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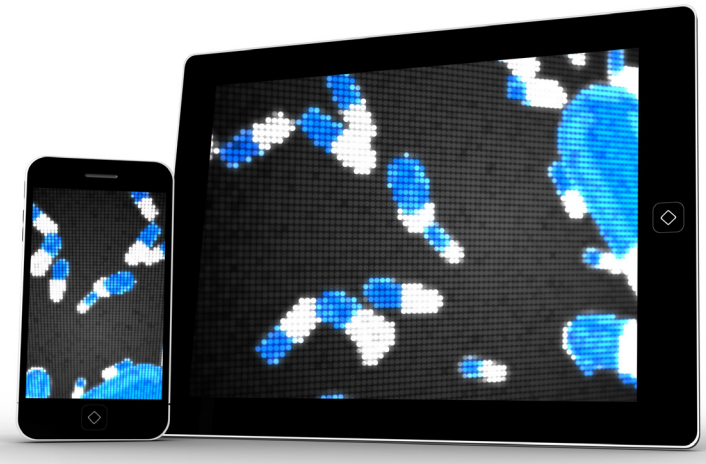
FROM APPS TO BIG DATA:
OPERATIONAL INNOVATIONS IN LIFE CYCLE MANAGEMENT



By Arlene Weintraub

When Johnson & Johnson's ($JNJ) Janssen unit introduced a mobile app for medication reminders in the fall of 2013, its goal wasn't to be the first or even the most popular healthcare product in the App Store. In fact, by the time the app—called Care4Today Mobile Health Manager 2.0—debuted, dozens of other apps were already available to help people remember to take their meds.

But for Janssen, Care4Today represented much more than just another way to get J&J's storied brands and reputation in front of customers. Rather, it offered a whole new avenue the company could traverse to improve its understanding of how patients adhere to drug regimens—regardless of whether the drugs are made by J&J or by other companies.

"This app is agnostic—it covers 40,000 drugs," says Fran Devlin, head of marketing for Care4Today Mobile Health Manager. "As our patient population grows, we are able to capture [anonymized] data and see, for instance, the aggregate level of adherence to a product. It may open our eyes. That's the goal: to determine if our assumptions are supported" by the actual behavior of real-world patients, he says.

Mobile apps such as Care4Today are among a growing collection of tools that life sciences companies are using to get closer to patients. In so doing, they are gathering insights that will help them breathe new life into old products—and perhaps more importantly, improve the process of developing new drugs. And it's not just about apps. Big data flowing from electronic medical records and from medical claims processed by insurance companies are also part of the treasure trove of information that's enhancing product development.

"With the rich amount of information that is now becoming available, companies can analyze in real time the interactions that are happening between

providers and patients, and start to understand what's happening at the point of diagnosis in terms of the treatments that are being recommended," says Shawn Roman, managing director in Accenture Life Sciences' Arlington, VA, office. "Ultimately, as they gain those insights, they can start to drive predictive models around what future treatment regimens could look like. The real opportunity here is for life sciences companies to get a better understanding of what is happening throughout the patient journey."

And patients seem to be perfectly willing to engage directly with pharmaceutical companies as part of that process. A recent Accenture survey of 2,000 consumers revealed that 76% of patients believe pharma companies are obligated to provide information to help them manage their health. A full 74% of people want to hear from a drug company as soon as they start taking that company's product. And the vast majority of patients are highly satisfied with the services they receive from health product makers.

That represents a major opportunity for the life sciences industry, Roman says: "There is a broader shift going on in the world around us. The service mindset permeates every product. Life science companies should be thinking about how they take advantage of the fact that the information they provide is perceived as valuable and is expected from them."

BUDDYING UP TO PATIENTS

For many companies, interacting with patients involves not just reminding them to take their pills, but also providing a suite of tools for managing chronic health problems. Acorda Therapeutics ($ACOR), for example, offers an app for patients with multiple sclerosis called "MS Self" and a related website, MoveOverMS.org. Patients can use the tools to keep a journal of their symptoms, share their experiences with their physicians, and read articles offering practical advice for managing their disease.

Acorda, which markets the MS drugs Ampyra and Zanaflex, has found some innovative ways to improve its app by leveraging mobile technology. The app's users can opt to share information with Acorda, such as how they've felt during certain days. "We can see what their calendars look like, and what the weather looks like," says Mike Russo, head of Acorda's corporate digital marketing strategy.

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>
> Fran Devlin, Director of Marketing, Janssen

The app can then respond with tips and information tailored to each patient's particular needs, he says. For example, if a patient records in their journal that they're having trouble exercising, the app will serve up a "fact card": an informative article providing tips for exercising with MS.

For the most recent iteration, Acorda advanced the app even further by capitalizing on the ability of mobile phones to access weather forecasts. "We know that MS patients have difficulty in some weather conditions, particularly if it's hot and humid. But to what degree they feel bad is personal," Russo says. "We plan to take the weather and apply it to a patient's data set. If you've reported in the past that certain weather has made you feel bad, and that's reflected in the future forecast, we'll alert you." In the future, the app will be able to tie all of that information into the user's calendar, suggesting that a patient reschedule certain activities if they're planned for days when symptom-exacerbating weather is predicted.

How does it benefit Acorda to be so embedded in patients' lives? Russo says the answer is twofold. First, it boosts the company's image by showing patients that a pharma company can "provide value outside of the pill," Russo says. "Trust is a big deal."

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>
> Mike Russo, Sr. Director, Corporate Digital Strategy, Acorda Therapeutics

Beyond that, the app allows patients to collect daily data on their disease, which they can share with their physicians in between office visits. "The self-measurement movement is a huge opportunity for the industry," Russo says. "What we're hoping to be able to do is create a larger data set." That will help physicians by offering them greater opportunities to spot trends that could, in turn, help them improve treatment regimens, he says. More broadly, the patient insights that are gathered could help companies like Acorda to better define endpoints in clinical trials, for example, or refine development efforts for drugs in the pipeline.

Other companies are finding innovative ways to gather insights about patients through their interactions with their doctors. In 2012, Merck ($MRK) formed a 5-year collaboration with the Regenstrief Institute, an Indianapolis organization that uses health data to improve the personalization of care. "Regenstrief houses one of the world's most sophisticated computer language laboratories, and they're the manager of a health information exchange that includes data from almost 100 hospitals," says Arnaub Chatterjee, associate director for health information partnerships at Merck. "It's a huge repository of clinical data that looks at about four-and-a-half billion pieces of clinical information on 13 million unique patients."

Merck hopes that by scrutinizing all that data, it will be able to glean clues about how practitioners manage patients with chronic diseases such as osteoporosis, diabetes, and chronic heart failure—all of which are markets the company addresses. "Our outcomes researchers were intrigued with these capabilities, not only from the science side but also from the analytical side," Chatterjee says.

For example, it might be possible for Merck to discover correlations between adherence to medications for treating diabetes or heart failure and hospital visits. Regenstrief's technology can also be used to analyze whether medication reminders change patient behavior for the better and improve outcomes, Chatterjee says.

Merck is also working with Regenstrief to build technologies with key capabilities, such as natural language processing, which would allow them to parse through so-called unstructured data, like handwritten doctor notes and hospital discharge summaries. "There are long-term studies that we're thinking about to look at segmenting patients by getting deeper than just what's in the clinical record, and actually looking at this world of unstructured

data, which captures social, environmental and behavioral factors," Chatterjee says. "When you get to that level of granular detail for each patient, it will enable you to better understand the best route for care. Unstructured data is going to be a big part of how people are looking at therapies in the future."

EMBRACING PAYER PARTNERSHIPS

When it comes to truly understanding patient behavior—and using that knowledge to enhance the life cycle of current and future products—many drug companies are finding valuable partners in health insurers. That's because insurance companies are rapidly developing sophisticated tools that can comb through claims data to answer tough questions about why patients do or do not adhere to drug regimens, and how that behavior correlates with their overall health status.

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Over the past few years, insurance giant Wellpoint ($WLP) has formed one research partnership with AstraZeneca ($AZN) to study real-world evidence in the management of chronic conditions such as cardiovascular disease, respiratory disorders, and autoimmune diseases, and a second alliance with Boehringer Ingelheim (BI) to look at several disease

states, including non-valvular atrial fibrillation. Humana ($HUM) has teamed up with Eli Lilly ($LLY) to investigate health outcomes across a range of diseases, including diabetes.

AstraZeneca and BI are both working with Wellpoint's HealthCore research division, which for the past several years has been integrating claims data from a range of sources, including medical clinics, laboratories, and pharmacies. "We've been evolving since 2008, working with life sciences companies to try to generate more meaningful [research] designs that will have a broader impact on the healthcare system, including payers," says Mark Cziraky, vice president of research for HealthCore.

Much of that work involves filling in gaps that have traditionally prevented payers and drugmakers from getting a full picture of how drugs are being used in real-world settings. "Historically we have worked with administrative claims data, but it's not good for a lot of things we want to ask because of the limitations that exist," Cziraky says. "In the [medical] practice setting there are a lot of gaps."

Those gaps start to show as soon as a doctor writes a prescription for a patient. "Say you go to your doctor and they write a prescription for a cholesterol-lowering medication, but you never go to get it

filled," Cziraky says. You know you're not taking the drug, but your doctor and the company making the drug may not. "We're trying to eliminate that disconnect in our healthcare system by integrating clinical data at the electronic medical record level with administrative claims data."

Such research could help drug companies and insurers alike develop tailored approaches to getting nonadherent patients to take their meds—an outcome that would not only lead to increased sales of some drugs, but also help limit the risk faced by payers when patients suffer long-term complications of improperly treated diseases.

HealthCore's research capabilities supplement the work that AstraZeneca was already doing to try to understand drug-adherence behavior, says Javier Jimenez, global head of observational research at the drugmaker. For example, using claims data, AstraZeneca developed methods for measuring two obstacles to treatment adherence: procrastination, which it defines as failure to engage in health activities that are unpleasant in the short term, and avoidance—the complete abandonment of long-term health goals in favor of immediate gratification. The company "found a correlation of those claims-based measures with patient adherence," Jimenez says. With further research, it may be possible "to predict patient adherence to drug regimens, allowing targeted intervention on those patients," he adds.

For BI, partnering with HealthCore could help solve a vexing trend among patients with atrial fibrillation: Despite the recent introduction of alternatives to warfarin—an inconvenient and sometimes dangerous blood thinner—patients are being switched to the new drugs at a slower-than-expected rate, says Jeff Huth, senior vice president of managed markets for BI. The company makes one of those alternative treatments, Pradaxa.

"I think the whole industry has been a bit surprised by the fact that there hasn't been a more rapid adoption" of warfarin alternatives, Huth says. "We can see prescription-level data, and we can clearly see some movement. But we don't understand why. What are the decision criteria?" Working with HealthCore, he says, "will help us really understand what is going on with the real-world management of warfarin and what the barriers are to a broader adoption" of newer drugs.

> "Type 2 diabetes in particular is as much a behavioral disease as it is a disease of insulin and other issues."
>
> Brad Curtis, Principal Research Scientist, Global Medical Affairs, Eli Lilly

For Eli Lilly and its widely used diabetes drugs, pickup isn't nearly as big an obstacle as adherence. That's why the company turned to the Humana unit Comprehensive Health Insights for help in understanding all the forces that converge in the treatment of diabetes. "Adherence is the nirvana for health services research, in terms of trying to understand the issues, particularly in diabetes," says Brad Curtis, principal research scientist of global medical affairs for Lilly Diabetes. "Type 2 diabetes in particular is as much a behavioral disease as it is a disease of insulin and other issues."

Lilly and Humana already have a project underway to try to define the factors that will allow them to predict which patients will be most likely to stick with drug regimens, Curtis says. "The most expensive drug is the one the patient doesn't take," he says. "So there's definitely an imperative from all stakeholders to make sure that we're maximizing people's ability to take the therapies that we produce and that Humana pays for."

Nick Patel, research manager of collaboration research at Humana's Comprehensive Health Insights, says the collaboration between the two companies is focused not just on understanding medication use, but also quality of care, and care transitions—the decision-making that happens

when a patient is moved from one therapy to another. Humana and Lilly are also wrapping in demographic factors such as age, gender, and income to try to determine whether those characteristics play into the choice of one therapy over another.

Understanding all of that could help both companies tailor drug plans to individual patients. "The end goal is to improve the care of these patients," Patel says. "We're really trying to discern patient journeys, especially in the diabetes space. Some folks progress along the disease spectrum faster than others. The question is why is that the case and what is it that we can do to identify who those patients are [and] perhaps get in earlier—before the disease starts to impact other areas like medical co-morbidities, or psychological factors that impact their ability to function."

ENHANCING CURRENT AND FUTURE DRUGS

Although research partnerships such as those formed by Wellpoint and Humana are still in the early days, there's little doubt the real-world evidence being gathered will ultimately strengthen the relationships between payers and drug companies. It's already happening in the world of medical devices, says Kim Ramko, America's life science advisory lead for Ernst & Young in Nashville. "The data being collected is helping our clients prove the product is making a difference in that person's health outcome—that it's actually becoming more affordable from a healthcare cost perspective to sustain that individual's health at a higher level," Ramko says.

Any life science company that can prove that level of real-world evidence will ultimately boost their position with every insurer they deal with, Ramko says: "This helps the whole act of contracting around managed care—the formularies and what's going to get reimbursed. We finally have real-world data that we can turn around and point to, and that the payers trust, because they can see from the claims side that the cost of a person's healthcare has gone down."

And on the other end of the drug-development timeline, all this real-world data might even help drug companies design better clinical trials. "Historically, the pharma industry has focused almost exclusively on getting regulatory approval, working with the FDA," says BI's Huth. "That's still critical, but we also have to make sure we have the correct pharmaco-economic endpoints in our trials, so we can truly demonstrate value. By really doing a deep dive into how diseases are currently managed in the real world, it might suggest opportunities for different types of clinical endpoints or incorporation of more patient-reported outcomes."

Even patient-facing apps such as J&J's Care4Today could someday help clinical trial investigators plan and run trials, says Janssen's Devlin. "We've had a lot of interest, because one thing they try to estimate when they're looking at data is adherence" to clinical trial drug regimens, Devlin says. "With our app's dashboard feature, they can get a hard number on that. Absolutely it's something we'll be looking at using in clinical trials both internally and externally."

It's clear that pharma companies are reaping the benefits of getting closer to their customers—regardless of whether those customers are patients, providers, or payers. "We're trying to transition from just a products company to a healthcare company," Devlin says. "If we can provide that extra wraparound service piece, I think that's a real positive. At the end of the day, it's good for the patient, it's good for the physician, it's good for the pharmacy, and it's good for us." ■