Product Launches

Mitigate Challenges with Timely Product Availability in the e-Rx/EHR Systems
Session Objectives

- Understand drug product knowledge and the time it takes for a new product to become available in an e-Rx/EHR system
- Analyze the drug product flow for gaps which contribute to the delay in new drug product knowledge at the point of prescribing
- Discuss forces which create hurdles for launches of medications that are not available in e-Rx/EHR systems
- Investigate internal and external opportunities to minimize the delay of product availability in the e-Rx/EHR systems
The Situation
Challenge at Product Launch

- Getting the drug on formulary

- Getting drugs in the EHR

- Getting the drug on formulary
For over a decade the Federal Government has influenced ePrescribing and Medication Management

- **HIPAA**
  Established transaction standards

- **MMA**
  Established Medicare Part D, ePrescribing standards and pilots

- **PQRI**
  Provides ePrescribing Incentives

- **MIPPA**
  Provides ePrescribing Incentives

- **ARRA/MU**
  Provides Incentives for EHRs and includes ePrescribing criteria

- **Affordable Care Act**
  Establishes ACO pilots, HIX, health insurance mandate, payment reform

- **EPCS Allowed**
  The DEA’s interim final rule for ePrescribing of Controlled substances passes

Timeline:
- 1995
- 2000
- 2005
- 2010
- 2015
ePrescribing is now a Standard of Care

Today, 79% of physicians are prescribing electronically¹

By 2018, 90% of physicians will be prescribing electronically²

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¹ ONC Health IT Dashboard, Quick Stat #9, through 2013
² Letter from CBO to Hon. Henry Waxman, Chairman, Committee on Energy & Commerce, January 2008
ePrescribing has evolved to be much more than an electronic prescription writer.

Enables transference of information and decision-making from the point of dispensing to the point of prescribing potentially increasing: formulary compliance, generic dispensing, and changes in prescriptions at the point of care due to interaction alerts.
Most ePrescribing Occurs within EHRs

Ideal ePrescribing Software Features within an EHR

- Generates a medication list
- Select medications, transmit prescriptions, respond to refill requests and conduct safety checks electronically
- Customize DUR alerts based on user’s preferences
- Provide eligibility-informed formulary data, medication history, and prior authorization requirements electronically from the patient’s drug plan.
- Provide mail-order eligibility information and ability to transmit to mail-order electronically
- Ability to handle ePrescribing of controlled substances (EPCS)
- Import diagnosis codes and other relevant medical information from the EMR into electronic prescription
Two types of information exist in EHR

- Drug knowledge content are provided by the Drug Compendia
- Health plans and PBMs provide formulary information to EHR vendors

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What is included in drug compendia?

- Drug information including:
  - Drug monographs (including warnings)
  - Strengths
  - Forms
  - Route of administration
  - Packaging
  - Patient instructions/SIG (optional)

- Clinical decision support (Drug Utilization Review)
  - Drug–drug interactions
  - Drug–allergy warnings
  - Drug–diagnosis warnings
  - Dose warnings

This drug content promotesPatient safety measures
Drug Product Knowledge Flow into eRx/EHR Systems

Further complicating the matter:

Some EHRs don’t use a national compendia.
Typical Timelines for Drug Knowledge update in eRx/EHR

- **Automatic Update**
  - Month 1: Subscribe
  - Month 2: Process
  - Month 3: Release
  - Month 4: Practice Download
  - Month 5: Install
  - Month 6: Practice Download

- **Typical Practice- Triggered Update**
  - Month 1: Subscribe
  - Month 2: Process
  - Month 3: Release
  - Month 4: Practice Download
  - Month 5: Install

- **Worst Case- Quarterly Updates/ Practice Triggered**
  - Month 1: Subscribe
  - Month 2: Process
  - Month 3: Release
  - Month 4: Practice Download
  - Month 5: Install

**Drug data subscription varies among EHR vendors from weekly to quarterly**

**3 step process for eRx/EHR**
- Subscribe
- Process
- Release

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Why is the information that appears sometimes confusing?

- Rx process has changed from freeform text to select/structured fields
- Dosing is often on dose/form vs dose/route
- Non-tablet drugs can be an issue because many systems were designed for tablet prescriptions
  - Liquids and inhalers are not clear
  - Creams and pre-packaged products have had issues
  - Requirements for quantities are confusing to calculate
- Presentation of medication does not appear as a provider is used to writing/prescribing
Why does drug information take so long to appear?

- **eRx/EHR Systems**
  - Every update process takes resources
  - Older technology in some EHRs includes batch processes
  - Haven’t heard issues from users

- **Practice Sites**
  - Inconsistent drug content updating among practice sites
  - Quirks with system updates

- **Physician familiarity of technology**
  - Not all physicians know the full capabilities that their systems can provide
Meaningful Use certification has become a priority on all EHR software companies leaving other improvements on hold.

Extra development costs and requirements put a strain on priorities that ultimately prevent:
- Improvements in usability (due to limited resources)
- Update improvements (due to an Inability to improve/upgrade infrastructure)

Pressure to invest to gain more physician users during the last stages of the ‘land grab’
Practice Triggered Sites Process and Issues

When practices must perform their own updates, there are potential issues:

Technology is constantly improving, and the practice may not have the latest and greatest

Practices are sometimes constrained by resources — either having enough or having those with the right skills

It may not always be clear to practices why having the latest version of core data is critical
Physician familiarity of System Capabilities

- Physicians and practice managers are not demanding EHR services around automatic product updates or more timely updates leading to
  - Practices not prescribing the missing drug
  - Practices stating they cannot write a paper script due to meaningful use
Potential Solutions
Potential Solutions

1. Engage stakeholders to improve/upgrade the process & technology

2. Advance Patient Safety Objectives

3. Prepare for and Address Challenges Proactively
Engage stakeholders to improve/upgrade the process & technology

- Identify & Engage the appropriate key stakeholders
  - MDs, EHRs, compendia, intermediaries, Standards Organizations
  - Bring it up with your trade organizations, ie PhRMA

- Propose sustainable practices and technology for timely updates in EHRs
  - EHR charging pharma fees to upgrade
    - Is this unsustainable?
    - Is it setting a precedent?
    - What are alternative options for pharma?
Advance Patient Safety Objectives

- Identify opportunities within current Government Policies to emphasize the benefit of drug updates to patient safety and access to medicines
  - Explore Meaningful Use, Standards, Certification, Quality Measures
  - Push industry to go from dose/form to dose/route
- Emphasize potential patient safety improvement opportunities of having frequent updates
  - Ensure that we are not creating two standards of care for patients by drugs/drug information not being available in the e-system
- Raise awareness through Whitepapers and published research
  - Use a published study to press for standards and/or regulations
  - NCPDP is developing a white paper ‘Prescribable Medication Information at Point of Care to Support Patient Safety White Paper’ to raise awareness around the gaps and patient safety issues
Prepare for and Address Challenges Proactively

- Manufacturers need to understand how product data and other reference information is communicated between parties
- New product launches need to incorporate these new e-challenges into their launch strategy
  - Sales ability to discuss with practices the need for current drug information and need for updated information
- Have resources to assist sales representative with questions from practices
  - Guide conversations reps have with practices
  - Timetable to id when the new product will appear in the EHR
  - Helpdesk to take questions from the field
  - Instructions to add a product at the practice
Internal Keys for a Successful Launch from an EHR Perspective

1. Pre-launch activity to prepare
   - Know the customers, systems and issues
   - Prepare material to support the launch
2. Train on issues and reactions
   - Provide information specific to the EHR
3. Stay in formation
   - Structured question mechanism and responses
   - Address issues fast
4. Sales leadership buy in
   - Memorable tools change behavior
5. Marketing leadership buy in
   - EHR discussion don’t take away from the HCP sales call
6. EHR use is about improving the quality of care
   - Enable the quality of care
7. Encourage patient engagement
   - Use existing materials during and after the visit
8. Adapt to formulary issues
   - Trap issues on formulary quality to identify root causes
   - Understand formulary display and quality information
Prepare for Issues with Added EHR Capabilities

Virtually all sales messages need to be adjusted for the EHR world:

- Understand of Clinical Decision Support in EHRs and the need to configure capabilities at a practice level
- Using EHRs for clinical improvement initiatives to increase quality-based care
- Discussion guides customized to product quality objectives to improve outcomes in Integrated Delivery Networks and other large practices
- Electronic Prior Authorization landscape
- Formulary and contract issues and evaluation
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