

ZumeLife

Innovative tools for living well

A Billion Little Experiments

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INTRODUCTION

Billions of little health experiments are constantly going on, as every day people around the world try new foods, medications, therapies. Many people conduct their experiments without their doctor's involvement and often against the healthcare industry's official recommendation: "consult your physician first." While health professionals often lament "people won't take responsibility for their health," many people are in fact grabbing the reins.

The billion little experiments, carried out by individuals for their own purposes and without orchestration, could generate deep and varied data, impossible to acquire through formal clinical trials. This data holds the potential to improve life.

There is good business in it too, in providing products and services that guide individual experimentation and help analyze results. Healthcare institutions can use the data from these experiments to improve their services. So can medical researchers. Government and nonprofits can use the data to understand population health trends, and to spread public health messages more effectively, while employers can reduce their healthcare costs and increase worker productivity.

This is a business opportunity, obviously; but it is also a world-changing positive social trend. To see it clearly, you have to rethink common notions of what "health" means and of the issue of "adherence".

HEALTH: A RESOURCE FOR LIVING

What is health? Most would likely say it is the opposite of illness. But that is a very limited definition. The World Health Organization (WHO), upon its establishment in 1948, adopted a broader view: "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." In 1986, WHO's *Ottawa Charter* added a key notion: "Health is a resource for everyday life, not the objective of living." Health is just a part of a tapestry of competing goals: family, work, money, social responsibilities; not to mention desire for fun. Health goals often have less priority than other responsibilities. That's just the way life is. And as life changes, so do our health goals. Health is not a static ideal; it is not something that can be achieved. Health must be constantly *optimized*.

The challenge of optimization is not unique to health. The field of quality improvement has been addressing this since at least 1939, when Walter Shewhart and W. Edward Deming published their initial work on using statistical methods to improve quality. Japanese auto manufacturers were amongst the first adopters. A manufacturing line is constantly being tested and modified to provide ever higher quality. The improvement process never ends, as there are always changes—changes to a car's design, new technologies, new government regulations, and changes in the public's desires. Deming described a continuous cycle of learning and improvement characterized by four key phases: Plan, Do, Study (aka Check), Act. This cycle is essentially a continuous version of the classical scientific method of hypothesis-experiment-evaluation. It is a cycle of constant experimentation. To improve health, we must treat it as an on-going process, and one that is in the service of life rather than an end in itself.

EXPECTING THE IMPOSSIBLE: UNDERSTANDING NON-ADHERENCE

A correct diagnosis and the perfect health regimen prescription will have little impact if the patient does not or cannot follow the advice. In the end it all depends on the patient's actual behavior. As former U.S. surgeon general Dr. C. Everett Koop famously said "Drugs don't work in patients who don't take them."

Unfortunately, the problem of poor adherence—the inability of patients to follow their health regimens accurately and consistently—is widespread and well known. Also well accepted is the belief that improved adherence to medical treatment would have far larger effects than any improvement in the treatments themselves.

Given its importance, many studies have been conducted to understand the problem. These studies have identified a variety of causes for poor adherence: psychological problems, particularly depression; cognitive impairment; asymptomatic disease; inadequate follow-up or discharge planning; side effects; patient's lack of belief in benefit of treatment; patient's lack of insight into the illness; poor patient-provider relationship; barriers to medication; missed appointments; treatment complexity; and costs. Based on this research, many efforts have been made to increase adherence including more education, easier regimens, financial rewards and threats, smart pillboxes, and reminder systems. Nothing seems to make a big difference. Discouraged healthcare practitioners conclude that people don't care enough about their health.

This diagnosis is flawed. While it is true that if a person is unmotivated or uninformed then he is likely to be non-adherent, that does not mean that the reverse is true, that because a person is non-adherent it implies that he is unmotivated or uninformed. Even well-educated, health-conscious, financially-comfortable, capable people are often unable to adhere well to their own self-defined regimens. There is a deeper, more fundamental cause. Adherence is poor because it is not possible. Take a look at what is going on *in the context of daily life*.

Consider diabetes, which afflicts 24 million US adults. Of these, nearly 10 million also have one other chronic illness, while another 6 million have two or more other chronic illnesses. An average diabetic person's daily health regimen may include:

- Prescription drugs—long-lasting insulin (taken 2x/day), rapid-acting insulin (4x/day), another diabetes related medication (2x/day), and a medication for hypertension (1x/day)
- Other medications and/or supplements—say three different items (1x/day each)
- Checking biometrics—blood glucose level (4x/day), blood pressure & pulse (1x/day), weight (1x/week)
- Tracking symptoms and health indicators — such as fatigue, thirst, urination, mood, pain and sleep, noting these on a daily basis and/or when an event occurs, say on average 6x/day in total
- Food—recording both a qualitative description of the food consumed as a journal (4-6x/day) and the calories or carbs consumed (4-6x/day)
- Exercise—ideally 30 minutes/day (1x/day)

This turns out to be 19 unique items, and roughly 34 distinct actions spread across 8-10 occasions during the day. Many people have regimens that are more complex. Tens of millions of US adults are on five or more prescription medications. Tens of millions of US adults have three or

more chronic illnesses. Their daily health regimens can include twenty or more medications & supplements, several biometrics, and numerous symptoms and indicators to track. There can easily be fifty distinct daily actions, to be performed at a dozen or more different times.

The regimens may change slightly every day, both due to planned daily variations and due to changes in the health condition. Some actions may vary depending on the outcomes of other actions. For diabetics, for example, insulin dosage depends on glucose level. The patients trying to follow these regimens are usually not able to devote their full attention to their health care. They are busy with work and family. The regimen, in this context, is a logistical nightmare.

Ironically, when problems of excessively complex regimens affects *doctors*, rather than patients, the difficulty is well understood. Recently, I visited an innovation center of a major health care provider. One of the projects proudly presented involved using facial recognition technology to automatically detect which doctor was currently sitting at the computer. Normally, doctors have to log-on and log-off a computer every time they step into a different room. Though each log-on takes only 5-10 seconds, the doctors find this requirement difficult to comply with. Rather than just lecturing the doctors about the importance of complying with proper computer security, smart people are spending a lot of time and money to solve the problem. But if it is unrealistic to ask a well trained doctor to do the same brief task 40-50 times a day, how can it be reasonable to dismiss the problems patients have in executing far more tedious and complex health regimens?

Thomas Edison said “Vision without execution is hallucination”. We must stop hallucinating about the ease of adherence. People need help. To take better care of themselves, they need better tools for personal health management.

ADDRESSING SELF-CARE: EMPOWERING THE INDIVIDUAL

Most importantly, personal health management tools must help people, on an hour-to-hour basis, *remember* to do the items in their health regimen, and *record* what they have done (so that they know something has been done—to avoid accidental overdosing, for example—and in case it impacts a later activity). But we cannot add another burden, another chore to their day: the person needs an easier life now. So these tools must be simple and integrate into the person’s everyday life.

At the same time, we cannot achieve simplicity by addressing only one part of the health regimen, such as pills or diet. A tool that is focused only on part of the overall health regimen will have to be complemented by numerous other similarly focused tools, and so fail to help simplify people’s lives. A personal health management tool must be easy to use, but it also must be comprehensive. In other words, it must be “mass customizable”. It must be designed to be both flexible, and simple to use.

From the perspective of helping people with their lives, and of improving adherence, this—reminders and recordings that ease the burden of hour-to-hour health chores—is of primary importance. What follows, taking advantage of the collected data, is secondary though of enormous benefit. To reverse the priorities, to put “tracking” above “easing life,” is ineffective and misguided.

With appropriate prioritization, however, a personal health management tool should also offer:

- Visualization features that make it easy for a person to spot patterns over time and across varied data.
- Auto-analysis that reveals important patterns.
- People-like-me connections that identify people with very similar health situations, making it possible to learn from other people's experiences.

In daily use, a good personal health management tool that had access to a record of a person's behaviors could provide:

- Auto-alerts to the person and his caregivers if there has been a significant divergence from plan.
- Regimen recommendations based on automated analysis and expert review.
- Personal support in the form of encouragement that goals are being met or acknowledgement of difficulties.
- What-if analyses providing an educated guess as to the potential value or effect of a new treatment based on an analysis of the person's own extended health history, as well as comparisons with other people with similar situations and applicable scientific data.

All of this is possible to do using existing technology and good design. The payoff comes not only from better adherence with existing health regimens, but also from new insights gained from new experiments.

IMPROVING HEALTHCARE: THE POWER OF DATA

We expect that once a patient presents himself to a doctor, the doctor will be able to make a correct diagnosis, an accurate determination of what is wrong. However, correct diagnosis and treatment prescription is often very difficult, and sometimes impossible. A major part of the difficulty lies in the fact that the doctor doesn't have a full picture. Unless the doctor thinks of asking, and only if the patient is able to remember and describe accurately, the doctor will be unaware of potentially important clues.

Another major problem is that an individual doctor simply cannot be abreast of all that is known in the world of medicine. For example, there are roughly 8,000 so-called "rare diseases" that together afflict about 10% of Americans. Most doctors will have no experience with these rare diseases, and so are unlikely to recognize such in their patients. Even the most common chronic illnesses often involve a complex interplay of symptoms and affect multiple body systems. In addition, people often suffer multiple maladies. Having multiple chronic illnesses is becoming ever more commonplace—over one-quarter of the overall US population and more than two-thirds of those over age 65, in 2005. The current medical system is incapable of properly handling such situations.

To see the challenge of correct diagnosis starkly, compare humans to airplanes. Some years ago, I worked for NASA, and some of my research involved analyzing aircraft accidents. On June 1, 2009 an Air France Airbus A330 jet crashed in the Atlantic Ocean after leaving Brazil. The design of the A330 is well known. There are design specifications down to the micrometer; tens of thousands of hours of data from computer simulations, wind tunnel tests, and years of flights; and detailed records on the specific A330 that crashed, from the moment it began on the assembly line to its

last maintenance report. Enormous efforts were made to locate and retrieve the crashed airplane's "black boxes" that will provide detailed data from numerous on-plane sensors as well as cockpit conversations. If the accident had occurred closer to land, there might also have been data from radar systems and weather sensors. Despite all this information, it will likely take a large team of experts many months, at least, to diagnose what went wrong. In contrast, our body is far more complex than today's most advanced airplane, and there are far fewer sensors providing less accurate information measured far less often. Given these limits on what is known about the body, it is amazing that doctors are able to make good diagnoses even some of the time.

Even when properly diagnosed, settling on the "right" therapy, the right prescription is difficult. As an example, as recently described in *The New York Times*, there are currently at least five very different courses of treatment for common prostate cancer, ranging from watchful waiting (about \$2500/year) to proton radiation therapy (about \$50,000/year), but still the best course of treatment is unknown. An all too common situation is that without proper data doctors mistake drug ineffectiveness as patient non-adherence, leading to incorrect treatment recommendations and demoralizing the unjustly accused patient. The combination of a lack of appropriately detailed knowledge about the patient, insufficiently detailed and situationally-relevant scientific research, and poor access to existing knowledge means that diagnosis and treatment prescription are often poor.

Doctors would be able to provide much better care if they had rich, accurate and timely information about their patient's health. Though obvious, it can be surprising how much of an impact it can make. Let me relate two examples involving pain management.

- A doctor who treats many patients with migraine headaches told me that she always asks her patients a basic question: How often have you had migraines, and how severe have these been? She added however that she expects little of value to be found in her patients' answers. They simply cannot be expected to remember accurately. She only asks because she knows her patients expect her to, and would feel ill-treated if she did not ask. Unless the patient is keeping an accurate journal, she has to rely on other objective measures.
- One early user of Zume Life's prototype personal health management system suffers from scleroderma, a condition that amongst other things results in occasional bouts of internal pain. After a few weeks of using Zume Life to track her health activities and condition, she looked at her charts and was surprised to discover that she was experiencing 4-5 episodes of severe pain each week. Her doctor too was taken aback. But, with the benefit of such information, over the next few weeks he made many small adjustments to her medication regimen and observed the results. Within 5 weeks, her pain was reduced to just one mild episode per week.

There is much demand today for doctors' pay to be contingent on "performance," meaning healthy outcomes for their patients. However, demanding better performance without better data for doctors and without better tools for patients is fruitless and counter-productive.

Doctors know they would be much more effective if they had "better patients"—patients who were able to follow their regimens, who could cope with changes and experimentation, who could track their health, and who could provide rich, accurate, timely information. On the other hand, doctors are not ready to deal with such patients. They will not be able to cope with a daily deluge of data. Some filtering mechanism or service will need to be developed to provide doctors with the right

data at the right time.

The cutting edge of health management lies at this intersection of patient, doctor, and data. There are currently 6.8 billion people in the world. Each of these people has a slightly different context—different body, environment, food, medications, activity, etc. Their daily health data, captured through personal health management tools, would provide an incredibly rich source of data. The amount of data that could be created by even a tiny fraction of the world's population gets into petabyte territory.

Such rich data would also enable the characterization of ever smaller groups with a common illness, ever more well defined illnesses. As noted earlier there are approximately 8,000 “rare diseases”. By definition these are diseases that (1) have been characterized clearly enough so that a knowledgeable doctor could confidently diagnose the disease, and (2) impact fewer than 200,000 people. Though each specific disease is rare, about 10% of the US population has some particular rare disease. This is in contrast to more common diseases such as hypertension or diabetes that effect millions of people. But, how valuable is this distinction when it comes to treatment? For each common disease there are numerous treatment options, many of which will have no positive impact on a significant portion of those with that illness. The reality is that within each of these common diseases, there are many, many subgroups. Without a clear understanding of these subgroups, treatment is often a long and slow trial-and-error process. With petabytes of data, the scientific community will be able to make huge strides in developing far more refined characterizations.

To take advantage of all of this data may however require some difficult changes in mind-set. The second generation of web innovation (“Web 2.0”) has shown that the impact of harnessing collective and demonopolized information and of unleashing the creativity of humanity is tremendous. The planned efforts to conduct “comparative effectiveness research” in healthcare will be severely limited, even ineffective, if they ignore user-generated data. In fact, encouraging the creation and use of such data should be atop their priority list. Though each person will likely focus only on their own and their family's health, their efforts will benefit everyone as the collective data set grows. Crowd-sourcing websites such as *PatientsLikeMe.com* and *CureTogether.com* have already shown that significant findings can come from data supplied by individuals, even from limited data entered by hand by a small group of people. That is just a start. Petabytes of data supplied by a broad spectrum of people will revolutionize medical learning.

PROMOTE SELF-CARE: A CALL TO ACTION

In summary, we can and must:

- Enable self-care success with great personal health management tools.
- Empower self-experimentation through education, encouragement and assistance.
- Exploit the data from these experiments to advance health care and science.

There are numerous opportunities for entrepreneurs and innovators to develop the tools and services that will assist this transformation. But there is also a need for a cultural change.

Health professionals need to be prepared for patients who do take full responsibility for their health, to play a role as facilitators and partners, rather than as the ultimate authority.

Health researchers should prepare to embrace a world awash in unstructured but rich data, that is unlike the clean, but extremely circumscribed, world of double-blind or randomized clinical trials that has been the norm.

Employers should adjust their thinking on health & wellness programs away from their current prescriptive approach and toward one of enabling and supporting self-care.

Philanthropists should widen their horizons beyond the promise of *tomorrow*, as in “the search for a cure for _____”, and help people live better *today*. The focus needs to be less on the disease and more on the health and wellbeing of the person. American charitable giving for health was \$22 billion in 2008. The value of this philanthropy would be greatly enhanced by focusing much more on helping people take care of themselves.

Similarly, foundations with an interest in health need to broaden their perspective. They should expand their efforts to support individual & family self-care. One area that might especially benefit from foundation attention is improving public health education to teach people the fundamentals of self-care and better self-experimentation (not simply following the doctor’s orders, but learning for yourself what works and what doesn’t in your life), and providing self-care assistance services for those segments of society that need help.

Fortunately, it is not necessary for all of these changes to happen together or to be coordinated. People are already motivated to care for their health. With the right tools, the flood of personal health data will grow.

Let’s unleash the power of a billion experiments. Individuals will lead; institutions will follow.

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