NEW FRONTIERS for Big Data

Five areas in which innovative uses of data and analytics promise to improve outcomes along the healthcare continuum. **Marc Iskowitz** reports

After a two-year fellowship at an elite cancer center, and some marathon cramming, IBM's Watson supercomputer may finally be ready to pass its biggest healthcare test yet: enabling doctors to quickly tap its expertise in ascertaining how to treat cancer patients.

Since 2012 the oncologists at Memorial Sloan Kettering Cancer Center have been training Watson—famous for whipping two formidable human contestants on *Jeopardy!* in 2011—for use in the healthcare trenches. To transform from quiz-show champ to cancer-treatment advisor, Watson has been ingesting copious amounts of information from journals, health records and doctors' notes.

Still in beta-testing, the partners hope the advisor tool, called IBM Watson Oncology, will be ready for use in real-time clinical practice by year's end.

"Patients fear the day where a computer rolls into the room, and the physician doesn't show up, and the patient simply talks to the computer," says Andrew Seidman, MD, a medical oncologist at MSK who specializes in breast cancer, in an interview with *MM&M*. "In no way is Watson intended, in any shape or form, to replace the very important human aspects of cancer care."

Making oncology elementary

Nor does it dictate to the clinician. Watson provides several options with degrees of confidence for each, plus the evidence used to arrive at the optimal treatment. Doctors enter information on an iPad, and within 30 seconds Watson crunches the data to produce a drug regimen tailored to the individual.

That's the theory, anyway. It was reported that the treatment-advisor tool would be ready for use on MSK's oncology service by the end of 2013. What's behind the delay?

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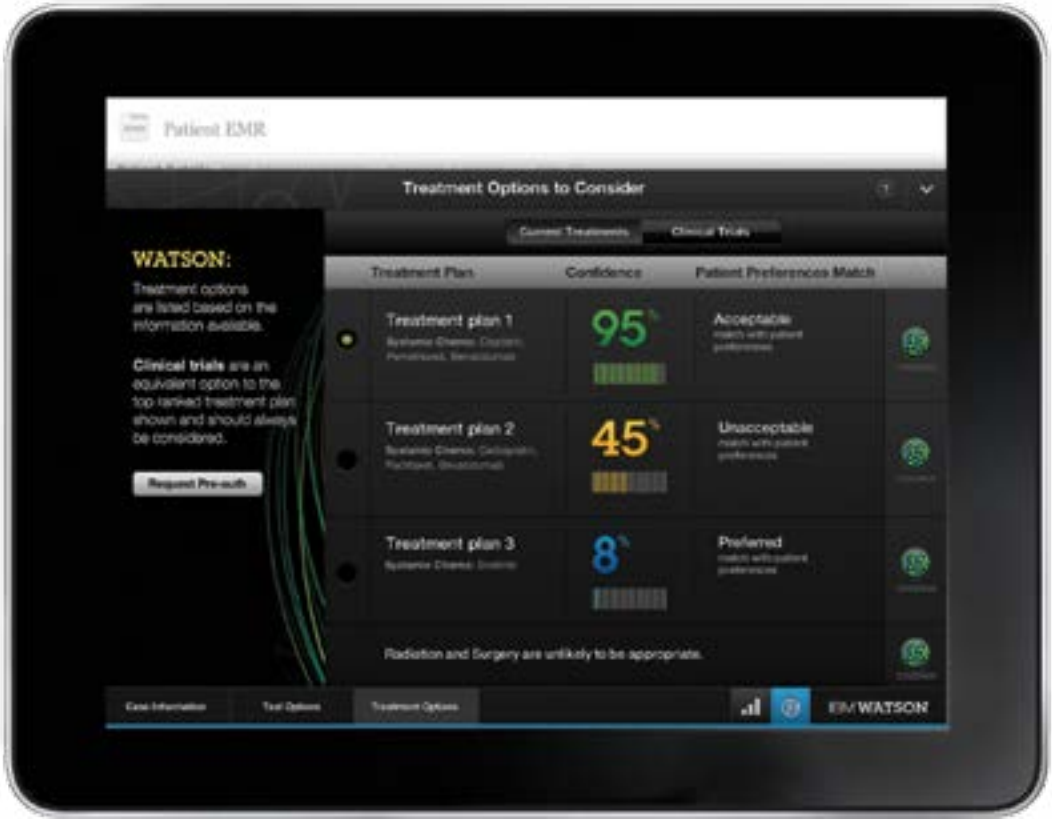


"As with any process, there are fits and starts along the way," says Seidman, who's been testing Watson for the past year. "There have been some obstacles to the full implementation of natural-language processing as a method of obtaining the key information. This is something we're actively working on."

What computer wonks call a cognitive system, Watson is not programmed with hard-coded rules. Similar to its *Jeopardy!* training regimen, it's given cases and then suggests therapies. "Watson feeds off of unstructured content—think about the clinical notes that are captured as part of the patient evaluation," explains Steven Gold, VP, Watson Group.

In order to give it sufficient cases, the MSK doctors are using both real anonymized ones and, to provide the outlier cases, manufactured ones, says Seidman. This amounts to 1.5 million records, according to Gold. Add to that 42 publications that are providing content, as well as other public and third-party information, along with best-practice guidelines, and you get a laborious process.

Even so, "Through this process of machine learning, Watson gets smarter and smarter," Seidman says, "and we've been able to show an increased level of precision with each series or batch of cases."

Watson lets physicians "extend the way they would normally think through and resolve the question, 'What's wrong with me?'" says Gold.

IBM's partnership with MSK started out focusing on the two most common cancer types, breast and lung, and has since expanded to about a dozen other tumor types. A parallel program at Houston's MD Anderson Cancer Center has centered on leveraging Watson for leukemia research.

The partnerships follow IBM's work with the insurer Wellpoint to use Watson to tackle a simpler problem—utilization management and the adjudication process that occurs between doctor and health plan. The Wellpoint work, which Gold recalls as "our initial foray into health," resulted in a product launch a year ago among five providers; well over 3,000, he says, now use its Interactive Care Reviewer.

Eventually, the computer services giant wants to allow other hospitals and healthcare networks to buy or rent Watson for decision support via the cloud or their own server. (It's no longer the "room-sized beast of a machine" that smoked Ken Jennings and Brad Rutter on *Jeopardy!*, but a server the size of a pizza box that's also 240% faster.)

In January, IBM announced its intent to invest a billion dollars in the Watson business unit and to establish a dedicated headquarters for the unit in Manhattan's Silicon Alley. In so doing, it's making Watson a showcase of its shift into cloud services—a big bet for a company which has long made money acting as clients' "back office" and selling them pricey software and hardware, yet has seen seven straight reported quarters of falling revenue.

In addition to the delayed roll-out of the treatment-advisor tool, IBM may face other hurdles in rolling out Watson Oncology to the greater provider market.

The basic technology that IBM scientists used to train the Watson system to interact with medical-domain experts in a way that's more natural—called WatsonPaths—was developed during a yearlong partnership with the Cleveland Clinic Lerner College of Medicine.

"Based on what we understand WatsonPaths is being used to do, we do not believe it is the type of function we would regulate," Jennifer Rodriguez, an FDA press officer, told *MM&M* by e-mail. But WatsonPaths was primarily geared for classroom use. What about ramping up the technology for doctors in real-life clinical scenarios?

"How quickly this moves into broader adoption is a byproduct of a number of factors, some of which are regulatory in nature, some of which are integration, some of which are inherently embodied in the technology and how it gets trained," concedes Gold.

Apart from enabling busy oncologists to quickly get at the best treatment plans, Watson could streamline the payer review process.

"An instrument that has been vetted to provide valid, up-to-date information that is evidence-based, that is expert, curated—there shouldn't be any need for a third party to sit in a back room at Aetna or Blue Cross Blue Shield deciding whether or not this is something they should approve," adds Seidman.

The oncologist also has hopes for making the decision-support tool "more granular and specific," including seeing it go beyond tumor characteristics to, when appropriate, factor in patient preferences and provide a visual representation of the likelihood of side effects.

"Patients may assign different values to experiencing possible side effects from treatment, whether it be hair loss or nausea or fatigue," says Seidman. "So the best tool would be one that will consider not just the patient's key attributes in terms of their co-morbidities and

pre-existing medical conditions but also incorporate the patient's own values about her care." IBM also has said it wants to expand into chronic disease states, and Gold says it may one day be able to read—but not interpret—x-rays and other images.

The tech giant is counting on Watson to be a big contributor toward meeting its 2015 revenue target in its analytics software and services division, a goal which the company recently raised from $15 billion to $20 billion.

Pregnant with possibility

The now-infamous "Target episode"—chronicled in Charles Duhigg's 2012 book *The Power of Habit*, about how the retailer, leveraging its Guest Marketing Analytics department, pinpointed that a teenager was pregnant before her dad did and then started messaging to her—highlights the promise and pitfalls of using big data for marketing.

Yet the parallels between how verticals, like CPG or financial services, leverage big data to solve engagement problems with end users and how health companies like pharma might use it, are limited.

"When you look at how other industries are using the data, they always have a very direct line of who their customers are," said Brent Rose, director, US marketing, inflammation & immunology, for the biotech firm Celgene, at IIR's ePharma Summit in February. "From a pharma perspective, that's a huge gap for us. Finding ways to bridge that gap, and use that information so we can provide more content and help people when they need it and how they need it is important."

A few digital publishers believe they're starting to. Remedy Health offers a tool called MyMD&Me that patients sign up for at their doctor's office. The tool matches patient data that it receives from the physician office software management system to send content specific to that patient. A person who visits an endocrinologist, for example, and signs up, then gets an e-mail from the doctor with Remedy diabetes content.

On the back end, a third-party firm, Crossix, then takes a panel of data from Remedy and matches it against a panel of similar people submitting insurance claims. Based on the comparison, it forecasts the total number of people that likely would have been exposed to the MyMD&Me content who also went and filled a prescription.

In one case, about 200,000 patients with high blood pressure who received a series of three communications directly from their physician's practice were 4.8 times more likely to stay on their treatment, Remedy says. "We've been routinely tracking outcomes for 18 months, so we can tell partners—manufacturers—what the results are," says Jim Curtis, Remedy's chief revenue officer. "We mark better outcomes by adherence and after-care with the doctor."

EverydayHealth has been doing that, too, based on consumers who opt-in to the online publisher's programming—patient-education centers and the like. "Hand-raisers give us high-quality data and a huge understanding of who our audience is," says Greg Jackson, chief data officer for the digital health media firm.

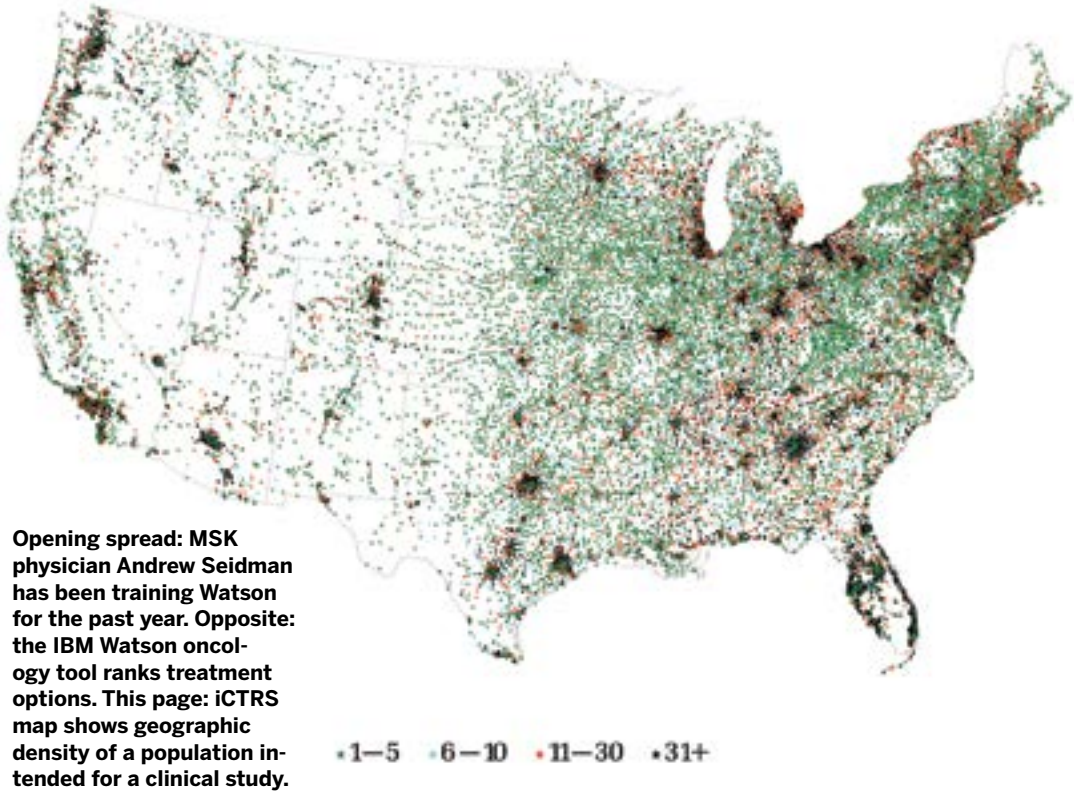
It then works with third parties, including IMS Health and Crossix, to prove the impact on prescription compliance. TrackRx, a service being rolled out this year by EverydayHealth, brings the capability to a real-time environment, says Jackson. That is, in a HIPAA-compliant way, marketers can understand the characteristics of an audience and optimize their digital campaigns during, not just after.

Real-world evidence evolves

For years pharma companies have been using real-world evidence (RWE)—which leverages observational data, such as claims, healthcare registries and, increasingly, EMRs—to provide additional information about a treatment's clinical and economic outcomes and how it works outside of randomized clinical trials.

A notable example of RWE for comparative-effectiveness research (CER) was AstraZeneca's PATHOS study, published in the *Journal of Internal Medicine* in 2013, that showed that patients treated with AZ's Symbicort Turbuhaler (budesonide/formoterol) are significantly less likely to suffer from COPD-related exacerbations and are significantly less likely to be hospitalized for COPD than those treated with GlaxoSmithKline's Seretide (fluticasone/salmeterol).

As COPD exacerbations are a major driver of the direct costs associated with the disease, "We are using [the study] compliantly with payers to show them data they may not be aware of," said Brian Sweet, executive director, US payer and real world evidence, AstraZeneca, during a presentation at *MM&M*'s SkillSets Live event in December.



Opening spread: MSK physician Andrew Seidman has been training Watson for the past year. Opposite: the IBM Watson oncology tool ranks treatment options. This page: iCTRS map shows geographic density of a population intended for a clinical study.

The last few years have seen partnerships between payers who have this type of data and the pharma industry, including AZ and HealthCore, which is part of Wellpoint, as well as Humana and Pfizer.

Now, big payers like Wellpoint and Optum are starting to proactively look for this type of data, and this past year, the Academy of Managed Care Pharmacy (AMCP) began requiring manufacturers to submit RWE with their formulary submissions.

The AMCP's move "clarifies that RWE and CER are important in the new guidelines for what industry should share with payers—that's quite new and novel," says Jennifer Graff, director of CER at the National Pharmaceutical Council (NPC).

What's more, RWE is evolving into a way for industry to understand the safety and efficacy of treatments in almost real time, says Graff, by sending research protocols out to the so-called distributed data networks of clinical institutions or health systems.

A big question going forward, says Robert Dubois, NPC chief science officer, is, "Can industry use results of these types of studies in their communications?" He explains, "these studies typically are not going to be found in the PI, so who is it that industry can share the information with? At the moment, there's not much clarity from the FDA."

There could be. "As the FDA becomes more accustomed to this kind of data," said Marcus Wilson, president of HealthCore, also at *MM&M*'s SkillSets Live, "there could be a lot of public interest in play if [the agency] puts this data out there in the right way."

Data interoperability's moment

Device, pharma and EHR companies are all amassing unique data streams. Can they connect their disparate data sets to advance health?

Perhaps, but the big EHR players could be an impediment to such collaboration, said Raj Amin, executive chairman and co-founder of e-health start-up Mana Health, which was picked last year by New York to develop the state's upcoming patient health record (PHR).

"There are too many silos of data today," Amin said at the ePharma Summit. "The biggest players in the EHR market…companies like Epic, don't really release their data in any massive way yet."

The whole industry, said Amin, is moving toward standardization, a more open data model. For example, the government is pushing the idea of the Health Information Exchange (HIE), an initiative designed to get providers' EHR systems to talk to each other.

Mana's PHR, set to debut this year, is being built to integrate multiple data sources in the patient record, including quantified-self devices like Fitbit and Nike FuelBand, and comes with ways for patients to visualize and interpret biometric data.

Mana's portal also promises data interoperability, as long as providers connect up, because it's tethered to NY's preexisting HIE. That differentiates it from Google Health or Microsoft Health Vault, or the other consumer-directed PHRs untethered to any larger network.

"The problem with tethered systems is they don't follow the patient," cautions Missy Krasner, formerly head of Google Health who also served in the first Office of the National Coordinator for Health IT under David Brailer. That means that as soon as the patient leaves that system, the data flow may stop.

Still, if biometric data such as going to the doctor, going to the gym, measuring blood sugar and online connectivity converge in the PHR, it could help patients better manage the health journey.

HIEs, said Amin, "were designed at a statewide level to create a consolidated point for all that data to live so that when you show up at the ER, all your data can be accessed by that particular provider." It also "leads to a lot more options for pharma or employers to access that data for business purposes."

Design for Mana Health's patient portal, which graphs various biometric data as part of a consumer-friendly aesthetic

A-hunting we will go

In the old days of recruiting for clinical trials, sponsors rarely hit their timelines. Today, they're helping achieve those deadlines by leveraging data. About 14% of drugmakers and research organizations use social media, online data-mining and EHRs to recruit participants, according to the Tufts Center for the Study of Drug Development.

One, Blue Chip Marketing Worldwide, cut 14 months from what was expected to be a two-year recruitment process for a trial involving Orexigen Therapeutics' Contrave diet drug, using a combination of paid search, social media, TV, print media and direct-marketing pitches, and buying some consumer profiles from data broker Experian.

Had they not, there's a good chance Orexigen "wouldn't have made it to the finish line," Blue Chip EVP Neil Weisman told *MM&M* last year. The drug firm filed an NDA for Contrave in December and expects to hear from FDA in 2014.

Jim Kremidas, SVP, patient recruitment & retention, for iCTRS, inVentiv Health's clinical trial recruitment arm, says rather than just targeting its messaging, iCTRS spends a lot of time ensuring a compelling message—something he says niche recruiters don't focus on.

The firm taps pharmacies when looking for patients with certain characteristics, a procedure it's followed to find volunteers for a COPD trial and for studies in other disease areas. "We do the usual things—social listening or digital listening," adds Ritesh Patel, global head of inVentiv Digital+ Innovation, the network's digital arm. But, "one thing we pride ourselves on at iCTRS is…[that] people have opted-in to receive information from us and there are no gray areas."

The firm MD Online, which helps small physician practices track redemption of claims electronically, is leveraging patient-level data to help recruit possible trial subjects. In one interesting use of its interface, the firm worked with a company that has an ultra-rare disease therapy, to help providers identify those with the signs and symptoms.

"Because we have all of the diagnostic codes in our database, we can say to our provider, 'This patient has had these three diagnoses in the last 12 months…consider testing them for that rare disease,'" says Jeff Meehan, chief commercial officer, MD On-Line. "We're utilizing these diagnostic clusters to drive identification of diseases that typically have a very long duration of diagnosis." ■