug that inhibits proinflammatory cytokines, stimulates T-cell proliferation and NK cell activity, has antiangiogenic activity, and pro-apoptotic activity is some cell lines
- It metabolism has not been fully studied, but 2/3 of the drug is eliminated in the urine.
- In vitro studies with human liver cell lines indicate that lenalidomide is not affected by, does not inhibit or induce cytochrome P450 isoenzymes and therefore there is little chance for a drug interaction with this metabolizing pathway.
- Lenalidomide was studied in a single-arm, open label, multicenter study (003) in patients with myelodysplastic syndrome with a del 5q cytogenetic abnormality who were RBC transfusion dependent.
- In addition, patients had low or intermediate-1 risk IPSS scores.
- Lenalidomide, given at 10mg daily for 21 days every 28 days or 10mg daily eliminated transfusion dependence in 64% of patients for a median duration of 52 weeks.

**Safety**:

- A large percentage of patients experienced adverse events.
- The most common adverse events were neutropenia, thrombocytopenia, and infections.
- The most serious adverse events were neutropenia and thrombocytopenia
- Up to 80% of patients required at least one dose interruption or dose reduction during therapy
- A Black Box warning for 1) teratogenicity 2) neutropenia and thrombocytopenia and 3) deep vein thrombosis and pulmonary embolism are contained in the package insert.

**Recommendations**:

- Lenalidomide produces substantial benefit by eliminating RBC transfusion dependence in a large percentage of patients with MDS and a del 5q cytogenetic abnormality but with a large risk for and adverse event.
- Lenalidomide should not be added to the national formulary at this time. Criteria for use include patients with transfusion-dependent myelodysplastic syndrome with a deletion (5q) cytogenetic abnormality.

# Criteria: Within Document

Criteria for Use include:

1. Low or Intermediate-1 risk transfusion-dependent Myelodysplastic Syndrome with a deletion (5q) cytogenetic abnormality
2. ECOG performance 0-2

N.B. Use in Low or Intermediate-1 risk transfusion-dependent Myelodysplastic Syndrome patients without a deletion (5q) cytogenetic abnormality must take into account the lower hematologic response rate and lack of published data. In these cases the patient and prescriber should weigh the benefits and risks versus alternative therapies.

Exclusion Criteria:

1. Baseline ANC < 500/mcL or platelets <50,000/mcL
2. Baseline serum creatinine > 2.5 g/dL
3. Pregnant or lactating female
4. Nutritional anemia (uncorrected)
5. Ongoing thrombosis

# Criteria for Use: Novoseven

**RECOMMEND FOR CONSIDERATION (Quality of Evidence/Strength of Recommendation)**

rFVIIa may be considered in the following situations:

- **Intracerebral hemorrhage** (1B-one study) **IF**: (All criteria must be met)
  a. Symptom onset <4 hrs
  b. Glasgow Coma Scale >5
  c. No plan for surgical evacuation within 24 hrs
  d. No history of thrombotic or vaso-occlusive disease (nonstatistical increase in serious thromboembolic events in the rFVIIa group vs. placebo 7% vs. 2%, respectively)

**RECOMMEND AGAINST USE (Quality of Evidence/Strength of Recommendation)**
(Because of a lack of data and/or data demonstrating ineffectiveness or harm)

rFVIIa should NOT be utilized in the following situations: (Because of lack of benefit or harm)

- **Cessation of variceal bleeding/prevention of variceal rebleeding in patients with cirrhosis** (1B-one study showing no benefit in bleeding cessation, rebleeding or death at 24 hrs or 5 days)

Surgery:

- **Preoperative use (at first incision) in major liver resection** (1A-two studies showing no reduction in RBC transfused)
- **Preoperative (at first incision) and/or planned perioperative use in orthotopic liver transplantation** (1A-two studies showing no reduction in RBC transfused)
- **Preoperative use (at first incision) in patients undergoing major reconstructive surgery for pelvic or pelvic-acetabular fracture** (1B-one study showing no reduction in transfusion of blood products or number transfused)

rFVIIa use is UNCLEAR in the following situations. The lack of evidence suggests use should be considered only when standard/conventional treatments have been exhausted or proven ineffective.

- **Reversal of prolonged prothrombin time (PT) prior to invasive procedures** (e.g. liver biopsy) **in patients with liver disease** (3C- three case series, no control group, unknown effectiveness in bleeding after procedure)
- **Reversal of anticoagulation** (3C-No trials comparing rFVIIa with FFP and/or vitamin K for reversal of excessive anticoagulation with warfarin. As for fondaparinux, there is one study in healthy, nonbleeding volunteers. The benefit/risk ratio of rFVIIa in bleeding patients due to fondaparinux is unknown).
- **Other Hereditary Coagulation Disorders/Platelet Function Defects** (3C-unknown effectiveness, no controlled trials)
  a. Consider only after standard treatments have proven inadequate and/or patient has developed inhibitors to clotting factors.

# Simple Prescribing Scenario

- Provider at health center requests Rx
- Reviewed by local P&T or delegated person(s)
- Assure it meets criteria (or is granted an exemption)
- Prescribing continues per regulations and any local procedures (e.g., specify a timeframe)

# Smart Prescribing

Technology and Prescribing

# Smart ePrescribing

- Concept of using available technology and resources to improve and guide clinicians
- Goal is to improve overall prescribing:
  - Efficacy
  - Safety
  - Monitoring
  - Outcomes
- Applicability for RISKMAPs?

# Directing Pharmaceutical Choice Using ePrescribing Technology

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Jeffrey Sayers PharmD (Chief of Pharmacy)
VA Greater Los Angeles Healthcare System
2004 (updated 2007)

# CPRS Technology Circa 2004

- Primary objective is to guide appropriate, safe and cost-effective drug choice.
- Options for “smart” prescribing are somewhat limited by technology.
- However, current technology can be used in a variety of ways to assist clinicians.

# Types of Options

- Consult Menu Utilization
- Medication Utilization Templates
  - Developed at Baltimore VA (Sylvan DeLisle)
- Clinical Reminder Technology
- Basic Template
  - Pop-up
  - Display Restrictions/Guidelines
- Quick Order and Decision Trees
  - Non-interactive
  - Simple
  - Complex

# Consult Menu

- Useful for non-formulary and prior authorization medications
- Templates can be specific or generic
- Point and click technology
- Can incorporate discrete laboratory information, documented ADEs, and other extractable information from CPRS/VISTA
- Interrupts prescribing process so must be used with discretion

# Example: Cilastozol Template

Reason for Request: CILOSTAZOL

Please refer to the link(s) below for guidelines.

Pharmacy Guidelines for Cilostazol

RESTRICTED TO VASCULAR SERVICE ONLY

1. Diagnosis:
   - ○ Claudication due to Peripheral Arterial
   - ○ Disease (PAD)
   - ○ Other:

2. Eligibility Screening:

   Inclusion Criteria:

   a. Diagnosis of claudication by vascular surgeon: *○ Yes ○ No

   b. PAD only known reason for walking limitation: *○ Yes ○ No

   c. Please explain other reason(s) for limitation:

   Exclusion Criteria:

   a. History of congestive heart failure: *○ Yes ○ No

   b. History of pulmonary edema: *○ Yes ○ No

   c. Ambulation limited by:

      1. Dyspnea: *○ Yes ○ No

      2. Angina: *○ Yes ○ No

      3. Fatigue: *○ Yes ○ No

      4. Neuromuscular disorders: *○ Yes ○ No

   d. Renal Failure (creatinine >3.0): *○ Yes ○ No

* Indicates a Required Field | Preview | OK | Cancel

# Clinical Reminder Technology

- Already available at all VA's through CPRS
- Can trigger on, for example, medication and laboratory tests
  - e.g., can check if patient on atypical antipsychotic has had lipid profile within 6 months
- Must be used selectively due to provider burden and informatics expertise
- Does not provide real-time advice while prescribing but is helpful at subsequent visits to guide providers on important items.

# Clinical Reminder Screen for Pain Medication

an provide link
o guidance or
olicy

Options for clinicians

Reminder Resolution: Pain Medication Use Agreement

A yearly pain management agreement is needed for patients who have received 5 opioid prescriptions in the past 6 months and/or who have received more than 500 tablets of those agents in the past 3 months. This should now be done by using the CPRS progress note template entitled, "Pain Management Agreement". This will resolve the reminder for 1 year. Patients with terminal illness (e.g., due to malignancy) are excluded from this process.

View Pain Contract Policy

- ( ) Patient agrees to initiate a contract regarding use of pain medication. A separate note titled Pain Management Contract Note will be initiated.

  NOTE: This reminder will not resolve until the PAIN MANAGEMENT CONTRACT note is written.
- ( ) Contract already established in medical record.
- ( ) No pain management agreement necessary as expected additional opiod use is expected to be less than 3 months.
- ( ) Patient has terminal illness and does not require a contract.
- ( ) Patient refuses to initiate pain medication contract.

Clear | Clinical Maint | Visit Info | < Back | Next > | Finish | Cancel

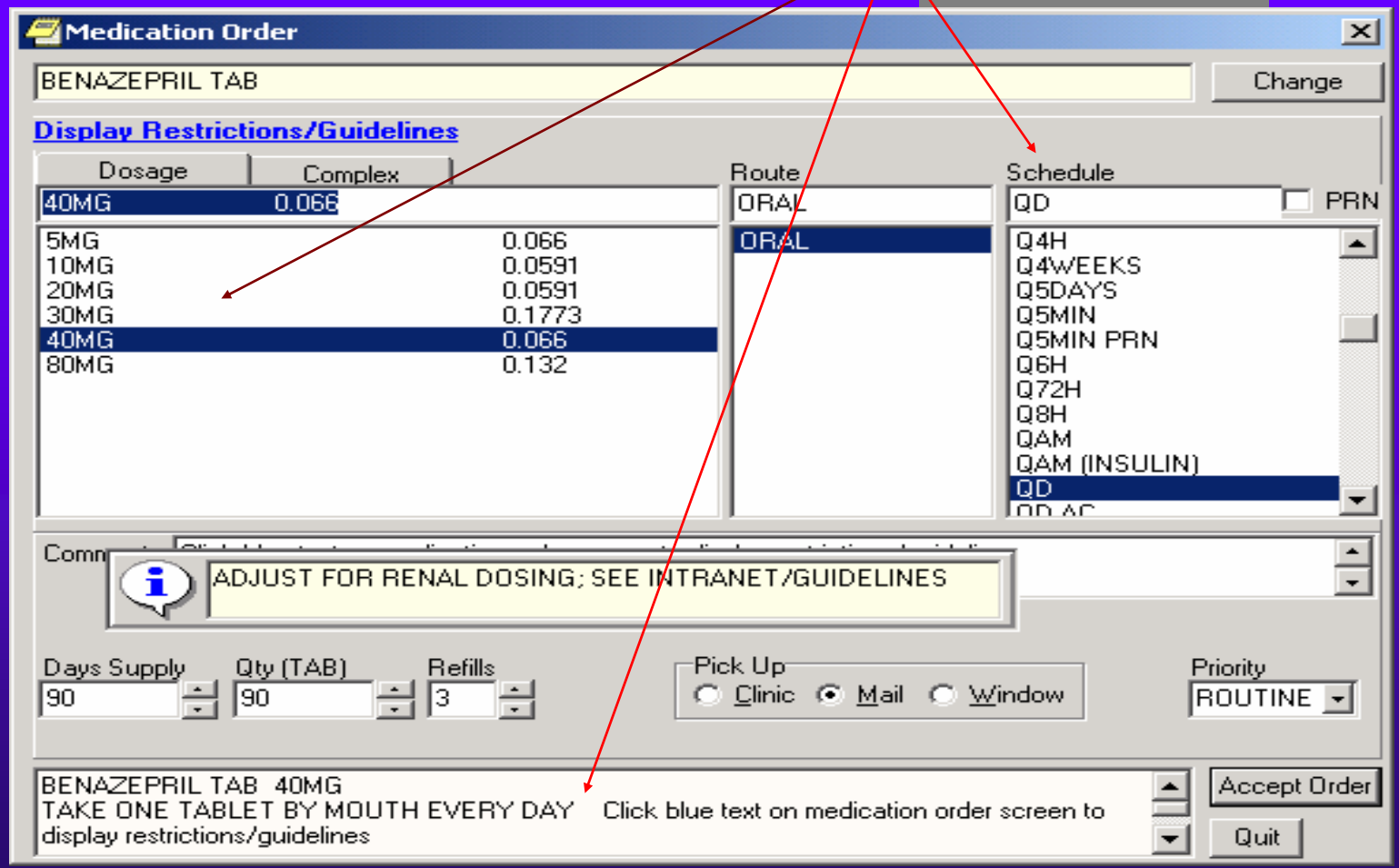
<No encounter information entered>

# Basic Prescribing Template

- Three options for providing information:
  - Adding in default dosing and other labeling
  - Using Pop-up Box to give brief statement
    - Limited to 64 characters
  - Utilizing Display Restrictions/Guidelines
    - Click option, can display substantial text

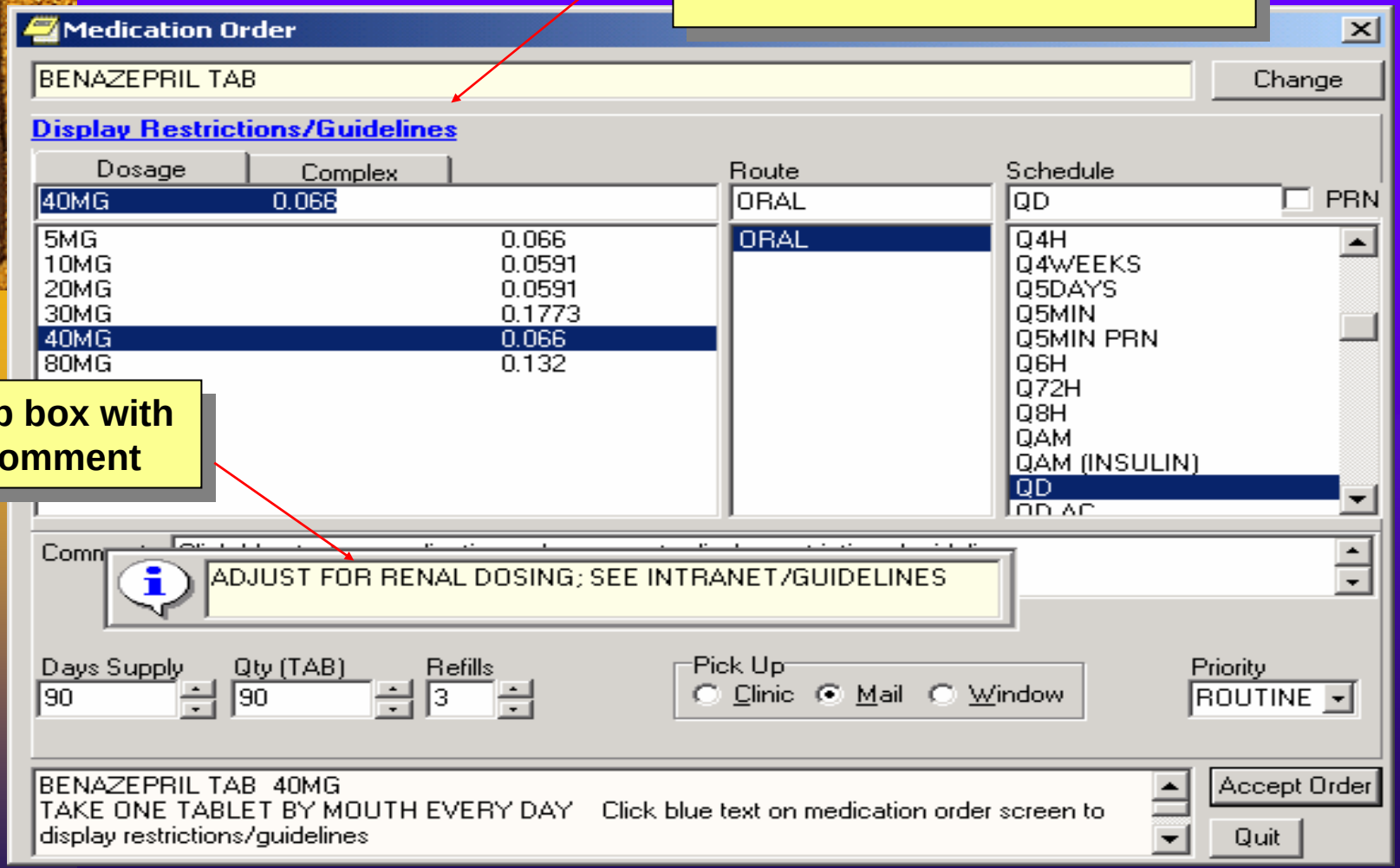
# Benazepril Template

Default dose, schedule, route and labeling



# Pop-Up Box and Display Restrictions/Guidelines

**Click here for displaying information (see next slide)**




**Pop-up box with brief comment**

# “Display Restrictions/Guidelines”

**Content can include short or extensive text** – closing box returns prescriber to template

Restrictions/Guidelines

Initial dosing:

| CREATININE CLEARANCE | INITIAL DOSE |
|---|---|
| greater than 60 mL/minute | 10 mg |
| 30 to 60 mL/minute | 10 mg |
| 10 to 30 mL/minute | 5 mg |
| less than 10 mL/minute | 5 mg |

Maintenance dosing:

| GFR (mL/minute) | Percentage of normal dose | Interval |
|---|---|---|
| over 50 | 100% | QD |
| 10 to 50 | 50%-75% | QD |
| under 10 | 25%-50% | QD |

* Maximum dose for renally-impaired patients is 40mg QD

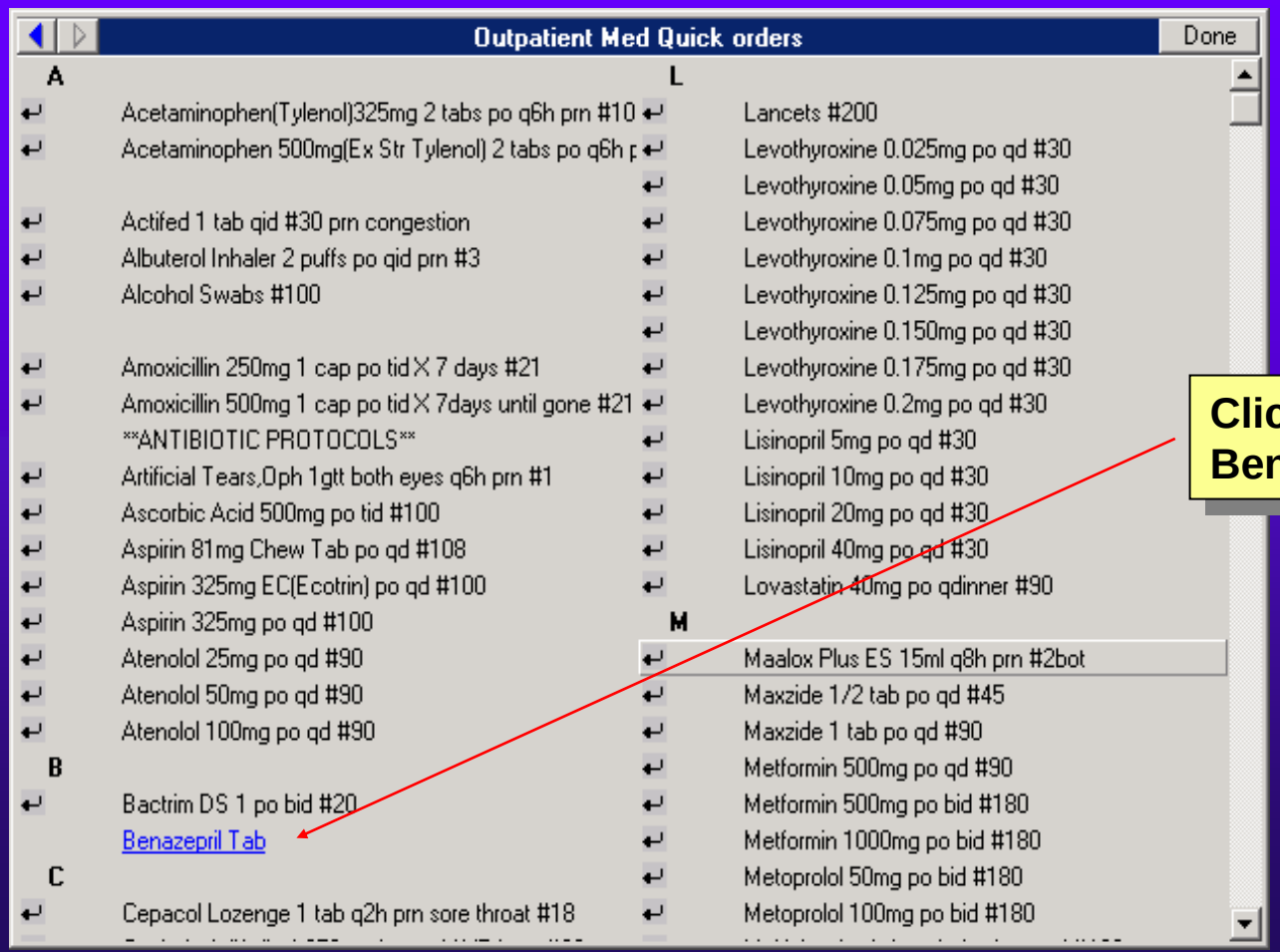
If you have any questions, contact a pharmacist.

Print Close

# Quick Orders

- Can be used in a variety of ways to guide prescribing:
  - Information only
  - simple or complex decision trees
  - checklists
- Minimizes prescriber burden
- Useful for commonly used drugs
- Can remove orderable item from list, assuring that quick orders must be used

# Quick Order Screen




**Click on Benazepril**

# Non-Interactive Quick Order: Warning for Benazepril

**This displays first when quick order for benazepril is clicked.**

Reason for Request: BENAZEPRIL TAB

Click blue text on medication order screen to display restrictions/guidelines

| CREATININE CLEARANCE | INITIAL DOSE |
|---|---|
| greater than 60 mL/minute | 10 mg |
| 30 to 60 mL/minute | 10 mg |
| 10 to 30 mL/minute | 5 mg |
| less than 10 mL/minute | 5 mg |

Maintenance dosing:

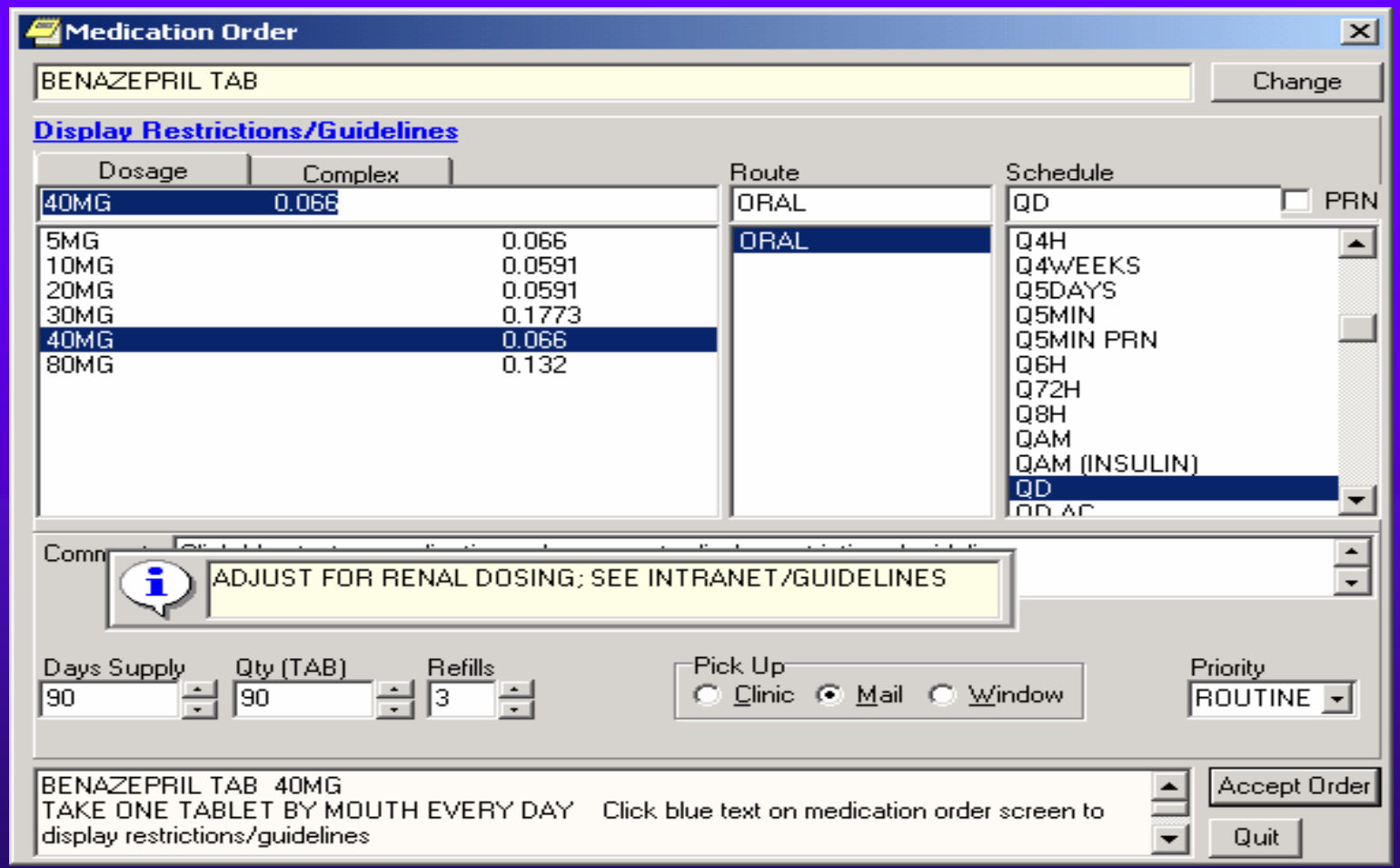
| GFR (mL/minute) | Percentage of normal dose | Interval |
|---|---|---|
| over 50 | 100% | QD |
| 10 to 50 | 50%-75% | QD |
| under 10 | 25%-50% | QD |

* Maximum dose for renally-impaired patients is 40mg QD

* Indicates a Required Field | Preview | OK | Cancel

**Clicking "OK" brings provider back to order template (next slide)**

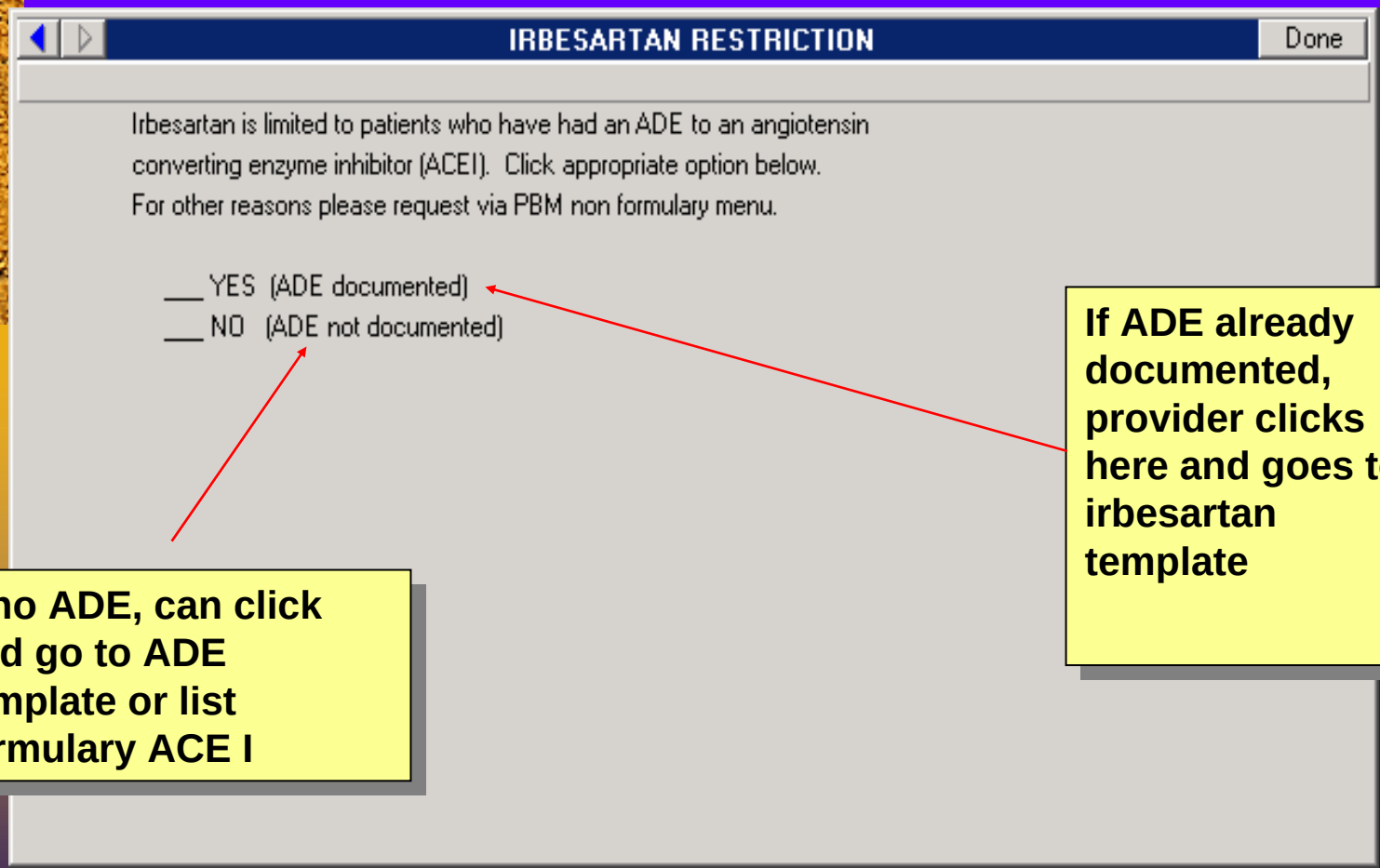
# Benazepril Template



# Quick Order: Simple Decision Tree

- Useful for two-step processes
- Relatively easy to build
- Guides but does not substantially slow prescribing process

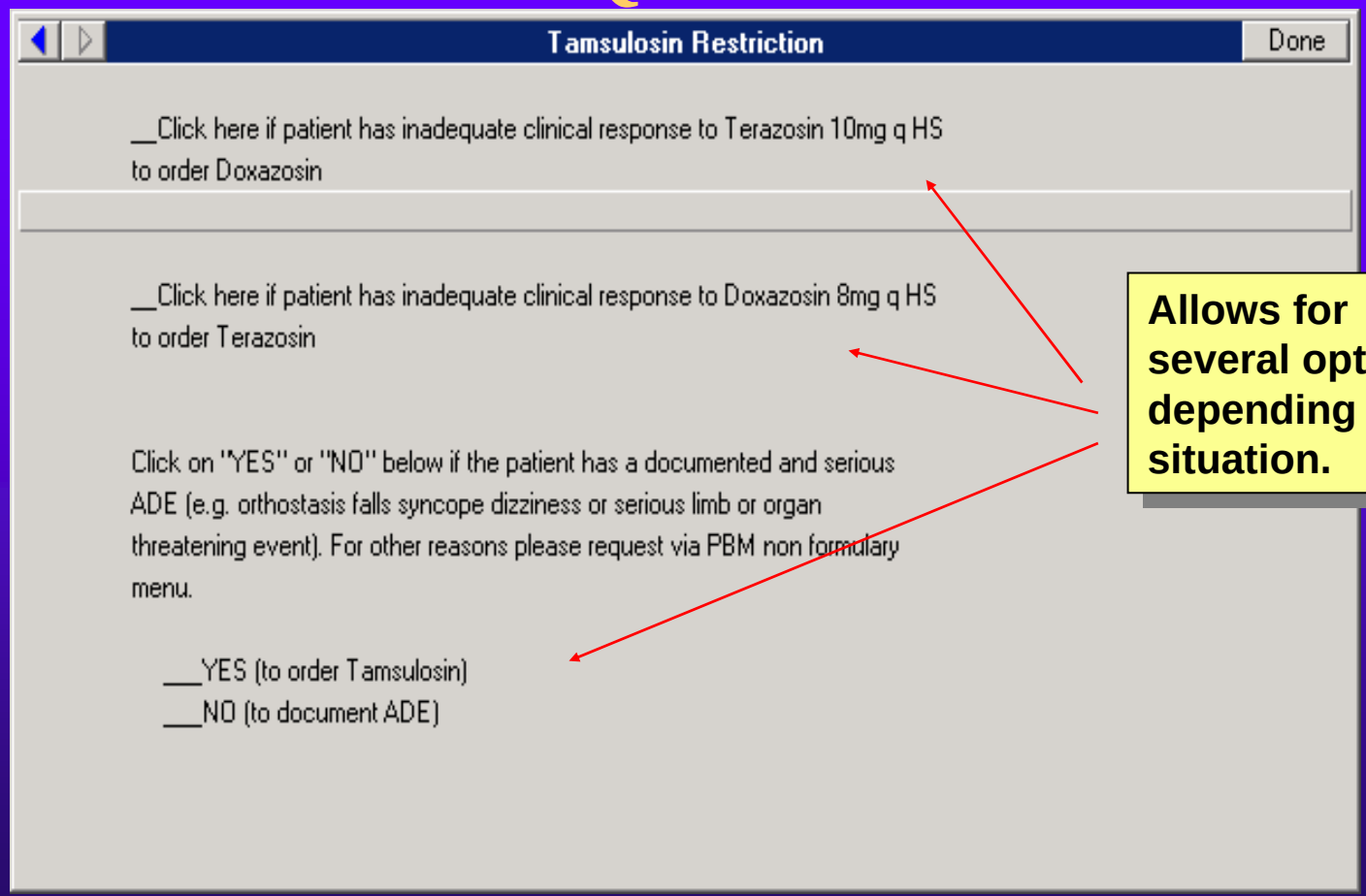
# Simple Decision Tree: Quick Order for Irbesartan




**If ADE already documented, provider clicks here and goes to irbesartan template**

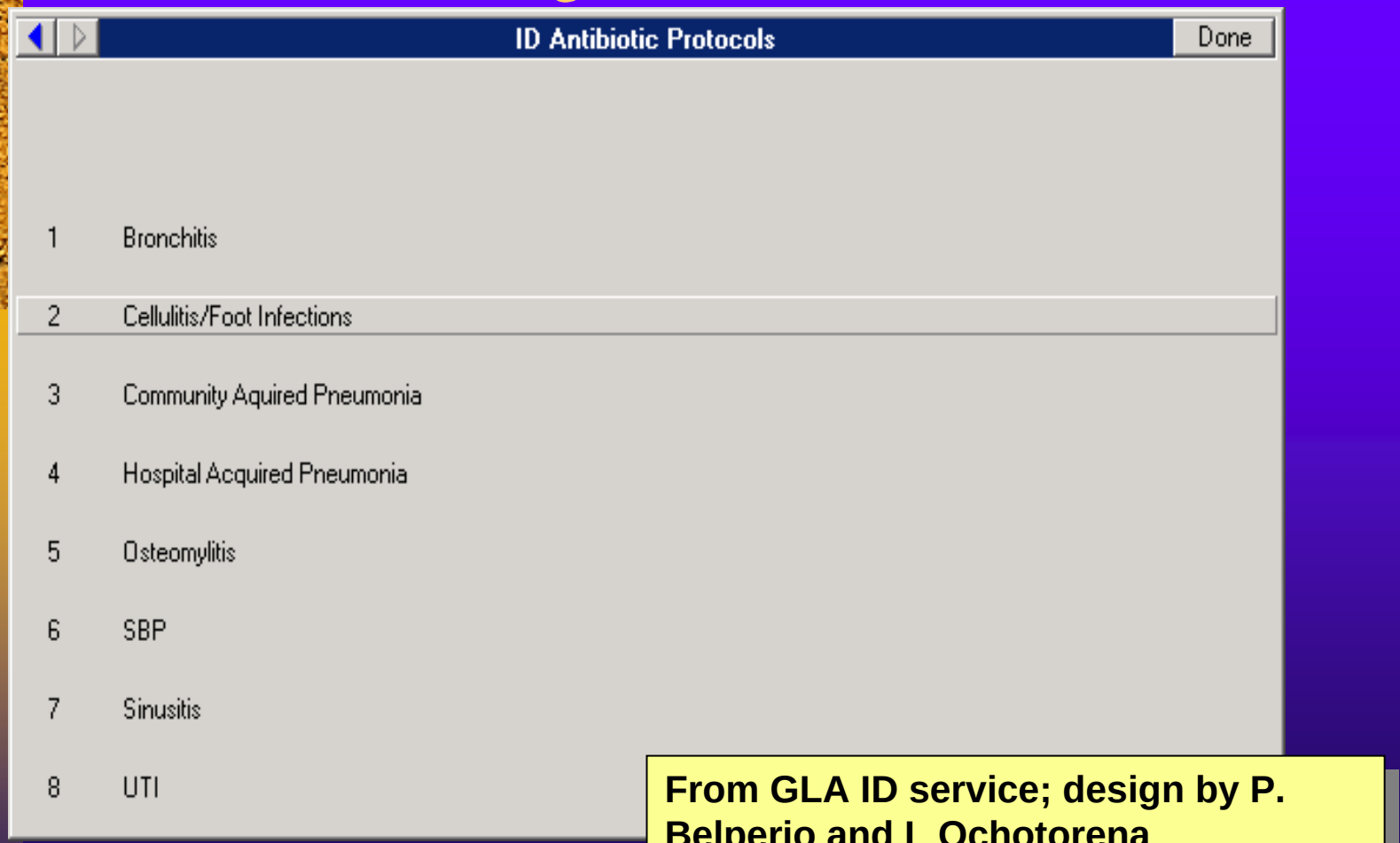
**If no ADE, can click and go to ADE template or list formulary ACE I**

# Decision Trees: Tamsulosin Quick Order



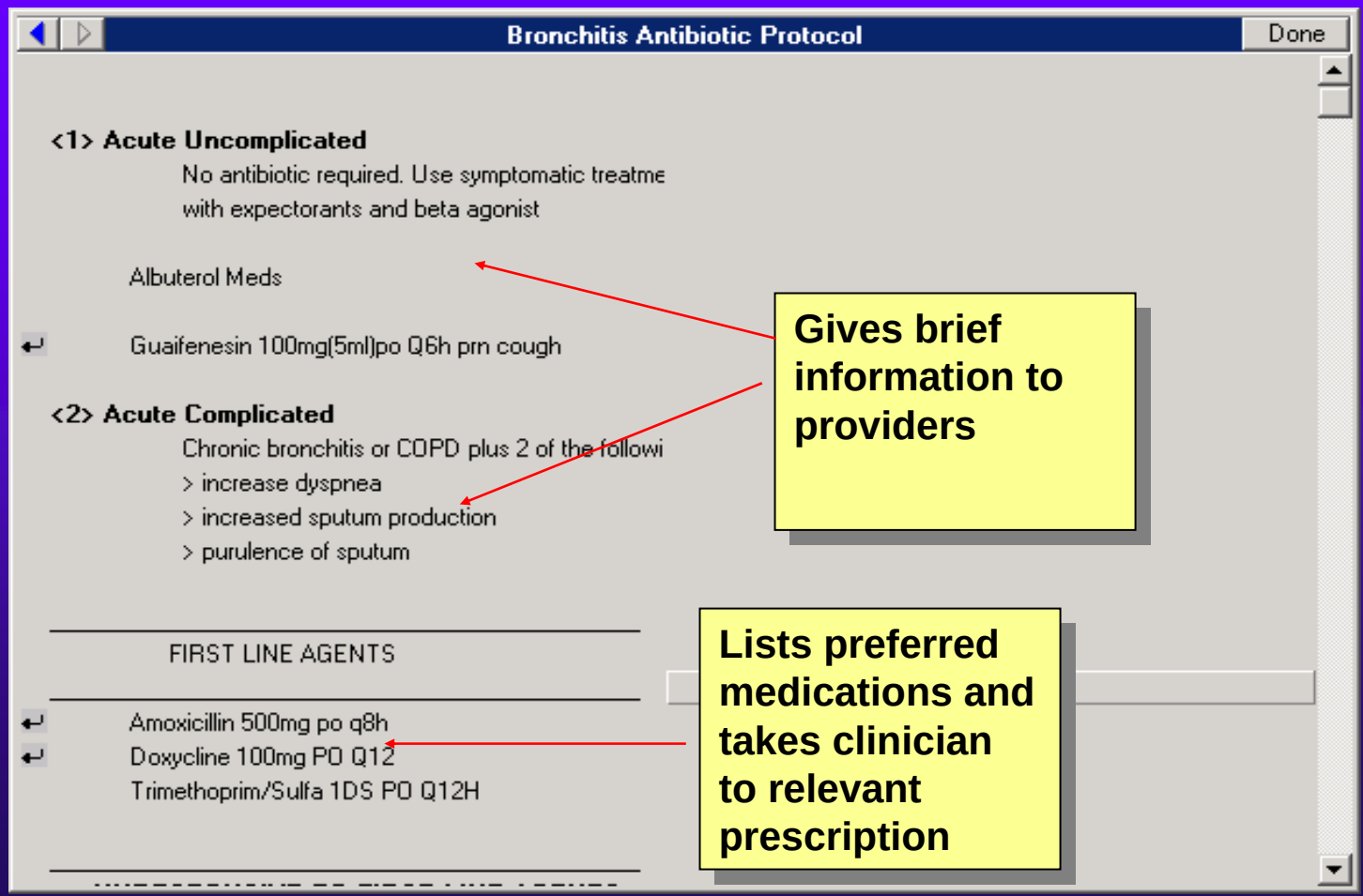

**Allows for several options, depending on situation.**

# Complex Decision Trees: Antibiotic Quick Order Screen




**From GLA ID service; design by P. Belperio and L Ochotorena**

# Order Screen: Bronchitis



# Order Screen: Bronchitis

**Lists when other medications can be used, if needed. Clicking on drug opens prescribing template**

Outpatient Bronchitis Antibiotic Protocol

Done

**<1> Acute Uncomplicated**

No antibiotic required. Use symptomatic treatment with expectorants and beta agonist

Albuterol Meds

Guaifenesin (alcohol/sugar free) 5ml qid prn #240ml

**<2> Acute Complicated**

Chronic bronchitis or COPD plus 2 of the following

> increase dyspnea
> increased sputum production
> purulence of sputum

FIRST LINE AGENTS

Amoxicillin 500mg tid x10d
Doxycycline 100mg bid x 10d
Bactrim DS bid #20

**UNRESPONSIVE TO FIRST LINE AGENTS**

Amoxicillin/Clavulanate 875mg PO q12h X14D

If patient allergic to PENICILLIN

Moxifloxacin 400mg PO QD
___Click for QT Warning

# Quick Order Checklists: Amiodarone for PCPs

**Lists items required for prescribing and which can, if desired, be checked by local pharmacists**

**Reason for Request: AMIODARONE TAB**

TAKE WITH FOOD FOR IRREGULAR HEART RHYTHM

*☐ I will read/I have read guidelines on Amiodarone use
(click on blue "Display Guidelines/Restrictions" on order template)
*☐ Indication is for maintinaing NSR in patients with hx of AFib
(for any other arrhythmias, refer to Cardiology)
*☐ Baseline Pulmonary Function Tests have been completed and are on file
*☐ DLCO is >20% (If DLCO is <20%, refer to Cardiology)
*☐ Baseline chest X-Ray is on file (or has been reviewed/reported)
and has no pulmonary fibrosis
*☐ Pt. does not have new onset dyspnea or worsening dyspnea
(if so, consult Guidelines)
*☐ TSH has been done in past 6 months
(if TSH indicates hyperthyroidism--DO NOT ORDER--Consult Cardiology)
(if TSH high, consult Guidelines)
*☐ LFT's have been done in past 6 months
(for abnormal LFT's, consult Guidelines)

Prescribe no more than 6-months supply

* Indicates a Required Field | Preview | OK | Cancel

# Amiodarone Template

**Guidelines are available to prescribers by clicking here**

Medication Order

AMIODARONE TAB

Change

Display Restrictions/Guidelines

Dosage | Complex

| | |
|---|---|
| 100MG | 0.07475 |
| 200MG | 0.1495 |
| 300MG | 0.22425 |
| 400MG | 0.299 |

Route: ORAL

Schedule: QD — PRN

Q5MIN PRN
Q6H
Q72H
Q8H

Comments: TAKE WITH FOOD FOR IRREGULAR HEART RHYTHM

Days Supply: 30 | Quantity: 30 | Refills: 5

Pick Up: Clinic | Mail | Window

Priority: ROUTINE

Patient Instruction

-TAKE WITH FOOD

AMIODARONE TAB 200MG
TAKE ONE TABLET BY MOUTH EVERY DAY -TAKE WITH FOOD TAKE WITH FOOD FOR IRREGULAR HEART RHYTHM

Accept Order

Quit

# Quick Order Checklist: Vardenafil Quick Order

**Can use to reinforce safety issues**

**Reason for Request: VARDENAFIL TAB**

```
LIMIT 4 DOSES/MONTH
NOTE: Statements with * must be selected before the pharmacy will fill
prescription.
------------------------------------------------------------------
*☐ -Provider is, or note is cosigned by, authorized prescriber.
*☐ -Pt not on any nitrates from the VA or other Provider.
*☐ -Pt not at high risk of receiving nitrates emergently.
*☐ -Annual liver and renal function tests are in CPRS or current progress note.
*☐ -Patient does not have aortic stenosis
*
☐ -If patient is on alpha blocker, reviewed with and counseled patient on concurrent use
*☐ -Patient has been counseled on the potential for sudden vision loss.
*
    ○ Patient currently on Vardenafil
    ○ Patient never taken Vardenafil start at 10mg and titrate as needed
    ○ Patient >65 years or on alpha-blocker start at 5mg and titrate as needed
------------------------------------------------------------------
```

* Indicates a Required Field  Preview  OK  Cancel

# Questions?

# Consult Menu for Restricted Drugs