Considerations for the design and development of connected inhalation systems

Using human-centered design to deliver value to patients

Paul Upham, BS
Roche/Genentech

With the increasing prevalence and use of digital technologies applied to drug delivery devices and software solutions to support inhaled therapeutics, there are multiple considerations that patients, healthcare professionals, payors and pharmaceutical manufacturers can and should observe. Key considerations include identifying the stakeholders required to ensure a successful solution; identifying the value to deliver to each stakeholder, starting with patients; system design—including environmental sustainability; and the various laws and regulations with which the system must comply—health regulations as well as data privacy and cybersecurity laws.

Key stakeholders

When considering a connected drug delivery system of any kind, design and development activities should include the critical stakeholders involved in the system, whether as users of the hardware and software, users of the data or information generated by the system, or regulators. Patients are the highest priority among these stakeholders, and are closely followed by healthcare professionals, caregivers, payors (whether public or private) and the various regulatory authorities. Each of these stakeholders will have needs to derive value from the connected system. These needs will drive the prioritization of requirements to ensure that the final system delivers value to all the relevant stakeholders in a safe, effective and compliant way.

Identifying the value

A key value proposition often associated with the design and development of connected inhalation devices is to improve adherence and/or persistence to therapy. Traditionally, this is considered to be a matter of ensuring that a device is usable and acceptable to the patient—especially beyond the traditional aspects of human factors engineering that focus on safe and efficacious use. For many pharmaceutical manufacturers, the business case for addressing improved adherence/persistence is very straightforward: for most products, especially those that have a higher price, a small increase in adherence/persistence is directly linked to increased prescription refill rates and associated revenue increases per year. However, the ease of making such a straightforward business case for an adherence improvement value proposition is countered by the difficulty most companies have had in creating sustained adherence/persistence over a complete course of therapy with a particular product.

The World Health Organization's 2003 report on adherence to long-term therapies [1] described the situation well:

"Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments. Studies consistently find significant cost-savings and increases in the effectiveness of health interventions that are attributable to low-cost interventions for improving adherence. Without a system that addresses the determinants of adherence, advances in biomedical technology will fail to realize their potential to reduce the burden of chronic illness. Access to medications is necessary but insufficient in itself for the successful treatment of disease."

To effectively achieve improvements in adherence and persistence to therapies requires a deep understanding of a variety of factors, including patient's unmet needs, lifestyle challenges and self-management practices; as well as how the patient's healthcare system is organized and the ways in which they interact with it. While digital solutions may not address all of these factors, there is an opportunity to leverage connected devices and software solutions to help

reduce the "friction" that many patients might experience in managing their conditions.

Patient and caregiver value

For patients and caregivers, a key value of these connected inhalation systems is to ease the burden of taking medication and help them better fit self-management into their busy lives.

Healthcare professional value

For the healthcare team, real-time collection of patient health/disease state information via connected device systems can enable real-time decision-making on treatment continuation (maintain/alter dose) or discontinuation. These systems can also enable early and ongoing dialogue between the patient and their healthcare team, thereby helping prevent severe treatment-related events that would require additional costs and resources for intensive care, including hospitalizations.

Payor value

Payors find value in home-administration of medications when it is associated with significant cost and resources savings. However, use of self-administered medications outside of a healthcare professional setting increases uncertainty around adherence to treatment. Connected devices can empower and enable patient-centered disease management through increased digital homecare (outpatient setting).

Payors might base reimbursement decisions for a "companion drug" on the data derived from connected devices (i.e., adherence and outcomes data, patient-reported outcomes, etc.).

These types of data can support performance and value-based payment solutions by tracking of ongoing performance in post approval/post marketing to confirm outcomes of the randomized controlled trials in the real-world setting.

System design

When these systems are designed with the intent of improving medication adherence or persistence, or for any outcome that requires a patient to change their behavior, the application of behavior design principles to the design process is critical. This also highlights why a simplistic use of connected inhalation technology is insufficient to address complex issues like medication adherence or persistence.

Behavior Design is a systematic process of applying models and methods and frameworks from diverse fields of behavioral science in order to think clearly about behavior and to design effectively for behavior change. Some examples of behavior design frameworks are: B.J. Fogg's "B=MAP" that includes "motivation," "ability" and "prompts" [2]; University College London's "COM-B" that includes "capability," "opportunity" and "motivation" [3]; and Irrational Labs' "3B" that considers "behaviors," "barriers." and "benefits" [4].

The application of behavior design models is reflected in many parts of our lives. For example, the use of a default choice for organ donation that requires the individual to opt-out will likely increase the population of organ donors because no action is required to become one. Other examples are frequently encountered in social media and in digital spaces where one might receive "awards" or "badges" for activities, milestones or use of systems over time. One might also encounter behavior design in the "Autoplay" functions built into many online video services where "Autoplay" is on by default and requires the user to take an action to turn it off, thereby decreasing the likelihood that they will.

For connected inhalation systems, the first step for a design team is to understand the key behaviors desired of patients and caregivers. Only then can concept phase brainstorming begin to focus on features and functionality that might support behavior change in these areas. Fortunately, there are a wide variety of technologies available to enhance the inhalation devices, whether they are nebulizers, metered dose inhalers (MDIs), dry powder inhalers (DPIs) or supporting technologies like spirometers, sleep sensors, activity monitors or cough measurement devices. These technologies include sensors that can measure medication-taking events with a date and time stamp, or passively capture and wirelessly transmit the information generated by supportive devices.

Using a human-centered design process that involves seeking regular feedback from patients and other stakeholders is critical for a design team to ensure that what they are developing continues to address the key unmet needs, issues and challenges they may face. This is especially true as the design team starts to make trade-off decisions about which features and functionality to prioritize for initial release versus saving for later as part of the product's lifecycle roadmap.

A key consideration for the selection of features and components in a device and digital solution is a clear understanding of the molecule/brand strategy and the digital ecosystem into which the connected devices and software will integrate, as shown in Figure 1.

Laws and regulations

Given the highly regulated nature of medicines and medical devices, it is no surprise that a number of laws and regulations apply to these systems. However, in the case of connected inhalation systems and other connected drug delivery and digital health systems, there are laws and regulations that apply

above and beyond the traditional pharmaceutical and device regulations. These include the regulation of software as a medical device (SaMD), and laws related to data privacy as well as to the cybersecurity of connected systems.

Software as a medical device (SaMD)

According to the International Medical Device Regulators Forum (IMDRF) [5]:

"[E]xisting regulations address public health risks of software when embedded in a traditional medical device. However, the current application of regulations and controls may not always translate or address the unique public health risks posed by Software as a Medical Device (SaMD) nor assure an appropriate balance between patient/consumer protection and promotion of public health by facilitating innovation."

Most often, a connected inhalation system requires some type of software application (mobile or otherwise) that receives data from the inhalation device then provides analytics and data displays. Sometimes, these software applications have medical purposes and performs these without being part of a hardware medical device like an inhalation device. As a result, the design and development of the software itself needs to comply with the set of regulations that numerous countries have for physical medical devices.

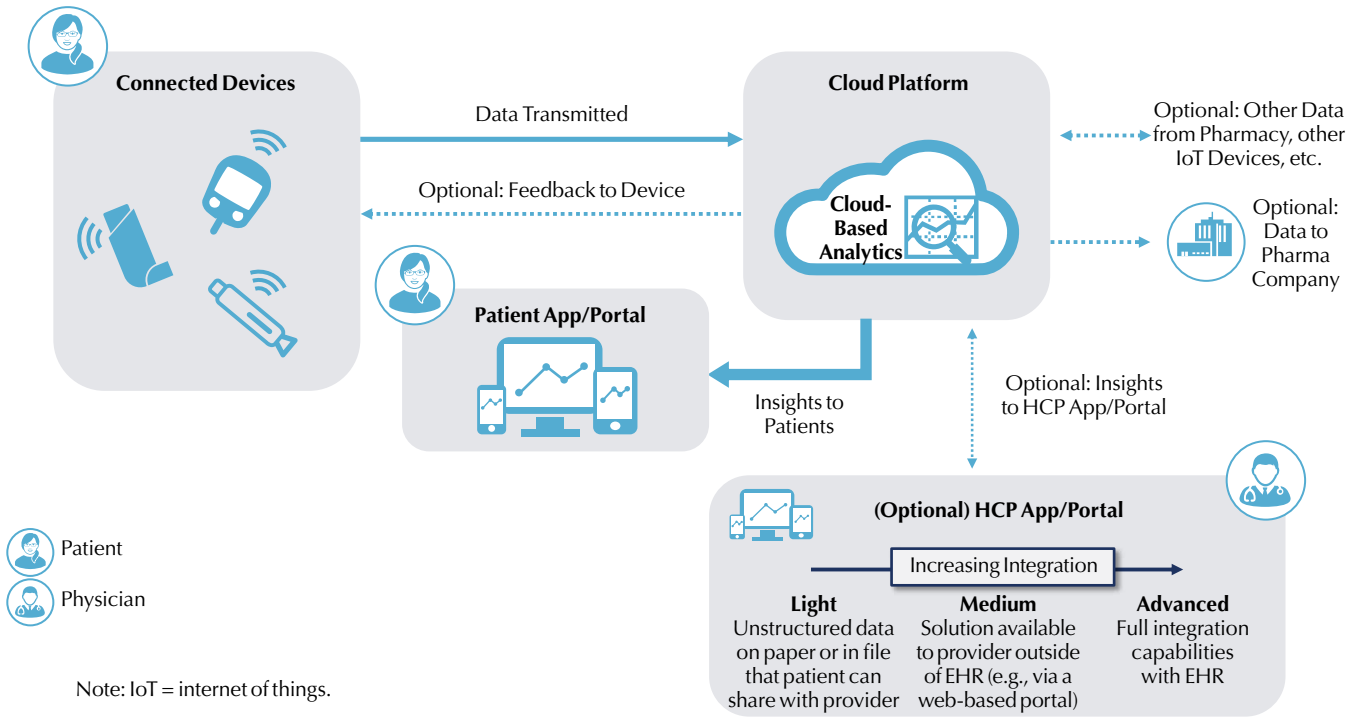
Of course, because there are no moving or mechanical parts in a software application, regulators have created new rules that help explain how to adapt the medical device regulations to software products that have a medical purpose. At the heart of these rules are the same objectives for SaMD that all regulated medical devices have: to ensure that the products can be safely and effectively used by patients, caregivers and healthcare providers.

Data privacy and cybersecurity

Highly publicized data breaches [6-8] and revelations about the various ways consumer data is collected, stored and used have recently spotlighted companies' data privacy policies and the regulations that govern them. Recent developments showcasing the extent to which this data is also sold or otherwise disclosed to third parties, with users left unaware, have further highlighted the need for more transparency in this area. Two major data privacy laws [9, 10] passed in the European Union (EU) and the state of California, (the EU's General Data Protection Regulation

Figure 1

This diagram illustrates the complex digital ecosystem in which a connected inhalation system must exist. While the patient is the primary user of the connected devices depicted in the upper left, that is only the starting point for the data that are generated by those devices. The data often move to a cloud platform to perform a variety of actions, including analytics, interfacing with electronic health record (EHR) systems, and importantly, providing insights back to patients in a patient app or portal, as well as to their healthcare team in a healthcare provider (HCP) app or portal, if not directly integrated into an electronic health record.



Note: IoT = internet of things.

(GDPR) and the California Consumer Privacy Act (CCPA), have the ability to shape how many companies must approach the issue, with other laws in development both globally and domestically.

For connected inhalation systems and their associated software applications, these global laws and regulations apply regardless of the medical device status of these products. Therefore, design and development teams need to ensure that data collected, stored and transmitted at any point in the system have compliant controls in place to ensure data privacy.

Critical controls required in these systems include cybersecurity measures. However, cybersecurity involves more than ensuring the protection of private data and includes security controls to ensure no harm can come to the patients who use the systems.

The IMDRF has also addressed cybersecurity [11] and defined it as "A state where information and systems are protected from unauthorized activities, such as access, use, disclosure, disruption, modification, or destruction to a degree that the related risks to confidentiality, integrity, and availability are maintained at an acceptable level throughout the life cycle."

These cybersecurity requirements therefore become another key consideration in the design of connected inhalation systems and an area for ongoing vigilance and maintenance, given the dynamic, never-ending nature of cybersecurity threats.

Conclusion

Patients with respiratory diseases, their caregivers and their healthcare teams can benefit significantly from connected inhalation systems, if the design and development of these systems takes into account the key stakeholders, the value to deliver to each, the appropriate system design, and the various laws and regulations with which the system must comply. Conducting the appropriate research and analyses, and implementing the appropriate system design are not trivial, especially considering increasing regulatory and legal requirements—with data privacy and cybersecurity requirements being among the most challenging and dynamic. However, the benefit to patients in terms of improved health outcomes makes it imperative to consider all these factors and provide systems and solutions that can truly enable those improved health outcomes.

References

1. World Health Organization: Adherence to Long-Term Therapies: Evidence for Action. World Health Organization, Geneva, Switzerland: 2003.

2. Fogg Behavior Model. Stanford University Behavior Design Laboratory. https://behaviormodel.org.

3. West, Robert and Michie, Susan. A Brief Introduction to the COM-B Model of Behaviour and the PRIME Theory of Motivation. Qeios. 2020. doi:10.32388/WW04E6.2.

4. Irrational Labs: The 3B Framework: Designing for Behavior Change: Find Actionable Paths to Behavior Change Using the Latest Behavioral Science Research. https://behavioraleconomicsbootcamp.com/3bs-framework-download-confirmation/?_ga=2.75748305.517574209.1666200992-77571502.1663692702.

5. Software as a Medical Device (SaMD). IMDRF International Medical Device Regulators Forum. https://www.imdrf.org/working-groups/software-medical-device-samd.

6. The 15 Biggest Data Breaches of the 21st Century. CSO, Foundry Network. https://www.csoonline.com/article/2130877/the-biggest-data-breaches-of-the-21st-century.html.

7. Yahoo Execs Botched Its Response to 2014 Breach, Investigation Finds. CSO, Foundry Network. https://www.csoonline.com/article/3176181/yahoo-execs-botched-its-response-to-2014-breach-investigation-finds.html.

8. LinkedIn Denies Data Breach That Reportedly Exposed 700 Million User Records. IT Pro. https://www.itpro.co.uk/business-strategy/data-controller/360053/linkedin-data-breach-denial.

9. General Data Protection Regulation (GDPR). Intersoft Consulting. https://gdpr-info.eu.

10. California Consumer Privacy Act (CCPA). State of California Department of Justice. https://oag.ca.gov/privacy/ccpa.

11. Medical Device Cybersecurity Guide. IMDRF International Medical Device Regulators Forum. https://www.imdrf.org/working-groups/medical-device-cybersecurity-guide.

Paul Upham, BS, is Head, Smart Devices at Roche/Genentech, upham.paul@gene.com, www.gene.com.