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PHARMACISTS & BIOSIMILARS

The Impact of Naming Conventions and Notification on Biosimilar Substitution

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EDUCATION:

- Sept. 2009 - Sept. 2014 Ph.D. in Social and Administrative Pharmacy, University of Minnesota, College of Pharmacy
- Sept. 2005 - May 2009 Pharm.D., University of Minnesota, College of Pharmacy
- Sept. 2002 - May 2005 Pre-Pharmacy (No degree earned), University of Wisconsin – Madison, College of Liberal Arts
- Member, Public Policy Committee Member, Academy of Managed Care 2012-present.
- Board member, Minnesota Pharmacists Association, serving as a board member since May of 2014.

RESEARCH AREAS:

Measuring pharmacists involvement in political advocacy, measuring the impact of student activities, and evaluations of patient focused medication experience biosimilars.

Health Care: Transforming Toward the Triple Aim:

IMPROVING HEALTH

IMPROVING CARE

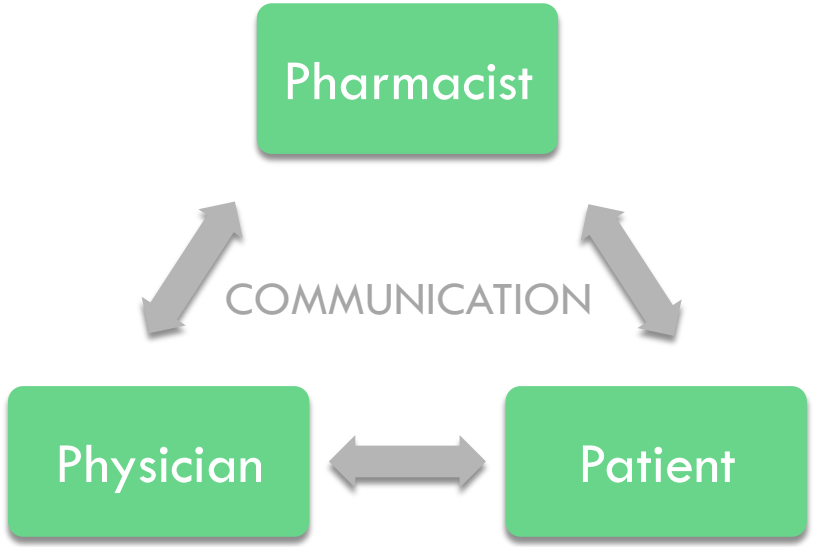
REDUCING COSTS

- Proposed by Berwick and Nolan in 2007 to re-vision healthcare around 3 core values[1]

http://content.healthaffairs.org/content/27/3/759.full

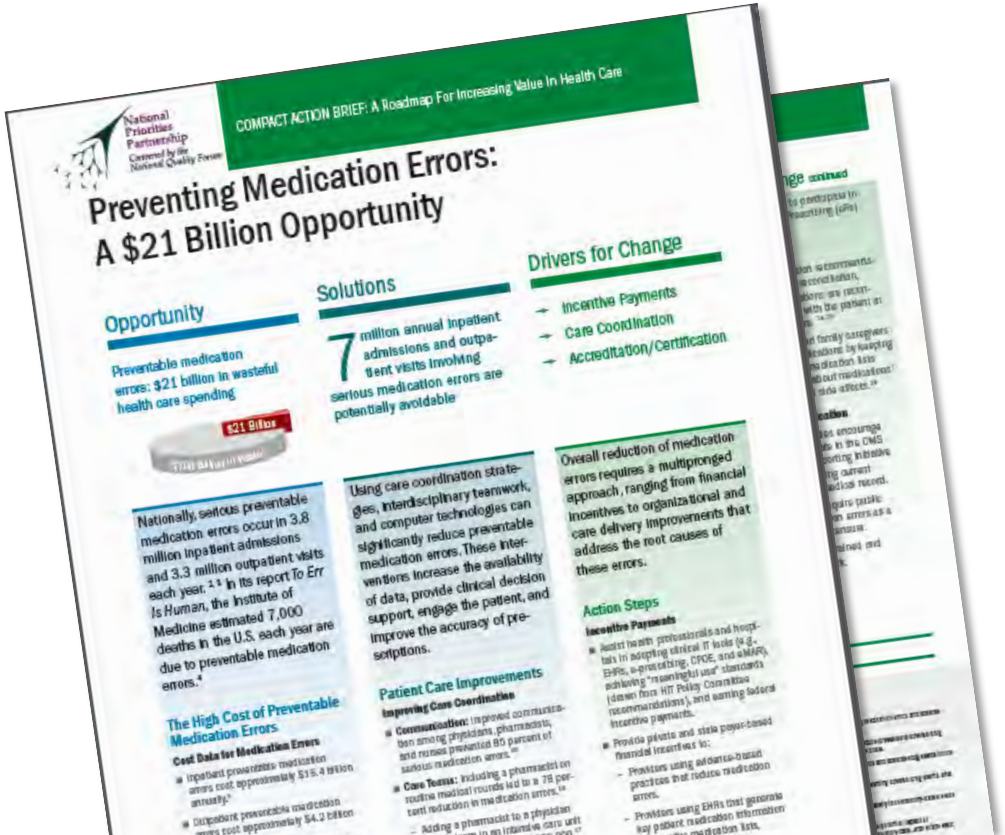
Why Is Collaboration on Biologics Important?

- Pharmacists are playing an increasingly important role as health care providers
- We are the last line of defense before the patient receives the medicine.
- Collaboration and communication with physicians and patients are key to good pharmacovigilance, and avoiding errors.
- As biosimilar policy is created at the Federal and State levels, it is important for pharmacists to lead on this issue by being educated and engaged.



NEHI and RWJF Work Lays Out Benefits of Collaboration Well. Let's Borrow!

- We are not the only stakeholders who think pharmacist engagement can bring savings to the system.
- This is particularly relevant with biologics because of their sensitivity, fragile structure, and inherent risk on immunogenicity
- Paper available at http://www.nehi.net/bendthecurve/sup/documents/Medication_Errors_%20Brief.pdf



Preventing Medication Errors:

A $21 Billion Opportunity

Made possible through support from:

WELLPOINT FOUNDATION

Learn more about ways to Bend the Curve in health care costs at: www.nehi.net/bendthecurve

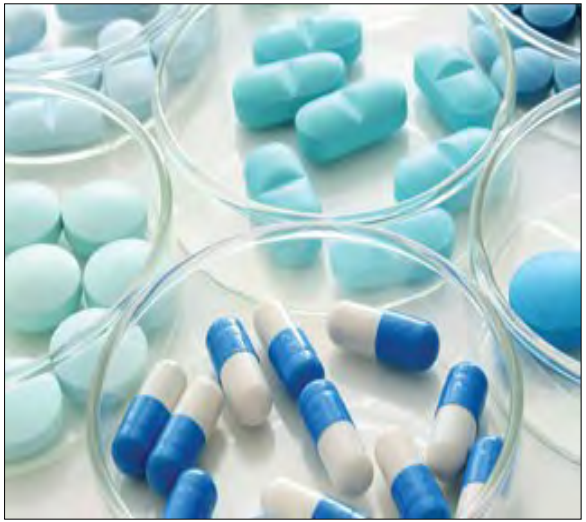
A $21 Billion Opportunity

Notes

1. NEHI. (2008). How Many More Studies Will It Take? A Collection of Evidence That Our Health Care System Can Do Better. Retrieved from http://www.nehi.net/publications/30/how_many_more_studies_will_it_take. Last accessed October 2011.

Scope of Medication Errors

- Serious preventable medication errors occur in:
  - 3.8 million inpatient admissions[2]
  - 3.3 million outpatient visits[3]
- Mortality from preventable medication errors:
  - 7,000 deaths each year[4]

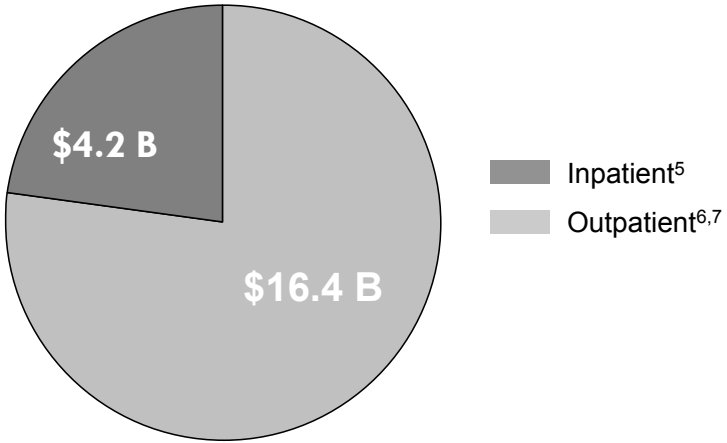


Notes

2. Massachusetts Technology Collaborative (MTC) and NEHI, 2008. *Saving Lives, Saving Money: The Imperative for CPOE in Massachusetts*. Updated to 2008 figures. Cambridge, MA: NEHI, 2008. Available at: http://www.nehi.net/publications/8/saving_lives_saving_money_the_imperative_for_computerized_physician_order_entry_in_massachusetts_hospitals.
3. Center of Information Technology Leadership (CITL), *The Value of Computerized Provider Order Entry in Ambulatory Settings*. Updated to 2007 figures. Available at: http://www.partners.org/cird/pdfs/CITL_ACPOE_Full.pdf. Last accessed October 2011.
4. Institute of Medicine (IOM). *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 1999.

Costs of Medication Errors

Annual Cost of Preventable Medication Errors by Setting



Notes

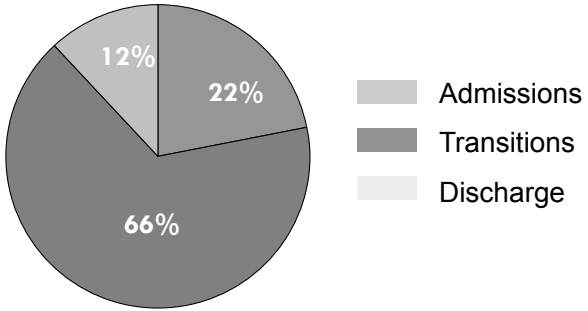
5. Massachusetts Technology Collaborative and NEHI. 2008.
6. Center of Information Technology Leadership. 2007.
7. Burton, M.M., Hope, C., Murray, M.D., et al. (2007). The cost of adverse drug events in ambulatory care. AMIA Annu Symp Proc, 90-93.

Driver: Prescription Errors

Types of Prescription Errors

- Dosing errors make up 37% of all preventable medication errors.[8]
- Drug allergies or harmful drug interactions account for 11% of preventable medication errors.[9]
- Approximately 100 undetected dispensing errors can occur each day as a result of the significant volume of medications dispensed.[11]

Settings for Medication Reconciliation Errors[10]



Preventable medication reconciliation errors occur in all phases of care.

Notes

8. Bobb, A., Gleason, K., Husch, M., et al. (2004). The epidemiology of prescribing errors. Arch Intern Med, 164(7), 785-792.
9. Bobb, Gleason, Husch, et al. 2004.
10. Santell, J.P. (2006). Reconciliation failures lead to medication errors. Jt Comm J Qual Patient Saf, 32(4), 225-229.
11. Cina, J.L., Gandhi, T.K., Churchill, W., et al. (2006). How many hospital pharmacy medication dispensing errors go undetected? Jt Comm J Qual Patient Saf, 32(2), 73-80.

Other Drivers

Fragmentation of Care

- Only 13% of primary care physicians reported that they communicated with a pharmacist regarding new prescriptions.[12]

Lack of Information Technology Infrastructure

- EMR systems that are described as fully functional and had a prescribing function were reported by 70% of physicians.[13]
- Although E-Prescribing is on the rise, communication remain primarily 1-way in nature

Notes

12. Ranelli, P.L., Biss, J. (2000). Physicians' perception of communication with and responsibilities of pharmacists. J Am Pharm Assoc, 40(5), 625-630.

13 ONC Data Brief. E-Prescribing Trends in the United States. Available at https://www.healthit.gov/sites/default/files/oncdatabriefe-prescribingincreases2014.pdf. Last Accessed 2016

Solution: Improve Care Coordination

- Communication:
  - Improved communication among physicians, pharmacists and nurses prevented 85% of serious medication errors.[15]
- Including a pharmacist on routine medical rounds led to a 78% reduction in medication errors.[16]
  - Adding a pharmacist to a physician rounds team in an intensive care unit led to annual savings of $270,000.[17]

Notes

15. Fortescue, E.B., Kaushal, R., Landrigan, C.P., et al. (2003). Prioritizing strategies for preventing medication errors and adverse drug events in pediatric inpatients. Pediatrics, 111(4 Pt 1), 722–729.
16. Kucukarslan, S.N., Peters, M., Mlynarek, M., et al. (2003). Pharmacists on rounding teams reduce preventable adverse drug events in hospital general medicine units. Arch Intern Med, 163(17), 2014-2018.
17. Leape, L.L., Cullen, D.J., Clapp, M.D., et al. (1999). Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. JAMA, 282(3), 267-270.

Solution: Facilitate Patient Engagement

- Engagement of Patients and Families:
  - Active engagement of patients and family caregivers with the care team
  - Use of patient safety checklists
  - Increased awareness of publicly reported hospital safety records

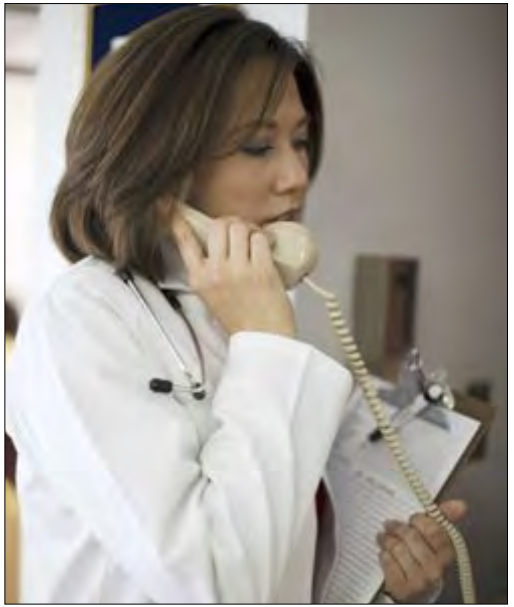
- Adopt Joint Commission recommendations for medication reconciliation, ensuring that medications are reconfirmed and reviewed with the patient at each transition in care.[18,19]
- Empower patients and family caregivers to manage their medications by keeping PHRs and personal medication lists and informing them about the purpose, effects and side effects of their medications.[20]

Notes

18. Joint Commission on Accreditation of Healthcare Organizations. (2006). Using medication reconciliation to prevent errors. Sentinel Event Alert, 35, 1-4.
19. National Priorities Partnership. (2008). National Priorities and Goals: Aligning Our Efforts to Transform America's Healthcare. Washington, DC: National Quality Forum.
20. Sabogal, F., Coots-Miyazaki, M., Lett, J.E. (2007). Ten effective care transitions interventions: improving patient safety and healthcare quality. CAHQ Journal, 31(2), 15-19.

Solution: Require Pharmacist Follow-up

- Patients who received pharmacist follow-up calls
  - 88% less likely to have a preventable medication error resulting in an ED visit or hospitalization.[21]



Notes

21. Schnipper, J.L., Kirwin, J.L., Cotugno, M.C., et al. (2006). Role of pharmacist counseling in preventing adverse drug events after hospitalization. Arch Intern Med, 166(5), 565-571.

Importance of Collaboration with Biologics

- Complex medications to treat complex diseases
- Increased PBM oversight
  - Need to manage Prior Auths
  - Keep patients engaged
  - Ensure proper use and adherence
- Pharmacists may recognize patient use concerns
- Pharmacists can be ideal source of follow-up between clinic visits

The Pharmacists Role in Biosimilars

- Potential for confusion
  - What product is required by PBM
  - What product was dispensed and when
    - Help ensure adherence isn't causing apparent non-response
  - Potential product overlap with care transitions
  - Help patients navigate specialty pharmacy requirements

The Pharmacist's Role in Biosimilars (cont.)

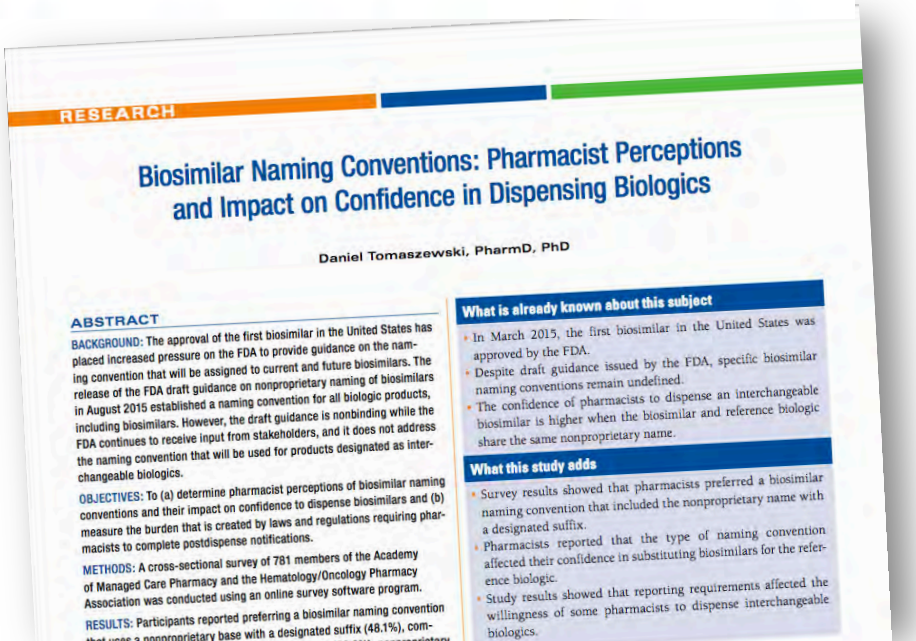
- Manage Patient Needs
  - Patients may need to transition from reference product
    - Concerns over safety and effectiveness of new product
    - Need to ensure patient confidence
    - Provide additional patient education on biosimilars
  - Potential confusion over product naming

Whitepaper: Biosimilar Naming Conventions

JMCP JOURNAL OF MANAGED CARE & SPECIALTY PHARMACY
A Peer-Reviewed Journal of the Academy of Managed Care Pharmacy

PUBLISHED August 2016 (J Manag Care Spec Pharm, 2016 Aug;22(8):919-926.)

OBJECTIVE: Determine to what extent BIOSIMILAR NAMING CONVENTIONS impact PHARMACIST PERCEPTIONS, CONFIDENCE in DISPENSING BIOLOGICS…



RESEARCH

Biosimilar Naming Conventions: Pharmacist Perceptions and Impact on Confidence in Dispensing Biologics

Daniel Tomaszewski, PharmD, PhD

ABSTRACT

BACKGROUND: The approval of the first biosimilar in the United States has placed increased pressure on the FDA to provide guidance on the naming convention that will be assigned to current and future biosimilars. The release of the FDA draft guidance on nonproprietary naming of biosimilars in August 2015 established a naming convention for all biologic products, including biosimilars. However, the draft guidance is nonbinding while the FDA continues to receive input from stakeholders, and it does not address the naming convention that will be used for products designated as interchangeable biologics.

OBJECTIVES: To (a) determine pharmacist perceptions of biosimilar naming conventions and their impact on confidence to dispense biosimilars and (b) measure the burden that is created by laws and regulations requiring pharmacists to complete postdispense notifications.

METHODS: A cross-sectional survey of 781 members of the Academy of Managed Care Pharmacy and the Hematology/Oncology Pharmacy Association was conducted using an online survey software program.

RESULTS: Participants reported preferring a biosimilar naming convention

What is already known about this subject

- In March 2015, the first biosimilar in the United States was approved by the FDA.
- Despite draft guidance issued by the FDA, specific biosimilar naming conventions remain undefined.
- The confidence of pharmacists to dispense an interchangeable biosimilar is higher when the biosimilar and reference biologic share the same nonproprietary name.

What this study adds

- Survey results showed that pharmacists preferred a biosimilar naming convention that included the nonproprietary name with a designated suffix.
- Pharmacists reported that the type of naming convention affected their confidence in substituting biosimilars for the reference biologic.
- Study results showed that reporting requirements affected the willingness of some pharmacists to dispense interchangeable biologics.

Study in Context: FDA Naming of Biosimilars

- **March 2015:** FDA approves first biosimilar Zarxio (filgrastim-sndz).
  - Distinct name: Shared root name with suffix.
  - Meaningful suffix based on manufacturer name "Sandoz"= "-sndz"
- **May-June 2015:** Data collection for study.
- **August 2015:** FDA releases Draft Guidance on Biologic Naming
  - Proposes to use random suffixes, proposes to change name of several current biologics (including "filgrastim-sndz" to "filgrastim-bflm").
  - FDA solicits feedback from stakeholders on naming preference.
- **April-September 2016:** FDA approves three more biosimilars, all with random suffixes.
- **August 2016:** Study published.

Methodology

- Online Web Survey conducted May-June 2015
- N=781
- Respondents are members of the Academy of Managed Care Pharmacy and the Hematology/ Oncology Association

AMCP Academy of Managed Care Pharmacy®

AMCP position: supports use of same approved name/ nonproprietary name as reference product. [1]

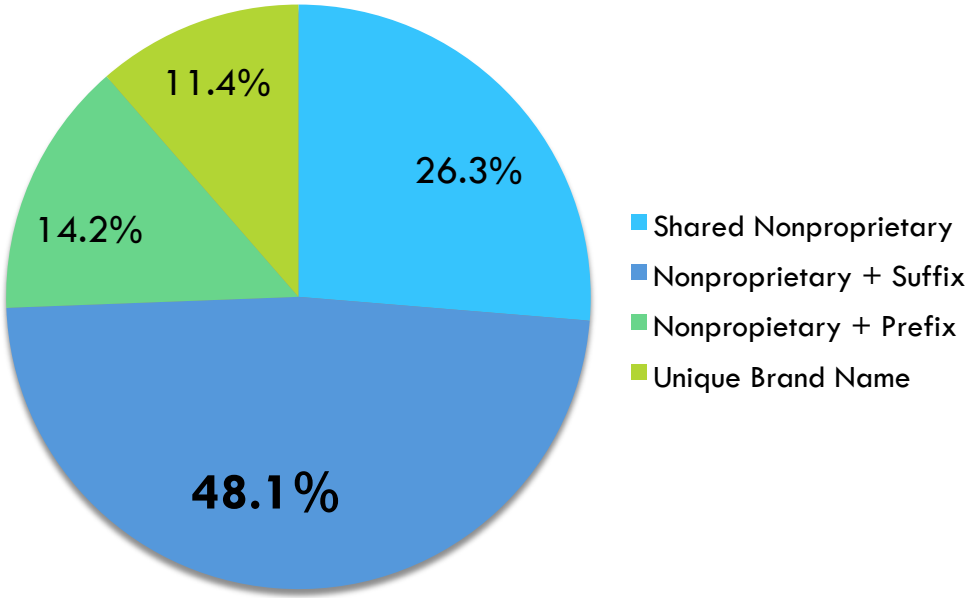
HOPA Hematology/Oncology Pharmacy Association

HOPA position: prefers root name + prefix, but supports root name + meaningful suffix for non-interchangeable biosimilars. [2]

1 http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=20018
2 http://www.hoparx.org/uploads/Health_Policy/2016/HOPA_Biosimilars_Issue_Brief.pdf

Naming Preference: Total

- Strongest preference was for Nonproprietary name + Suffix (48.1%) n=362
- All employment sectors reported this preference, except specialty pharmacy.



Naming Preference: Breakdown by Sector

TABLE 2 Reported Preference of Biosimilar Naming Convention by Employment Type

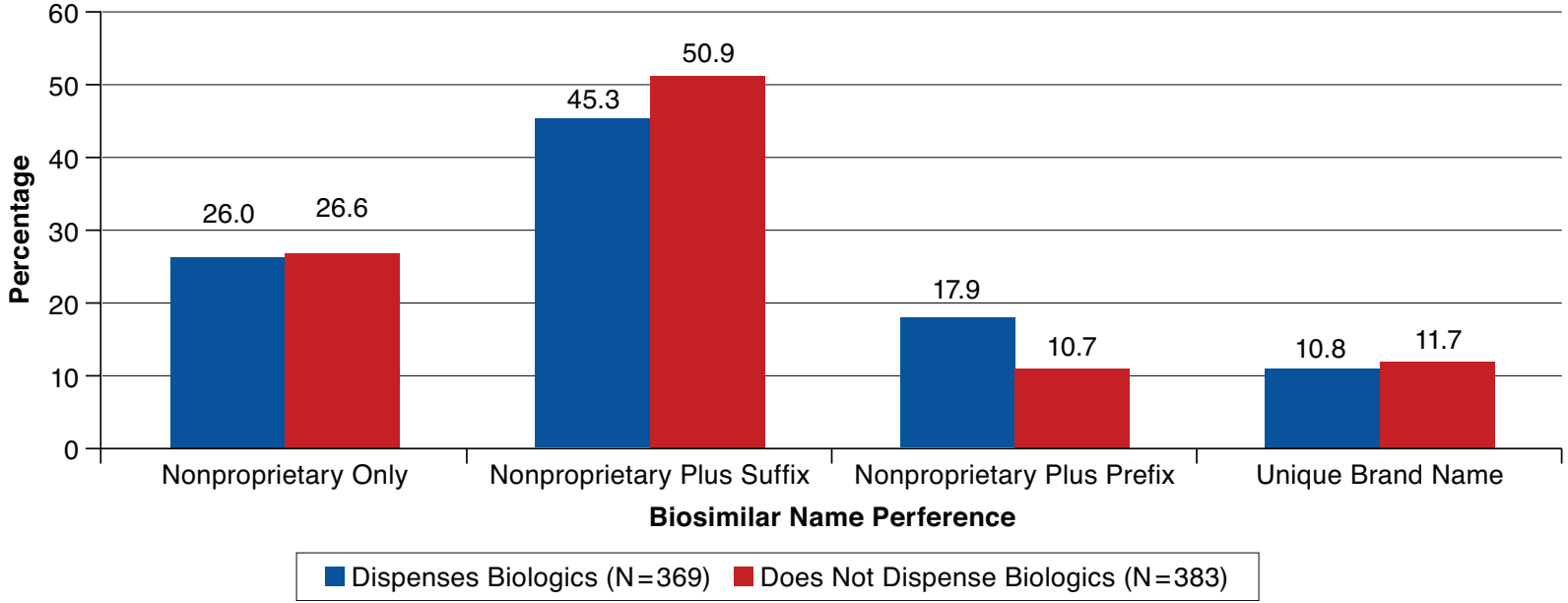
Employment Type	Nonproprietary Only %	(n)	Nonproprietary Plus Suffix %	(n)	Nonproprietary Plus Prefix %	(n)	Unique Brand Name %	(n)
Hospital (n=116)	17.9	(21)	44.4	(52)	29.1	(34)	7.7	(9)
Outpatient pharmacies[a] (n=124)	29.8	(37)	45.2	(56)	13.7	(17)	11.3	(14)
Specialty pharmacy (n=26)	38.5	(10)	34.6	(9)	19.2	(5)	7.7	(2)
MCOs (n =233)	31.3	(73)	50.2	(117)	6.9	(16)	11.6	(27)
Manufacturer (n=78)	16.7	(13)	50.0	(39)	15.3	(12)	17.9	(14)
Academia (n=37)	21.6	(8)	43.2	(16)	29.7	(11)	5.4	(2)
Other/unreported (n=139)	25.9	(36)	52.5	(73)	8.6	(12)	12.9	(18)
Total	26.3	(198)	48.1	(362)	14.2	(107)	11.4	(86)

[a]Includes those reporting independent, small chain, large chain, clinic nondispensing, and clinic dispensing.
MCO=managed care organization.

Only **specialty pharmacy** expressed a preference for shared nonproprietary name (38.5%) over nonproprietary + suffix (34.6%)

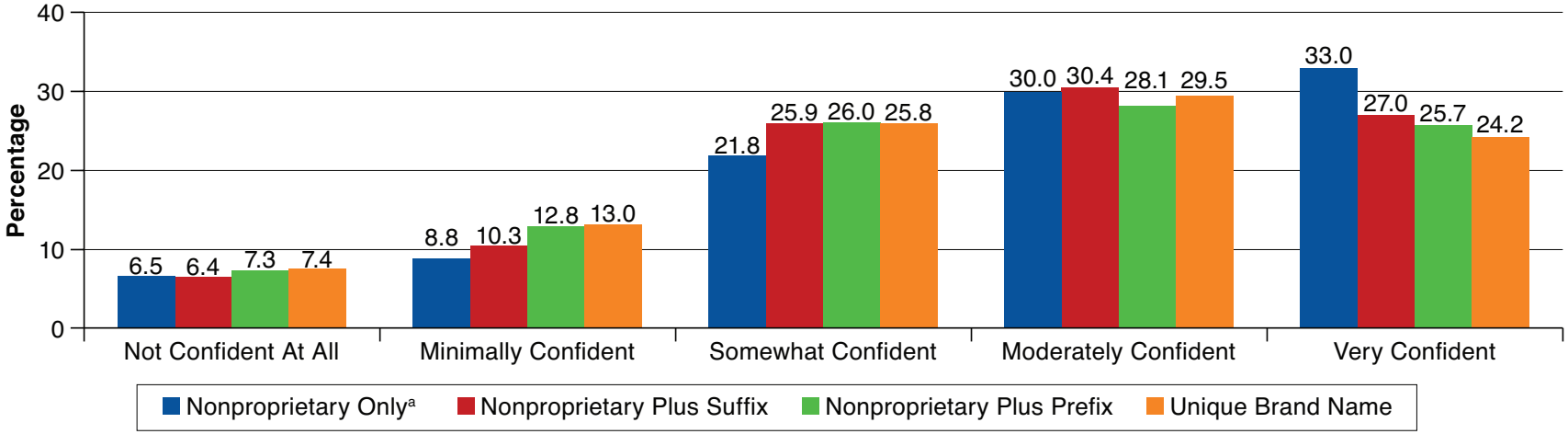
Naming Preference: Dispense/Do Not Dispense Biologics?

FIGURE 1 Naming Preference Dependent on Reports of Dispensing Biologics (N =752)



Impact on Confidence Level

FIGURE 2 Confidence of Pharmacists in Dispensing an Interchangeable Biologic Based on Naming Convention Use (N =619)

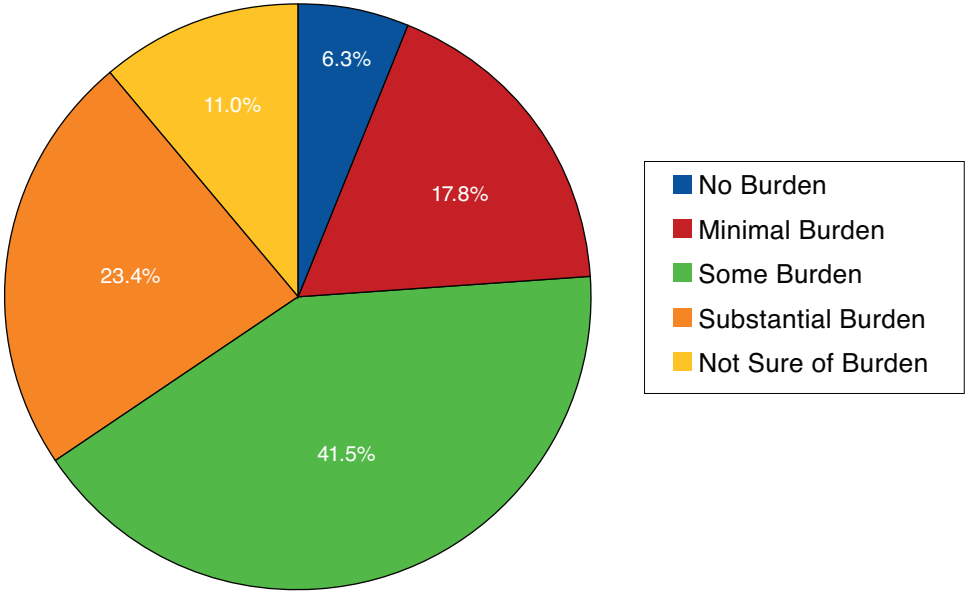


While expressing a preference for Nonproprietary name + suffix, respondents did not demonstrate increased confidence when dispensing an interchangeable biologic using this naming convention.

Burden of Prescriber Notification

- Most popular response was "some burden" (41.5%)
- 23.4% considered this burden "substantial".
- A similar percentage (24.1) considered there to be "no burden"(6.3%) or "minimal burden"(17.8%)
- 11% were unsure of the burden.

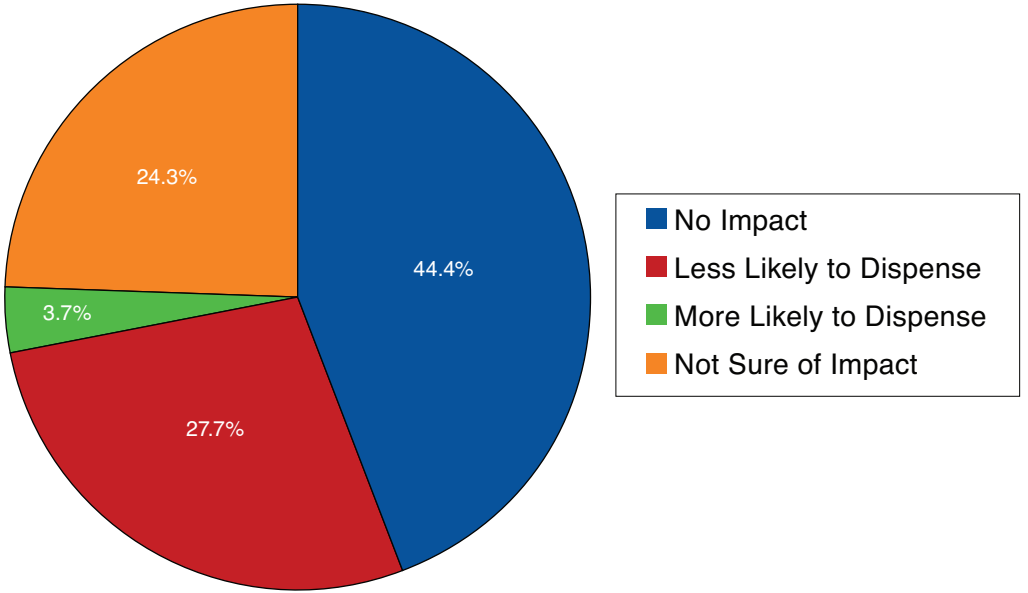
FIGURE 3 Pharmacist-Reported Level of Burden Associated with Postdispensing Notification Requirements When Dispensing a Biosimilar (N =381)



Effect of Notification Requirement on Likelihood to Dispense

- Most popular response was “no impact” (44.4%)
- Yet 27.7% felt less likely to dispense.
- 24.3% were unsure of the impact.
- Only a small percentage (3.7%) felt a notification requirement would make them more likely to dispense.

FIGURE 4 Effect of Likelihood to Dispense Biosimilar If Postdispensing Notification to Prescriber Is Required (N = 383)



Primary Take Away From the Study

- Overall pharmacists support the FDA decision to require a suffix
- The use of a suffix did result in lower pharmacist reported confidence in dispensing the biosimilar
- Requiring post dispense prescriber reporting increases pharmacist burden
- Naming convention adds further complexity to an already complex concept (biosimilars in general)

Considerations in Developing a Biologics Curriculum

- Understanding the fundamental differences between biologic and chemical medicines:
  - Complexity of proteins potential to lead to minor manufacturing differences/molecular modifications
  - Clinical considerations- Pharmacists need to further engage in care
  - Need to describe the importance of two-way provider communication
- Provide a balanced, unbiased scientific based education on biosimilars
- Keeping track of FDA policies (e.g., labeling, naming, indication extrapolation, interchangeability, etc.)
- Understanding development of regulations at state level (e.g.,) related to substitution and record-keeping, which differ from state to state

Biologics/Biosimilar Curriculum (cont.)

- Need to focus on providing fact driven data
- Help to eliminate confusion about current policies
- Encourage better pharmacist engagement in specialty drug utilization
- Engage students in discussions about misinformation that is being spread
- Ensure appropriate medicinal chemistry, pharmacologic, and therapeutic understanding of biologic agents
- Incorporate coverage/formulary/utilization management strategies likely to be put in place by PBMs around biologics/biosimilars

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THANK YOU FOR YOUR ATTENTION

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