

Implementation of Risk Minimization  
Action Plans to Support Quality Use of  
Pharmaceuticals: Opportunities and  
Challenges: A Public Workshop  
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# Right Drug for the Right Patient at the Right Time

# Reminder Systems

“We recommend that tools in the reminder systems category be used in addition to tools in the targeted education and outreach category when targeted education and outreach tools are known or likely to be insufficient to minimize identified risks.

Tools in this category include **systems that prompt, remind, double-check or otherwise guide healthcare practitioners and/or patients in prescribing, dispensing, receiving, or using a product in ways that minimize risk.** Examples of tools in this category are as follows:

- **Patient education** that includes acknowledgment of having read the material and an agreement to follow instructions. These agreements are sometimes called *consent forms*.
- Healthcare provider training programs that include testing or some other **documentation of physicians' knowledge and understanding.**
- **Enrollment of physicians, pharmacies, and/or patients in special data collection systems that also reinforce appropriate product use.**
- Limited number of doses in any single prescription or limitations on refills of the product.
- Specialized product packaging to enhance safe use of the product.
- **Specialized systems or records that are used to attest that safety measures have been satisfied** (e.g., prescription stickers, physician attestation of capabilities).”

# Performance-Linked Access Systems

“Performance-linked access systems include systems that **link product access to laboratory testing results** or other documentation. Tools in this category, because they are very burdensome and can disrupt usual patient care, should be considered only when (1) products have significant or otherwise **unique benefits in a particular patient group or condition**, but **unusual risks** also exist, such as irreversible disability or death, and (2) **routine risk minimization measures**, targeted education and outreach tools, and reminder systems are known or **likely to be insufficient** to minimize those risks.

Examples of tools in this category include:

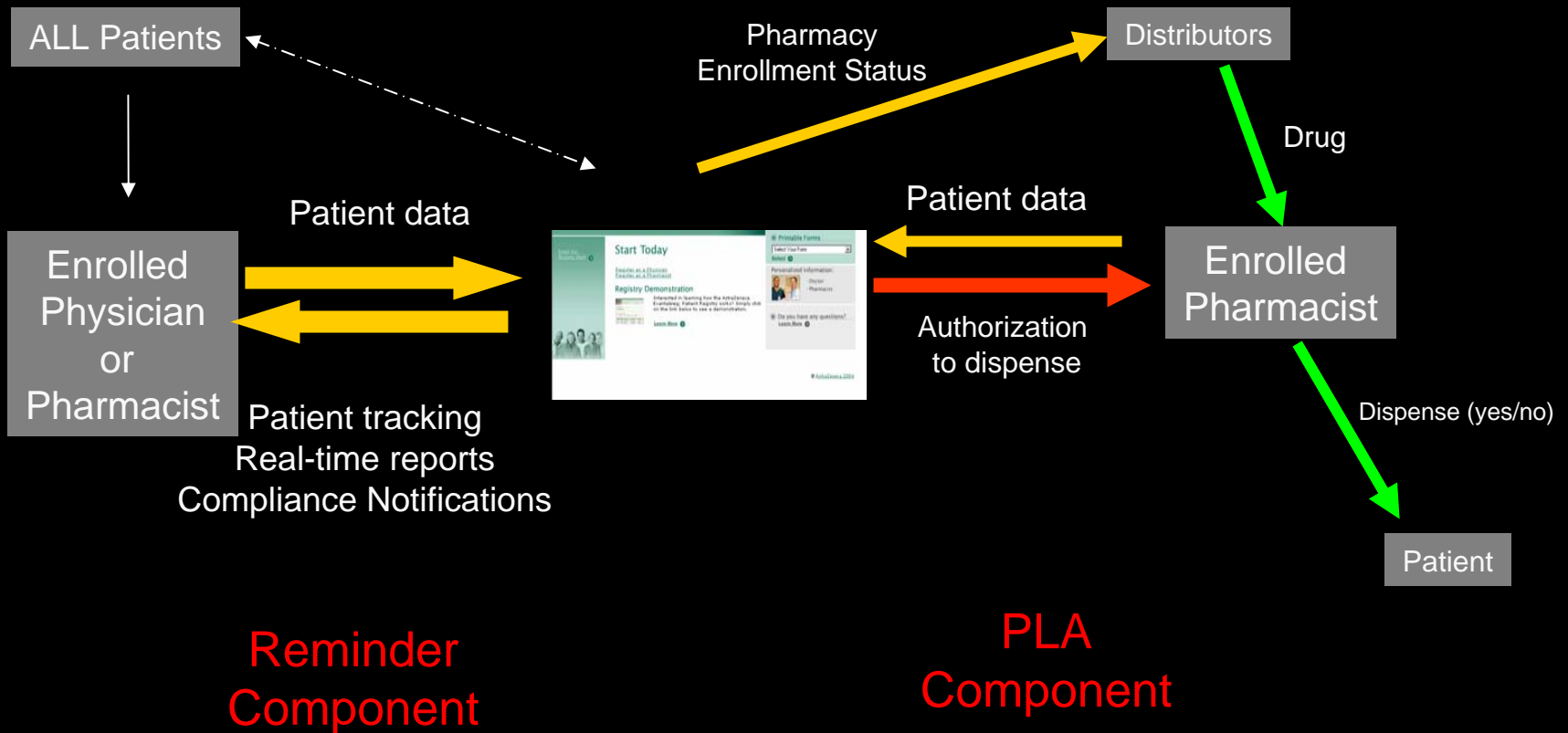
- prescription only by specially **certified** healthcare practitioners

- product dispensing limited** to pharmacies or practitioners that elect to be **specially certified**

- product dispensing only to patients with evidence** or other documentation of **safe-use conditions** (e.g., lab test results)

Performance-linked access systems should seek to avoid unnecessary or unintended restrictions or fragmentation of healthcare services that may limit access by physicians, pharmacists, or patients, or that may lead to discontinuities in medical or pharmacy care.”

# Patient Registry RiskMAP System Diagram With Reminder and Performance Linked Access (PLA) Components



# Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors

David W. Bates, MD; Lucian L. Leape, MD; David J. Cullen, et al. *JAMA*. 1998;280:1311-1316.

**Objectives.**— To evaluate the efficacy of 2 interventions for preventing nonintercepted serious medication errors, defined as those that either resulted in or had potential to result in an ADE and were not intercepted before reaching the patient.

**Design.**— Before-after comparison between phase 1 (baseline) and phase 2 (after intervention was implemented) and, within phase 2, a randomized comparison between physician computer order entry (POE) and the combination of POE plus a team intervention.

**Interventions.**— A physician computer order entry system (POE) for all units and a team-based intervention that included changing the role of pharmacists, implemented for half the units.

**Main Outcome Measure.**— Nonintercepted serious medication errors.

was compared with the POE plus team intervention combined, the team intervention conferred no additional benefit over POE.

**Conclusions.**— Physician computer order entry **decreased the rate of nonintercepted serious medication errors by more than half**, although this decrease was larger for potential ADEs than for errors that actually resulted in an ADE.

## Improving residents' compliance with standards of ambulatory care: results from the VA Cooperative Study on Computerized Reminders.

Demakis JG, Beauchamp C, Cull WL, et al. JAMA. 2000;284:1411-1416

CONCLUSIONS: Our data indicate that reminder systems installed at multiple sites can improve residents' compliance to multiple SOC. **The benefits of such systems, however, appear to deteriorate over time.** Future research needs to explore methods to better sustain the benefits of reminders.

“alert fatigue”

# Recommendations

- ♦ Standardization of RiskMAPs and a scalable, RiskMAP technology model based on open interchange standards
  - ♦ Scalable to accommodate a larger number of personalized medicines
  - ♦ Utilize disparate health information systems by being standards based
  - ♦ Centralized processing
    - ♦ Computational complexity, changing elements, multiple targets for information outputs, etc.
    - ♦ Patients move between systems of care



# Recommendations

- ◆ Potential roles for AHRQ and FDA
  - ◆ Collaboratives to improve definitions of “risk” and to fine tune the conceptual framework for RiskMAPs
  - ◆ Evaluate the relative effectiveness of different RiskMAP systems in different situations and improve definitions of “success”
  - ◆ Demonstration project towards establishing an open standards RiskMAP technology model