

RESEARCH

From junk science pawn to public-led trials

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ABSTRACT

Junk scientists and unethical healthcare providers often tell the public that systematic reviewers reject real research because of bias or that universities and the FDA are paid off by the pharmaceutical industry. I was snared in this trap during my role in a spinal injury foundation after sustaining significant brain and spine injuries. I was too naïve and damaged to understand that not all doctors are ethical or that the role of the FDA is in protecting public health. As my brain started to recover I began attending classes at the Open University and I found the world of ethics, research methods and cell biology. Soon my days at the spinal organization were numbered as I pointed out errors in the protocols and discrepancies in what the participants should know. I shared that vulnerable persons need to be informed they are participants and not patients and that it was unethical to charge patients for experimental research or use them as shields against the recommendations of the FDA. The organization battled the FDA who won a permanent injunction against them. I was dismissed long before this but felt like I had blood on my hands. I decided I would become an informed healthcare provider and I proceeded to learn Evidence-Based Healthcare at the University of Oxford where I completed the Masters and went on to become a Doctor of Philosophy student to bring evidence-based healthcare and public led trials to the masses. This is my story:

Keywords: public-led trials; fecal implants; citizen health research; public engagement; evidence-based healthcare

THE CHANGE

At an Open University neuroscience class a list of extra reading was given. One series of papers on the list changed the way I read and understood research because I finally learned what was important and how methods speak. I learned that two-thirds of what I read was speculation and hope without an anchor and I learned that theory without evidence is like a boat with a leak. The series was “How to Read a Paper” authored by Trisha Greenhalgh¹⁻⁴. The materials were linked to a site that led to the Center for Evidence-Based Medicine and the University of Oxford⁵.

THE NEED

I needed to know HOW to read a paper by myself without someone else’s filter confusing my simple mind. 50% of papers are now open access⁶. Patients and the public want to know does it work, and if not, why not. The public asks can I count on this and does it apply to me⁷. They want to know how many people will need to take an intervention before one gets well. They do not care about politics, dependencies and speculation. They want to be informed so they can participate in decision-making about their own health care without being manipulated⁸. More and more people are accessing the web for health information⁹. (See Figure 1.)

“If I read and memorized two medical journal articles every night, by the end of a year I’d be 400 years behind”, states Donald Lindberg, the Director of the National Library of Medicine (NLM). In 2010 it was estimated that 75 RCTs and 11 systematic reviews are produced daily¹⁰. Information alone is not enough. Conversations can center around shared informed decision making, patient and public participation and putting academic copy into plain

language but clearly online engagement is a fertile field that needs active engagement to harness information for the benefit of research¹¹. Medical providers lack the time to stay abreast of the newest development for every condition yet for the patients, new developments may signal a window of opportunity for a failing life¹². Many patients have the motivation and the focus for researching their own health conditions, why not use patients and the public to crowd-source evidence and get it into practice⁸?

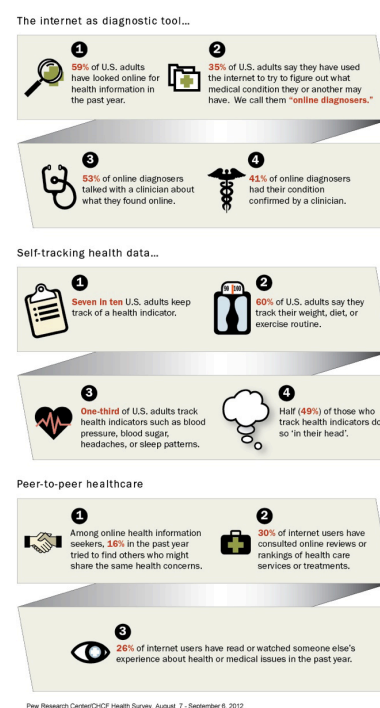


Figure 1. The internet as diagnostic tool⁹

There are many decisions about healthcare that are straightforward and need no extra discussion while others require more information and time to think about the risks and the options¹³. At no time is this exchange equal in terms of experience and knowledge, my medical provider and I both bring strengths and weaknesses to the table, there is mutual respect because of relationship rather than the imagination of perceived rights. For decision making to be real, it needs to be informed and have elements of choice that consider personal values¹⁴. A patient, doctor or research participant can use what is good for the population as a guide for care but it is not the whole story.

DO IT YOURSELF HEALTHCARE AND RESEARCH

Do it yourself healthcare can lead to great benefits or it can do more harm than good¹⁵. For example fecal implants have recently come to the attention of the Food and Drug Administration (FDA) who indicate this intervention needs to be seen as an IND or investigational new drug. Their rationale is that the fecal matter could be contaminated by bacteria, carry disease, introduce donor complications or change the mechanisms of response within the body and for these reasons it should be classified and investigated as a new drug¹⁶.

It was not always this way. In January 2014, the New England Journal of Medicine reported that just one fecal transplant helped 13 of 16 research participants with *Clostridium difficile* (C-Diff) to recover and that the sufferer's condition improved with just one transplant. Two of the non-responders received a second transplant from an unrelated donor and their conditions also improved. C-Diff is a serious bowel infection that can lead to death. The study was stopped so that everyone in the control group could also benefit from the treatment. There were no complications and yet access to the treatment was limited by the FDA's decision to consider this intervention as an investigational new drug¹⁷. This classification comes at great cost to the patient who must suffer in agony with bowel distress and possibly bowel surgery or death as the wait for trials completion continues to validate the intervention. Drug research costs money and future patients will bear the increased cost for the intervention.

Patients and their relatives decided to take matters into their own hands with some hiring others to provide feces for transplantation and even parents performing the transplants on their own children. They report figuring out how to do this from do-it-yourself Internet sites and report greatly simplifying the process with good results. In the hospital this can be done through a colonoscopy procedure but at home people are using simple and inexpensive enema equipment with the same results.

The negative picture is that although hospital treatment sites report good results after 1-2 transplants people at home are afraid to stop and no one knows the results of long-term daily fecal transplants. It seems reasonable that it would increase the risk for parasites, infection and injury¹⁸.

Patients might use their own data assisted by responsible health professionals to contribute to a crowd-sourced cure or an effective targeted intervention. This was the result in the OMERACT¹⁹ research for rheumatoid arthritis where it was participants and not the researchers who identified exhaustion as the target for intervention.

REAL EVIDENCE-BASED HEALTHCARE (EBHC)

There is criticism about EBHC with some claiming that it is only formula driven medical care that fails to reflect patient values but this is a fallacy²⁰. What if we looked at evidence and shared informed decision making like two wheels on a bike? They both need to be full of substance, well connected, lubricated and working in balance with a competent driver with good vision on the seat to get the vehicle where we want it to go. By the same rationale that evidence is necessary but not sufficient for decision-making, values are necessary but not sufficient for evidence and they may default to feelings based on social pressures and peer influence without a focus on evidence and how to apply it. Maybe the bike needs a check-up from time to time and a little maintenance to run safely and at optimum performance, evidence based healthcare could be seen the same way. The effects of co-morbid conditions, age, access to diagnostic screening campaigns, social demographics, existing trauma, chronic pain and multiple pharmaceuticals on individual quality of life are under-reported in healthcare²¹. The public are the authorities on their own lives but they are seldom granted a voice or the tools to self-implement testing and evaluation of interventions that affect them. Healthcare professionals could change how evidence is brought into practice by sharing what EBHC is and how to make use of it to embrace public and patient values. The platform from which we have chosen to consider public values in evidence-based healthcare and make evidence known is PLOT-IT²².

USING PUBLIC INITIATED HEALTH SCIENCE RESEARCH TO CURATE AND ENGAGE

PLOT-IT (Public-led online trial-infrastructure and tools) is a platform where researchers, health care providers and the public share evidence-based public research solutions for all who value being active participants in their own healthcare. PLOT-IT collaborates with health science groups using an infrastructure for generating and running public-led online trials. The public will access real-time data from which they will be trained and equipped to do their own hypothesis generating and testing. Participants have full access to their own data and can choose to share it. Shared data will be de-identified and put into the public domain for discussion and analysis. PLOT-IT includes randomization algorithms and the use of validated Patient-Reported Outcome Measures. Communication is important for health knowledge delivery and moderated discussion groups are available for the formation of communities of interest. PLOT-IT supports the inclusion of solution based

learning workshops to improve online trials methodology for the public and for those generating health research. In summary, PLOT-IT turns the current model of health research on its head by having research questions generated and answered by the public themselves. Health citizens will be supported by established health researchers to ensure that all research is methodologically sound, ethical and clinically safe. Public initiated research trials can capture observational data that may be otherwise lost to healthcare science. Access to these observations could potentially change the practice of medicine²¹.

CONCLUSION

The public potential for improving decision-making, education and methodology in clinical trials is a valuable and untapped resource. It is exciting to be part of this new evolution in shared health research. By putting research tools in the hands of a hungry public we can engage citizens directly in health research. The time is ripe, the technology is ready and the passion and drive to engage the public in their own health research is now!

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