OUTCOMES-BASED AGREEMENTS: CANADIAN EXPERIENCE AND PERCEPTIONS

SURVEY RESULTS

October 12, 2021

The following report contains the findings of research conducted by the 2021 RWE & OBA Working Group.
Please contact **info@20sense.ca** for all inquiries.

ABOUT THE RWE & OBA WORKING GROUP

The mission of the Real-World Evidence and Outcomes-Based Agreements Working Group is to advance the opportunity for the use of outcomes-based agreements in Canada.

Established in 2019, the working group brings together organizations inspired by the opportunity for real-world evidence (RWE) generation to support outcomes-based agreements (OBAs) in Canada. The scope of the working group includes all therapeutic areas and both public and private payer markets.

The working group values inclusion, knowledge sharing and collaboration, and invites input and participation from all relevant parties, with the objective of advancing opportunities for OBAs to the benefit of all stakeholders in the Canadian healthcare system.

It is recognized that there are many challenges to overcome with the development and implementation of OBAs in Canada, and that the landscape is constantly evolving. The working group's method is to actively address these challenges and to find potential solutions and approaches that will provide value to all stakeholders.

The 2021 RWE & OBA Working Group Members include AstraZeneca, Bayer, BioScript Solutions, Janssen, Novartis, Pfizer, and 20Sense.

More on the RWE & OBA Working Group can be found at
https://www.20sense.ca/the-rwe-oba-working-group.
Please contact **info@20sense.ca** for all inquiries.

RESEARCH OBJECTIVES

The *Canadian Outcomes-Based Agreement Experience and Perceptions Survey* was conducted by the RWE & OBA Working Group to understand Canadian stakeholders' positions and knowledge of outcomes-based agreements (OBAs), current experience with OBAs, and future plans for OBAs.

Research was conducted from August to September 2021. It included an online self-serve survey and qualitative follow-up interviews. Participation was open to individuals from the following organizations, current or past: Patients and patient organizations; Regulatory; HTA; pCPA; Public Payers; Private Payers; Physicians/HCPs; Academics/Researchers.

The objective of this this research is to provide insights into the current state of OBAs in Canada.

TERMINOLOGY

An **outcomes-based agreement (OBA)** is an innovative market access agreement based on the principle of sharing risk between manufacturers and payers, by linking payment for a drug to a real-world health outcome. These agreements typically include both a data-collection component and a commercial agreement component to delineate the risk-sharing terms. Depending on the jurisdiction, such market access agreements are also known as value-based, managed-access, or performance-based agreements. For the purpose of this survey, the term **OBA** will be used.

A **patient support program (PSP)** is a service which, depending on its associated drug, may educate patients on the disease and drug, liaise with insurers to assist with reimbursement, setup treatment schedules and reminders, provide updates to physicians, and deliver medication to its destination.

SURVEY PARTICIPATION

There were 38 individual respondents to the online self-serve survey, with affiliations as follows:

- Academic & HTA (10)
- Patient organization & Physician/HCP (15)
- Public & Private payers (13)

Follow-up qualitative interviews were conducted with 5 respondents to validate survey responses and collect additional input.

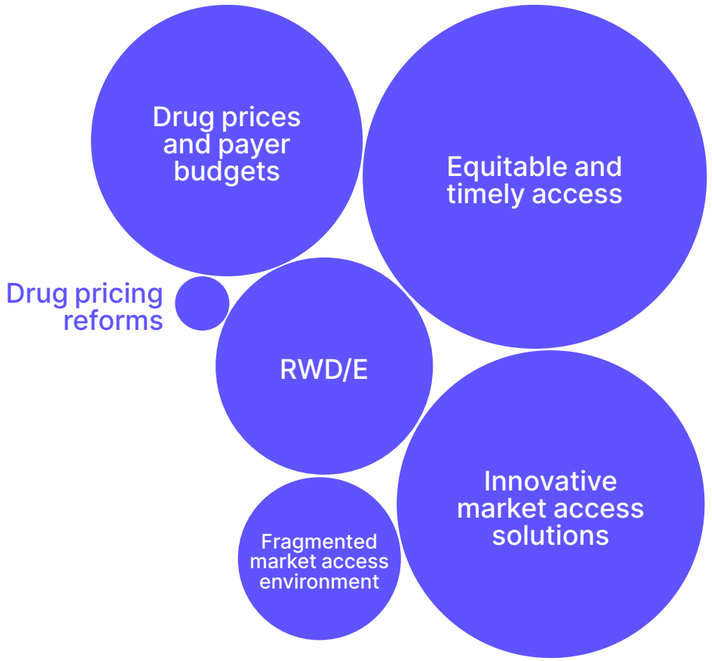
Survey results are shown in aggregate. Individual participants and organizations are not identified. All responses are confidential. Each result includes a legend indicating the original question and the number of responses.

Q2: WHICH OF THE FOLLOWING BEST DESCRIBES YOUR AFFILIATION, CURRENT OR PAST? N= 38

OUTCOMES-BASED AGREEMENTS: CANADIAN EXPERIENCE AND PERCEPTIONS

SURVEY RESULTS

What do you think are the biggest opportunities and/or challenges with drug reimbursement in Canada today?



Equitable and timely access

"Timely access for patients post-NOC."
"Too many discrepancies between the drugs approved by health Canada and the ones reimbursed."
"Equity across jurisdictions."
"There is a pressure to give earlier access, but it often implies that there are more uncertainties."

Innovative market access solutions

"Lack of flexibility and creativity in achieving public funding, and in government processes to support innovative ideas."
"Payer willingness to do things differently."
"Lack of federal policy to direct payers."

Drug prices and payer budgets

"Drug budgets are not able to keep up with the cost of the new drugs."
"Very high drug prices, with sometimes little benefits over current practice."
"Health system sustainability."

RWD/E

"Lack of robust data to inform decision making."
"Lack of guidance on use/acceptability of RWE."

Fragmented market access environment

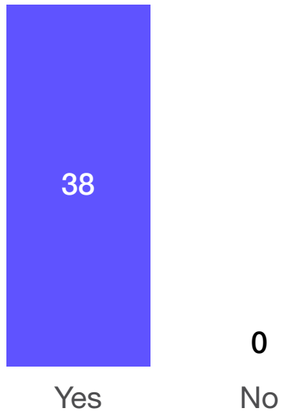
"Patchwork of funding programs across Canada."
"Too many government bodies doing overlapping activities."

Drug pricing reforms

"Uncertainty with pricing reforms."

Q4: IN YOUR OPINION, WHAT DO YOU THINK ARE THE BIGGEST OPPORTUNITIES AND/OR CHALLENGES WITH DRUG REIMBURSEMENT IN CANADA TODAY? N=75

100% of respondents see a need for real-world data collection in Canada



Respondents noted:

"It would provide an option to fund important products that have challenges in generating data in traditional clinical trials." **– Public Payer**

"To better inform clinical practice, patient care, and re-visit funding decisions. For further learnings and for demonstration of value." **– Public Payer**

"RWD can support submissions for therapeutic areas where there is high levels of uncertainty based on trial data alone." **– Academic**

"RCT inherent limitations mean that we don't have the full picture about the effects on the general population. These are very important in order to assess the real value of a product." **– HTA**

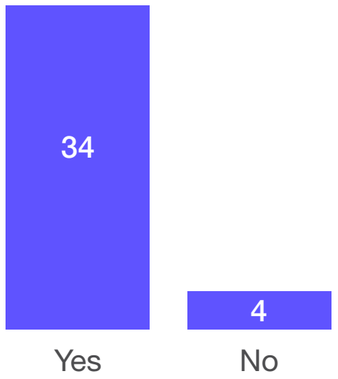
"Data can provide information regarding real-world drug effectiveness. Studies are not often done with real world comorbidities and diagnostic uncertainties." **– Physician/HCP**

"To support reimbursement decision makers' data requirements. Collecting as much data as possible informs fair and evidence-based policy making and reimbursement decisions that benefit patients in a real-world context. " **– Patient organization**

"We can only improve what we measure." **– Patient organization**

Q5: DO YOU SEE A NEED FOR REAL-WORLD DATA COLLECTION IN CANADA? N=38

The majority of respondents see a need for OBAs in Canada



Q6: DO YOU SEE A NEED FOR OBAS IN CANADA? N=38

Those who responded “yes” noted:

“Helpful for complex drugs that have significant data gaps and uncertainty. For example, there may be new drugs that have a small population in which it is not feasible to do a phase 3 trial.” **– Public Payer**

“Need to pay for results; cannot afford inefficiencies.” **– Public Payer**

“OBAs are a necessary tool for advancing early access while managing risk.” **– Private Payer**

“OBAs are needed as drugs are prohibitively expensive and unsustainable. Some will never get paid for otherwise.” **– Physician/HCP**

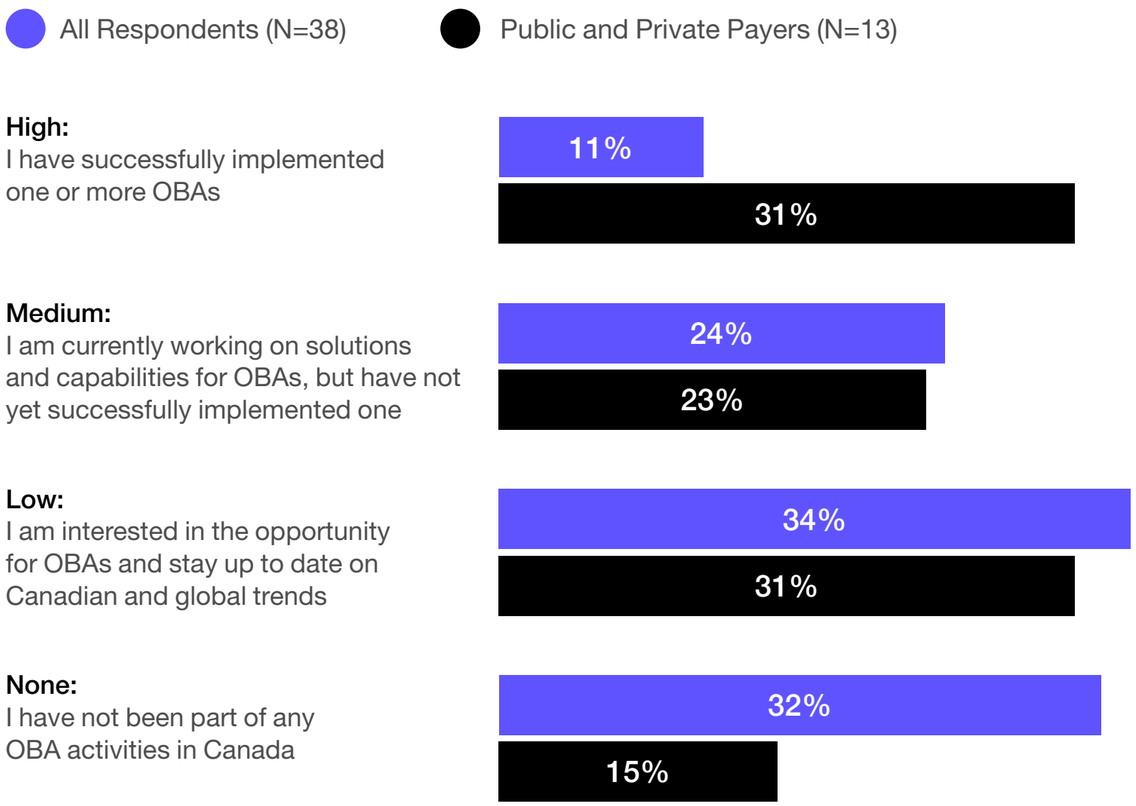
“Optimization of drug/health technology use in real world context.” **– HTA**

“Yes, to enhance expeditious access to life saving and quality of life enhancing drugs, and to mitigate the risk for payers of uncertainly.” **– Patient organization**

Those who responded “no” noted:

“OBAs place a lot of cost and therefore risk on the payer. It should be the responsibility of the manufacturer to have the data to show the value of their product, not the responsibility of the payer to pay to create this data.” **– Public Payer**

What best describes your experience with OBAs?



Based on the respondents' experience levels, some stakeholders are doing outcomes-based agreements in Canada.

Payers:

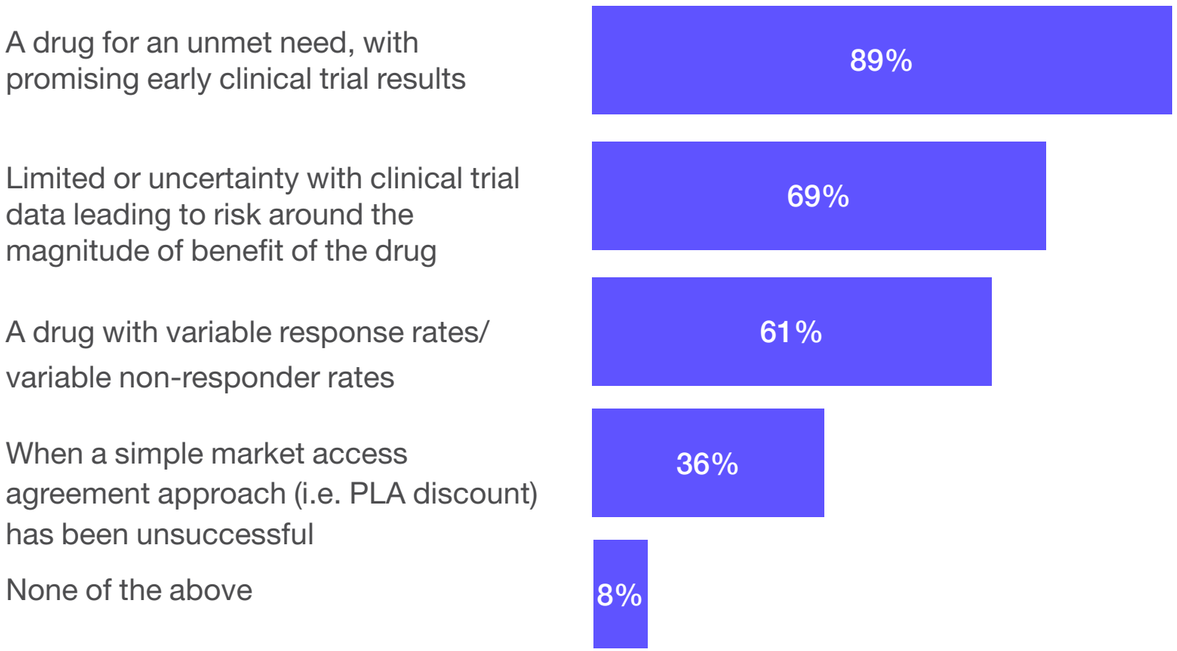
4 (31%) indicated that they have successfully implemented one or more OBAs.

7 payers (54%) have either medium or low OBA experience.

2 payers (15%) have not been part of any OBA activities.

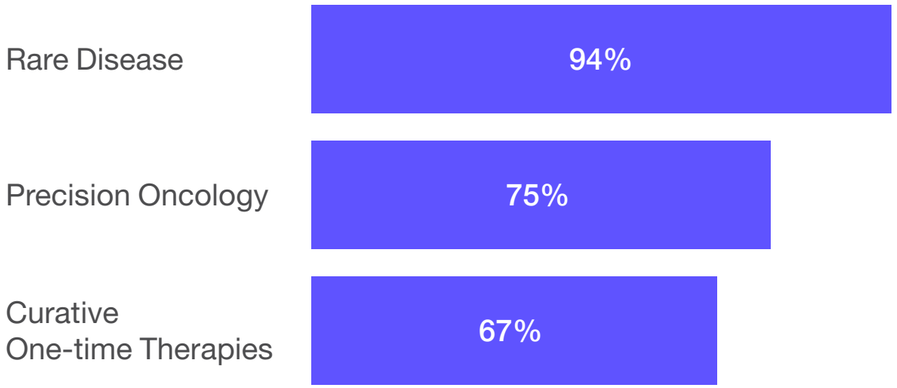
Q7: PLEASE SELECT THE FOLLOWING OPTION THAT BEST DESCRIBES YOUR EXPERIENCE WITH OBAS. N=38

In which situations would it be appropriate to consider using an OBA?



Q8: IN WHICH OF THE FOLLOWING SITUATIONS, IDENTIFIED BY RWE & OBA WORKING GROUP RESEARCH, DO YOU FEEL IT WOULD BE APPROPRIATE TO CONSIDER USING AN OBA? PLEASE SELECT ALL THAT APPLY. N=36

Rare disease and precision oncology have the most urgency for OBAs



Respondents noted that there is also an urgency for OBAs for with:

"When there are few patients (i.e., less than 50), like with many rare disease therapies, the data collection for an OBA should be possible to do. We could track via manual processes." **– Private Payer**

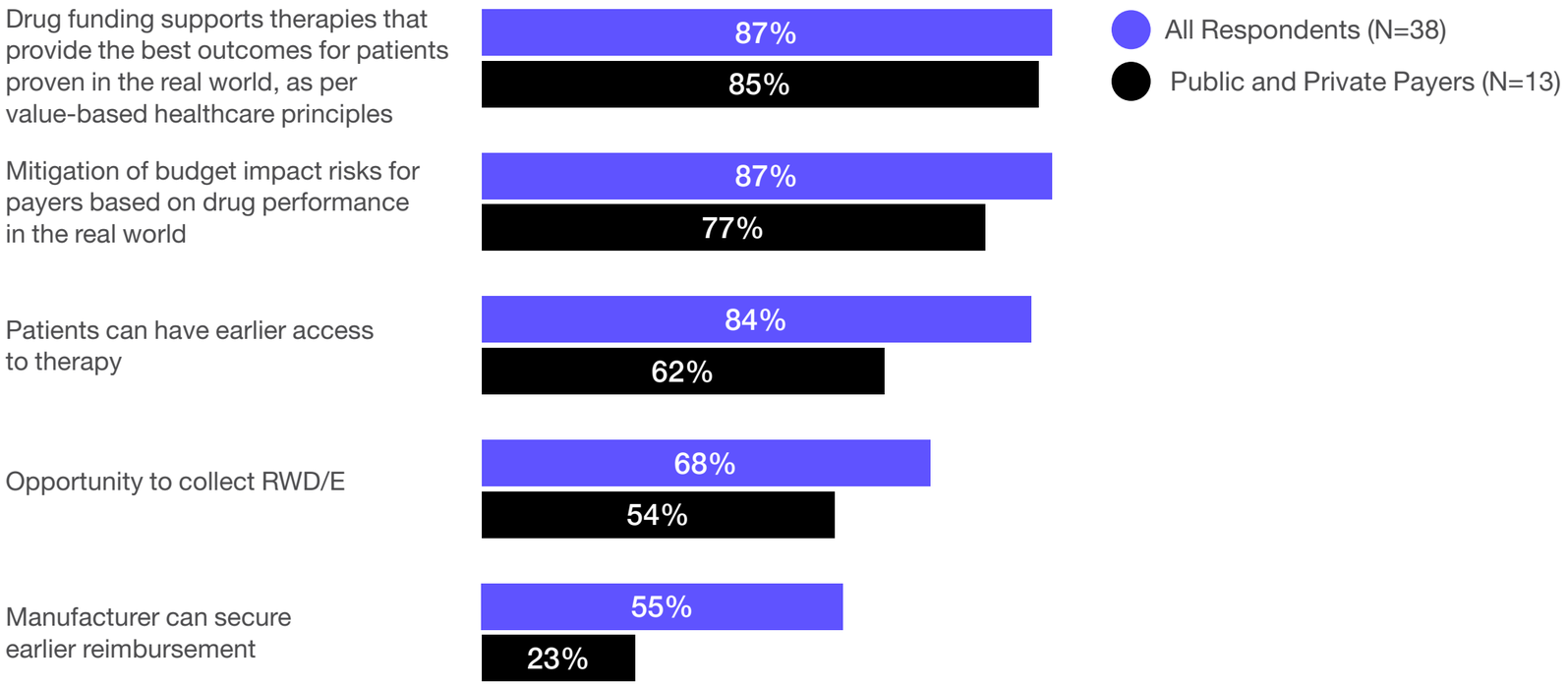
"Complex, combination, or expanded use therapies." **– Private Payer**

"New therapies approved with limited/speculative data." **– Patient organization**

Q9: WHICH AREAS DO YOU FEEL HAVE THE MOST URGENCY FOR OBAS? PLEASE SELECT ALL THAT APPLY. N=36

The greatest potential benefits of using OBAs are in **supporting the best outcomes for patients** and **mitigating budget impact risks for payers.**

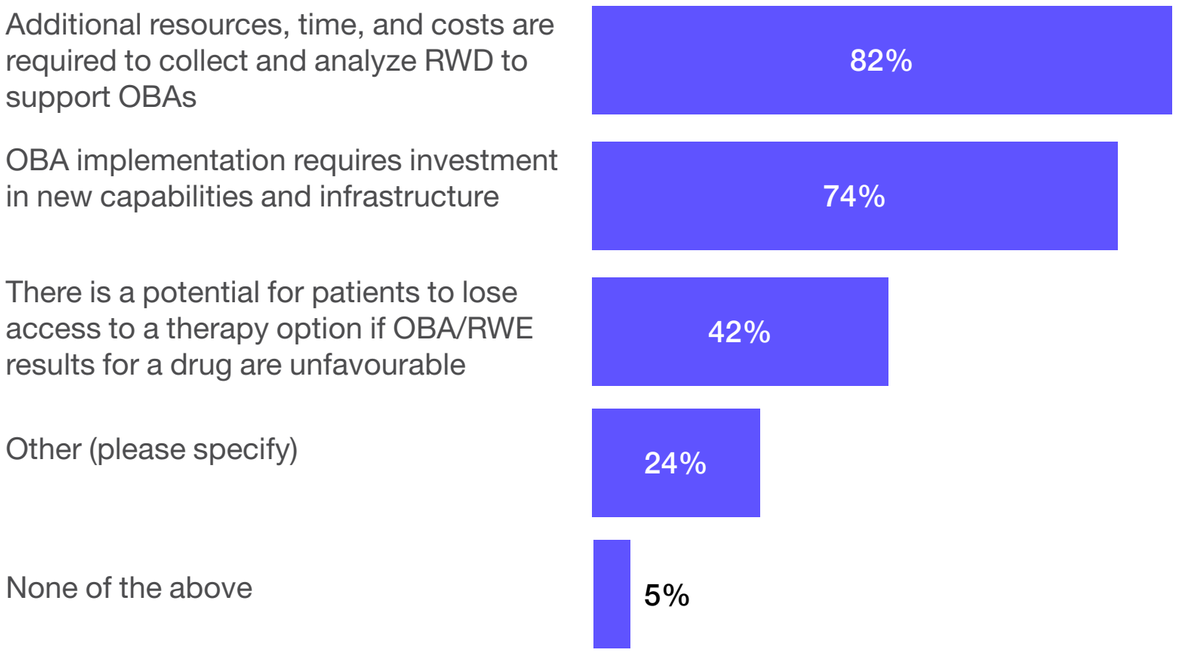
Potential benefits of using OBAs



Q10: PLEASE CHECK ALL THAT ARE POTENTIAL BENEFITS OF USING OBAS, IN YOUR OPINION. N=38

The greatest potential downside of using OBAs is the **additional resources, time, and costs required to collect and analyze RWD**

Potential downsides of using OBAs



Respondents noted:

"Outcome measures that are not developed with patients, families, and clinicians and become barriers to access; quantitative transformation of RWE prevails over the more qualitative outcomes that are relevant to patients." **– Patient organization**

"There is a risk that if OBAs become too common, they will be expected for a lot of new drugs. This could lead to industry setting higher prices before negotiation and collecting fewer data before access." **– HTA**

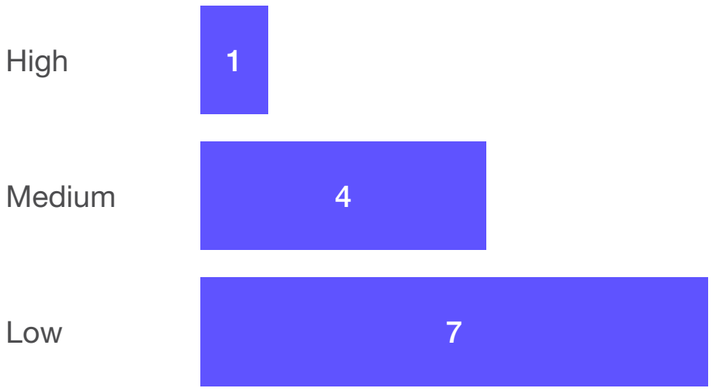
"Systems are habituated to simple agreements. Patients do not want to risk loss of access. Health systems are not structured to collect comparative real-world data." **– Public Payer**

"[A challenge for OBAs is] ensuring timeliness of data capture and interpretation of results." **– Public Payer**

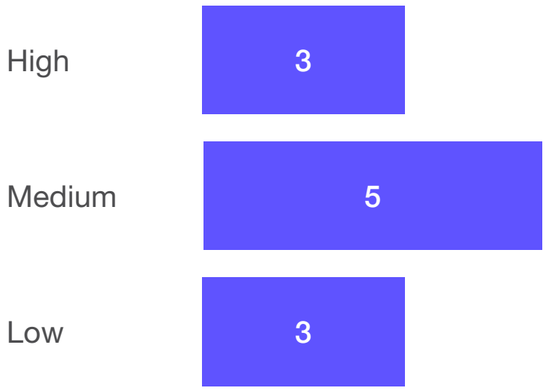
Q11: PLEASE CHECK ALL THAT ARE POTENTIAL DOWNSIDES OF USING OBAS, IN YOUR OPINION. N=38

Payers: How would you rank your organization's implementation readiness and willingness to do an OBA today?

Payer Readiness (N=12)

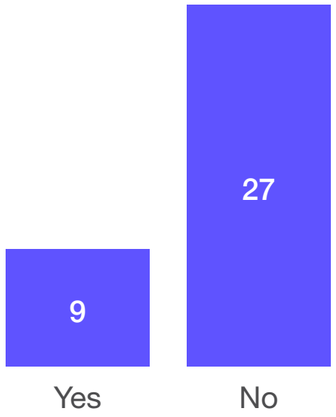


Payer Willingness (N=11)



Q15: HOW WOULD YOU RANK YOUR ORGANIZATION'S IMPLEMENTATION READINESS AND WILLINGNESS TO DO AN OBA TODAY? N=12

Does the current drug listing process have an appropriate pathway to entertain discussions about the potential use of an OBA for a specific drug?



Those who responded “yes” noted:

“The process through the pCPA does allow for this to happen. The starting conversations about OBAs have typically been enthusiastic… then barriers were applied. It often defaulted to a PLA.” **– Public Payer**

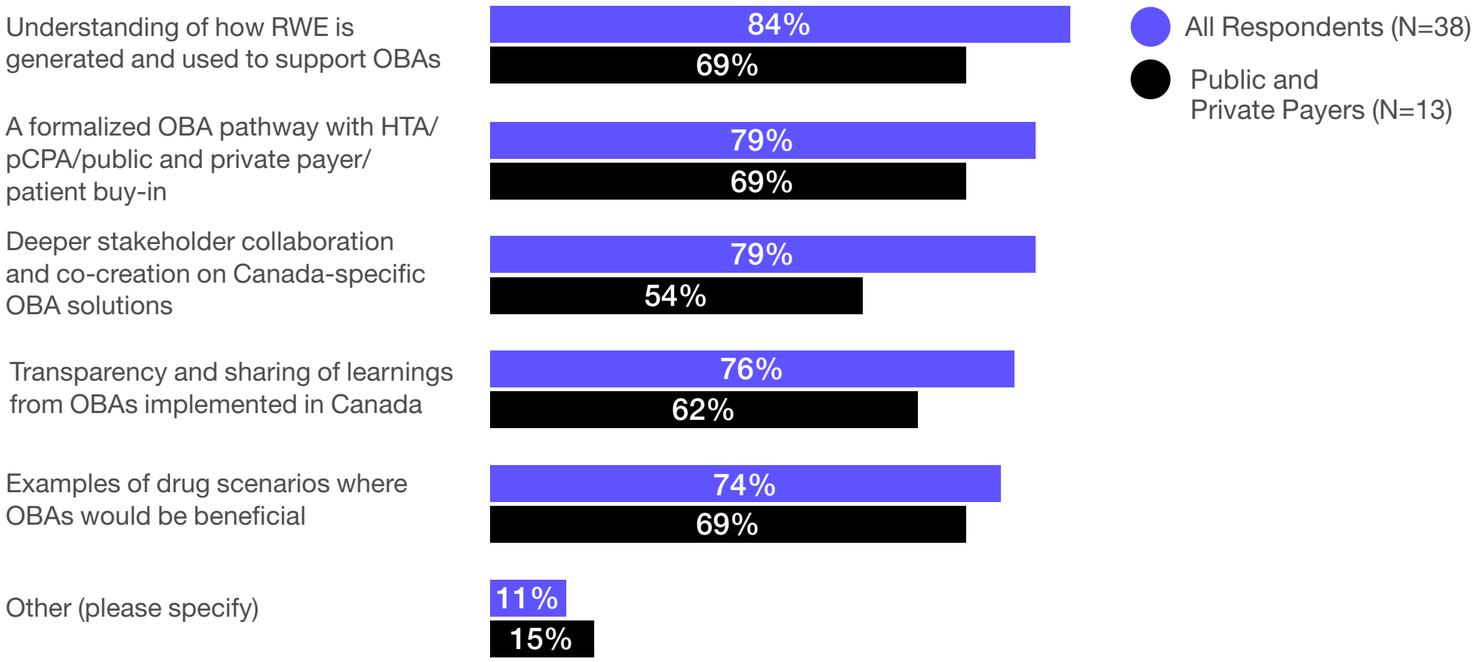
“There is a pathway to have discussions through the pCPA but figuring out the ‘how’ is a major obstacle. In theory, OBAs are a good idea.” **– Private Payer**

“Yes – and because the pathway isn’t formulaic, there is room to be creative, which is a positive. Each drug can be treated on a case-by-case and can lend themselves to tailor-made OBA solutions.”**– Private Payer**

“There is a pathway to entertain discussions, but maybe not an appropriate or specific one to formally discuss OBA’s. They have been the exception rather than the norm, so processes have not yet been modernized accordingly.” **– Patient organization**

Q13: IN YOUR OPINION, DOES THE CURRENT DRUG LISTING PROCESS HAVE AN APPROPRIATE PATHWAY TO ENTERTAIN DISCUSSIONS ABOUT THE POTENTIAL USE OF AN OBA FOR A SPECIFIC DRUG? N=36

Which of the following options should be focused on to help advance OBAs for Canada?



Respondents noted:

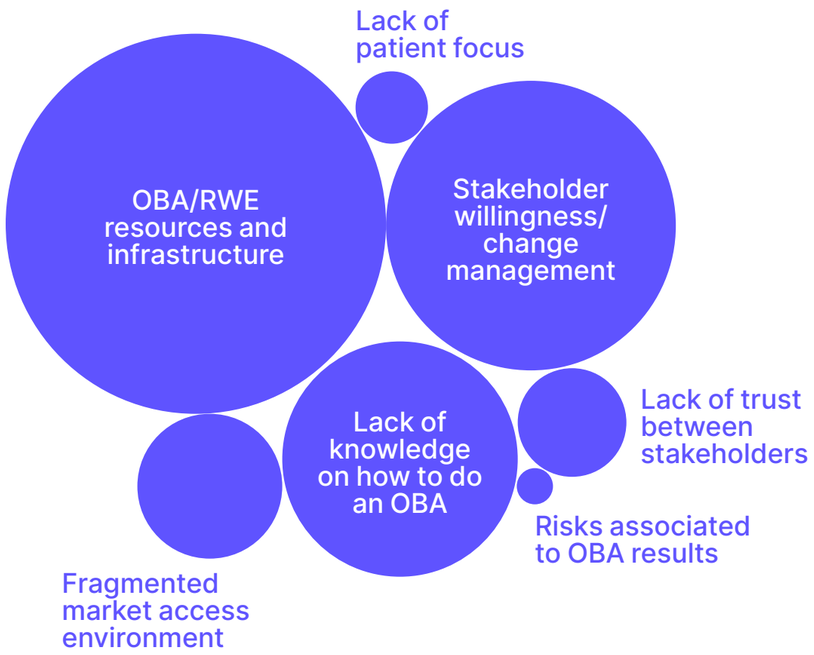
"A supplemental, modified, pathway with clear criteria for when to use OBAs." **– HTA**

"Need funding for the staffing required to support [OBAs]." **– Public Payer**

"Need to have agile pathways that are not grounded in formalized pathways since we have no idea what is required in many cases and not enough examples of successful OBAs." **– Patient organization**

Q14: IN YOUR OPINION, WHICH OF THE FOLLOWING OPTIONS SHOULD BE FOCUSED ON TO HELP ADVANCE OBAS FOR CANADA? PLEASE SELECT ALL THAT APPLY. N=38

What do you see today as barriers to OBAs in Canada?



OBA/RWE resources and infrastructure

"Time/resource commitment required for OBAs."
"Extra workload for clinicians."
"Lack of structure for data capture."
"Lack of funding in infrastructure for collection of RWE."

Stakeholder willingness/change management

"Habituated to static access to medicines and simple agreements."
"Willingness to modernize existing reimbursement processes and tie funding to outcomes."
"Resistance to change from stakeholders."

Lack of knowledge on how to do an OBA

"Don't know how to implement."
"No clear framework, processes on how and when to negotiate OBAs."

Fragmented market access environment

"Fractured reimbursement pathway across jurisdictions and payers."
"Different level of readiness by region/province."

Lack of trust between stakeholders

"Mistrust of industry by a number of stakeholders."
"Lack of transparency on the process."

Lack of patient focus

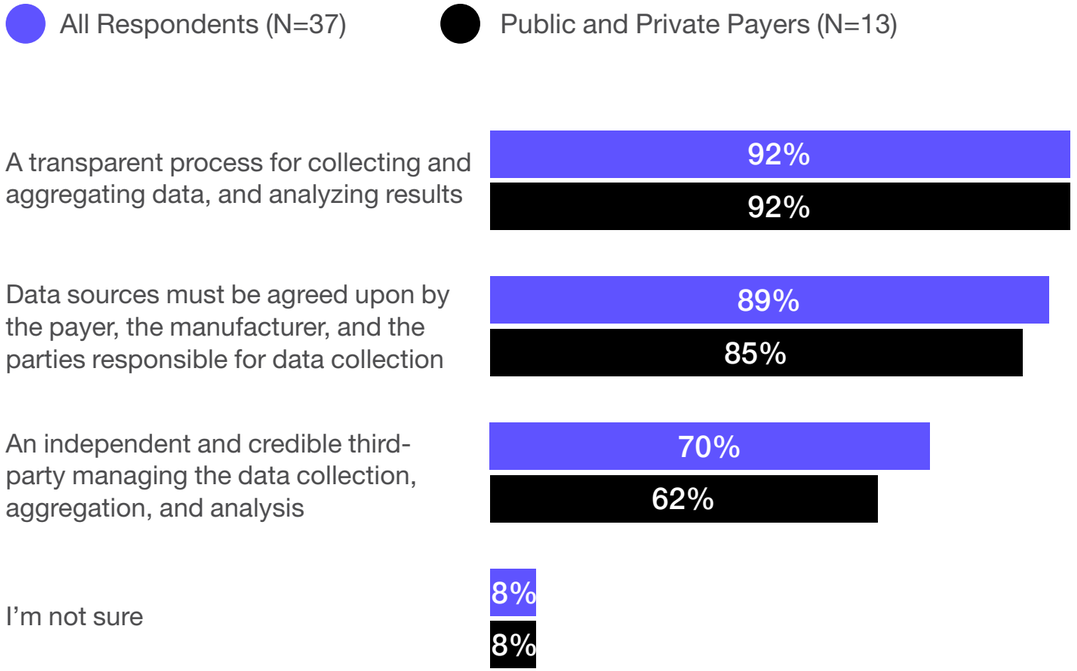
"Discussions are first about money, then about patient care."
"Focus on price and budgets as opposed to patient outcomes."

Risks associated to OBA results

"Fear of the unknown outcomes of an OBA, and what that will change."

Q16: WHAT DO YOU SEE TODAY AS BARRIERS TO OBAS IN CANADA (INTERNAL OR EXTERNAL TO YOUR ORGANIZATION)? N=70

What data management qualities are important for OBAs?



Respondents noted:

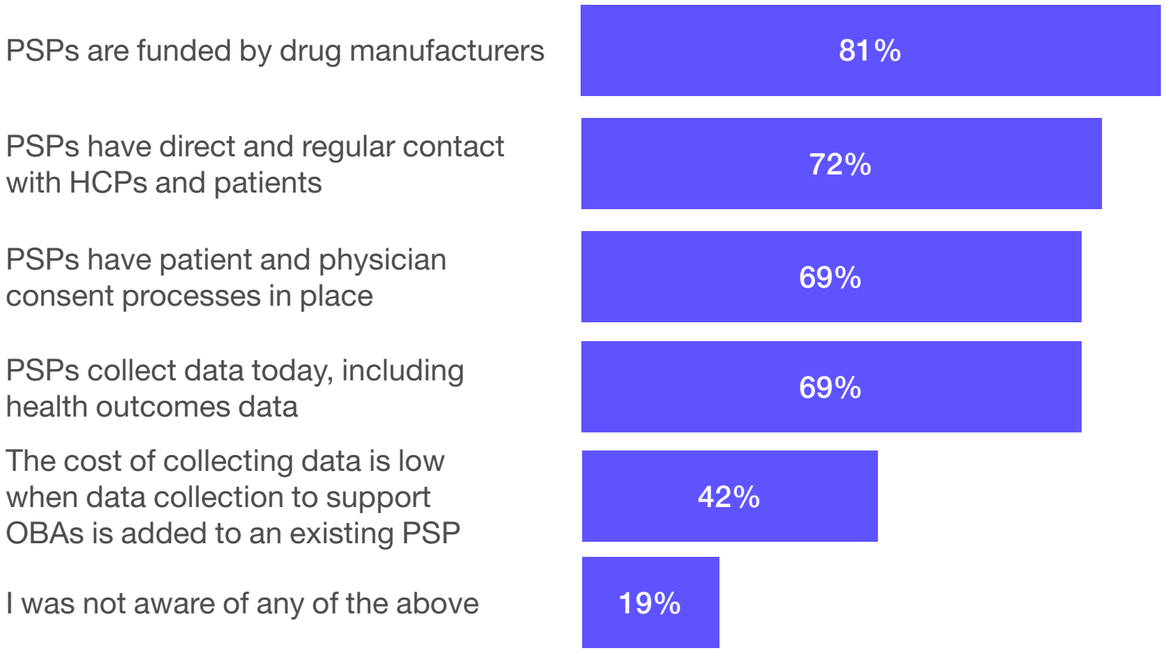
"Better data transparency by industry and patient consent as part of access." **– HTA**

"Data collection must be based on patient-reported outcomes and must meet the Declaration of Personal Health Data Rights in Canada[1] created under the auspice of Patients Redefining the Future Of Health Care In Canada Summit." **– Patient organization**

[1]: https://saveyourskin.ca/wp-content/uploads/Declaration.pdf

Q17: IN YOUR OPINION, WHAT DATA MANAGEMENT QUALITIES ARE IMPORTANT FOR OBAS? PLEASE SELECT ALL THAT APPLY. N=37

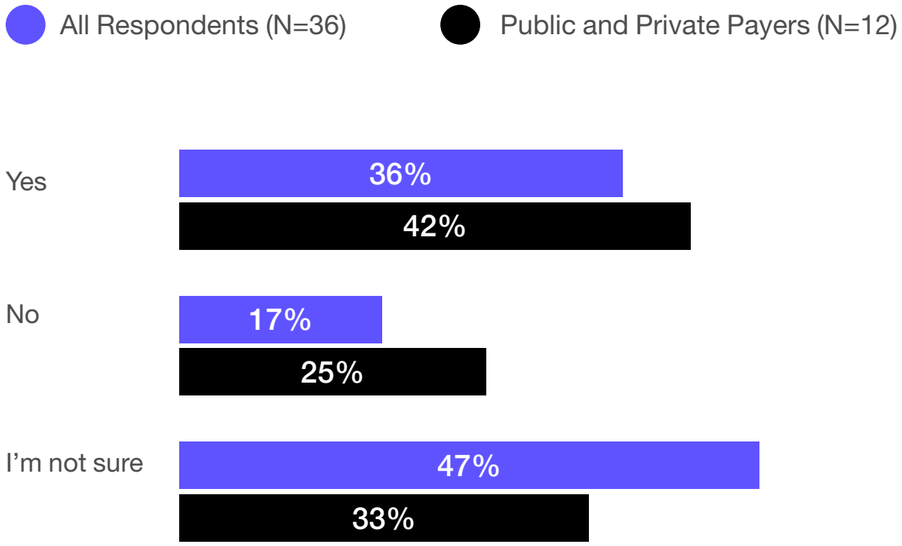
Are you aware of the following for patient support programs?



As the patient support program (PSP) infrastructure contains many of the necessary requirements to collect outcomes data to enable OBAs, respondents were asked to indicate their awareness levels of various PSP elements.

Q18: IN 2020, THE RWE & OBA WORKING GROUP CONDUCTED RESEARCH WHICH FOUND THAT THE EXISTING CANADIAN PATIENT SUPPORT PROGRAM (PSP) INFRASTRUCTURE CONTAINS MANY OF THE NECESSARY REQUIREMENTS TO COLLECT OUTCOMES DATA TO ENABLE OBAS. ARE YOU AWARE OF THE FOLLOWING FOR PSPS? PLEASE CHECK ALL THAT APPLY. N=36

Do you think PSPs are a feasible solution to operationalize OBA data collection?



Q19: DO YOU THINK PSPS ARE A FEASIBLE SOLUTION TO OPERATIONALIZE OBA DATA COLLECTION? N=36

Respondents noted:

"As a temporary transition towards an eventual public collection of RWE, PSPs are at the highest readiness out of any type of organization to start collecting RWE. However, public and private data sources must be pooled and shared, and the data should not belong exclusively to the private sector." – **Patient organization**

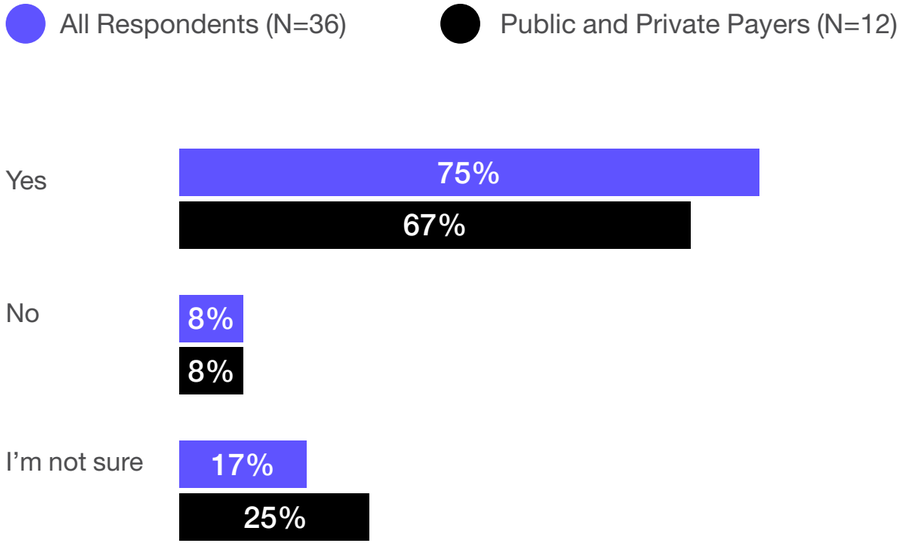
"PSPs are national and have access to database resources for collecting large amounts of data. Not all patients are enrolled though." **– Physician/HCP**

"In some cases – it all depends on the question that you are trying to answer and, hence, the data you need to collect. PSPs are controlled by manufacturers, which is the biggest barrier to trust in use of PSP data." **– Public Payer**

"Transparency is a crucial success factor." **– Private Payer**

"They would need to have a robust research framework in place and early collaboration with payers on data collection methods and outcomes." **– Academic**

Do you think patient-reported outcomes (PROs) could be used to support OBAs?



Respondents noted:

"PROs are critical to assess the real value." **– HTA**

"It is essential that PROs are collected as they measure the real impact of a treatment on the patient's overall well being, and what is important to patients, not just the usual clinical outcomes like PFS and OS."
– **Patient organization**

"PROs are important to capture "quality of life" aspects related to a drug." **– Physician/HCP**

"It depends on the specific situation – are other objective measures available, or only PROs? There should also be objective medical outcomes provided by prescribers, when possible." **– Private Payer**

Q20: DO YOU THINK PATIENT-REPORTED OUTCOMES (PROS) COULD BE USED TO SUPPORT OBAS? N=36

Is there anything else you would like to share about OBAs for the purposes of this research?

"OBAs need to be kept simple and should not become academic exercises/mechanisms to gather huge amounts of data. Keep it simple and you will succeed. If you make it too complicated, it will take years to come to agreement and/or you will fail." **– Public Payer**

"Consider how this can be built into existing contracts for hospitals through their group purchasing organization (GPO) partner." **– Public Payer**

"Europe is far ahead of Canada and we should catch-up – but with transparency on these agreements for shared learning." **– Academic**

"A legislative framework is needed to make sure OBAs are done according to what was planned by all parties involved." **– HTA**

"OBAs could be simplified if outcomes like retention are used vs. health outcomes." **– HTA**

"Patient voices and organizations need to be included in the process so that OBAs that are put in place improve access equity and timeliness. The implementation of OBAs cannot increase the barriers to access in Canada." **– Patient organization**

"Payers and industry must demonstrate a stronger sense of urgency to implement OBAs." **– Patient organization**

"Early payer engagement on OBAs is important." **– Physician/HCP**

Q21: IS THERE ANYTHING ELSE YOU WOULD LIKE TO SHARE ABOUT OBAS FOR THE PURPOSES OF THIS RESEARCH? N=13

Each year, the RWE & OBA Working Group leads a series of initiatives to help advance the opportunity for OBAs, to the benefit of all stakeholders in the Canadian healthcare system. Where would you like to see the group focus on next?

"Examples of risk-sharing arrangements: theoretical structures, and practical implementation examples." **– Public Payer**

"Present OBAs in terms of their impact on health systems challenges." **– Public Payer**

"Education to key stakeholders." **– Public Payer**

"Implementation and proof of concept of OBAs." **– Public Payer**

"Conduct and/or present a hypothetical OBA scenarios to illustrate to payers the value of OBA." **– Physician/HCP**

"OBA infrastructure." **– HTA**

"Pick a good case model to demonstrate the benefits to all parties, including patients, of these agreements." **– Patient organization**

"A white paper or recommendations on the collection of RWE necessary to implement OBAs, or a proposed framework for OBAs in Canada." **– Patient organization**

"Education though webinars and other means to help stakeholders understand what OBAs are; how they are constructed; what are the roles, rights and obligations of all parties ; what needs to be done to move them ahead." **– Patient organization**

Q22: EACH YEAR, THE RWE & OBA WORKING GROUP LEADS A SERIES OF INITIATIVES TO HELP ADVANCE THE OPPORTUNITY FOR OBAS, TO THE BENEFIT OF ALL STAKEHOLDERS IN THE CANADIAN HEALTHCARE SYSTEM. WHERE WOULD YOU LIKE TO SEE THE GROUP FOCUS ON NEXT? N=21

Please contact **info@20sense.ca** for all inquiries.