Biologics and Biosimilars Access and Traceability

Point·of·Care PARTNERS | HEALTH IT MANAGEMENT CONSULTANTS

Project Overview

- **Summary:** In-depth research and review of Biologics and Biosimilars as it relates to **Healthcare Information Technology (HIT)**

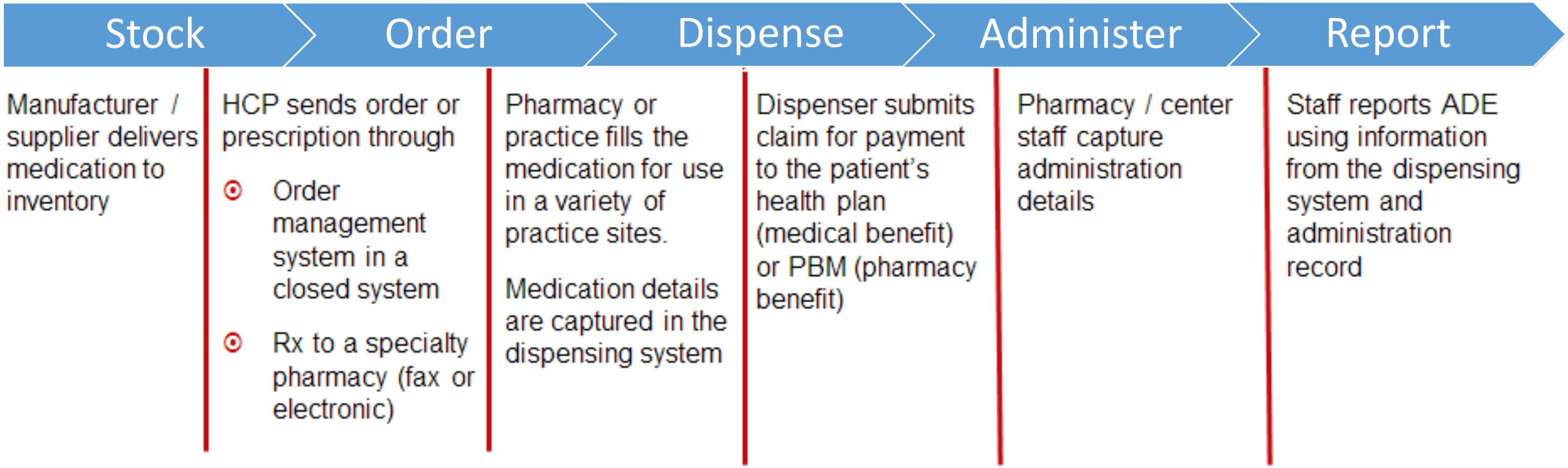
- **Goal:** Develop **Best Practices** for information and data flows for electronic prescribing and patient records for Biologics and Biosimilars

- **Project Deliverables:**
  - Information Scan
  - Stakeholder Research and In-Depth Interviews and Discussions
  - Standards Research
  - Legislative Research

Key Findings

- Enhancing the ability to trace outcomes back to biologics/biosimilars requires **alignment of multiple stakeholders,** all of whom hold patient safety in high regard but have a limited exposure to biologics/biosimilars
- Any efforts moving forward must be considered against a **prevailing mindset among many stakeholders to treat competitor biologic products exactly like multisource, single molecule drugs**
- There are workflows and processes that can be adapted to trace outcomes to biologics/biosimilars such as the tracking, tracing and reporting of vaccines, discontinuation of prescription and reporting and connecting to prescription drug monitoring programs*. There is also legislation (DSQA/DSCSA) that can be leveraged. However, **regulations or legislation will be required to compel EHR users to report ADEs**
- The mapping of relevant information flows overlaid by existing standards reveals that **batch/lot # and manufacturer need to be added to a number of NCPDP and HL7 standards, and recorded in EHRs.** There is also a need for improved reporting of ADEs, some of which are being piloted.
- For biologics/biosimilars not administered in the practice, there are two transactions that could support getting this information back into the EHR – Medication History and RxFill. Of those, **RxFill has fewer challenges.**

Information flows: Across all channels follow a flow



Information flow details and transactions to support patient care varies by the medication requirements for administration and payers requirements

Information flows: Ambulatory Clinic

Stock

Manufacturer / supplier delivers to the pharmacy that supplies the ambulatory clinic

Data standard

Per DQSA / Drug Supply Chain Security Act provisions

Content includes

- Manufacturer
- NDC
- batch/lot number

Order

a) Clinic EHR transmits patient-specific order to the supplying pharmacy

Data standard

SCRIPT 10.6 NewRx

Content includes

Med name, strength, dose form, route

Med ID at brand + formulation level (Representative NDC, RxNorm)

b) Clinic orders med to stock. Manual or proprietary process

Dispense

a) Dispense details transmitted to prescriber's EHR

Data standard

SCRIPT 10.6 RxFill

Content includes

Mfr., brand, NDC

batch/lot # (New std.)

b) Med detail printed on package incl. mfr. brand name

Data standard

GS1 (proposed)

Content includes

GS1 barcode representing GTIN, batch/lot#

Textual name, NDC, batch/lot#

Administer

Clinic staff capture administration details

Content includes

- Reference to dispensed med
- Admin date/time
- Amount administered

Report

Clinic staff reports ADE using med information transmitted electronically from the dispensing system or printed on package

Data standards

- Current FAERS: ICH E2B(M)
- Future: ICH E2B(R3) / HL7 ICSR R3

Content includes

- Mfr., NDC, batch/lot number
- Admin dates / times
- Amts. administered

Information flows: Specialty Pharmacy, Infusion Center

Stock

Manufacturer / supplier delivers to the specialty pharmacy or infusion center

Data standard

Per DQSA / Drug Supply Chain Security Act provisions

Content includes

- Manufacturer
- NDC
- batch/lot number

Order

Clinic transmits order to the pharmacy via manual or proprietary electronic process

Data standards

- NCPDP use limited: NewRx
- Manual / fax process for most specialty orders

Content includes

- Med name, strength, dose form, route. Med ID at brand + formulation level

Dispense

Specialty pharmacy or infusion center readies the med for onsite administration.

Medication details are captured in the dispensing system

Data standards

- NCPDP RxFill from dispenser to EMR

Content includes

- Dispensed NDC
- Mfr., brand name
- **batch/lot number** (proposed addition to NCPDP RxFill)

Claim

Pharmacy submits to:

- Health plan * (X12 837/835) or
- PBM (NCPDP D.0)

* Claims interactions with the health plan are outside the ADE solution flow

Administer

Pharmacy / center staff capture administration details

Content includes

- NDC, brand name, mfr., lot
- Admin date/time
- Amt. administered
- PBM (NCPDP D.0)

Report

Staff reports ADE using information from the dispensing system and administration record

Data standards

- Current FAERS: ICH E2B(M)
- Future: ICH E2B(R3) / HL7 ICSR R3

Content includes

- Mfr., NDC, batch/lot number
- Admin dates / times
- Amts. administered

Information flows: Hospital

Stock

Manufacturer / supplier delivers to the hospital pharmacy

Data standard

Per DQSA / Drug Supply Chain Security Act provisions

Content includes

- Manufacturer
- NDC
- batch/lot number

Order

Hospital EHR transmits order to the hospital pharmacy

Data standard

- HL7 v2.x OMP or ORM

Content includes

- Med name, strength, dose form, route
- Med ID at brand + formulation level (Representative NDC, RxNorm)

Dispense

Pharmacy transmits dispensed med details to EHR and electronic med admin rcd (eMAR)

Data standard

- HL7 v.2x RDS and RGV

Content includes

- **- Actual dispensed NDC**
- **- batch/lot #**
  (proposed: increase adoption of existing HL7 elements)

Administer

Nurse captures administration details in eMAR, which transmits admin details to EHR

Data standard

HL7 v.2x RAS

Content includes

- **- Actual administered NDC & batch/lot #**
  (proposed: increase adoption of existing HL7 elements)
- Admin. amt., time

Report

Hospital staff reports ADE using information from the dispensing system and administration record

Data standards

- Current FAERS: ICH E2B(M)
- Future: ICH E2B(R3) / HL7 ICSR R3

Content includes

- Mfr., NDC, batch/lot number
- Admin dates / times
- Amts. administered

Information flows: Self Administered

Stock

Manufacturer / supplier delivers to the retail or mail service pharmacy

Data standard

Per DQSA / Drug Supply Chain Security Act provisions

Content includes

- Manufacturer
- NDC
- batch/lot number

Order

Clinic EHR transmits order to the retail or mail service pharmacy

Data standard

SCRIPT 10.6 NewRx

Content includes

- Med name, strength, dose form, route
- Med ID at brand + formulation level (Representative NDC, RxNorm)

Dispense

a) Dispense details transmitted to prescriber's EHR

Data standard

SCRIPT 10.6 RxFill

Content includes

Mfr., brand, NDC

batch/lot # (New std.)

b) Med detail printed on package

Data standard

GS1 (proposed)

Content includes

GS1 barcode representing NDC, batch/lot#

Mfr., brand, NDC, batch/lot#

Admin.

Patient administers the medication at home

Report

a) Patient reports online

or b) Patient reports the event to a provider. The provider views med package if present, scans the med package's GS1 barcode if available, and/or consults own system

Data standards

- Current FAERS: ICH E2B(M)
- Future: ICH E2B(R3) / HL7 ICSR R3

Content includes

- Medication info from: package: Mfr., NDC, batch/lot number
- Administration times, amounts

Information flows: Long-term or Post-Acute Care (1)

Scenario One: Medication sourced from LTPAC pharmacy stock

Stock

Manufacturer / supplier delivers to the LTPAC pharmacy

Data standard

Per DQSA / Drug Supply Chain Security Act provisions

Content includes

- Manufacturer
- NDC
- batch/lot number

Order

Facility or clinic EHR transmits order to the LTPAC pharmacy

Data standards

- SCRIPT 10.6 NewRx
  (alternatively, HL7 2.x OMP, or ORM if within same org)

Content includes

- Med name, strength, dose form, route
- Med ID at brand + formulation level (Representative NDC, RxNorm)

Dispense

LTPAC pharmacy transmits dispense details to facility EHR. Facility updates eMAR

Data standards

- SCRIPT 10.6 RxFill
  (alt: HL7 2.x RDS and RGV within same org)

Content includes

- Actual dispensed NDC (reflecting mfr, brand name, form, strength)
- **batch/lot #**
  (proposed add to RxFill; increased adoption of existing HL7 elements)

Administer

Facility staff captures administration details in eMAR, which transmits admin details to EHR. (Or admin is noted in paper records)

Data standard

HL7 v.2x RAS

Content includes

- **Actual administered NDC & batch/lot #**
  (proposed: incr. adoption of existing HL7 elements)
- Amount administered

Report

Facility staff reports ADE using information from the EHR and/or eMAR

Data standards

- Current FAERS: ICH E2B(M)
- Future: ICH E2B(R3) / HL7 ICSR R3

Content includes

- Medication info from: package:
  Mfr., NDC, batch/lot number
- Administration times, amounts

Information flows: Long-term or Post-Acute Care (2)

Scenario Two: Medication obtained from a specialty pharmacy

Stock

Manufacturer / supplier delivers to the specialty pharmacy

Data standard

Per DQSA / Drug Supply Chain Security Act provisions

Content includes

- Manufacturer
- NDC
- batch/lot number

Order

Facility or clinic EHR transmits order to the LTPAC pharmacy

Data standards

SCRIPT 10.6 NewRx (alternatively, HL7 2.x ORM, RDE or OMP if within same org)

Content includes

- Med name, strength, dose form, route
- Med ID at brand + formulation level (Representative NDC, RxNorm)

Dispense

LTPAC pharmacy *obtains the med from a specialty pharmacy (w/ batch/lot # and other details),* delivers and transmits details to facility EHR

Data standards

SCRIPT 10.6 RxFill (alt: HL7 2.x RDS or RGV in same org)

Content includes

- Mfr., brand, NDC
- **batch/lot #** (proposed add to RxFill; increased adoption of existing HL7 elements)

Administer

Facility staff captures administration details in eMAR, which transmits admin details to EHR. (Or admin is noted in paper records)

Data standard

HL7 v.2x RAS

Content includes

- **Actual administered NDC & batch/lot #** (proposed: incr. adoption of existing HL7 elements)
- Admin date/time, amt

Report

Facility staff reports ADE using information from the EHR and/or eMAR

Data standards

- Current FAERS: ICH E2B(M)
- Future: ICH E2B(R3) / HL7 ICSR R3

Content includes

- Medication info from: package: Mfr., NDC, batch/lot number
- Administration times, amounts

Thank you

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