Information Wanted: Finding the Balance in Pharmaceutical Evidence Exchange With Payers and Providers

Introduction

Twenty years ago, Section 114 of the Food and Drug Administration Modernization Act (FDAMA) of 1997 created a pathway for communication of healthcare economic information (HCEI) between biopharmaceutical companies and formulary committees or similar entities.[1] However, lack of further regulation or guidance from the Food and Drug Administration (FDA) has sown confusion among affected stakeholders on what the legislation permitted.

As lawyers debated the bounds of the legislation, payment and reimbursement models for payers and providers began shifting from volume- to value-based payment—all the while leaving manufacturers wondering what types of evidence payers and providers find useful, what is permissible to communicate under FDAMA Section 114, and how Section 114 might evolve. Similarly, payers and providers often were making population treatment decisions without adequate information.

While Section 3037 of the 21st Century Cures Act, signed into law in December 2016, added considerable detail and clarification to permissible HCEI communications between manufacturers and payers, formulary committees, or similar entities, questions remain.[2] Subsequently, in January 2017, the FDA released draft guidance documents to address the exchange of information and sought comment on these changes. But questions remain about what information would be useful to payers and providers and what information is permitted as the guidance is finalized.

In March 2017, Xcenda surveyed payers and providers to understand the types of information they desire and value in this shifting environment—and the potential benefits and unintended consequences of broader distribution of HCEI and information beyond the FDA-approved label.

Findings

Payers and Providers Desire More Information and Believe It Will Affect Decision Making

Perhaps not unexpectedly, the survey found that most payers and providers are interested in getting more, and better, information. The majority of payers cited at least 6 aspects of a drug as being very/extremely important to understand as part of making medical policy and coverage decisions, of which only 3 are typically available in a product's FDA-approved label: how well patients do clinically, comparative information about effectiveness and safety relative to treatment alternatives from a clinical trial, and what side effects might occur **(Figure 1)**.

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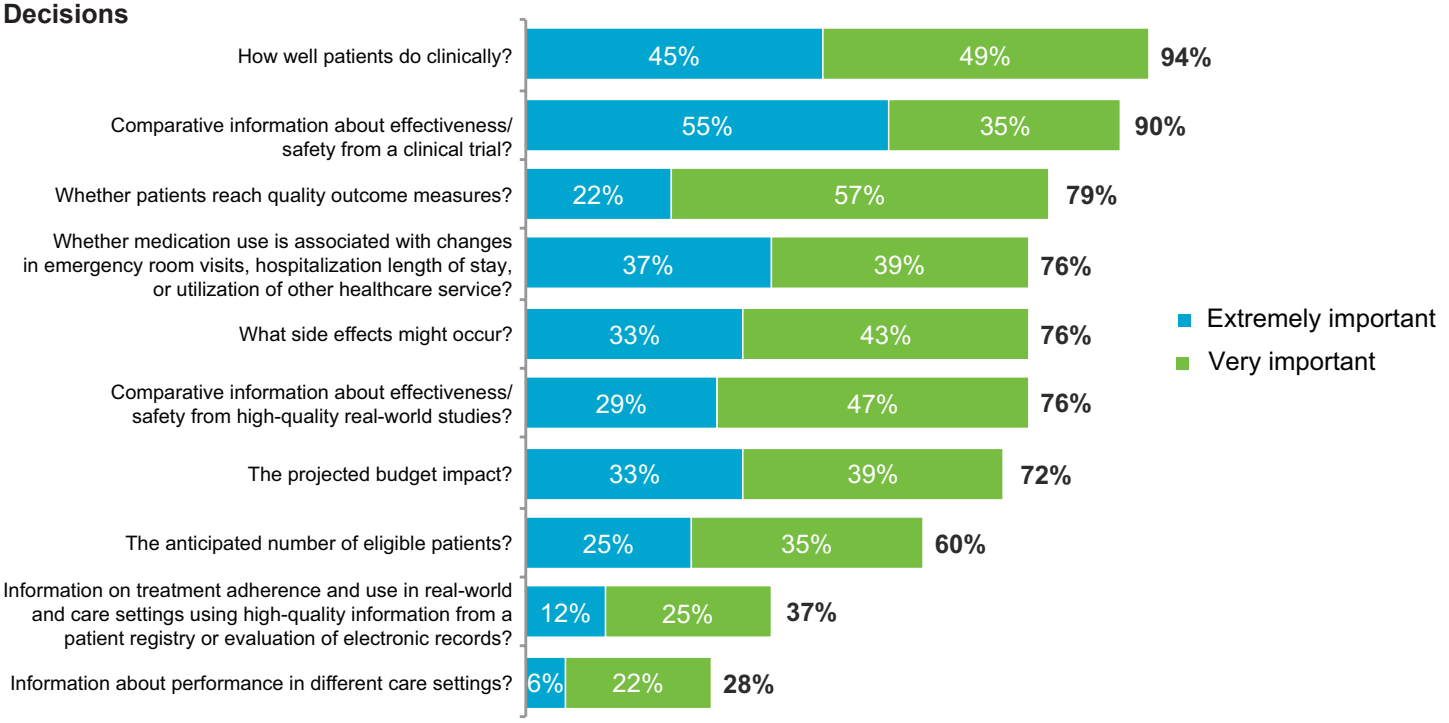
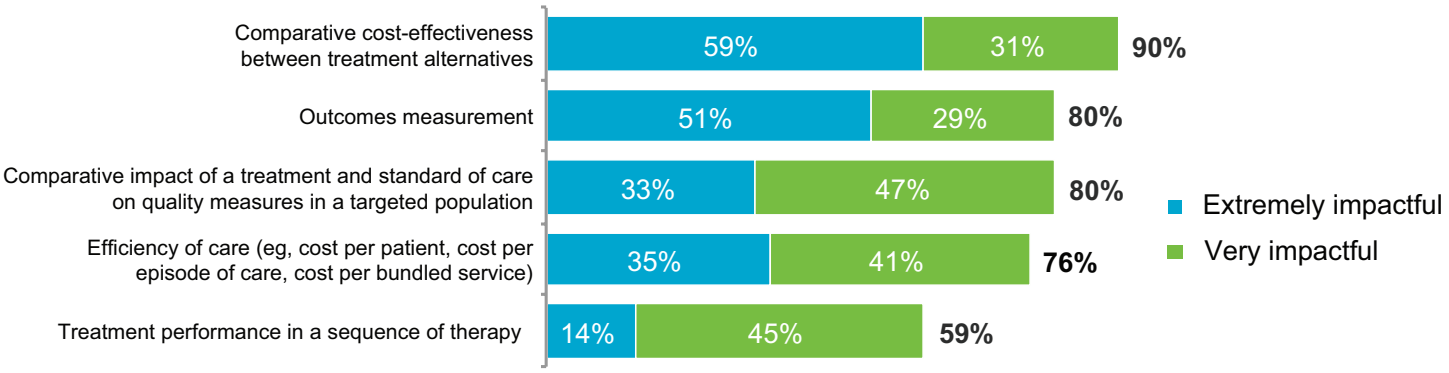
Figure 1. The Majority of Payers Found Many Types of Information to Be Important for Coverage and Policy Decisions



Q: When you are part of a medical policy or P&T committee, and you are making decisions about a therapy, how important is it to understand...? (N=51)

In the next 3 to 5 years, payers believed that multiple types of information **(Figure 2)** will be impactful in guiding healthcare decision making, with a clear interest in comparative product information (cost-effectiveness, impact on quality measures, outcomes measurement, and efficiency of care).

Figure 2. The Majority of Payers Believed Comparative Product Information Will Be Very or Extremely Impactful in Guiding Healthcare Decision Making



Q: Compared to today, please anticipate how impactful you think the following types of information will be in guiding healthcare decision making in the next 3 to 5 years. (N=51)

Providers felt similarly as payers about valuing a large number of types of information when making treatment decisions. Again, the majority of these do not appear on a product's FDA-approved label.[a]

Providers also felt that those product qualities would be important in decision making, though to a lesser extent; the percentage who felt that these would be very or extremely impactful ranged from 52% to 81%, with outcomes measurement receiving the highest importance rating.

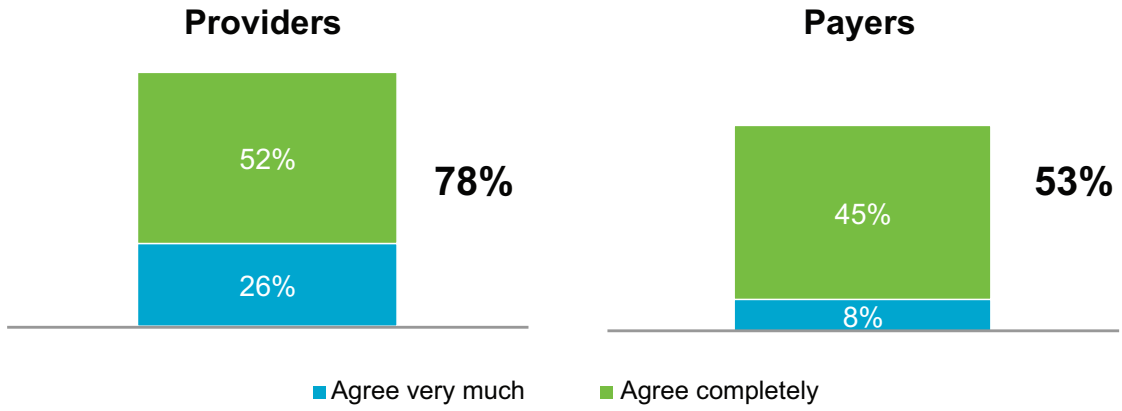
[a] Note that not all data are shown. Full survey results are available on the NPC website.

Quality Measures May Affect Treatment Decisions Moving Forward

Quality measures can help payers reward better care, and new delivery models reward provider groups for quality of care. And yet, this information may not always be shared under current regulations.

Over 75% of providers, who are often reimbursed based on meeting quality measures, agreed that a product's impact on quality measures will influence treatment decisions in the next 3 to 5 years **(Figure 3)**. Payers were less likely to agree, with only 50% concurring.

Figure 3. Three Out of 4 Providers Agreed That Quality Measures Will Influence Decision Making in the Future; Payers Less Sure

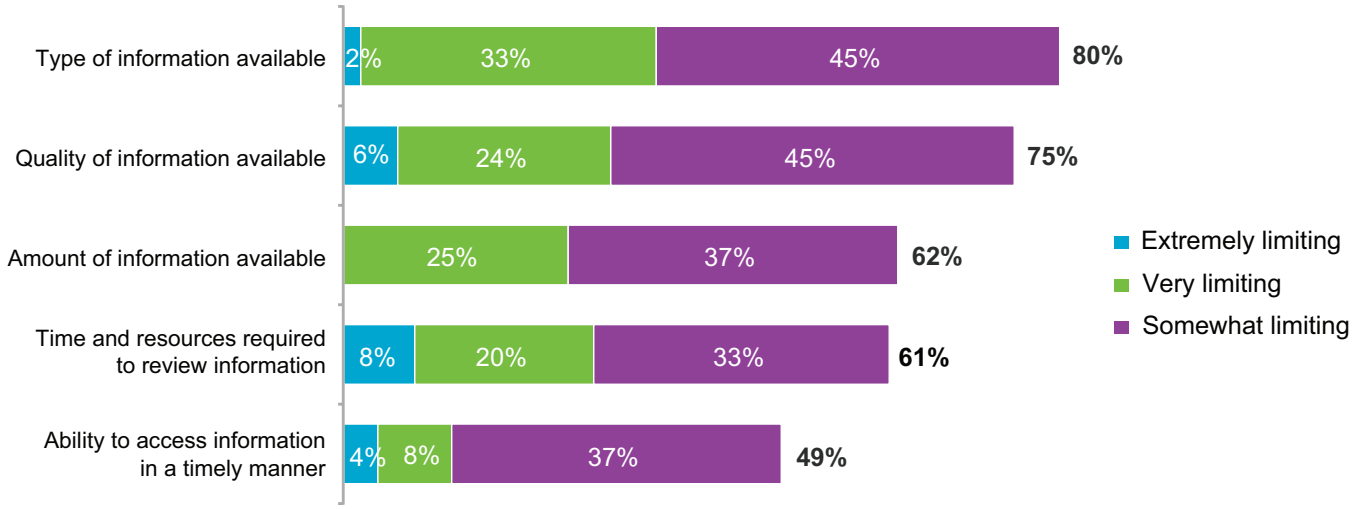


Q: How much do you agree or disagree with the following statement: "A biopharmaceutical product's impact on quality measures will influence coverage decisions in the next 3 to 5 years"? (Provider, N=31; Payer, N=51)

Decision Making Is Limited by Available Information

In terms of constraints for formulary decisions, payers were much more likely to emphasize being limited by the type and quality of information available vs having the time and resources to review the information or the ability to access information in a timely manner **(Figure 4)**.

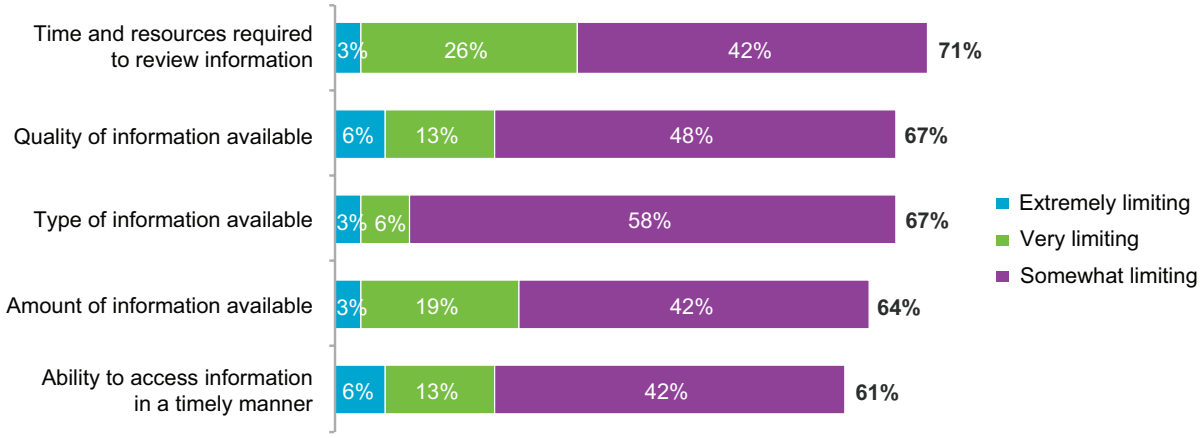
Figure 4. Payers Feel Most Limited by the Type and Quality of Information Available



Q: To what degree do you think your organization's formulary decision making is limited, or not, by each of the following? (N=51)

On the other hand, providers felt time and resources limited their ability to use information for making treatment decisions more than payers did **(Figure 5)**.

Figure 5. Providers Felt Time and Resources Limit Their Ability to Use Information to Make Treatment Decisions



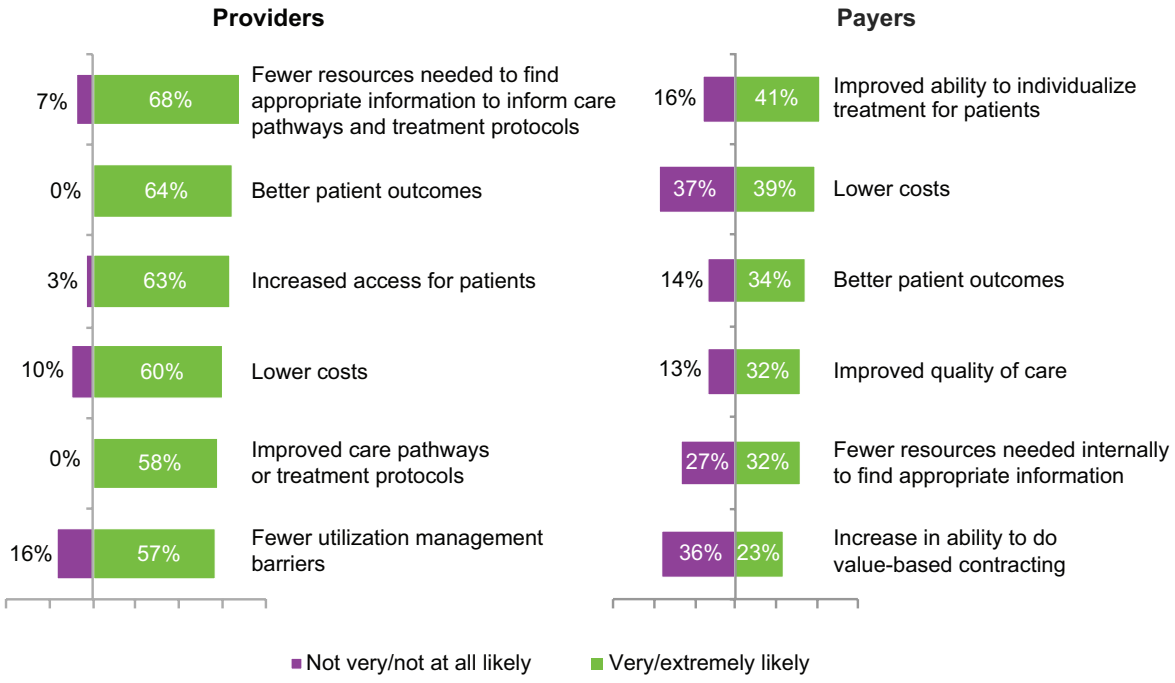
Q: To what degree do you think your organization's treatment decision making is limited, or not, by each of the following? (N=31)

Potential Benefits of Additional Information Outweigh Potential Harms

When asked to discuss the potential benefits of additional information exchange consistent with, but beyond, the FDA-approved product label, providers overwhelmingly thought several benefits were very or extremely important: fewer utilization management barriers (87%), increased patient access (84%), and better patient outcomes (81%). Payers found benefits such as lower costs (88%) and improved patient outcomes (80%) to be very or extremely important.[b]

Both providers and payers were optimistic that additional sources of information would lead to a number of benefits. Providers were more convinced than payers about the likelihood of such benefits **(Figure 6)**.

Figure 6. Providers Are More Optimistic Than Payers of the Potential Benefits of Broader Information Exchange



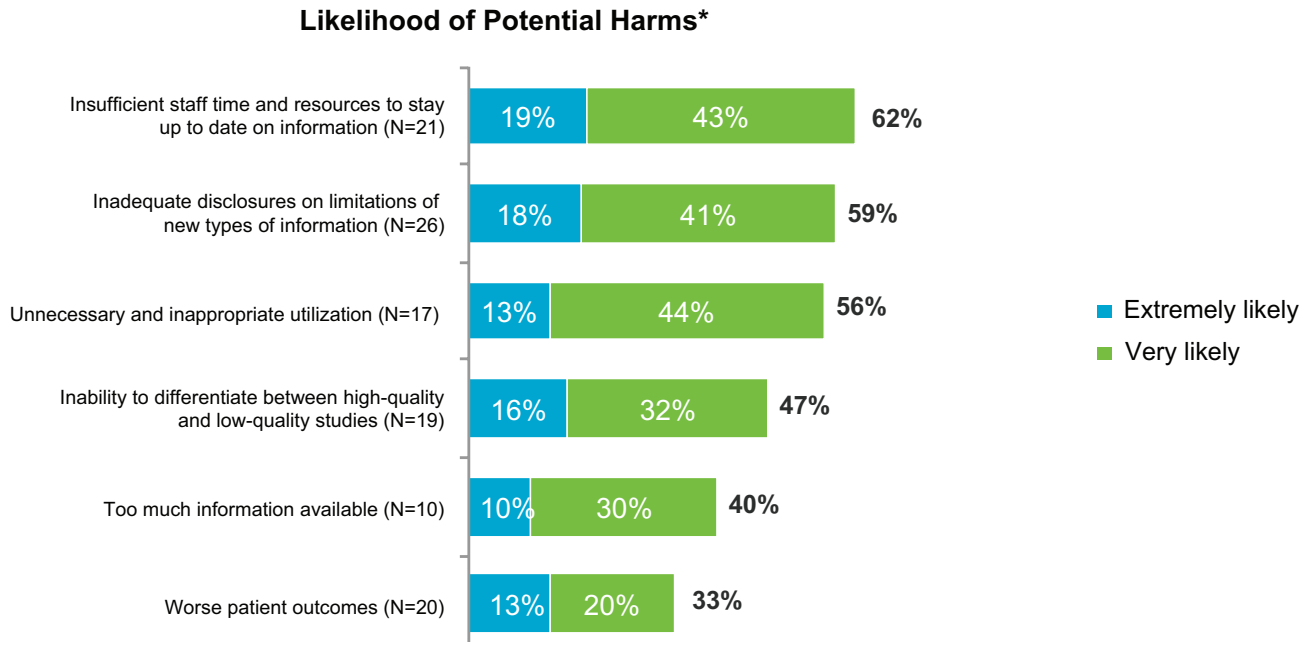
Q: How likely is each of the potential benefits you indicated as being important in the previous question to occur? (Provider, N=28–31; Payer, N=37–49). N differs from the total sample as these questions were only asked to respondents who felt that there were potential benefits.

[b] Q: How important is each of the following as a potential benefit for clinical decision making, coverage, and/or reimbursement if information that is consistent with but not included in the FDA-required label for an approved medication (eg, comparison to a drug with the same indication, additional information on adverse reactions not included in label, onset of action, additional long-term safety or efficacy for chronic use medications, effects among specific patient) was shared? (Provider, N=31; Payer, N=51). N differs from the total sample as these questions were only asked to respondents who felt that there were potential benefits.

Unaided, neither providers nor payers consistently envisioned a specific potential harm with additional information exchange. Payers were most concerned that the additional information beyond the product's FDA-approved label could encourage unnecessary and inappropriate utilization, while providers were comparatively much less concerned that the additional information would lead to harms **(Figures 7 and 8)**.

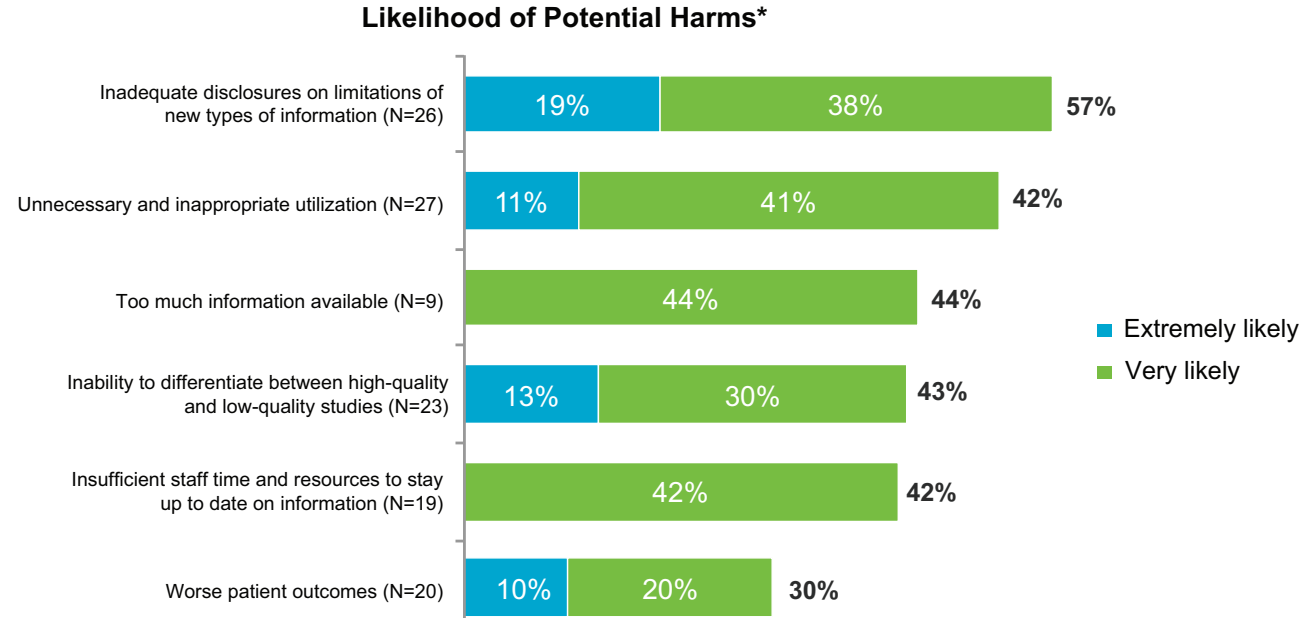
When asked about the likelihood of various potential harms, both payers and providers rated inadequate disclosures on the limitations of new types of information as likely to occur. Providers were more worried about having the time and resources to stay up to date.

Figure 7. Providers Concerned About Adequate Time, Resources, Disclosures, and Utilization



Q: How likely is each of the potential harms you indicated in the previous question to occur? (N=10–21)

Figure 8. Payers Concerned About Disclosures and Utilization

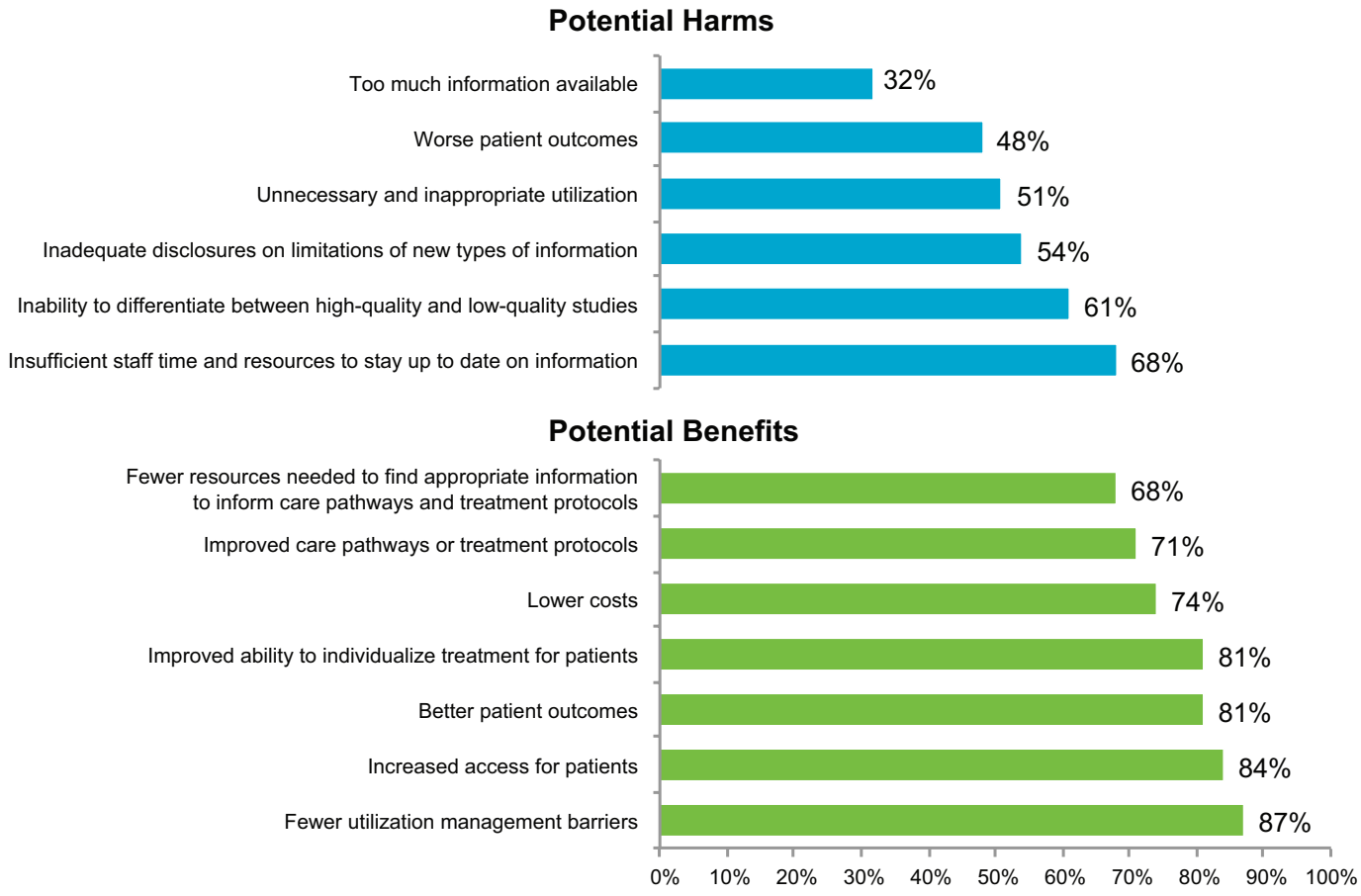


Q: How likely is each of the potential harms you indicated in the previous question to occur? (N=9–27)
**N differs from the total sample as this question was only asked to respondents who felt that there were potential harms.*

Benefits of Additional Information Outweigh Risk for Both Payers and Providers

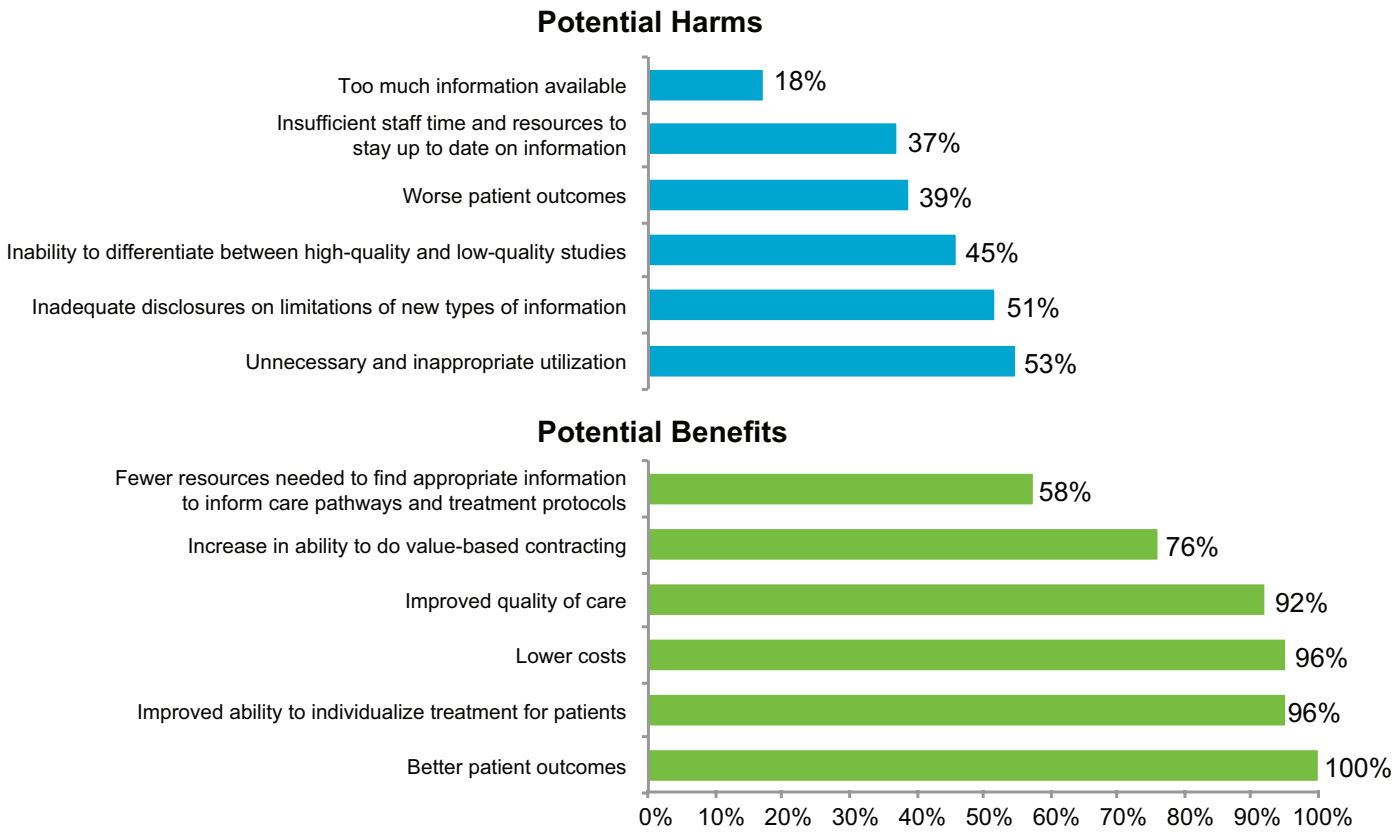
Despite payers and providers acknowledging potential harms from information beyond the FDA-approved label, both groups believe the potential benefits (in terms of importance and likelihood) outweigh the potential harms **(Figures 9 and 10)**.

Figure 9. Importance of Potential Benefits Appears to Outweigh Potential Harms for Providers



Q: How much do you agree or disagree that each of the following is a potential harm for clinical decision making, coverage, and/or reimbursement if the information that is consistent with, but not included in, the FDA-required label for an approved medication was shared? (N=31). How important is each of the following as a potential benefit for clinical decision making, coverage, and/or reimbursement if information that is consistent with, but not included in, the FDA-required label for an approved medication was shared? (N=31)

Figure 10. Importance of Potential Harms Outweighed by Potential Benefits for Payers



Q: How much do you agree or disagree that each of the following is a potential harm for clinical decision making, coverage, and/or reimbursement if the information that is consistent with, but not included in, the FDA-required label for an approved medication was shared? (N=31). How important is each of the following as a potential benefit for clinical decision making, coverage, and/or reimbursement if information that is consistent with, but not included in, the FDA-required label for an approved medication was shared? (N=51)

Sources of Information

Both payers and providers utilized a variety of resources for researching information relevant to medical decision making. Seventy-five percent of payers and 65% of providers use 6 or more information sources on a monthly basis, with the internet cited as being used daily.[c] Over the next few years, the sources of information payers and providers expect to use remain fairly consistent.[d]

Methodology

A web-based survey of payers (N=51) and providers (N=31) was conducted in March 2017. Participation was voluntary and fully blinded. An honorarium was paid to survey respondents.

Payers

Payer representatives consisted of pharmacy directors (61%) and medical directors (33%); contracting directors, industry-relations directors, clinical services directors, and “other” accounted for the remaining 6%. Payers represented managed care organizations (75%), pharmacy benefit managers (22%), integrated health delivery systems/integrated delivery networks (10%), accountable care organizations (4%), specialty pharmacies (4%), and health systems/hospitals (2%). (Organizations total to more than 100%, as some respondents serve in multiple capacities.)

[c] Q: How frequently do you currently utilize each of the following information channels? (Payers, N=51; Providers, N=31)
[d] Q: Thinking about the future, how frequently do you expect to utilize each of these channels in the next 5 years? (Payers, N=51; Providers, N=31)

Among the respondents, their organizations covered an average of 5.2 million lives each. One-third of the respondents' organizations offered national coverage. Of those who worked for organizations that offered regional coverage, 40 states (plus the District of Columbia) were covered. All who participated in this research were directly involved in medical policy, formulary decisions, and/or tracking utilization management.

Providers

Physician representatives consisted of a variety of specialties, including cardiology, endocrinology, emergency medicine, gastroenterology, general practice/family practice/family medicine, internal medicine, obstetrics/gynecology, oncology/hematology, and pulmonology. They averaged 18 years of practicing medicine full time and practiced in a variety of settings, including solo or group private practices, community hospitals, academic hospitals, and integrated delivery systems.

References

1. Food and Drug Administration Modernization Act (FDAMA) of 1997. Public Law 105-115. November 14, 1997. https://www.congress.gov/105/plaws/publ83/PLAW-105publ83.pdf. Accessed March 23, 2017.
2. 21st Century Cures Act. Public Law 114-255. December 13, 2016. https://www.congress.gov/bill/114th-congress/house-bill/34. Accessed March 23, 2017.

The research design was jointly developed by Xcenda/AmerisourceBergen Corporation and the National Pharmaceutical Council (NPC).