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Enhanced Delivery Options for Injectables

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Agenda for Today's Presentation

- **Global Trends Impacting Parenteral Therapies**
  - Advancing patient care
  - Total healthcare spending
- **Enhanced Delivery Case Studies**
  - Prefilled Syringe Study on Vaccines
  - Vial to Ready-to-Use IV Containers
- **Collaboration Considerations**
  - Effective collaboration management
- **Final Conclusions**

Global Healthcare Concerns

"The basic issues are the same everywhere: ensuring the widest possible access to care; encouraging innovation to improve care and reduce costs: making sure that profit-making parts of the system do not sacrifice patient care to the bottom line."

Source: *Healthcare Reform British Style*, The New York Times, August 4, 2010

Global Healthcare Trends

Moving Patient Care Forward

- Solutions continue to be sought to increase quality of delivery care
- Reduction of medication errors continues to be a global concern
- Impact of healthcare associated infections are an important wide ranging concern
  - 5% of all hospitalizations in the US
  - 8.7% in WHO cooperative study

To improve patient safety in drug therapy and to ensure the highest quality in medical treatment in European hospitals, the General Assembly of the European Association of Hospital Pharmacists, EAHP, demands:

- **The production of single dose-packaged** drugs from the pharmaceutical industry
- The mandatory inclusion of a **barcode** on each single dose

Sources: Hospital-Acquired Infections, eMedicine, July, 20, 2010 Request for the production of single dose-packaged drugs, June 2010, EAHP.

Global Healthcare Trends

Healthcare Spending

- Economic crisis driving austerity measures that could potentially impact national healthcare systems
- Concerns that the aging population will cause increased financial strain
- Increased length of stay due to preventable complications has financial implications

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT OECD

"In all OECD countries total spending on healthcare is rising faster than economic growth, pushing the average ratio of health spending to GDP from 7.8% in 2000 to 9.0% in 2008. Factors pushing health spending up - technological change, population expectations and population ageing - will continue to drive cost higher in the future."

Sources: "OECD Health Data 2010", OECD.29/6/10, Healthcare Reform British Style, The New York Times, August 4, 2010, Keeping German Doctors on a Budget Lowers Costs, NPR, July 2, 2008,

Moving Along…

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  - Advancing patient care
  - Total healthcare spending
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Case Study: Prefilled Syringe

- **Conducted by The Johns Hopkins University Bloomberg School of Public Health**
- **A study comparing Prefilled Syringes vs. Vials in the Preparation of Vaccines in a Clinic Setting**
- **Findings were presented at the World Vaccine Congress in April 2010, Washington DC**

Source: Originally presented at the World Vaccine Congress presentation. April 20, 2010. Presented by Dr. David Bishai, MD, MPH, PhD Johns Hopkins University Bloomberg School of Public Health. Research conducted by Dr. Bishai and Claudia Pereira, PhD, MS

Case Study: Prefilled Vaccine

Motivation for Study:

- A clinic's choice of pre-filled syringes vs. multi-dose vials affects work flow
  - To determine the time differences spent on the different vaccine presentations
  - To determine the resulting economic impact of different vaccine presentations

Overall Study Goals:

- **Primary:** To measure time and labor costs of influenza vaccination administered via pre-filled syringes vs. multi-dose vials
- **Secondary:** To observe adherence to and deviations from best practices in the preparation of vaccines

Previous Research: This has been previously been studied, but outside the US:

- France: Detournay et al., 1998
- Canada: Scheifele et al., 2000
- Japan: Kuroyama, 2009

Method: Observation during the 2009-2010 influenza campaign

- in 7 clinics, observing 39 Healthcare Workers preparing over 1,000 injection preparations

Vaccine Preparation Steps

Vaccine packaging and delivery systems will impact the vaccination administration process.

Vial & Disposable Syringes

1. Uncap vaccine vial
2. Swab stopper with swab
3. Unwrap syringe
4. Unwrap needle
5. Assemble needle to syringe
6. Inject needle into vial
7. Draw vaccine into syringe
8. Assure accurate dosage drawn
9. Passively recap needle
10. Remove needle from syringe and dispose
11. Unwrap new needle and assemble onto syringe
12. Inject vaccine into patient

Manufacturer Prefilled Systems (MPFS)

1. Remove prefilled syringe cap
2. Unwrap needle,
3. Assemble needle to prefilled syringe
4. Inject vaccine into patient

Results: Tasks and Time for Vials and PFS

Vial Tasks

Remove vial from box	2.07
Unpack syringe	11.43
Split needle packs	1.77
Attach fill needle	4.20
Expose stopper	0.36
Sterilize vial	4.32
Fill/Measure from vial	6.81
Unwrap new needle	2.27
Affix new needle	4.20
Uncap/cap/dispose	10.79
Write tracking #	1.49
TOTAL:	49.71

Total Time = 49.71 (A)

Common Tasks

Don gloves	0.87
Vaccine from fridge	1.25
Open box of needles	1.15
Split needle packs	1.77
Unwrap one needle	2.27
Tidy up	1.33
TOTAL:	8.64

Pre-filled Tasks

Open PF box (5 or 10)	1.61
Remove tracking #	1.19
Attach PF to needle	4.20
Uncap/dispose	5.42
TOTAL:	12.42

Total Time = 12.42 (B)

Difference between MDV and PFS (A-B) = 37.29 Seconds

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Results: Administration Costs

For 1,000 doses	MDV			PFS		
Resources	**Units**	**Price $**	**Total US$**	**Units**	**Price US$**	**Total US$**
Staff Time (Hrs)	13.81*	$35.75/Hr	493.71	3.45**	$35.75/Hr	123.34
Syringe	1000	0.39/unit	390.00	N/A	N/A	N/A
Needles	2000	0.31/unit	620.00	1000	0.31/unit	310.00
Alcohol	1000	0.03/unit	30.00	N/A	N/A	N/A
Gloves	1000	0.08/unit	80.00	1000	0.08/unit	80.00
Storage (doses/month)	1000	0.00045/unit	0.45	1000	0.0044/unit	4.40
Total			$1,614.16			$517.74
Difference	**$1,096 per 1000 doses**					

*Time units exclude mutual tasks to facilitate calculations
**Excludes the acquisition cost of vaccine

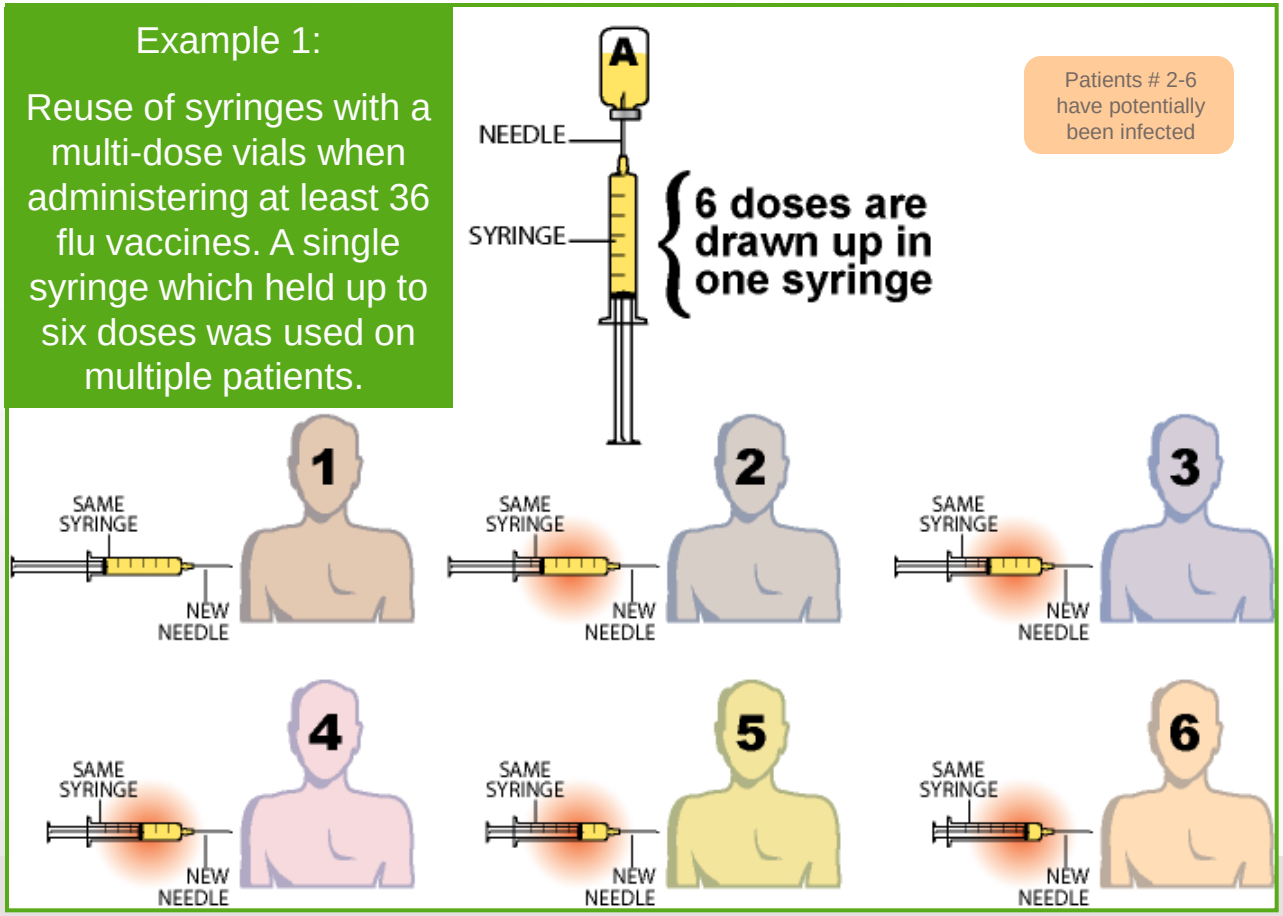
Implications: Vaccine Pricing Impact and Filling Costs on Clinics

- **Using pre-filled syringes would save $1.10 per dose in administration costs if the price per dose of flu vaccine was the same**
  - A vaccine packaged in a PFS priced $1.10 higher than a vial has the same net cost to deliver to patient
  - Savings is lower if health worker salaries and needle costs are lower; higher if the opposite is true.
- **Actual prices vary when considering list and market pricing with PFS ranging from $0 to $3.50 higher than vials**
- **Implications of 37.29 second gap:**
  - American birth cohort of 4 million infants encounters about 15 shots before age 1
    - Pre-filled syringes would save 621,500 person hours worth $22.2 million in health worker time
  - In a pandemic where 300 million Americans required vaccination
    - Pre-filled syringes would save 3.12 million hours worth $111.1 million in health care worker time

Potential for Contamination in Practice

Example 1:

Reuse of syringes with a multi-dose vials when administering at least 36 flu vaccines. A single syringe which held up to six doses was used on multiple patients.



Example 2:

In January 2010, Schofield Elementary School in Wellesley, MA:

- School staff received insulin instead of H1N1 vaccine
- Insulin belonged to a student and was stored in the same refrigerator

January 2008: Dr. E. Jacob Simhaee, Long Island, NY.

[7] Ochs, Ridgely . "Health commissioner wants to ban multidose vials." Newsday. 31 Jan. 2008.<http://www.newsday.com/news/local/suffolk/ny-lifink315558189jan31,1,5552274.story>.

6 Thompson, ND, Perz, JF et al, Nonhospital Healthcare Associated Hepatitis B and C Virus Transmission, United States, 1998- 2009, Annals of Internal Medicine, January 2009, Volume 150, Number 1, pgs 33 – 39

Source: http://multimedia.boston.com/m/28435510/insulin-mistaken-for-h1n1-vaccine-in-wellesley.htm

Study Conclusions

Vaccine Presentation Matters

- In Impacting Clinical Efficiency: It takes more than one extra hour to prepare 100 doses with a Vial vs. a PFS
- In Impacting Clinic Costs: Excluding acquisition costs, vaccines packaged in prefill syringes reduce administration costs by $1.10/dose
- In Minimizing Deviations from Best Practices in Vaccine Preparation: Increased number (+8) of steps results in significant observed deviations from published guidelines on best practices

Enhanced delivery in IV containers also matters . . .

Market Research: IV Ready-to-Use (RTU) Containers

- **2009 Second Consensus Development Conference on the Safety of Intravenous Drug Delivery Systems**
  - US panel convened to evaluate the relative safety and cost of available nonelectronic I.V. drug delivery systems for parenteral medications
- **2009 Study to understand clinical preference of Ready-to-Use (RTU) IV containers**
  - Vial conversion to RTU IV containers, impact on share and pricing strategy
- **Post-patent expiry preference for RTU IV containers**
  - Data over lifecycle of drugs in a ready-to-use IV container
- **2010 panel discussion of RTU supporting Pharmacy objectives**
  - Implementation of RTU increases available time for clinical involvement and patient care

Source: Second Consensus Development Conference on the Safety of Intravenous Drug Delivery Systems, Am J Health-Syst Pharm, Vol. 66 Jan 15, 2009; Enhanced Packaging Study, Eric Marder & Associates, 12/2009; Enhanced Packaging Panel discussion, 8/2010. IMS data, Anti-infective Molecule 6/2010.

Second Consensus Development Conference on the Safety of Intravenous Drug Delivery Systems

Product Type	Benefits	Problems
Manufacturer ready-to-use	• Low risk for contamination • Ease of use and dispensing • Maximum available expiration dating	• Products not available for special populations • Pharmacoeconomic data lacking • Frozen products may require thawing
Outsourced ready-to-use	• Can customize dose for each patient • Lower risk for contamination	• Cost analysis suggested • Requires advance planning and storage
Point of care activated	• Works well with automated cabinets • Maximum available expiration dates	• Products not available for special Populations • Cost analysis suggested • Risk of inactivation errors
Pharmacy Compounded	• Can customize dose for each patient • Significant quality control • Labeled in accordance with hospital standards	• Risk of contamination • Significant operational requirements related to *USP chapter 797*
Non-pharmacy compounded at point of care	• Can customize dose for each patient • Immediate availability	• High potential for error • Low compliance with regulatory requirements • Labeling typically handwritten or absent • Risk of contamination

Source: Second Consensus Development Conference on the Safety of Intravenous Drug Delivery Systems, Am J Health-Syst Pharm, Vol. 66 Jan 15, 2009

Second Consensus Development Conference on the Safety of Intravenous Drug Delivery Systems

Consensus Panel Ranking of I.V. Drug Delivery Systems					
	Manufacturer Ready-to-use	**Outsourced Ready-to-use**	**Point-of Care Activated**	**Pharmacy Compounded**	**Non-pharmacy Compounded at point of care**
Applicability	**4.0**	5.4	3.6	6.7	5.8
Ease of Use	**6.2**	5.5	4.9	3.7	3.6
Regulatory compliance	**6.5**	5.2	6.0	3.5	1.8
Cost	**4.0**	3.4	4.1	3.8	4.9
Safety	**6.0**	4.5	4.6	4.2	1.8
Implementation	**6.0**	4.9	4.7	3.6	2.6
Total	**32.7**	28.9	27.9	25.5	20.5

Manufacturer ready-to-use products ranked the highest of all Drug Delivery Systems

Source: Second Consensus Development Conference on the Safety of Intravenous Drug Delivery Systems, Am J Health-Syst Pharm, Vol. 66 Jan 15, 2009

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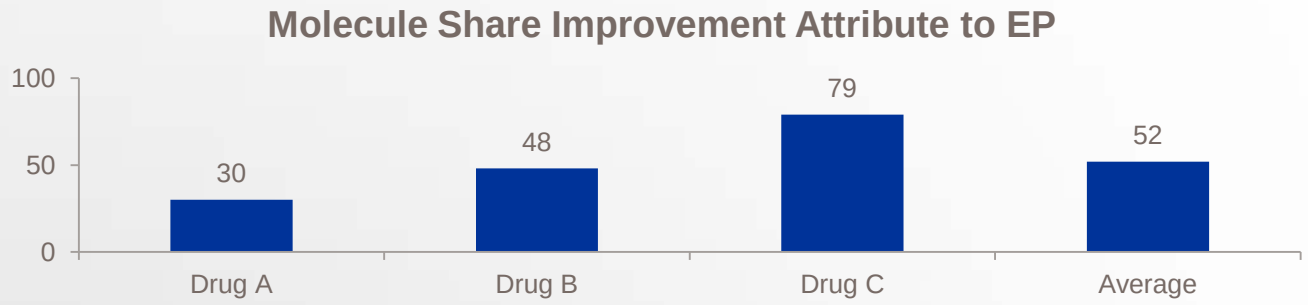
Vial to Ready-to-Use IV Containers

- **Interviews conducted with 450 hospital pharmacists**
  - Participants were required to be involved in hospital formulary decision making
  - Minimum 3 years experience with IV therapy and drug delivery systems
  - Review of all relevant systems to ensure share impact was fully characterized
- **Ready-to-use IV premix was preferred to vial based admixture**
  - Minimum 30% share gain



- **Demand for premix is as strong at a premium as it is at parity to a vial**

Further detailed information available upon request

Source: Enhanced Packaging Study, Eric Marder & Associates December 2009

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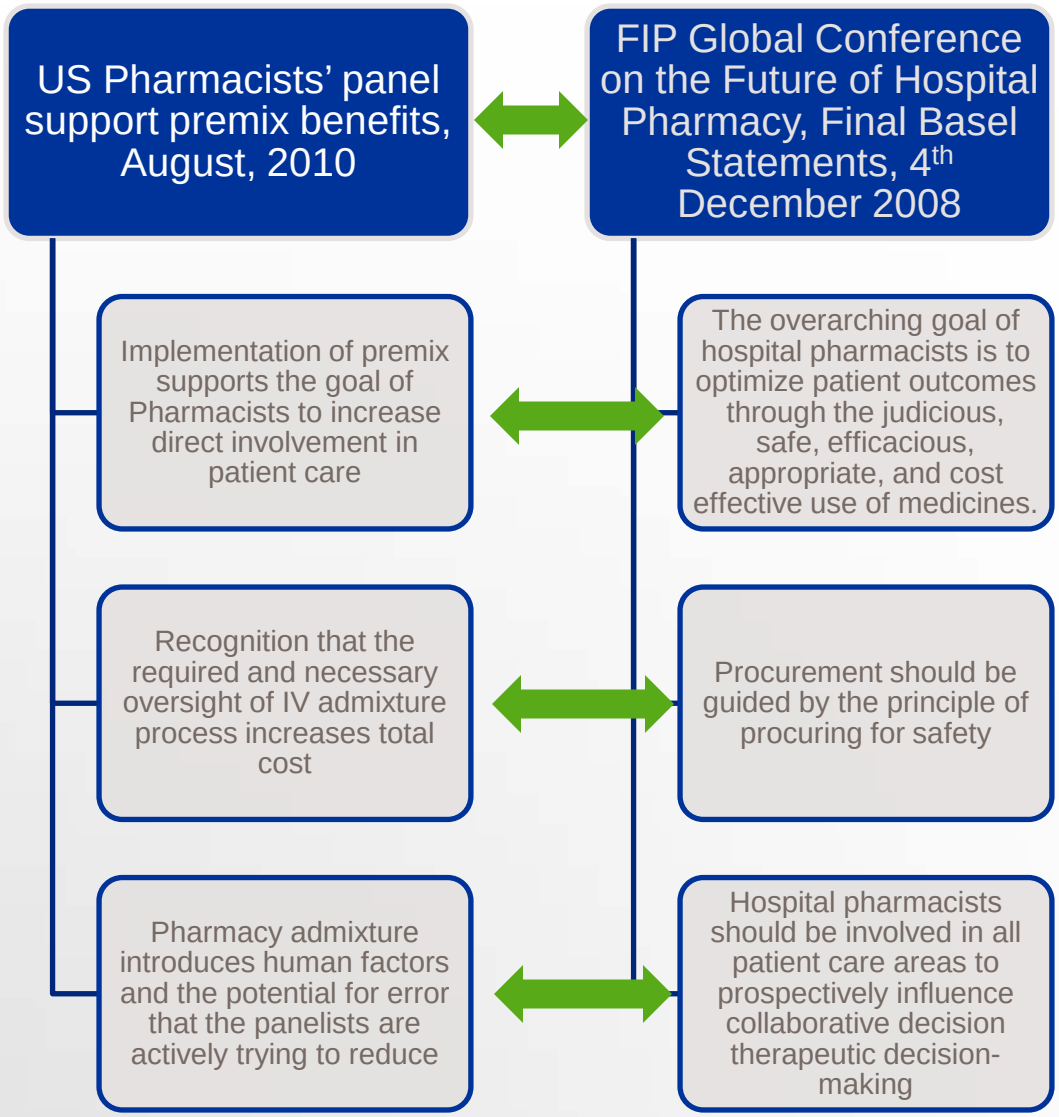
Global Pharmacy Objectives Align



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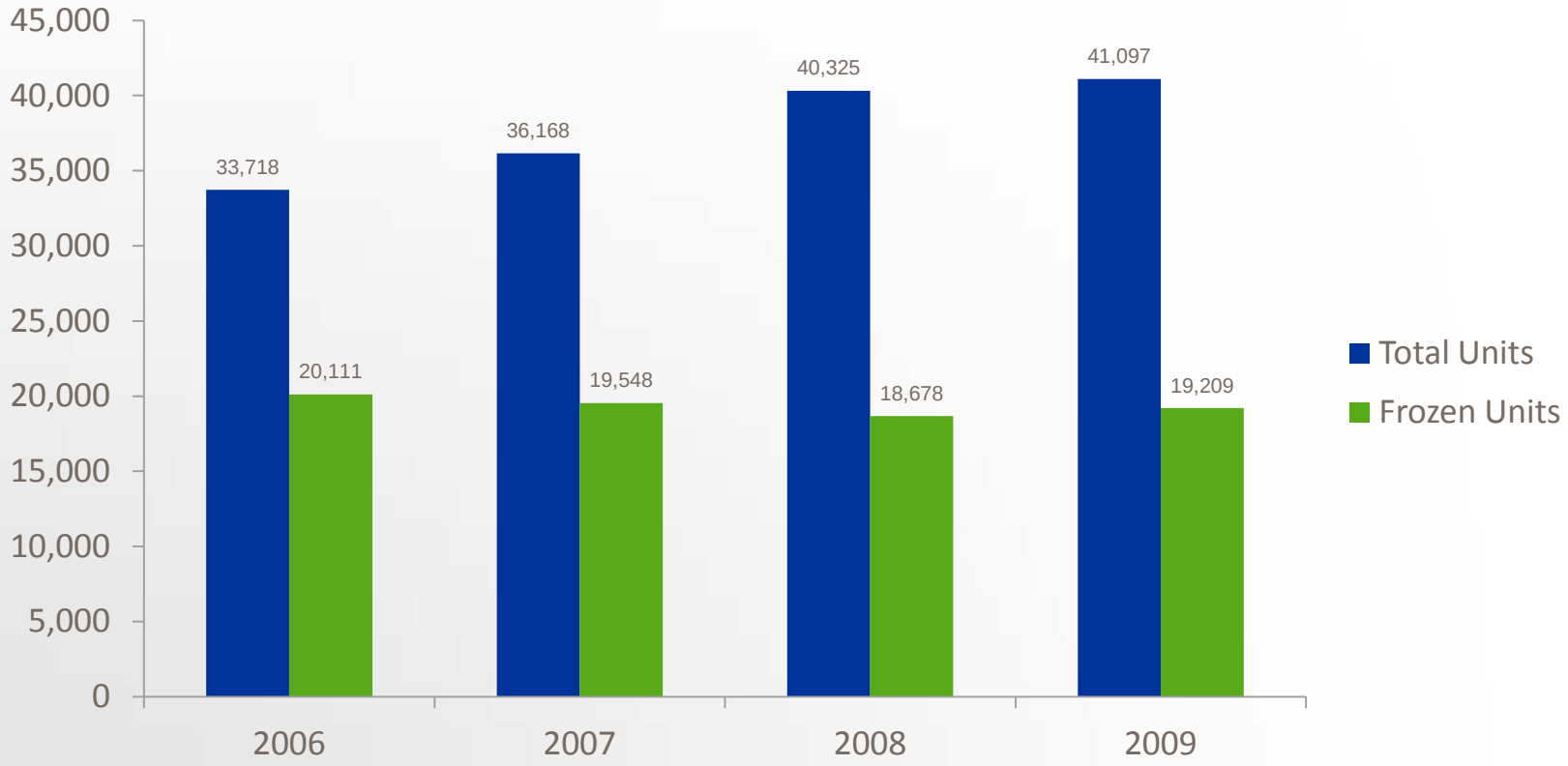
Share Retention Post-Patent

Enhanced packaging share retention post patent expiry



Source: IMS market information and Internal data

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Collaboration Considerations

- **Pharmaceutical and Biotech companies may gain a competitive edge by partnering or outsourcing select elements of their strategy to help manage costs and maintain core capabilities for other existing products.**
- **Working with a partner can provide access to specific technical expertise and specialized drug delivery technologies.**
- **It is important to find a partner that employs multidimensional strategies to achieve your objectives**
  - Investing in research related to the clinical use of enhanced delivery systems as it relates to optimized patient outcomes, health economics, and the interface of the patient and healthcare worker
  - Integrating best practices from project management, customer service, and Lean methodologies while utilizing continuous improvement and learning principles

These considerations can drive value for both parties entering into a collaboration

To Conclude…

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Enhanced Delivery Systems Support Objectives

Enhanced patient care

- Manufacturer prepared ready-to-use delivery systems support global initiatives to move patient care forward
  - Reduced likelihood of admixture related contamination
  - Manufacturer prepared labeling supports initiatives relating to the identification of unit dose of drugs

Improved total delivered cost

- In a vaccination clinic setting, the use a prefilled syringe can save $1.10 per dose in injection preparation costs vs. a vial
- RTU IV containers support labor efficiency objectives

Potential lifecycle management

- Share gain reflects clinical preference and impact of larger environmental issues relative to the delivery of care
- Pricing of RTU products can be used as an additional tool to increase adoption

Thank You for Participating!

Kristie Zinselmeier

Director, Marketing
Baxter Healthcare Corporation
BioPharma Solutions
kristie_zinselmeier@baxter.com

Brian Lynch

Marketing Manager
Becton, Dickinson
Pharmaceutical Systems
brian_lynch@bd.com

www.baxterbiopharmasolutions.com

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