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ALLIANCE FOR SAFE BIOLOGIC MEDICINE – PRESCRIBER SURVEY

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Kevin Olson, CEO
Industry Standard Research
919-301-0106 x701
KevinO@ISRreports.com

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Methodology

- Internet-based survey
- 376 U.S. prescribers, distributed equally across
  - Endocrinology
  - Dermatology
  - Oncology
  - Rheumatology
  - Nephrology
  - Neurology
- Average survey duration was approximately 10 minutes
- Confidence interval is + or - 5%

EXECUTIVE SUMMARY

Executive Summary

Nomenclature Preferences

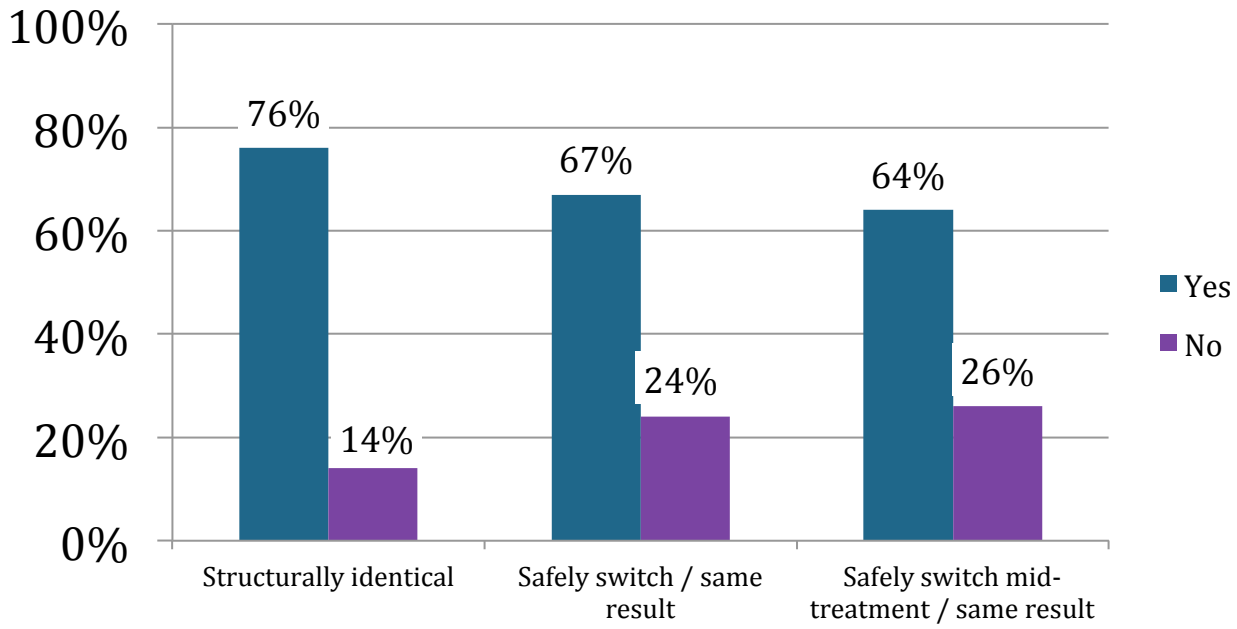
- Overall, prescribers refer to products by name
  - For recording in charts…
    - Brand name (49%) > Generic name (17%) > NDC number (0.3%)
  - For reporting adverse events…
    - Product name (86%) > NDC number (0.5%)

The one caveat or clarifier to this is that 32% told ISR "it depends" for recording in charts. The main driver of this was "memorability." Prescribers commonly told ISR that they record whichever name (brand or generic) was most familiar to them. If the product is an old one and they've prescribed the generic for some time, they often prefer to record the generic name. Again, this was primarily driven by memorability or familiarity.

Executive Summary

Interchangeability

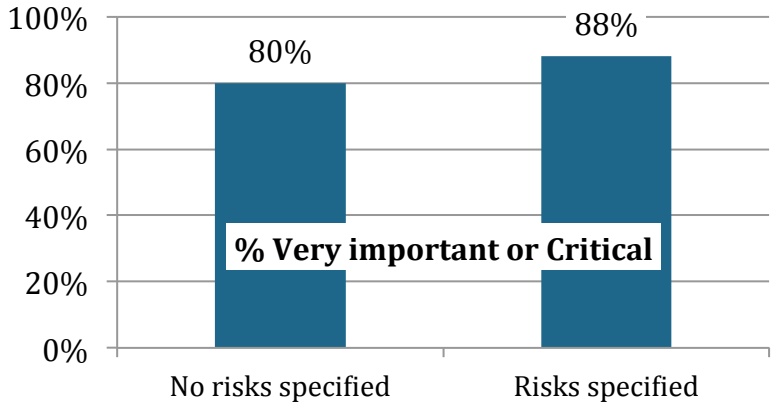
- Products with the same scientific name will largely be viewed by prescribers as interchangeable.



Executive Summary

Pharmacy Interactions

- 85% want DAW authority, just as they have it for chemical products
  - 80% rate this authority as "Very important" or "Critical" to them
- Notification of change is just as important to prescribers, and becomes even more so if additional risks are known for the products in question



- 86% want notification *prior to* the change

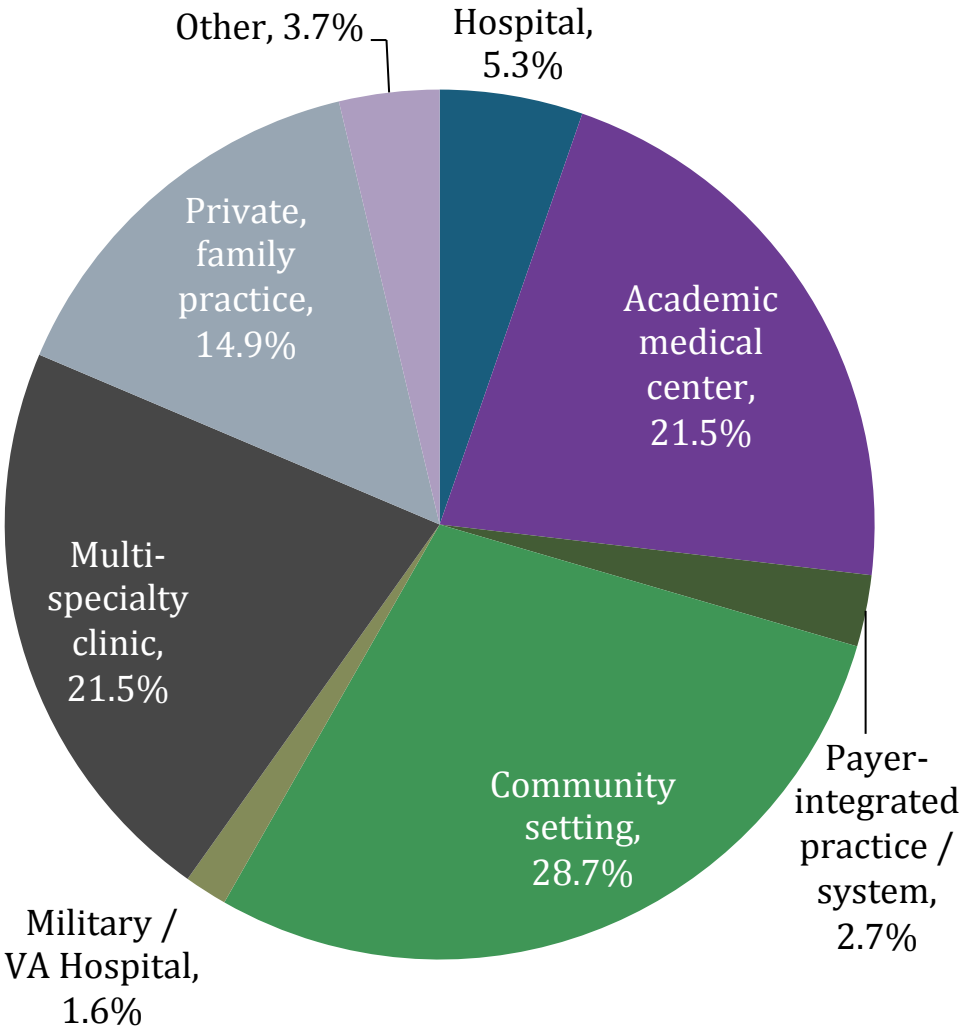
DEMOGRAPHICS

Question: Which of the following best describes the type of practice in which you work?

Practice Setting (n=376)

Respondents are well distributed across the several practice types.

The most significant numbers come from Academic medical centers, Community settings, Multi-specialty clinics, and Private, family practices.

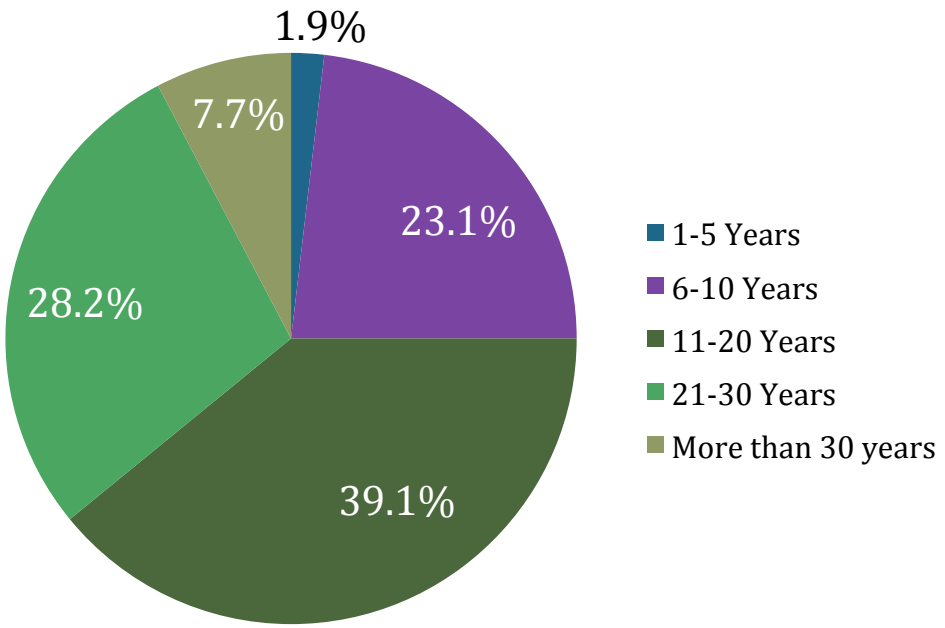


Question: How long have you been in the healthcare industry?

Industry Tenure (n=376)

Respondents possess a great deal of experience.

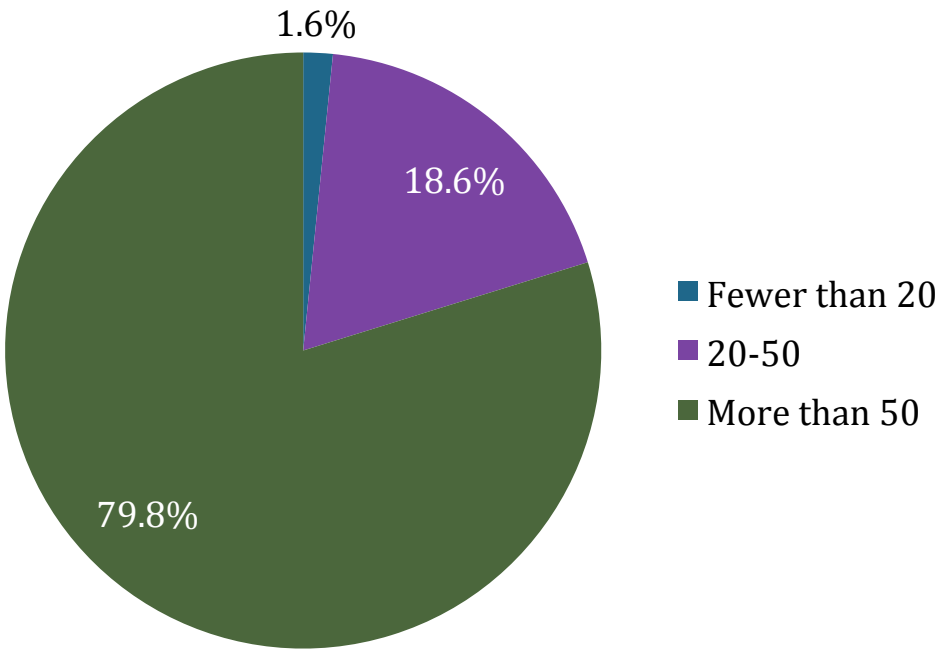
Average years of experience was 17.5 years (using mid-point mean calculation) and a wide range of experience was represented.



Volume of Patient Visits (n=376)

Question: On average, about how many patient visits do you conduct per week?

About 80% of respondents conduct more than 50 patient visits per week.



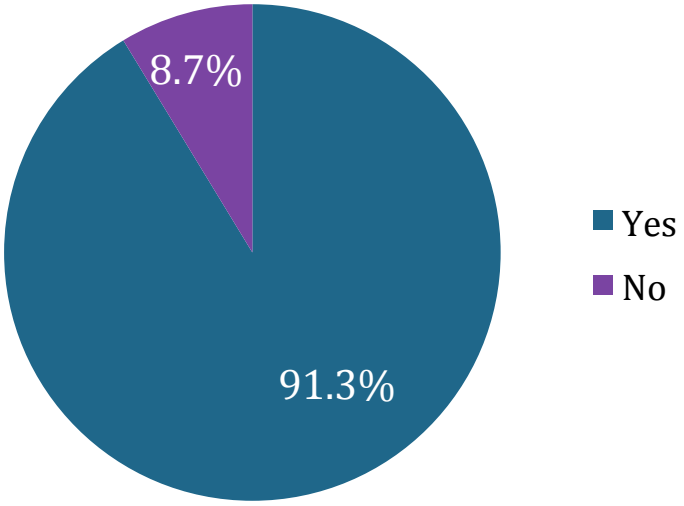
STUDY DATA

Experience with Biologics (n=376)

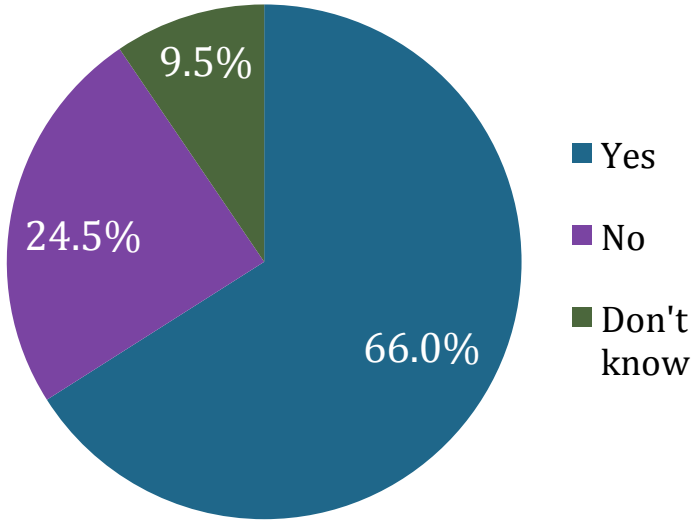
Question: Do you prescribe biologic medicines in your practice?

Question: Do you commonly treat patients who you are aware are being prescribed biologic medicines by another health care provider?

Own Patients



Other Prescribers' Patients



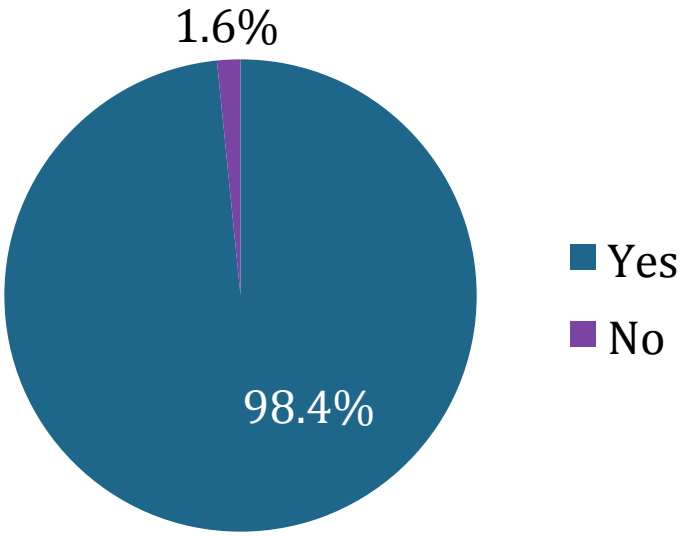
Sample shows a high degree of experience with biologics. Over 90% prescribe them to their own patients. Two-thirds see patients who have been prescribed biologics by other physicians.

Identification of Medication in Patient Records

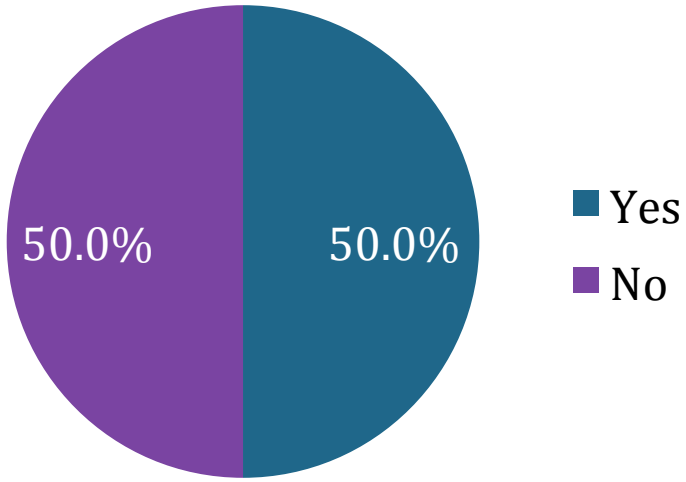
Question: When you prescribe medicine, including biologics, do you identify the medicine in the patient record?

Question: When you treat a patient receiving a biologic medicine prescribed by another health care provider, do you identify the medicine in the patient record?

Own Patients (n=376)



Other Prescribers' Patients (n=6; "no" in previous question)



Among their own patients, prescribers nearly unanimously report identifying prescribed medicines in their patients' records. Respondents are split regarding whether this is done for medicines prescribed by another health care provider.

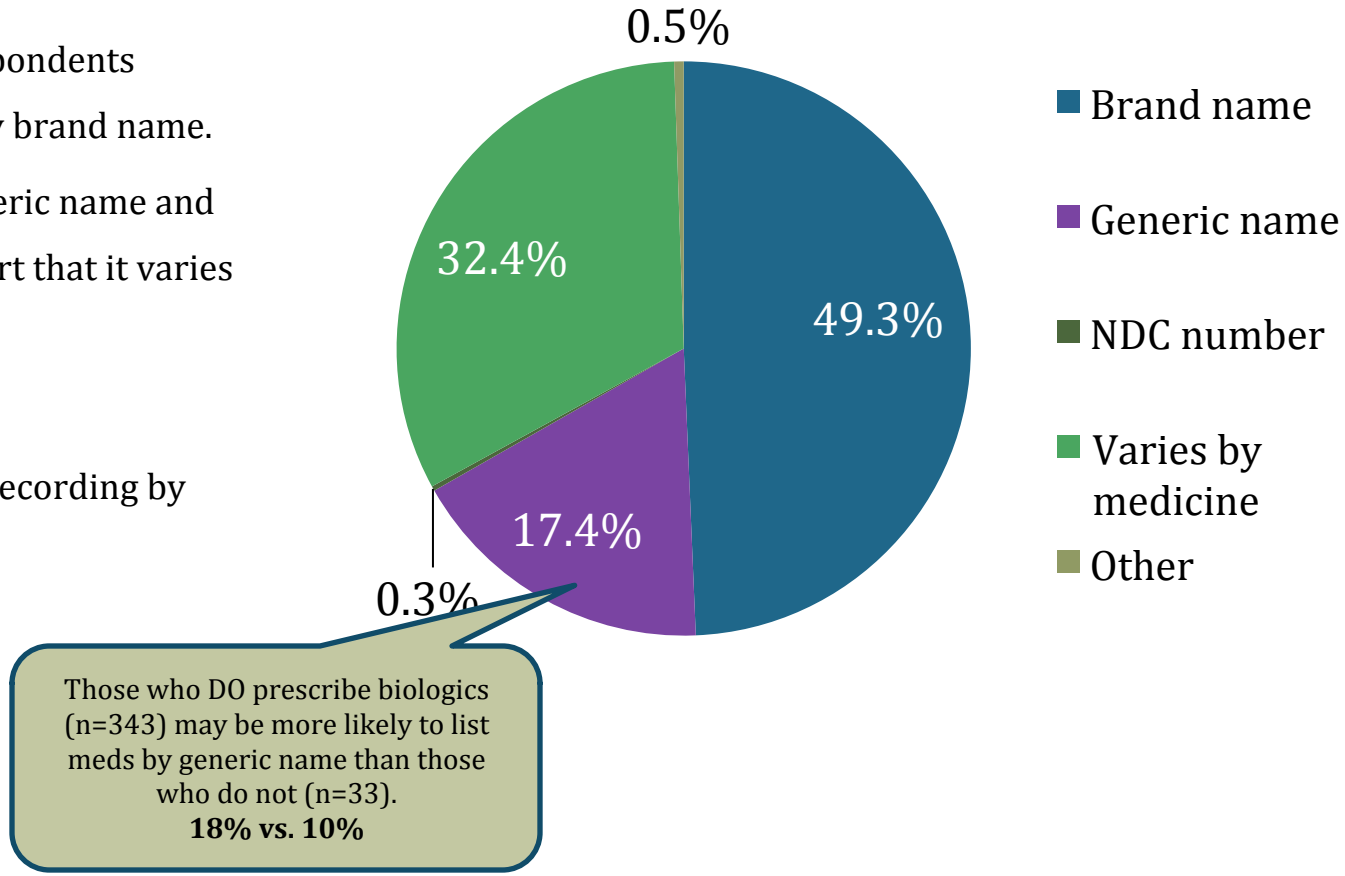
How They Identify Medicines (n=376)

Question: When you identify a medicine for prescription or recording in a patient record, are you more likely to identify the medicine by brand name, non-proprietary/ generic name, or NDC number?

About half of the respondents identify medicines by brand name.

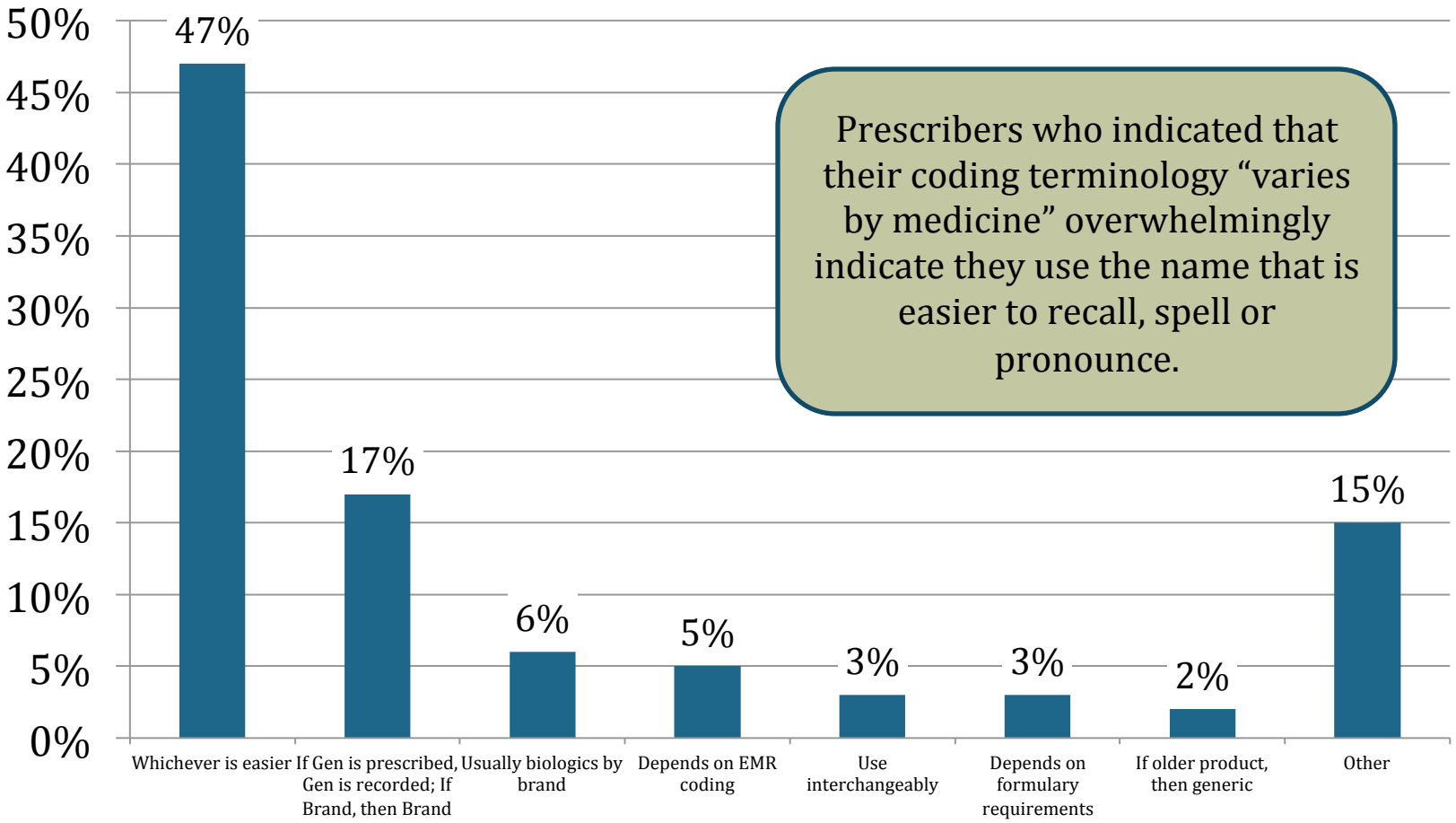
Another 17% by generic name and about one-third report that it varies by medicine.

Almost none report recording by NDC number.



Question: How does this vary by medicine? Please explain.

How / Why it Varies by Medicine – Coded, Open-ended Responses (n=93 responses)



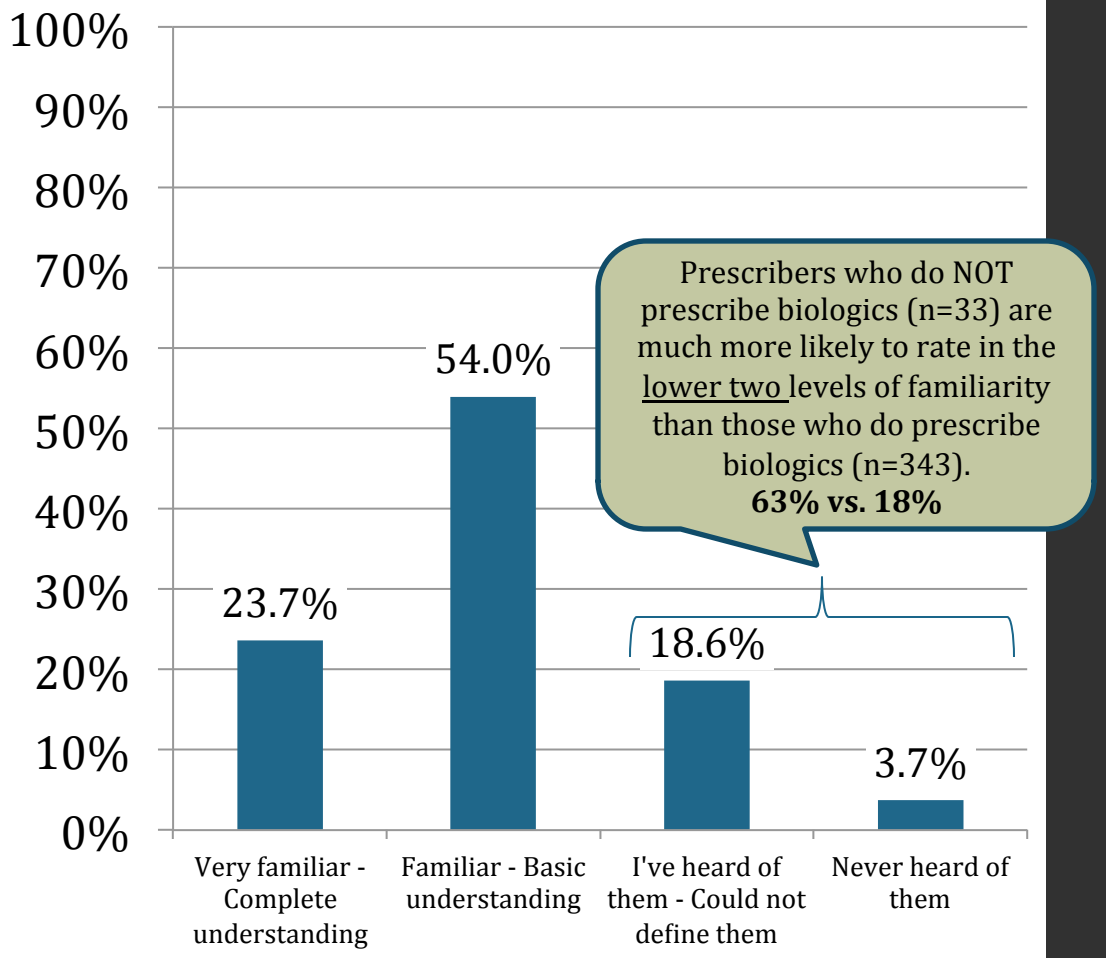
Biosimilars Definition Used

- Biologic medicines are therapeutic proteins produced using living cells. A copy of an original biologic made by a different manufacturer is referred to as a biosimilar or follow-on biologic rather than a generic because it will be similar, not identical, to the product it copies. Biosimilars are also referred to as subsequent entry biologics (SEBs) in Canada. In short, biosimilars are "copies" of biologic medicines, whereas traditional "generic" medicines are generally based on chemical products. As a result of the new biosimilar pathway to approval, biosimilar medicines will soon be available in the US market.

Question: How familiar are you with biosimilar medicines?

Familiarity with Biosimilars (n=376)

Nearly 80% of respondents indicated that they are "Familiar" or "Very familiar" with biosimilar medicines.

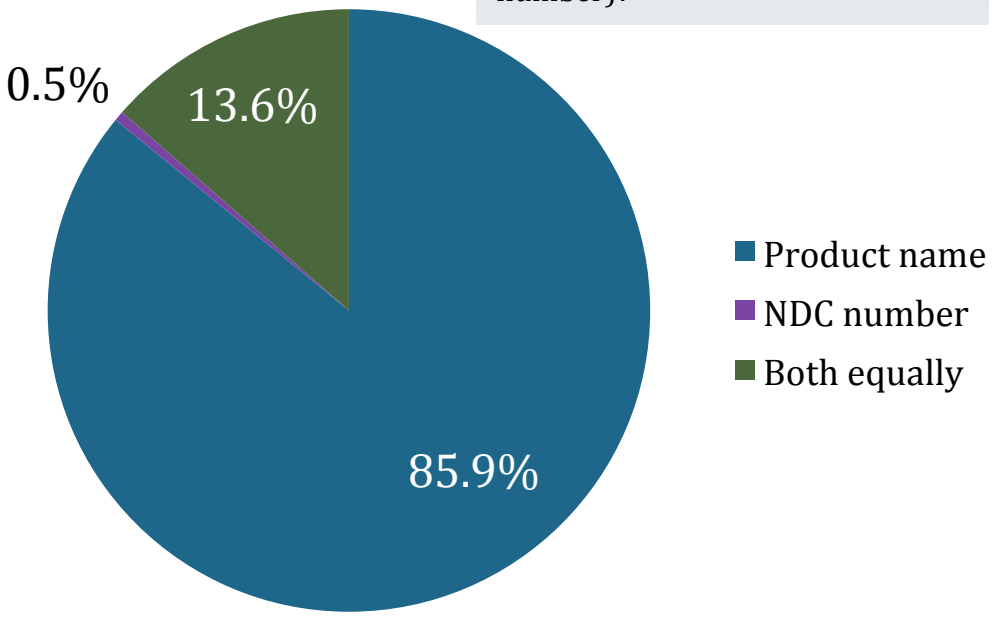


Preference for Identifying for Adverse Events (n=376)

Question: Physicians play an important role in the identification and reporting unexpected or serious adverse events to FDA and manufacturers. In the context of identifying a biologic (or, if you don't prescribe biologics, any other drug) for purposes of reporting an adverse event, would you prefer to identify the medicine by a product name or number (National Drug Code number)?

A very strong majority of respondents report a preference for reporting AEs by product name.

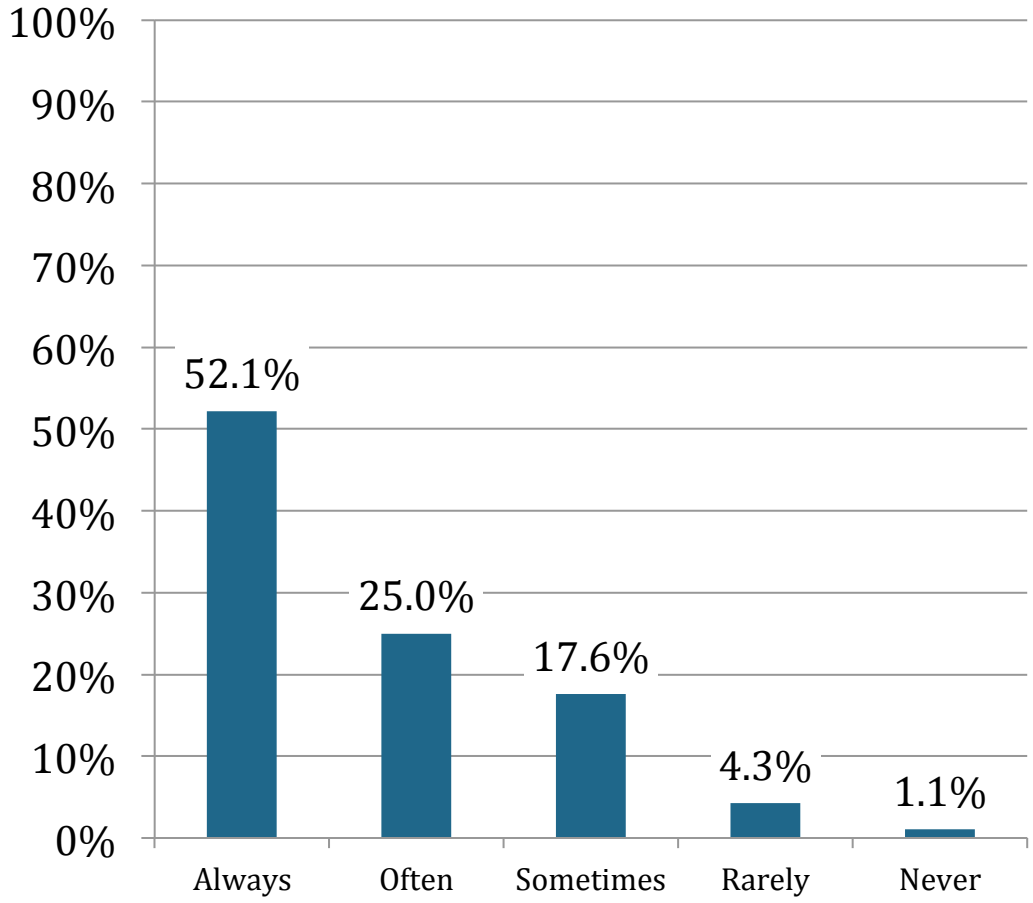
Almost none report a preference for reporting by NDC number.



Recording Pharmacy-initiated Changes (n=376)

Question: When a pharmacy contacts you regarding a change in the medicine a patient receives (for example, to request approval for a change due to insurance coverage), how often do you record that change in the patient's file?

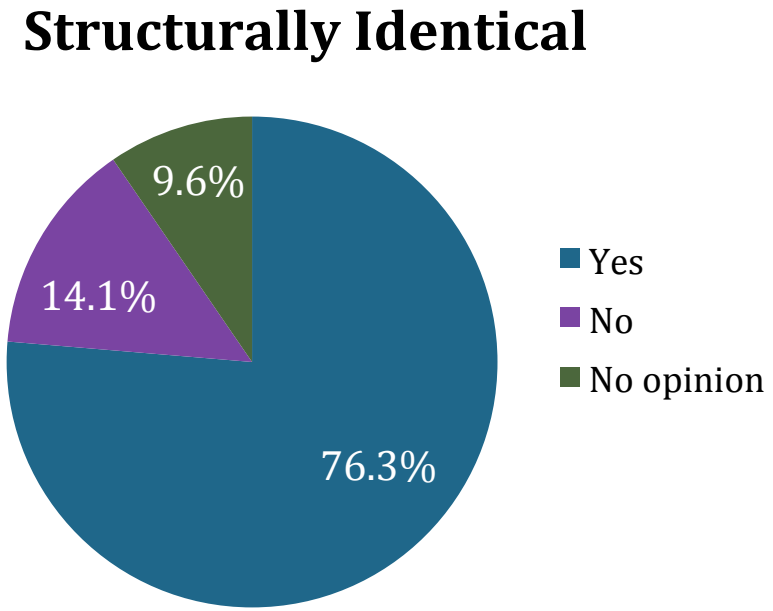
About half of respondents report "Always" recording a pharmacy-initiated switch in their patients' files.



Same Scientific Name = Interchangeability? (n=376)

Question: If two medicines have the same non-proprietary scientific name, does this suggest to you or imply that the medicines are structurally identical?

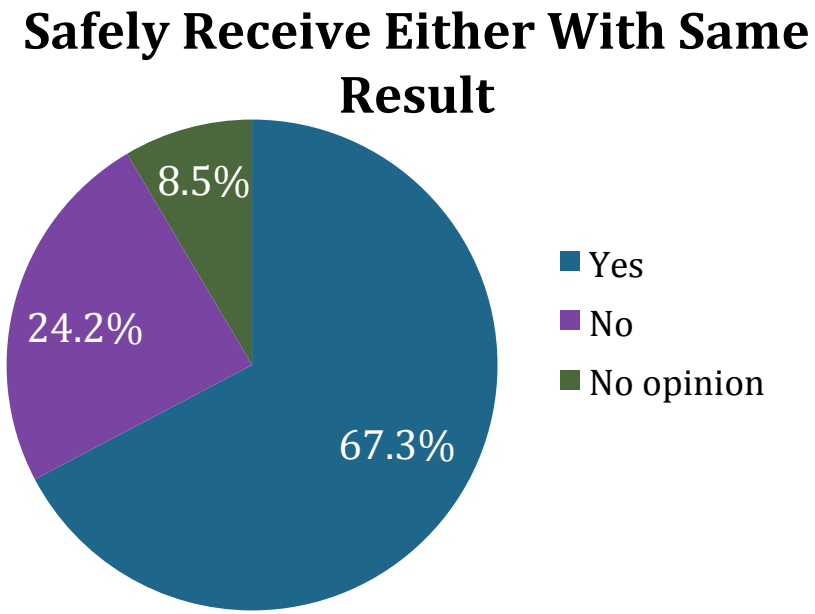
About ¾ of respondents report they would interpret a common scientific name for multiple medicines as meaning they are structurally identical.



Same Scientific Name = Interchangeability? (n=376)

Question: If two medicines have the same non-proprietary scientific name, does this suggest to you or imply that a patient could safely receive either product and expect the same result?

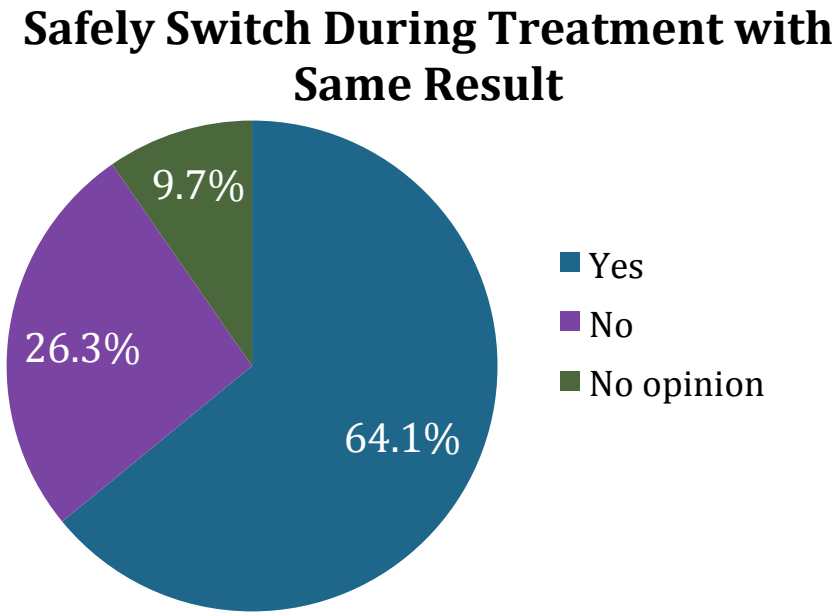
About two-thirds would interpret the common scientific name as meaning a patient could safely receive either product and expect the same result.



Same Scientific Name = Interchangeability? (n=376)

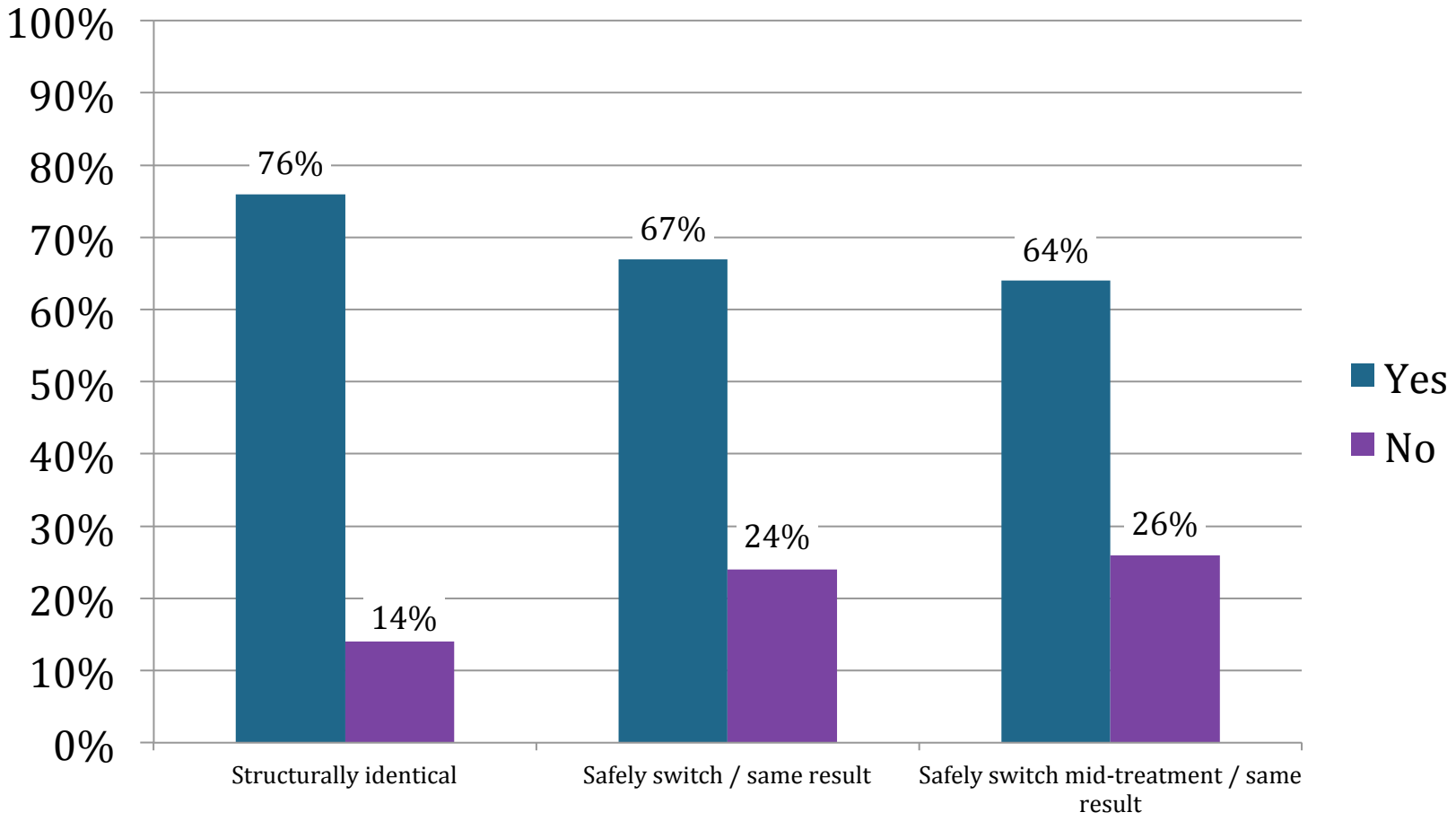
Question: If two medicines have the same non-proprietary scientific name, does this suggest to you or imply that a patient could be safely switched between the products during a course of treatment and expect the same result as treatment with only one of the products?

About two-thirds would interpret the common scientific name as meaning a patient could safely be switched between the products *during treatment* and expect the same result.



Question: If two medicines have the same non-proprietary scientific name, does this suggest to you or imply…?

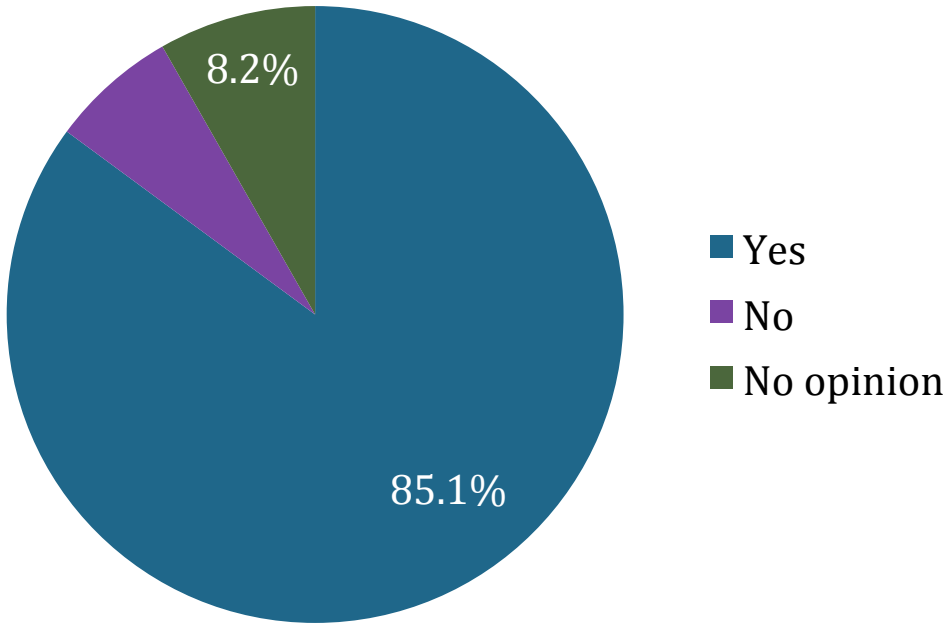
Interchangeability, compared



Desire for D-A-W Authority (n=376)

Question: Every state gives the prescriber the authority to specify that a generic chemical drug may not be substituted without contacting the prescriber, for example by specifying "DO NOT SUBSTITUTE" or "DISPENSE AS WRITTEN". Do you want that same authority in your prescribing of biologic medicines?

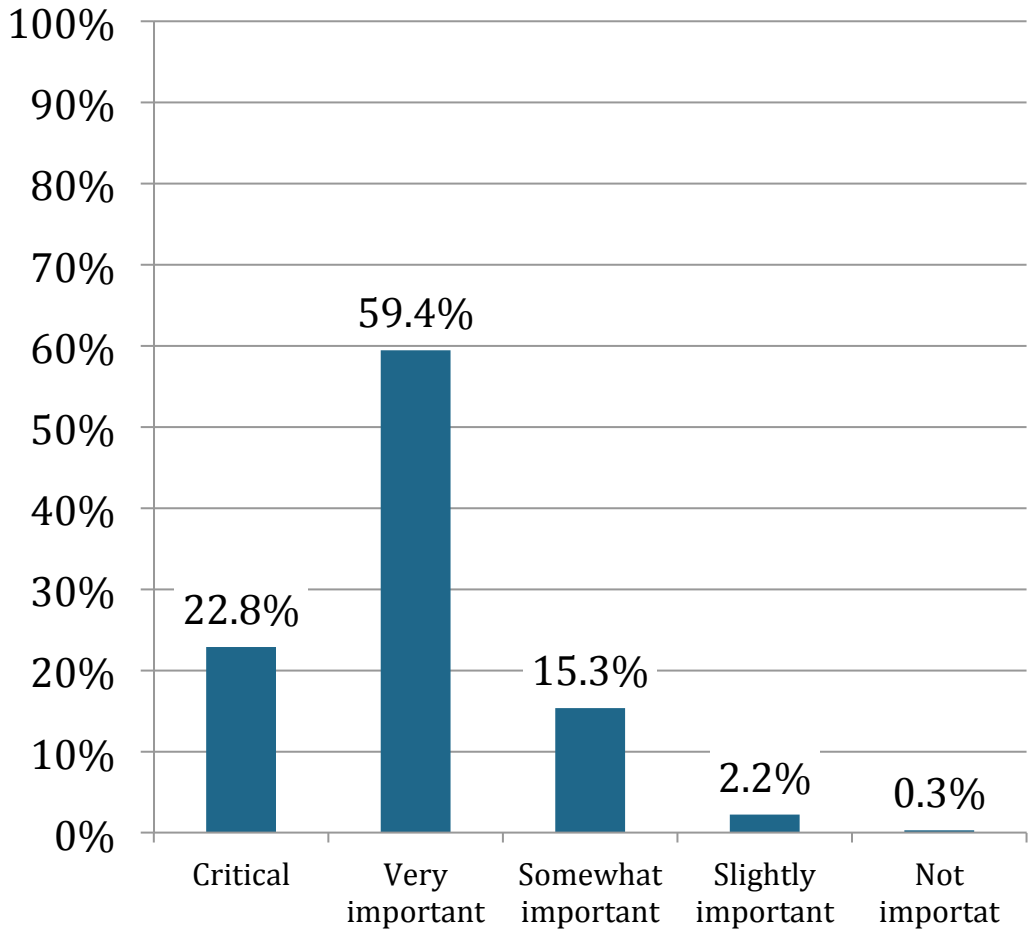
Respondents overwhelmingly (85%) want the authority to designate a biologic medicine as "DO NOT SUBSTITUTE" or "DISPENSE AS WRITTEN."



Importance of D-A-W Authority (n=320)

Question: How important is it to you to have the authority to designate a biologic medicine as "DISPENSE AS WRITTEN" or "DO NOT SUBSTITUTE"?

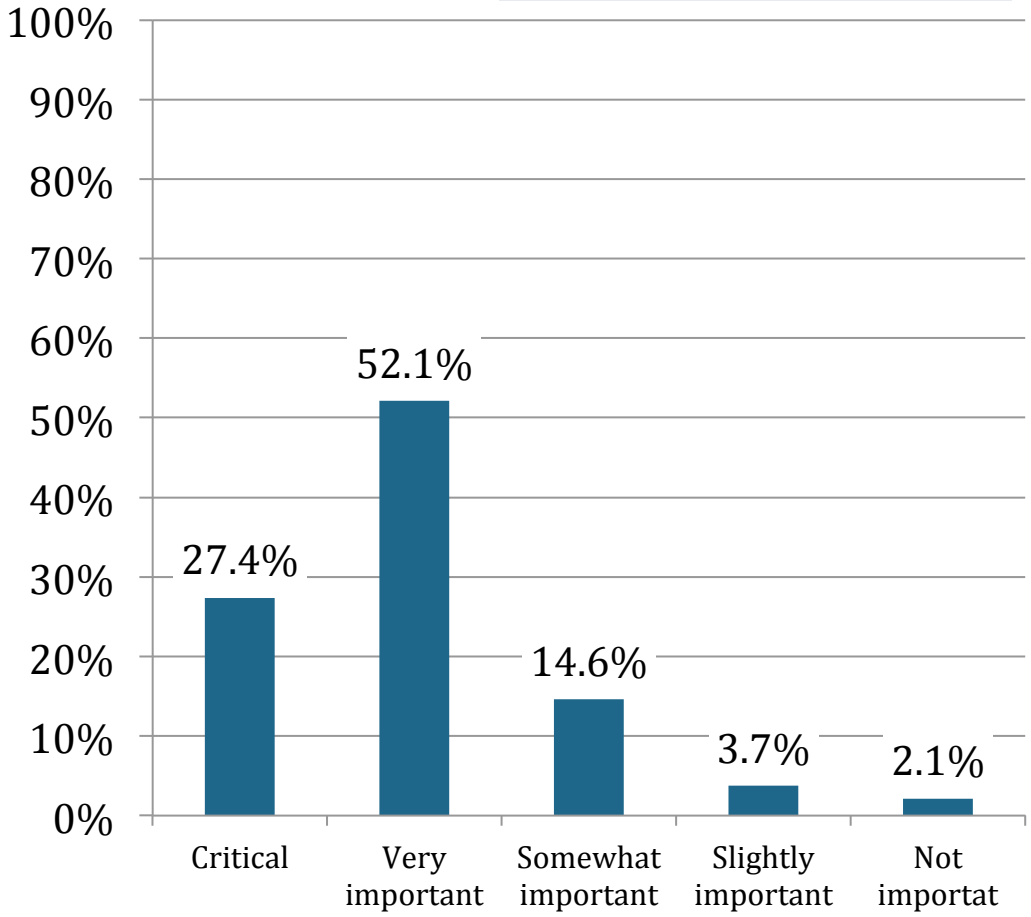
More than 80% of respondents consider this authority "Very important" or "Critical."



Importance of Notification of Change (n=376)

Question: Some states require the pharmacist to notify the prescribing physician if a product other than the one prescribed is dispensed at the pharmacy. How important is it to you to be notified by the pharmacist if your patient receives a biologic medicine other than the one you prescribed?

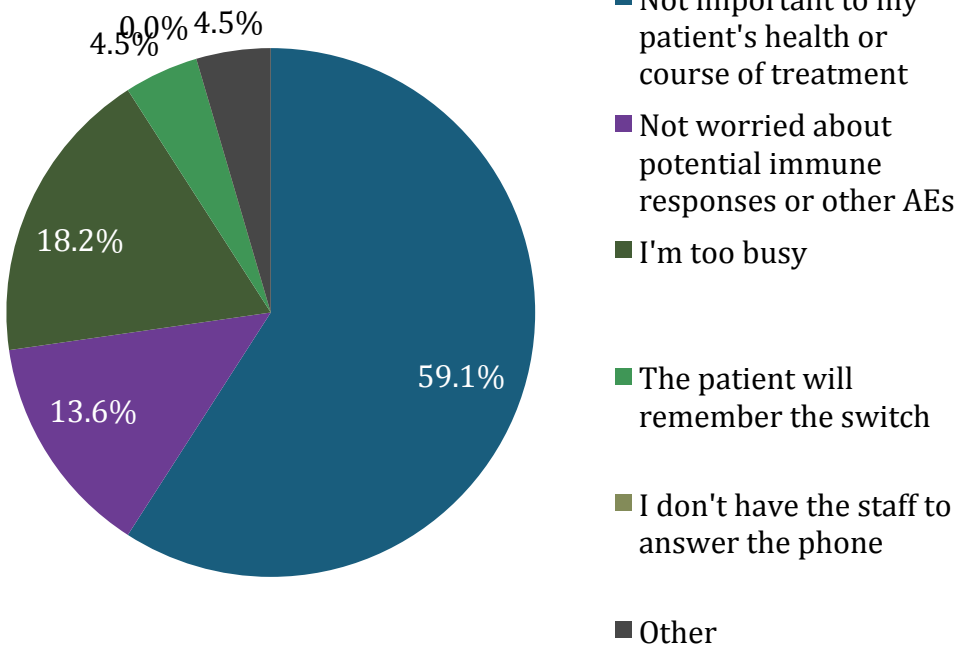
About 80% of respondents consider notification of a pharmacy's switch of a biologic medicine to be either "Very important" or "Critical."



Why is it Not Important? (n=22)

Question: Why is it not important [only slightly important] to you to be notified of a change from the medicine you prescribed?

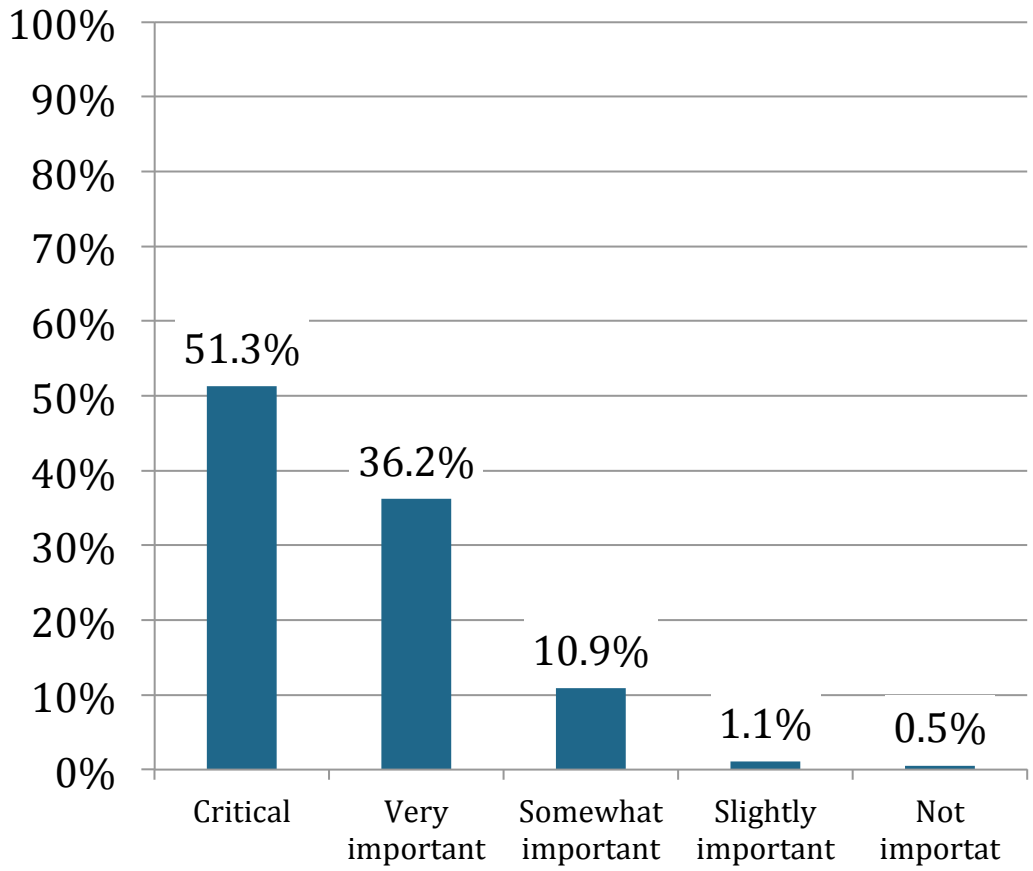
The majority (about 60%) of those who do not believe notification is important report a belief that it is not important to their patient's health or course of treatment.



Importance of Notification of Change – If Aware of Increased Risks (n=376)

Question: How important would it be for you to be notified by the pharmacist that your patient has received a biologic other than the one you prescribed *if you were aware that the product could cause an unwanted immune response in some patients or that small differences between brands could have clinical implications for patients?*

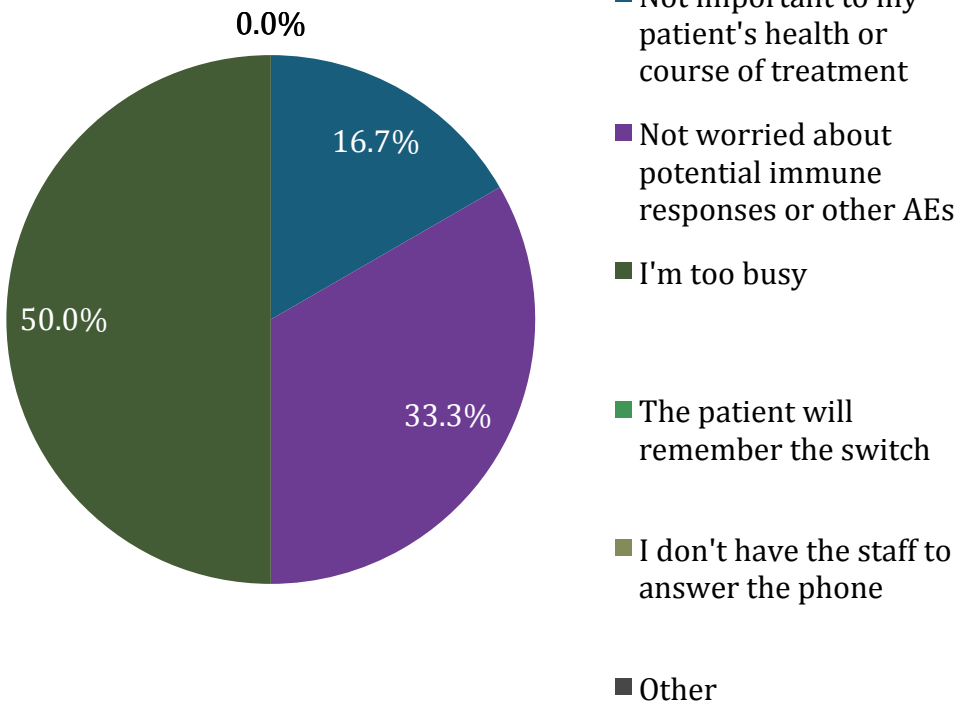
If prescribers are aware of particular risks associated with a product, nearly 90% indicate that being notified of a switch is either "Very important" or "Critical."



Why is it Not Important, In Spite of Risks? (n=6)

Question: Why is it not important [only slightly important] to you to be notified of a change from the medicine you prescribed, in spite of the risks outlined?

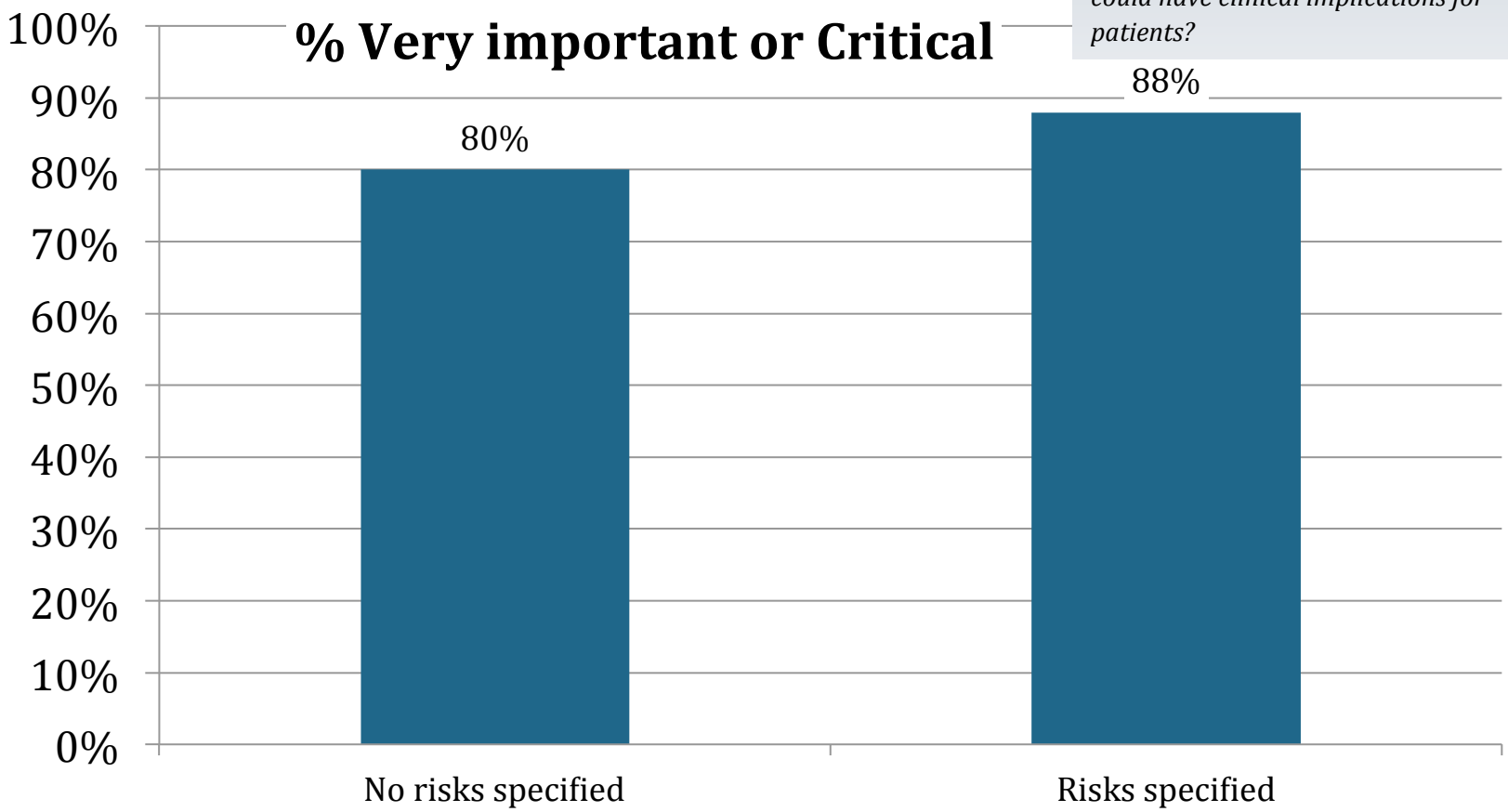
Very few indicated "Not important" or "Slightly important."



Importance of Notification, With and Without Known Risks

Question: How important would it be for you to be notified by the pharmacist that your patient has received a biologic other than the one you prescribed

…if you were aware that the product could cause an unwanted immune response in some patients or that small differences between brands could have clinical implications for patients?

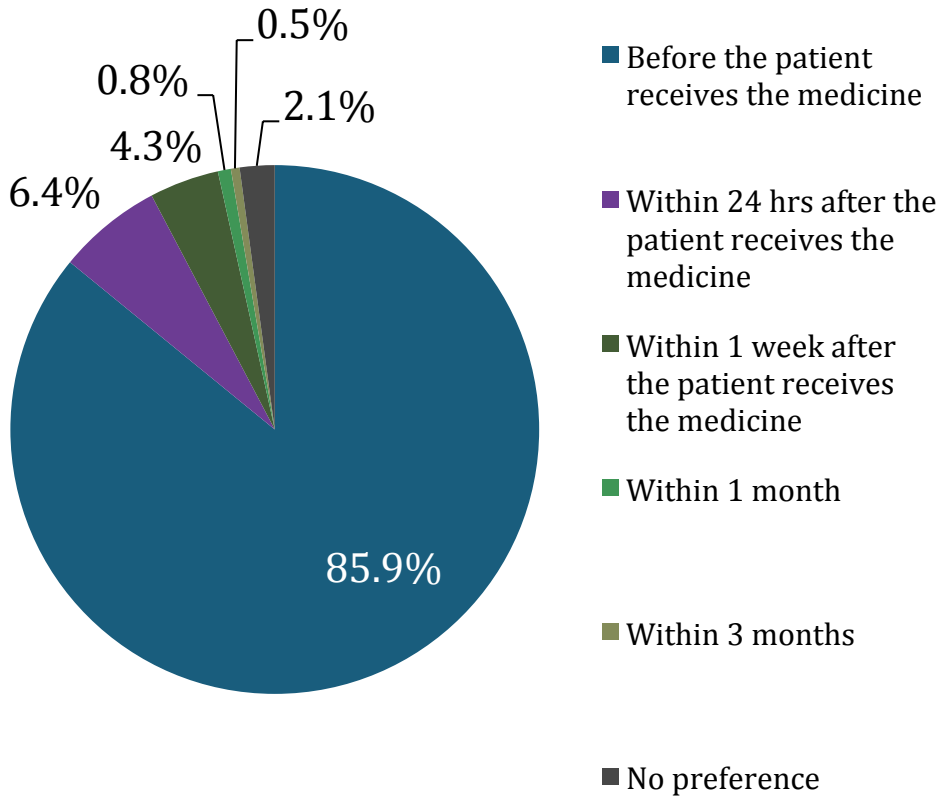


Timeline for Notification (n=376)

Question: At what point would you prefer to be notified of a change in the biologic medicine dispensed?

Respondents held clear preferences for their timelines for notification.

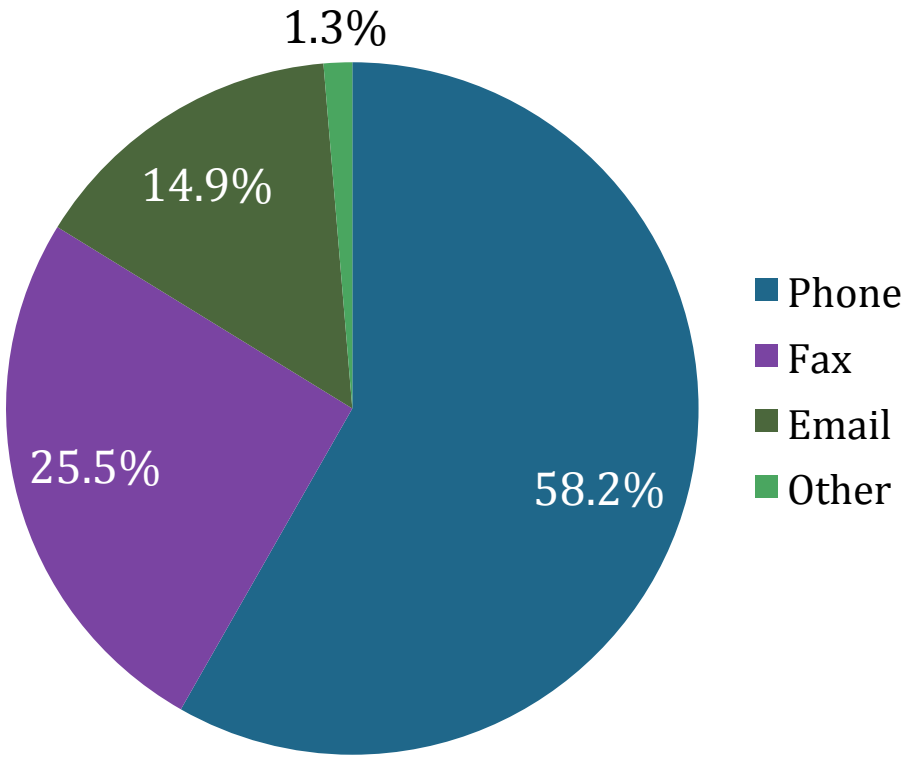
About 85% would prefer to be notified "Before the patient receives the medicine."



Question: How do you prefer to be contacted by a pharmacy about prescription changes? Please select one.

Contact Preference (n=376)

The majority (58%) of respondents indicated a preference for telephone notification. The remaining were split between fax and email.



APPENDIX

About Industry Standard Research

What we do…

Industry Standard Research (ISR) was founded serve the unmet needs of companies looking to better understand how their customers make decisions. ISR is different from other market research companies in that we combine operational-level expertise with rigorous, industry-leading market research methodologies.

What you get…

Confidence. Results and recommendations based on input from people who have been in the industry, owned P&Ls, developed strategies, and operationalized tactical plans. Results that impact your business, not just “nice to know” data points.

www.ISRreports.com
info@ISRreports.com
+1 919-301-0106