



Improving Patient Adherence Through Smart Packaging

Innovative drug packaging offers solutions to help patients who are struggling to take the right medication at the right time.

By Amy Scanlin, MS

AS MEDICATION adherence increasingly plays a major role in chronic disease management and increasing rates of drug resistance, the advent of smart packaging is a welcome addition to the pharmaceutical industry. Indeed, 25 percent of medications are never filled and another 20 percent are improperly taken, prompting the World Health Organization (WHO) to call the endemic of poor medication adherence a “worldwide problem of striking magnitude.”¹

Medication nonadherence poses significant challenges to understanding and tracking patient outcomes. The data necessary for making meaningful decisions are left incomplete: Providers are hampered in their ability to elicit the root cause of patients’ complaints and must guess how self-reported medication adherence is helping or hurting patients’ conditions. In fact, patients put themselves at a significant risk of adverse outcomes from nonadherence, whether they take medications in an incorrect amount or

order, at an incorrect time or skip doses altogether. And, their perception about the value of prescribed drugs may be reduced because they don’t fully experience the potential of the drugs’ positive effects.

But barriers to adherence are multifaceted. Memory, lack of understanding of drug purpose or dosing, cost and other factors contribute to nonadherence. For instance, nonadherence can be either unintentional (when patients don’t remember to take prescribed drugs or don’t understand how to take them) or

intentional (when patients purposefully choose to take medications incorrectly or not at all). Regardless of the reason, these barriers are major roadblocks to improved health outcomes. While there isn't any one answer, smart packaging is a step in the right direction.

The Problem of Nonadherence

By some estimates, only 50 percent of medications are taken as prescribed. In a study aimed at understanding nonadherence, approximately 50 percent of all clinical trial participants admit to not following prescribed dosing regimens. And, 30 percent of those are noncompliant in just 100 days. The same study showed nonadherence costs the healthcare industry upwards of \$100 billion annually — and that's just in the U.S. alone. In 2018, worldwide costs due to pharmaceutical nonadherence were estimated at \$564 billion. It is thought

that improving adherence rates — even by just 10 percent — could increase pharmaceutical revenues by \$41 billion in the U.S. and \$124 billion globally, not to mention improving mortality rates and health outcomes.²

Packaging Interventions — The Early Years

Packaging interventions have long been considered useful and, indeed, they have helped patients take medications as directed. Historically, blister packs listing days of the week have helped patients identify whether they have already taken the pill inside. Pill boxes prefilled by either patients or caregivers do the same thing and are particularly helpful when multiple medications are taken at once. Yet, although beneficial to a degree, these early interventions are limited in their effectiveness. Accuracy of medication monitoring is estimated to be just 70

percent when drug level markers are used, 60 percent when monitoring pill counts and 27 percent when relying on patient self-reporting.

Smart and Intuitive Packaging

Technology is bringing the next generation of packaging to the forefront. Electronic monitoring with time and day stamps, reminders to patients when medication is scheduled to be taken, and two-way communication between providers and patients all make improved medication adherence possible — and effective — to the tune of 87 percent when smart packaging is enabled. Smart packaging can even help monitor how medication has been stored such as confirming appropriate temperatures and alerting about degradation.

While certainly more costly than traditional packaging, these technologically advanced packages can provide numerous



benefits over traditional methods of monitoring for patients, their caregivers and the healthcare industry as a whole. Patient protocols and outcomes are more readily accessed using real-time data that is passively and seamlessly communicated to a cloud portal via Bluetooth and the Internet. From there, providers can use algorithms to get an accurate picture of how treatment is working, confirming whether it is even being used and, if so, how. That data gives a picture of any “drug holidays” and changes in dosage times or amounts, and it can determine whether the changes appear to be a one-off or part of a trend. The data also provides a starting point for discussions surrounding the treatment itself, an opportunity for further education and, when adherence is a challenge, plan revisions (if possible) to make course of treatment more suitable for patients.

It should be noted that in some surveys, the cost of smart packaging is a deterrent, particularly when it’s not covered by insurance.³ However, given the high cost of healthcare, particularly related to nonadherence, the benefits of smart packaging have the potential to offset expenditures.

New Technologies: Out of the Box

Medication adherence is a “modifiable risk factor,” making smart packaging a potential game-changer in the efforts to increase patient adherence. Radio frequency identification systems (RFID), smart blister packs, smart inhalers and injectable pens, bar code-enabled drug systems and more are currently used to help improve medication adherence. Importantly, the U.S. Food and Drug Administration (FDA) confirmed the efficacy of these technologies.⁴

RFID. RFID tags are already widely used in hospital settings to confirm patient identity, deliver care instructions, track treatment and more. This technology, when used in smart packaging, also assists with pharmaceutical behavioral adherence. It sends reminders to patients to take their medications and includes dosing and product handling instructions that are easily scanned by compatible readers on smart phones or other connected devices. These tags can also be used in conjunction with facial recognition software to prevent misuse. Smart bandages with embedded RFID technology are similarly being used to

monitor wound healing and deliver appropriate drug delivery.

All that is required for an RFID-enabled device is a microchip or transponder, an antennae and linkage to a software database. Then, data can be transmitted passively between the chip and monitoring device into a database where algorithms analyze medication use and outcomes from up to 1,000 meters away.⁵

An added benefit to RFID technology is the reduction of risk in the use of counterfeit drugs. Traceability throughout manufacturing, packaging and distribution can all be tracked. In combination with near field communication (NFC), the data are stored invisibly on the product and/or package, and codes can be scanned at any point during the process, including before secondary packaging. The same technology also enables faster and more coordinated recalls in the event of quality issues.⁶

Smart blister packaging. Smart blister packs enable monitoring through integrated circuits embedded in blister pack foil. Once the foil is broken, a time and day stamp is communicated via NFC-enabled smart phone applications to the cloud where, as with RFID, data

Benefits of Smart Packaging for Medication Adherence

Traceability

Ensure drug integrity by following from manufacturer to patient



Timing

Remote monitoring through time & date stamps and digital reminders



Temperature

Maintain ideal storage conditions remotely



Tracking

Oversee patient adherence in real time



are collected, stored and analyzed by algorithms for providers' use.

As an added bonus for patients, smart blister packs also track whether they have ever been perforated. Reminders can be sent to patients, alerting them that it is time take a pill or that they are about to take a duplicate dose. Still another kind of blister pack blocks the ability to mix medications, helping patients keep their drug plans separate and straight.

What's more, this smart technology can be integrated into existing package designs so the patient notices little if any difference.

Smart inhalers and injectables. Inhalers with electronic monitoring capabilities have been available for more than 30 years, although it is only in the last 10 years that widespread use has come to the forefront thanks to advances in associated electronic technologies. Offering real-time reminders, smart inhalers release proper dosage amounts and communicate status to patients' providers. They also communicate the effectiveness of the users' technique through measurement of respiratory flow rate.⁷

Likewise, smart injectable pens also make self-administration of medicines more convenient. Smart pens can benefit diabetics, for instance, by calculating the appropriate insulin dosage based on patients' current blood sugar levels, activity level, carbohydrate consumption and other inputs. They can deliver accurate half-unit doses and alert patients to expired drugs or temperature fluctuations that render medications potentially unsafe.

Bar code-enabled dosage forms. Using a handheld device, patients can monitor intake of medications embedded with an FDA-approved edible bar code. Edible bar codes verify tablet or capsule authenticity and provide any related information from the package insert.

In solid dosage forms, the smart bar code is applied via an excipient either to an existing film coating or as an immediate-release outer coating. In capsule form, it is mixed into inks and directly applied to the outer coating. In addition to real-time monitoring of patient adherence and two-way communication between providers and patients, bar code-enabled dosage forms offer immediate and accurate adverse events reporting.

the benefit of technology to determine reasons for medication nonadherence and to develop supportive solutions as needed. However, while smart packaging can make positive gains in medication adherence, the technology may go underutilized without patient buy-in.

As technological advances continue, the capabilities and usage of smart packaging will continue to grow with it, improving health outcomes and quality of life and reducing

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Security and Safety Concerns

Patients may have privacy concerns when smart packaging is introduced. While smart packaging poses the same inherent security risks as other wireless devices, great strides have been made to provide multi-layer security features such as user authentication that protects patient input and output. “Always on” connectivity, including Bluetooth, is required to communicate among many smart devices. In the event that wireless communications go down, a seamless switch to data communication must be made for continuity of monitoring and patient safety.

Health Outcome Goals and Medication Adherence

Employment of smart technologies offers a renewed opportunity for discussion between patients and providers to ensure medication goals are clearly articulated, understood and agreed upon. Think of medication adherence as a service enabling the entire care team to work together with

healthcare costs. Use of smart packaging in combination with a dedicated healthcare team can deliver a comprehensive solution to the costly problem of medication nonadherence. ❖

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