16

IRRATIONAL CHOICES, UNFATHOMABLE OUTCOMES: PATIENT ETHNOGRAPHIES IN PHARMACEUTICAL RESEARCH

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With the proliferation of oral therapies (in place of injectables) for many chronic conditions, the locus of medical treatment is shifting from the surveilled context of the clinic to the private space of the home. In the home, compliance and persistency – the extent to which patients take medications over time – have become pressing concerns. Non-compliance adversely affects health outcomes, and costs manufacturers millions. The medical community has difficulty understanding non-compliance, often relegating it to individual irrationality or dysfunction in the doctor-patient relationship. Ethnography opens up the issue by entering the private space of pill-taking to understand the beliefs, relationships, and activities that contribute to patient (non-)compliance.

INTRODUCTION: REBECCA HAS CANCER

In the hospital, the doctor told Rebecca to get her affairs in order. He'd found a tumor the size of a football nestled between her large intestine and her ovaries. There was no clean way to remove it, and – without a thorough pathology – no reliable way to tell what it was. The doctor assumed the worst.

Rebecca went home. An intensely social person, she refused calls from friends and family. She went online. She identified a surgeon who could remove the tumor. Two weeks later, he took out one of her kidneys, her spleen, and parts of her intestine, stomach and pancreas. The cancerous mass was gone.

Gastro-intestinal cancer is notoriously aggressive. Despite successful surgery, Rebecca's surgeon recommended further therapy. She went back to the Internet. The drug he suggested – the first of a new generation of so-called "targeted therapies" in oncology – is a simple, once-daily pill. Relative to old-school chemotherapy, its side effects are minimal. It promised to turn a once-fatal diagnosis into a mere chronic condition. Patients who took it were surviving for years without recurrence. But, Rebecca's insurance wouldn't cover it completely. Undeterred, she contacted the drug's manufacturer and arranged to receive it for free.

Up to that point, Rebecca was a model baby-boomer cancer patient: pro-active, informed, and determined to take control of her care. So, sitting in her living room in suburban New Jersey eight months later, it was hard to believe what she was telling me. After all she'd been through – after the shocking diagnosis, the invasive surgery, the exhausting battle with medical bureaucracy – Rebecca wasn't taking her medication.

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THE PROBLEM OF PATIENT NON-COMPLIANCE

In the course of product commercialization, the drug's manufacturer had talked with hundreds of physicians and nurses. Their enthusiasm was overwhelming, and their experience suggested that patients were exceedingly compliant with the therapy. None of the physicians or nurses seemed to know patients who stopped therapy of their own accord, or missed more than the very occasional dose. The manufacturer interviewed patients, who corroborated this story. But, by simple mathematics, the manufacturer knew otherwise. They compared the number of prescriptions written with the number of pills still sitting on warehouse shelves, and saw that something was off. A more complex calculation led to a statistical figure: only 77% of their patients were compliant with their life-saving therapy.[1]

This conclusion flabbergasted the pharmaceutical company. Their drug is efficacious, its side effects are "mild to moderate," and the medical community is fully behind it. There's no "rational" reason why patients should refuse it in such numbers. Patient non-compliance resulted in a three-pronged crisis for the manufacturer. First, by missing their prescribed dose, patients increased the likelihood that their cancer would recur. Second, by leaving their prescriptions unfilled, patients increased the likelihood that the marketing team would miss its annual revenue target. Third, by experiencing recurrence (and possibly premature death), the long-term market for the therapy was at serious risk of shrinking.

The company needed to act. In this case, action did not take the form of lab science and high-tech manufacturing --- the cornerstones of the pharmaceutical industry. It came through the vagaries of brand marketing, where drama and spin direct human impressionability. The advertising agency assigned to this drug believed that the drug's Direct-to-Patient communications were overly clinical, and did not sufficiently address patients' "emotional drivers." The providers of compliance programming felt that their offerings were missing important "behavioral cues" that lead to patient non-compliance. The marketing team worried that some people with cancer just have a death wish. How else could they make sense of their behavior?

The marketers convened several focus groups. They assessed patients' and physicians' knowledge of the disease and the drug. Their hypothesis – grounded in the tradition of health research on compliance – was that the more people know about their condition, the more likely they are to stay the course of therapy. And, the critical channel for knowledge of this sort is the patient/doctor interaction. What they found were knowledgeable, proactive patients like Rebecca, and relatively personable, committed physicians who were doing what they could to promote compliance. Patients and doctors were as surprised as the marketers to learn that people were not compliant. Everyone was stumped. The market research manager decided they needed a new approach. She commissioned an "ethnography," and I went to Rebecca's house.

A SOCIAL ANTHROPOLOGICAL APPROACH TO NON-COMPLIANCE

When I got there, I had every reason to believe that Rebecca was one of the compliant ones. We had spoken on the phone several times, and I knew how proactive she'd been in managing her illness and treatments. Over the phone, she told me she was taking the drug. Her doctor thought she was taking the drug. So did her nurse, her pharmacist, and her sister. But, her husband knew otherwise. After several hours of conversation, he told me that she didn't take the pill for several months after

receiving it, and then only took it a few times per week. He revealed this information without reproach. Her decisions were her business, he told me, and it's up to her to decide how to handle her disease.

Rebecca explained her situation more fully. After surgery, she was living in a fog. There were days when she would just sit and cry. Sometimes, she was afraid the cancer would come back. Other time, she was afraid the drugs would harm her more than the cancer itself. Most of the time, she was just afraid, and she really couldn't think of why. At that point, she wanted to wake up from the nightmare. But, the drug wouldn't let her. Rebecca explained: "They are giving you something that could possibly save your life, so, on one hand, why not take it and live with the side effects. On the other hand, it's like you never get out of that cancer world, because that's a reminder every day that you've got something…and maybe you don't necessarily want to do that." For her, the drug was intolerable not because of its bio-chemical formulation, but because of its symbolic resonance.

At first, Rebecca dealt with the situation by leaving her medication in its shipping box. Over time, she developed a more complex solution. On evenings when she knew she'd be at home – when she knew she could take the drug and then lie down if she felt sleepy or throw up if she felt nauseous or take a bath if she felt depressed – on those evenings, she'd take the pill. But, on evenings when she had plans to go out, she'd skip it. Every week, for example, she had dinner with her mother and her sister. In her Italian-American family, eating is everything. Rebecca was not about to risk experiencing symptoms with her family present. That wouldn't just ruin her dinner. It would highlight for her mom and sister that she was still not well, that she was still suffering and at risk for recurrence.

For Rebecca, as for many of the participants in our study, sociality is critically tied to compliance. There are countless examples. In Rebecca's case, both the revelation of her non-compliance and the explanation for it were tied up in her most intimate social relations. But this was not, *ipso facto*, the way our pharmaceutical clients would have seen things. Our clients' individualistic, cognitive model stood in stark contrast to an anthropological perspective that highlights sociality as a model for understanding seemingly "irrational" behavior.

This contrast is hardly unprecedented. Consider the Azande of Evans-Pritchard's time. Among the Azande, a growth of a reddish colour in the area of the intestine was not called gastro-intestinal cancer. It was called Mangu, and it represented the physical substance in the body that identifies an individual as a witch. In Evans-Pritchard's analysis, the presence of Mangu in and of itself was of relatively little interest to the Azande. It only became an issue when an act of witchcraft had been performed. The Azande, as Evans-Pritchard explains, "are interested solely in the dynamics of witchcraft in particular situations."[2] These situations are by and large instances of great misfortune. Take the example of the falling granary. The Azande know that granaries – elevated wooden structures that hold grain – are subject to the vicissitudes of wind and weather and termites. Sometimes they fall. So it goes. But, if people happen to be sitting under a granary when it falls, and they get hurt, then it is insufficient for the Azande to conclude that their luck was bad. The Azande demand a clearer causal explanation for the misfortune. The Azande look for a more rational, more scientific story. They look for malfeasance in local social relations. And they look – among the parties in question – for Mangu. Witchcraft.

Contemporary Western cultural logic is clearly quite different from that of the Azande. Our tolerance for coincidence is greater. In the granary example, we are satisfied with vague explanations about gravity and happenstance. People caught under the granary were in the wrong place at the wrong time. So be it. And – as our interest in genetics shows – we have a greater desire to understand the

physical substance of human beings prior to (rather than following) social phenomena. For example, the scientific principle behind Rebecca's targeted therapy has to do with the inhibition of genetically-triggered bio-chemical processes BEFORE they result in the phenomenon of gastro-intestinal cancer.

At the same time, the interpretive power of Evans-Pritchard's social anthropology helps unravel a pressing business question at the heart of the pharmaceutical industry. With the proliferation of oral therapies for various chronic conditions, the locus of treatment is increasingly shifting from the monitored context of the clinic to the private space of the home. In their homes, patients are free to do what they will, and report on it later. In this context, compliance has become an ever more pressing issue. The medical community has difficulty understanding non-compliance, because most approaches relegate it to individual irrationality or – in more enlightened treatments – dysfunction in the doctor-patient relationship.[3] Ethnography can open up the issue, to uncover the various elements of sociality that play into people's treatment experiences and decisions. In the context of an individual's treatment decisions, Rebecca's behavior appears irrational, even suicidal. But, in the context of her sociality, it's completely rational and imminently understandable.

Once we understand Rebecca's decisions, we find ourselves in a position to draft interventions that (with some luck) may increase her compliance --- improving both her health outcomes and the pharmaceutical company's bottom line. In this particular case, we made some concrete recommendations for this particular cancer therapy. Commitments to the client constrain the extent to which I can discuss those recommendations. But, broadly speaking, we suggested educating physicians to look for possible social roots of non-compliance, and provide patients with medically acceptable flexibility to address them. It is legitimate, for instance, for patients to alter the timing of their pill-taking to accommodate social events. We also highlighted the fact that side effects classed "mild to moderate" in clinical trials may feel more serious to some people, some of the time. The pharmaceutical and health care industries need to acknowledge those side effects, and offer real, workable ways for patients to address them. It's too early to know the extent to which the tactics we offered have worked. I am certainly optimistic. They are, in any case, a better start than our client had had previously.

CONCLUSION: PATIENT ETHNOGRAPHIES IN PHARMACEUTICAL RESEARCH

To be effective, patient ethnographies in pharmaceutical research must be much more than simply "in-context" studies of sick people and their families. Explaining the "irrationality" of Rebecca's non-compliance involves more than just sitting in her home with her husband. As her example clearly shows, the key to understanding patient non-compliance comes in shifting the lens from individual rationality to sociality. That is a theoretical move, not a methodological one. As Evans-Pritchard writes, "Anyone who is not a complete idiot can do fieldwork."[4] But, an active dialogue with the constructs of social anthropology a la Evans-Pritchard is critical to knowing what to look for in the field, and how to interpret it back at the office.

Theoretically-informed ethnography can supplement the individualist, rationalist models of Western biomedicine with a rich understanding of sociality. But, in the context of the pharmaceutical industry, this is far – very far – from a home run. As a whole, the pharmaceutical industry is invested in unpacking the mysteries of non-compliance. At the same time, it's invested in maintaining the individualist, rationalist epistemology of Western biomedicine. So, ethnographic work such as this is acceptable to the industry, but only when it's relegated to the vague, squishy, always-already suspect

world of marketing. Ultimately, the ethnographic intervention may improve health outcomes by helping to "sell" the best of modern pharmaceutical science. But, in this context, it's hard to imagine a scenario in which it might affect the direction of pharmaceutical science. For now, let's just say that mentioning Mangu to a pharmaceutical executive remains firmly out of the question.

NOTES

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The ideas, perspectives and ramblings herein are my own, and do not represent the official position of Hall & Partners Healthcare.

[1] In order to maintain the confidentiality of my client and the anonymity of all individuals discussed in this paper, I am unable to provide citations for certain proprietary corporate intelligence held by the company or its agents. I trust the reader will understand my predicament, and accept certain vagaries of citation.

[2] Evans-Pritchard (1976:4)

[3] The medical literature on compliance, persistence, and adherence is vast. I have included some representative works in the references section of this paper. Much of the literature provides psychological perspectives on patient medication-taking, suggesting that affect drives patient behavior. Some publications interrogate physician-patient interactions as the source of miscommunications (and non-communications) that result in poor adherence/compliance. Still others claim that the specifics of the therapeutic area (oncology, infectious disease, primary care, etc.) shape dynamics of patient compliance. To my knowledge, no systematic analysis of patient compliance takes an anthropological approach, grounding patient behaviors in broader issues of sociality and meaning.

[4] Evans-Pritchard (1976:243)

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