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Patient Engagement by Pharma—Why and How? A Framework for Compliant Patient Engagement

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Abstract

Engagement is increasingly recognized as a decisive factor for health-related outcomes in people living with a medical issue. It is their experience that drives this engagement. Therefore, providers who seek to develop better solutions, including medicines, must gain a deeper understanding of the patient experience. Beyond pathology, such understanding requires direct engagement with patients, something that has been historically avoided in the pharmaceutical industry. Whereas clear and comprehensive engagement frameworks are in place for direct engagement with health care professionals, such guidance does not yet exist for engagement with patients. A patient engagement framework has been developed at UCB to fill this gap, and it is herewith shared publicly as a contribution to setting and raising standards in patient engagement, with the ultimate aim of fostering the development of better solutions for people living with medical issues.

Keywords

patient, engagement, framework, privacy, insights

Introduction

The pharmaceutical industry ("pharma"), as a provider of solutions in the form of medicines, has always had the intent to improve patient outcomes, and it has a long track record of improving health outcomes through the development of new medicines. These solutions (ie, medicines), however, have been traditionally developed to meet patients' needs as seen by physicians, be they in clinical care, academia, industry, and/or regulatory agencies. This was logical because for centuries, physicians, with the best intentions, have been making the decisions to approve and administer medicines. Thus, pharma invested heavily in engaging with physicians to understand what they saw as patients' needs. To ensure that this engagement by pharma did not lead to undue influence over those decisions, compliance guidance and frameworks were put in place and further refined over the years. As long as the actual therapeutic decision was indeed driven by the physician, and accepted by the patient, this physician-centered model was appropriate.

The deep engagement with physicians, however, did not and does not address the fact that, in spite of their best intentions, medical expertise, and extensive experience, physicians simply lack the full picture of what it really means to live with a particular medical issue, unless of course they happen to have the medical issue themselves (Box 1).

The Empowered Patient

Today, most patients are no longer uninformed and passive recipients of health care. The main cause of their growing empowerment and engagement has been the Internet. Since 2000, the web has provided patients with more and more information, first on medical issues, then on treatment options, and increasingly on provider options. In recent years, the information available in these 3 domains has evolved from pure facts to ratings based on the experience of fellow patients. This evolution is very similar to what has happened in the consumer world, where product and provider ratings by other customers are now omnipresent and drive consumer purchasing decisions and (therefore) future development strategies. Experience-based information from fellow patients is now also increasingly guiding patient decisions about and engagement with both providers and therapies, especially in health care systems that

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allow for patient choice and which increasingly require a financial contribution by the patient.

The patient experience that drives their decisions and engagement has 2 dimensions: the WHAT (ie, the result, the health outcome achieved) and the HOW (ie, the journey to the result, which like every journey has several aspects, such as comfort, duration, and cost). The desired health outcome, as medically and "objectively" defined by physicians, is of course very important to patients too, but it is not their sole determinant. Patients want to balance this medical outcome with how important the desired health outcome is to them and with what it takes to get them there, and these considerations increasingly weigh in on the final decision and on the actual patient engagement.

Thus, the increasing empowerment of the patient has changed the fundamental nature of the medical transaction, from a charity model (where resources, knowledge, and decisions are almost all on the provider side) to a partnership model (where both parties bring in and share resources, knowledge, and decisions towards common objectives). Today, medical decision making and success require a partnership approach, whereby the opinion and objectives of the patient count as much as those of the physician. Even in health care systems where the therapeutic decision is often still made by the physician, the actual implementation of that decision (eg, adherence to a given medicine) depends most on the engagement of the patient, who may decide to follow or not follow the therapy, with all intermediate variances in between.

How we learn: three levels of knowledge

The basic level of knowledge comes from intellectual learning. Facts and figures provide a theoretical understanding of the subject. An example is reading a book about a foreign country or about parenthood. In medicine this is the study of facts and figures about the body in health and disease.

The second level of knowledge comes from relational learning. The interaction with experienced people provides an additional understanding of the subject. The example is talking to people who visited the foreign country, or to your friends and siblings who become a parent. In medicine this is first the observation of care being provided by others and later the direct interaction with patients and with those caring for them.

The third level of knowledge comes from learning by experience. The self-experience provides a very individual and unique understanding of the topic. The example is visiting that foreign city yourself or becoming a parent yourself. When it comes to disease this is the experience of being a patient, of living with a medical issue yourself.

The personal experience is the most powerful learning. While the learning of the first two levels can drive your initial choice, it is your own experience that will drive whether or not you chose that option again (eg, no matter what you read or what others say about a restaurant, once you have been there your own experience is the strongest determinant for a future visit). The overwhelming power of the personal experience also explains our general resistance to adapt new approaches and behaviors, unless we experience their success ourselves. In real life, one's own experience often still trumps evidence from other sources, and this is no different in the practice of medicine.

Box 1. The 3 levels of knowledge.

Consequences for the Providers of Health Care

In any economic system that allows for choice, those providers who deliver the best customer experience across both dimensions (ie, result and journey to this result) will survive and thrive; those who do not will simply disappear over time. Good intent is not enough.

This is not different in health care. Delivering a positive patient experience first and foremost requires an understanding of what drives that experience and what impedes it. Thus, all providers need to understand deeply what it means to be a patient and experience the solutions offered and then use these insights to design solutions that better fit patients' needs.

Importantly, the patient experience is not the only dimension to address with a good solution. The solution must still also engage the providers, both at the policy expert level (eg, regulators and payers, who operate at the intellectual knowledge and decision-making level) and at the delivery expert level (eg, physicians and other health care professionals administering care, who operate at the relational knowledge and decision-making level) (Box 1). Pharma has built considerable expertise in understanding and addressing the expectations of providers, but there is still considerable room for improvement when it comes to meeting patient expectations.

The patient experience is a new key driver for the development of solutions (eg, medicines, devices, information, support programs, apps) that are accepted by patients. What this means is that in the future, winning solutions will also, perhaps first and foremost, meet the expectations and needs of the patient, which can differ considerably from the expectations and objectives of the providers at the policy or delivery level. Thus, developers of solutions (including pharma) must deeply understand the patient experience from the patient's own perspective.

Like physicians, however, developers in pharma cannot completely understand what it means to live with a medical issue, unless they themselves live with it too. Direct observation of, and engagement with, individual patients is the only way to get as close as possible to the true and unique patient experience, which cannot be understood as deeply from group

statistics or second-hand (ie, filtered) insights, although both of these remain necessary as complimentary sources.

The Need for a Compliance Framework for Patient Engagement

There is concern that engagement with patients, no matter how essential for the development of better solutions, may result in undue influence on their decisions. For this reason, the promotion of medicines to patients is completely prohibited in most countries outside the United States. Even within the United States, where such promotion is permitted, it still needs to comply with strict regulations that ensure its quality and protect the patients. Reactive patient engagement by pharma, such as in answering unsolicited calls or in conducting clinical studies, is subject to specific regulations that have the same aims of quality and patient protection.

So as to ensure full compliance with the prohibition of direct-to-patient (or direct-to-consumer) promotion, pharma has historically simplified the message of "do not promote to patients" into "do not talk to patients." Similarly, and for the same reasons, some countries (eg, Spain, France) forbid pharma to directly reach out to individual patients, allowing only for some limited engagement with and via patient associations.

Engagement with patients to better understand their disease experience and their needs is nonpromotional. Indeed, when the aim is truly to observe, listen, and understand, then no influence is exerted. This kind of engagement (ie, "pulling information") is the opposite of promotion, which is to show, talk, and educate (ie, "pushing information") with an intent to influence a decision. What this means is that nonpromotional patient engagement, with the sole purpose of learning about and from the patients' experience, is possible in most if not all countries. At this time, however, most countries do not have any specific regulation or compliance framework for engagement with patients by pharma that falls outside the scope of systematic research (as in clinical studies or market research), promotion, and answering unsolicited requests.

As explained above, direct engagement with patients, with the sole aim of gaining a deeper understanding of their experience, needs, and expectations, is essential for the development of better solutions (eg, medicines and also associated products or services) that patients will engage with. Recognizing the void of guidance specific to this type of nonpromotional patient engagement, UCB decided to develop its own internal compliance framework for patient engagement.

Scope and Relevance

Our framework aims to address patient engagement that is nonpromotional and that falls outside the scope of systematic research or unsolicited medical information requests. Similar to existing guidance within those areas, the framework aims to ensure quality and to protect patients and their rights. In addition, the framework aims to protect the reputation and rights of the company, for example, intellectual property rights.

Unplanned patient engagement that is nonpromotional and that falls outside the scope of systematic research or unsolicited medical information requests is not rare. In fact, such unplanned exposure to patients is both frequent and unavoidable. As in all walks of life, people working in pharma often have patients in their families and social environment. In addition, some roles in pharma increase the propensity for direct exposure to patients.

What should an employee of a pharmaceutical company do when witnessing a stroke, heart attack, or seizure in a public place or when overhearing a discussion about health on a bus? Turn away just to avoid being seen or construed as promoting? And what about sales representatives, medical science liaisons, and clinical research associates who wait to interact with a health care provider or staff at a study site? They sit in waiting rooms that are full of patients and so cannot avoid exposure to patients and their stories. Similarly, every pharma employee who browses the Internet is bound to come across the ubiquitous sharing of patient experiences. Can they share it, use it, or even read it? Further examples are given in Box 2.

Unplanned *PASSIVE* IPE:

- I see someone having a seizure in the airport
- I hear a conversation on the bus about caring for a father with PD
- I sit in a waiting room and a conversation with someone else who appears to be a patient starts with someone else
- While browsing the internet I read a patient comment

Unplanned *ACTIVE* IPE:

- I sit in a waiting room and someone else who appears to be a patient starts a conversation with me
- I participate in a charity event and just happen to start talking to a patient who is also participating
- As someone who cares for a patient in my family I participate in a blog with other people caring for a patient

Planned *PASSIVE* IPE:

- I observe a patient-physician discussion
- I attend a patient group meeting/discussion
- I attend a congress/symposia where patients speak
- I follow a patient blog

Planned *ACTIVE* IPE:

- I ask a patient to participate in a team meeting
- I ask a patient to speak at an internal (eg, Leadership Team Meeting, Disease Awareness Day) or external meeting
- I ask a patient for feedback on a material/device/prototype
- I interview a patient as part of my project
- I go into a patient's home to speak to him/her about his/her condition

Box 2. Examples.

Planned engagement with patients is, of course, avoidable. Yet, as explained above, avoiding contact with patients does not serve their best interests. In order to develop better patient solutions, it is essential to understand the patient experience. Examples of planned engagements are given in Box 2.

So, what about patient engagement that is both unplanned (ie, no intent) and planned (ie, because a company has an interest to better understand the patient experience)? Today, patients participate at almost every medical or professional conference, and it is not always clear who is a patient and who is not. Similarly, fundraising events or annual meetings of patient associations often invite a representative of all their supporters, which often includes pharma. Thus, at events like these, people working in pharma should know how to handle both intentional (ie, planned) and unintentional (ie, unplanned) engagements with individual patients.

Clearly, guidance both for unplanned and planned patient engagements is needed, and this is what the proposed framework offers. The principles of the proposed framework, as well as its intended application, are global. As with any other global principles, local cultural and/or legal specifics will determine the actual local best practice.

The Basics

The basic compliance rules that must govern all forms of patient engagement are those that already exist and apply to any engagement by pharma. Specifically, this basic framework consists of the following:

- pharmacovigilance requirements and the reporting of product complaints,
- regulations governing the protection of personal data and information,
- regulations and guidance governing the (non)promotion of medicines,
- the code of conduct of the company, and
- good writing and documentation practices.

Regular training in the above is important for all employees, and reminder training is recommended for those employees planning to engage with patients.

Beyond these formal rules, there is an even deeper basic rule, which is to treat patients with the respect and care that they deserve. This includes not forcing them into meeting schedules and situations that may be the norm in the company but that are both threatening and exhausting to people living with a disease. We have found that assigning an individual buddy to each patient when visiting the company for a meeting or event is the best way to support the patient and to make sure that both logistics and interactions are adequate and adapted to the patient's needs, wishes, and abilities.

Similarly, patients should not be called or treated as ''vendors'' and should not have to wait 30 days (or more) to get reimbursed for their expenses or paid for their services. Importantly, patients also need timely and adapted information that is clear and brief, that matches their own pace, and that avoids jargon and complex legal or scientific wording.

Systematic or Group Engagement

This category of engagement includes clinical studies, market research, medical information, and interaction with patient associations. It does not include advisory boards, where individual expert feedback is sought and which are discussed below.

External guidance already exists for interactions with patient associations and should also be followed as ''best practice'' in those countries where no such formal guidance currently exists.

Market research is a very specific form of patient interaction and always planned. It can take many forms and be executed by pharma employees or by third parties. Because of the specific nature of and quality requirements for market research, we have reserved this activity for dedicated professionals within the company and developed specific procedures to guide them. In this way, market research is very similar to other specific types of systematic patient engagement, such as clinical studies or medical information activities. As with clinical studies and medical information, it is important to clearly communicate throughout the company that only specifically dedicated and trained employees should engage in or commission market research involving patients.

Individual Patient Engagement: Definition and Scope

We define individual patient engagement (IPE) as those situations when a UCB colleague has contact with a patient either by observing or by directly interacting. Thus, in IPE, the ultimate individual contact/observation is between a company colleague(s) and patient(s), even if a third party may be involved in logistics management or content development (eg, an agency that helps organize the participation of patients at a company event or activity). Such contact also does not require a physical presence (so telephones and digital devices are included) and consequently does include observation via digital media (eg, following a patient's blog, seeking out videos or stories online about patient experiences). Importantly, IPE can also occur in a group setting (eg, one attends a patient group meeting but interacts individually with the participants during the course of the activity).

The scope of our IPE framework is global and applies to all company employees, regardless of their role, location, or level.

- **Patient:** in the context of this article and the proposed framework, the term "patients" includes those people having a medical issue as well as their family members and those caring for them, and also those people without a medical issue who participate in research (eg, healthy volunteers).
- **Market Research** is the systematic and objective identification, collection, analysis, and dissemination of information for the purposes of assisting management in decision making related to the identification and solution of problems and opportunities in the marketplace. Market research encompasses primary data, secondary data, qualitative information, and quantitative data. Market research is distinct from advisory boards, which are generally conducted by company employees in person, using paid consultants and not on an anonymous basis.

Box 3. Key definitions.

In the IPE framework, we use a broad definition of "patient" (Box 3), which includes all patients (medically defined: ie, those having the medical issue) as well as caregivers and family members (ie, those also living with the medical issue). Indeed, a partner of a patient with Parkinson's disease also lives with the disease and needs to also benefit from any solution offered. Similarly, a parent of a child with epilepsy also lives with epilepsy. In fact, patients often say that one of the best ways to help them (ie, to provide a better solution for them) is to help those around them. In fact, many patients often worry more about the impact of their life-changing condition on their loved ones than the impact on themselves.

Our IPE framework also covers all forms of IPE, be it anonymous or named, planned or unplanned, active or passive, 1-way or 2-way, internal or external activities, individual or in a group environment, face to face or via telephone or email or a screen. Thus, the scope of our IPE framework includes all patients, all employees, and all forms of direct contact between them. The scope of our IPE guidance is limited, however, to interactions with external patients and their families and caregivers only. UCB employees who are also patients or who are family members or caregivers for a patient can, if they so wish, provide information to UCB about their experiences without having to complete specific approval forms or agreements (unless they themselves ask for such documentation).

Planned or Unplanned, Passive or Active

We define planned IPE as those situations where the predetermined intent of a company employee is to have contact with a patient. Consequently, in planned IPE, the company employee has a specific intention to engage with an individual patient. Thus, attending a fundraising dinner can qualify as either planned or unplanned, depending on the predetermined intent of the company employee to engage with a patient.

Passive IPE is when contact with a patient is unidirectional only; the company employee merely observes and/or listens. Active IPE is when contact with the patient is (or becomes) a 2-way interaction. Examples of both are provided in Box 2.

IPE With an Anonymous or Named Patient

Within our IPE framework, we consider contact to be anonymous when personal contact details are not shared within the company, and the patient thus remains anonymous to the company. This means that there is no way that the company employee who has (had) the contact, or any other employee, can further identify and directly contact the patient (broad definition) because he or she does not have the patient's personal or professional details or because the company employee who has (had) the contact will not pass their personal details to anyone else within UCB. Thus, the company employee may have the personal details but, for whatever reason, does not (want to) share these with the company (eg, when sharing anonymous observations or an insight from a discussion with an acquaintance or a friend).

Consistent with the definition of anonymous IPE, we define named IPE when contact details or personal information allowing identification are available to the company. In this case, the patient's name is known, and contact details or information is available that allows future contact by the company.

Anonymous IPE:

- I overhear a casual conversation on a bus between a patient and his caregiver but do not actively engage with them
- I have a casual conversation with a patient and his caregiver on the bus in a waiting line but do not exchange names
- I observe a patient group discussion at a hospital and start chatting to a patient called Susan during the coffee break but I do not know her surname or any other personal information/contact details
- In a personal capacity I speak to a friend or acquaintance who shares information about their life-changing condition and I share this insight in the company without providing any personal data that allows identification of my friend or acquaintance

Named IPE:

- I meet someone at a charity dinner and exchange contact details when they agree to speak further with me about their life changing condition
- I ask an agency to provide details of a patient who is prepared to speak about their life changing condition at a Disease Awareness Day in the company
- In invite a patient to an Advisory Board meeting

Box 4. Examples of anonymous and named individual patient engagements.

For named IPE, all the provisions of existing laws on the protection of personal data must always be adhered to. Examples of both named and anonymous IPEs are provided in Box 4.

Patient Involvement in Advisory Board Meetings

Patients are increasingly invited to both dedicated patient advisory board meetings and to advisory board meetings with health care professionals, such as physicians, researchers, and payers. Using the above definitions, such patient involvement is always planned, active, and named, thus requiring very careful and timely planning to ensure full compliance with the approval and contracting requirements. At UCB, approval and contracting for patient participation at advisory boards can follow the process for advisory boards or for IPE. Both processes will cover the same compliance elements; the difference is that the IPE process provides more patient-adapted materials, whereas the advisory board process provides more consistency between all participants of the advisory board.

Going back to basics, it is also important for patients to not be surprised or rushed into such meetings and to give them the time needed to understand the nature and expectations of the meeting and their involvement, including enough time and opportunity to raise any questions or concerns that they may have. Similarly, it is important to ask and plan for any specific assistance or facilities (including travel and rest) that the patient may require.

Identifying as a Company Employee in IPE

In many daily interactions, especially unplanned ones, those speaking do not fully identify themselves to the point of providing contact details or information that allows future contact. People in different cultures meet, shake hands (or not), say their first name (or not), and start a discussion.

When the discussion is around health issues, however, participants may want to know if someone works in pharma or even for which company they actually work. This knowledge can indeed determine what and how they share. At the same time, the company name may have no relevance whatsoever for the discussion, or in contrast, it may be important to keep the company name confidential so as not to bias the input given by the patient.

Within our IPE framework, we ask employees to use common sense and discretion and to always be sensitive to the patient and his or her privacy. When IPE is with an anonymous patient and passive in nature (see above for definitions), there is no need for the UCB employee to identify himself/herself, but (s)he may choose to do so. When IPE is with an anonymous patient and active (see above), then the company employee should identify herself/himself, as a minimum, as working in pharma and can choose to add the company name. In this case, when identifying oneself, the company employee can thus share the first name or full name or remain personally anonymous. When IPE is with a named patient, we always require the company employee to identify herself/himself as working for UCB.

Reporting Back

For IPE with anonymous patients, we do not require employees to report back. As a minimum, however, we ask employees to think about how what they have heard or seen might impact their approach to their work, and employees are actively encouraged to report back when the insight(s) gained may benefit teams to develop better solutions for people living with diseases. For IPE with named patients, we recommend employees to report back on any insight(s) gained.

A specific 1-page patient/caregiver observation template has been developed for this purpose. Importantly, this form is always an anonymous document (even when the patient has agreed to be named and signed all relevant documents) because it may be shared with a wider internal audience.

Contracts, Internal Approvals, and Documentation

It is self-evident that for unplanned IPE, no prior internal approvals are possible or needed. This does not mean, however, that there is never a need for internal approval or a contract for unplanned IPE. Indeed, an unplanned IPE may lead to a quote or photograph intended for further sharing, in which case documented approval from the patient is needed prior to such sharing (indeed, the sharing of the photograph is being planned). Thus, from a compliance perspective, an unplanned IPE activity may evolve into a planned IPE activity.

For planned IPE, our IPE framework applies the principle of the "2-country rule" that exists in the compliance framework for engagement with health care professionals. This principle states that for cross-border activities, a compliance check and approval, prior to the activity, are needed both from the country where the health care professional or patient is based as well as from the country where the planned activity takes place. For within-border activities, only local prior approval is needed. Prior internal approval is always needed when any sort of payment, expense reimbursement, or any other benefit in kind is due to the patient/caregiver or other third party.

A formal contract with the patient is required for all planned IPEs, whenever there is a service provided by the patient or paid by the company and in all cases when something that belongs to the patient (a photograph, a quote, an audio, or a video) is to be used by the company. Many people, particularly patients, but also employees, find agreements or contracts

	Identification *Do you need to tell the patient* *A. Who you are?* *B. What industry you work in?* *C. Which company you work for?*	**Internal Approval Form** *This is only required where a reimbursement/ payment is being made to the patient*	**Contract**	**Reporting** *Reporting is not mandatory but is actively encouraged to "Bring the Outside In." When speaking to patients, always tell them how you plan to share their information (ie, on an anonymous or a named basis) and ensure the patient is happy for you to do so.*
UNPLANNED				
Unplanned – Passive – Anonymous *No predetermined intention. It just happens by coincidence. You **listen** but **don't speak***	A. No B. No C. No	No	No	Optional
Unplanned – Active - Anonymous *No predetermined intention. It just happens by coincidence. You **listen** and **speak** BUT patient remains **anonymous** as you do not store any personal information about the patient on UCB systems*	A. Optional B. Yes C. Optional	No	No	Optional
Unplanned – Active – Named *No predetermined intention. It just happens by coincidence. You **listen**, **speak** and **exchange contact details** with intent to follow up with the patient in future*	A. Yes B. Yes C. Yes	No – *NOTE: if you re-contact the patient, Planned IPE requirements must be followed*	No – *NOTE: if you re-contact the patient, Planned IPE requirements must be followed*	Recommended
PLANNED*				
Planned – Passive – Anonymous You **observe** and **listen** but **don't speak.** *Patient remains **anonymous** as you do not store any personal information about the patient on UCB systems. No payment/reimbursement/benefit of any kind is made to the patient*	A. Optional B. Optional C. Optional	No	No	Optional
Planned – Active – Anonymous You **observe, listen** and **speak** *Patient remains **anonymous** as you do not store any personal information about the patient on UCB systems. No payment/reimbursement/benefit of any kind is made to the patient*	A. Optional B. Yes C. Optional	No	No	Recommended
Planned – Active – Named *Patient is **named** because you store personal information about the patient on UCB systems and so personal data is collected.+ A payment/reimbursement/benefit of any kind may or may not be made.*	A. Yes B. Yes C. Yes	Yes - if payment/ reimbursement/benefit of any kind No – if no payment/ reimbursement/benefit of any kind	Yes Yes	Recommended

You are responsible for checking that your planned engagement is permissible in your country. If in doubt, please check with your usual legal advisor/compliance champion.

+If you have the patient's email or phone number and proactively contact them, the rules for Planned – Active – Named IPE apply.

Box 5. Summary table of the Individual Patient Engagement framework.

intimidating, but the documents serve a very important purpose because they protect the patient's rights to know what is happening to the information and data that they provide; how the company will protect their privacy and personal information; and what, why, and how they will be paid, if permitted by local rules and regulations. Contracts also protect company assets, such as intellectual property rights, and the ability to have freedom to use insights and ideas obtained from patients to improve existing products and develop new ones.

UCB has worked hard to deliver short, plain language agreements, which properly protect the important rights of both patients and the company. Such contracts should be developed in the local language, with and validated by patients to ensure optimal understanding and acceptance.

Training and Implementation

Without adequate training, even the best guidance will fail to have an impact. Posting it on an Intranet site and sending it out in a broad email, while both needed and useful, is also neither fully effective nor sufficient.

We have found that live training (in-class and/or virtual) using real example situations and a lot of interaction are most effective. It is also important to select the target groups for such audiences and to measure their understanding and adherence.

Summary tables and decision algorithms are very useful in helping employees navigate the complexity of IPE (Box 5). Last but not least, an ongoing mechanism to answer questions and to collect user feedback is essential to adapt to the changing environment and continuously improve the IPE framework.

Conclusion

All providers need to better understand the patient experience to develop better solutions for them, and pharma is no exception. Direct patient engagement is necessary to understand the patient experience, which drives the acceptance of future solutions developed to improve their outcomes. Such direct patient engagement also requires IPE, for which no guidance has been historically available. Thus, IPE is complex and has many dimensions, so pharma needs a clear framework to guide their employees when engaging with patients and with people living with medical issues.

The foundation of all compliant patient engagement consists of applying already available guidance in many important areas, such as pharmacovigilance, (non)promotion of medicines, and protection of personal data. The first step on top of this foundation consists of developing clear definitions of the different types of IPE. Once this is done, specific guidance can be developed for each type of IPE to address issues such as anonymity/identification of both engaging parties, approvals, and documentation.

The UCB framework has been inspired by and developed with patients in a dedicated and collaborative cross-functional team effort. It has been successfully tested in practice and is now being shared because we believe that this will greatly benefit patients by helping all providers to engage more effectively and compliantly with them, their families, and their carers. We propose that this framework remain in the public domain and invite anyone to share comments and input to further enhance the proposed IPE framework and to continue to raise standards in this important area.

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