Harnessing experience: exploring the gap between evidence-based medicine and clinical practice

M. Cameron Hay PhD,¹ Thomas S. Weisner PhD,² Saskia Subramanian PhD,³ Naihua Duan PhD,⁴ Edmund J. Niedzinski PhD⁵ and Richard L. Kravitz MD MSPH⁶

¹Assistant Professor, Department of Anthropology, Miami University, Oxford, OH, USA

²Professor, Departments of Psychiatry and Anthropology, Center for Culture and Health, UCLA, Los Angeles, CA, USA

³Assistant Research Sociologist, Department of Psychiatry, Center for Culture and Health, UCLA, Los Angeles, CA, USA

⁴Professor, Departments of Psychiatry and Biostatistics, Columbia University, New York, NY, USA

⁵Assistant Professor, American River College, Sacramento, CA, USA

⁶Professor, Center for Healthcare Research and Policy, UC Davis, Davis, CA, USA

Keywords

clinical experience, decision making, Evidence-based Medicine, Evidence Farming, medical epistemology

Correspondence

M. Cameron Hay Department of Anthropology Miami University Oxford OH 45056 USA E-mail: mchay@ucla.edu

Accepted for publication: 10 March 2008

doi:10.1111/j.1365-2753.2008.01009.x

Abstract

Rationale, aims and objectives There is mounting evidence of a gap between Evidencebased Medicine (EBM) and physician clinical practice, in part because EBM is averaged global evidence gathered from exogenous populations which may not be relevant to local circumstances. Local endogenous evidence, collected in particular and 'real world' patient populations may be more relevant, convincing and timely for clinical practice. Evidence Farming (EF) is a concept to provide such local evidence through the systematic collection of clinical experience to guide more effective practice.

Methods We report on the findings of a pilot study of 29 individual and three focus group (n = 10) interviews exploring physicians' evaluations how they use multiple sources of information in clinical decision making and their thoughts on EF.

Results Physicians recognize a gap in translating EBM to practice. Physicians reported that when making clinical decisions, they more often rely on clinical experience, the opinions of colleagues and EBM summarizing electronic clinical resources rather than refer directly to EBM literature. Confidence in making decisions based on clinical experience increases over time, yet few physicians reported having systems for tracking their clinical experience in designing treatment plans and patient outcomes. Most physicians saw EF as a promising way to track experience, thereby making scientific evidence more relevant to their own clinical practices.

Conclusion Clinical experience is relatively neglected by the EBM movement, but if that experience were systematically gathered through an approach such as EF, it would meet a need left unfulfilled by EBM.

Introduction

Modern medicine is founded on scientific observation and research, but with the rise of Evidence-based Medicine (EBM) in the 1990s, random-controlled trials (RCTs) emerged as central for scientifically examining and validating hypotheses. Guidelines summarizing RCT evidence are developed by nominated experts in scientific societies as best practices to reduce practice variation and improve quality of health care through consistent use of EBMidentified best practices for managing a particular condition [1–4]. EBM is typically seen as the gold standard for medical knowledge, yet with relatively few exceptions [5], RCTs and the practice guidelines they have generated have had less effect on physician practice than expected [1,6,7]. It is known that clinically effective and financially efficient interventions often are not used past the point of external funding, potentially because the interventions were introduced in a 'top-down' manner rather than developed in collaboration with front line clinicians [8]. Indeed, a lack of adherence to guidelines is so commonly reported that there are manuals for improving the creation of guidelines [9], systematic RCT studies of guideline implementation campaigns [10] and formal recognition that guidelines may need to be 'styled' for a particular practice [11]. There have been a number of critiques of EBM, but these are largely limited to reminders that EBM guidelines must be evaluated for their relevance at the local level [12] and in each particular case [13], and concerns over how guidelines are developed and that they can go out of date [14–16].

A growing number of articles raise questions about the integration of EBM into practice as well as the EBM movement's fundamental assumption that RCT evidence can result in better patient care [17-19]. Some scholars point to how EBM peripheralizes the patient-at-hand [20], reorienting physician focus on guidelines and away from patients [21,22]. Others note that guidelines themselves are problematic on multiple fronts [17], and fail to address typical clinical problems such as treating patients for whom the complexities of comorbid disease, disease-drug interactions, or adherence can hinder treatment [23,24]. Another critique is that EBM often neglects patient education, leaving clinicians to translate RCT evidence in order to discuss with patients whether guidelines are the most appropriate for each individual person [25], given patient preferences [26]. Even when EBM attempts to pay attention to individual patient variation, the goal is to fit these into cost-utility calculations [27] which may lead to suboptimal therapeutic decisions [28-31]. Indeed, it has been suggested that 'EBM appears to play more and more into the hands of those non-clinical people who run the health care show,' [32,33] and in so doing may become more about cost than patient care or quality of life. Finally, a number of scholars question the validity of limiting 'evidence' to that which is produced in RCTs [34,35].

Evidence-based Medicine is most widely understood as global, exogenous evidence largely based on average treatment effects [36], which can be translated into guidelines developed from many studies with diverse populations in contexts of care that do not necessarily match those of clinicians. Such global evidence may not be relevant to a clinician's patients or the contexts in which they work. Local knowledge and evidence comes from actual physician experiences of treating particular patients in particular places: recording the specific treatment protocol, the living contexts of patients that affect adherence and patient outcomes. Systematically recording local experience can produce evidence on circumstances that affect treatment but which are not typically addressed in RCTs, including: comorbidities, ethnic and cultural beliefs about health, diet, illness causality, living situations and financial resource availability. Such local evidence also may be gathered in a more timely fashion than EBM. For all these reasons, harnessing experience as local endogenous evidence potentially has real value in patient care.

The case of the improvement of care in Cystic Fibrosis (CF) illustrates the importance of harnessing experience. CF is an inherited disease that once had life expectancies of 3 years for the children at diagnosis in 1957. With RCT on CF and the emerging guidelines, life expectancy was raised to 30 years by 1997. But the CF foundation noticed that some CF centres were consistently achieving better results extending life expectancies to 46 years or more. Why? A likely explanation is that some physicians were trying out ideas that went over and beyond the guidelines. Moreover, they kept track of the outcomes of these revised therapies, monitored patient care closely and refined practices based on their local evidence [37].

The improvements that were achieved in CF were accomplished by tweaking guidelines, carefully tracking patient outcomes, constantly refining protocols within local contexts and communicating these findings as evidence for care with colleagues. This is essentially the idea of Evidence Farming (EF). EF is conceived as a flexible, infrastructural digital tool that enables the systematic attention to, acquisition of and utilization of local experience to improve clinical practice and patient outcomes.

The idea of EF is not to bemoan yet again the lack of seamless fit between EBM and practice, but to recognize that the best medical care is a product of the front-line clinician systematically modifying EBM in line with their clinical experience and the needs and situation of the patient. EF expects that this is what physicians do, and offers a tool to take advantage of their experience in ways that legitimate these modifications as research bearing on clinical problems. In short, EF recognizes the vitality of the casuistic approach [20,38] to medical care by focusing on healing [39], and provides a tool for patient-centred empirical research to balance the top-down approach of EBM.

Evidence Farming basically consists of three steps in therapeutics. First, a physician tailors a treatment plan to optimize therapy for a particular patient. Second, the physician tracks the outcomes of that plan, making adjustments as necessary to provide optimal care. And third, the case becomes part of a searchable database that enables the physician (or a participating group of physicians) to build a body of knowledge of what actually works on the ground with particular population groups or in particular contexts.

We hypothesize that EF could usefully complement EBM, encouraging practitioners to be front-line researchers working with EBM and harnessing their clinical experience to provide optimal care for particular patients or population groups of patients, and disseminating that evidence as on-the-ground best medical practice within communities. Our report explores physicians' understandings of EBM, any gap they perceive between EBM and practice, and physicians' reactions to the EF concept. In so doing, it provides insight to the problems and potential solutions for mediating EBM with everyday clinical practice using EF.

Methods

A total of 39 physicians were interviewed (29 individually and 10 as part of three small focus groups). Individual interviews lasted 25–50 minutes and focus groups were approximately an hour in length. All interviews were semi-structured conversations, not closed-end response formats. Recruiting through snowball samples, we interviewed clinical professionals from multiple specialties and varying degrees of experience to capture a wide range of experiences, beliefs and practices, including specialists in family/ internal medicine, cardiology, rheumatology, surgery, infectious disease, pathology, paediatrics, integrative and psychiatry, as well as a nurse practitioner, a doctor of osteopathic medicine and eight fourth-year medical students. Respondents practiced in varied settings [academic medicine, community clinics, VA hospitals, private practices, Health Maintenance Organizations (HMOs)] and were all in the greater Los Angeles or Sacramento areas.

Interviews explored how physicians weighed different sources of information in their clinical decision making and whether physicians generally would be receptive to using a digitally based EF tool to improve their own practice and their future clinical decision making. We asked practitioners how they typically made diagnoses and treatment plans, what resources they accessed and in what combination (clinical knowledge/experience, consultations, EBM, or electronic clinical resources). We subsequently explored the extent to which they thought localized knowledge, whether at the community or clinical level would be useful to them and how they might employ that information in their diagnostic and treatment process. Finally, we inquired about what an ideal local experience collecting system would look like, what benefits they perceived such an EF system would bring and what barriers to adoption it might face. We focused primarily on therapeutics, where EBM has made its strongest contributions. Although a version of EF could be used for better understanding of history taking, diagnosis and other tasks as well, this study was not designed to examine these broader potential uses.

Interviews were transcribed and analyzed through ethnographic content analysis using template text analysis [40,41]. A codebook was developed based on variables identified by our research team at the beginning of the study as being theoretically relevant to the research questions and the literature. All interview transcripts were read and codes were assigned to relevant excerpts. The process was iterative; code categories were revised, expanded and created as the research progressed. We employed a web-based qualitative data analysis system, EthnoNotes [42] in order to code and extract data.

Results

We focus on three key questions: physicians' understanding of EBM, what gaps (if any) they recognize between EBM and practice, and physicians' reactions to the EF concept.

How do physicians understand EBM?

We found each physician likely to be, as a graduating medical student put it, 'a big believer in the randomized control trial.' Yet, physicians seldom 'go to the literature' when making clinical decisions. There are multiple reasons for this. First, physicians often do not need to research the EBM literature because they already know it from previous readings, from attending conferences, or from their training, particularly if the condition is common or the physician has abundant experience treating it. Second, physicians are less likely to go to the literature when clinics get busy. Going to the literature, searching for appropriate original RCT articles and critically reading them is timeconsuming. Experienced physicians reported going to the literature and reviewing articles for journal clubs or for answering general questions, but reported that they were less likely to go to it to answer specific clinical questions. As one senior physician and departmental chair put it: 'And when I'm busy, when I'm frantic and running an hour behind, it's just experience most of the time.' Some clinicians base decisions on textbooks (which often are not based on systematic reviews of RCTs and are not necessarily current). Many reported consulting with colleagues especially for treatment protocols in complex patients: 'I might very well call a colleague and say, "So I'm thinking about this. What do you think about that?" . . . [so] that I can at least get some courage from other people.' The problem of course is, as another physician noted, if one doesn't happen to know a colleague whose expertise or experience would encompass a particular case. Without colleagues to consult and in addition to consultations, when searching for informational support, most physicians reported using electronic clinical resources such as UpToDate or MD Consult. A strong finding from the majority of our interviews is that the use of electronic clinical resources is considered EBM practice. That, plus traditional textbooks and consultations with personal networks, are the ways most physicians review evidence – not literature review.

Physicians are less likely to engage in critical reading practices using electronic clinical resources compared with reading original RCT articles. The reasons given for not critically evaluating the answers found in electronic clinical resources were: (1) they are a summary of multiple RCTs; (2) they are written by experts (a graduating medical student speculated that 'there's people getting paid big bucks to do all that stuff, to do just journal review'); (3) many people subscribe to and rely on it (another medical student commented that 'medical students and residents swear by [it]'); (4) the clarity of the presentation style inspires confidence (as a fourth medical student put it: 'I think you want an answer so bad, that if it's presented so nicely, you almost take it as, like, 'Well, that's how we should do it.'); and (5) access to the proprietary resources must be paid for, therefore, the information is presumed valuable. A handful of physicians voiced a lack of confidence in electronic clinical resources. A senior clinician said 'I would take even that with a grain of salt because I realized that lots of times that's just somebody that decided what they thought and wrote it down.' And one medical student told an anecdote to explain why he had stopped using such resources. 'One of my chief residents would never let me cite UpToDate on anything. And so he'd always be like, 'Oh, where did you get that from?' and I'll be like, 'UpToDate.' And then he'd be like, 'Don't ever do that again. You bring me the journal article and I'd be like, okay.'

Even though all physicians took RCT as the gold standard for medical knowledge in general, as critical thinkers physicians recognize limitations to specific RCTs, limitations including: (1) the institution that ran the RCT might not be trustworthy (one senior expert noted that 'Some institutions I trust, some I don't. I know you know, and my area's relatively small and I know every - I know most of the people pretty well. And some of them, just what they write down, isn't trustable'); (2) the authors of the published RCT might not be clinically astute (that same expert also commented that 'many of them who sound terribly profound on paper are just awful when you actually give them a real case. And so I don't trust those folks'); and (3) a recognition that a given guideline might not offer optimal treatment for a particular case (a graduating medical student commented that 'they [the guidelines] don't always work, and that's, that's when your experience comes in').

What gaps (if any) are recognized between EBM and practice?

Physicians fully recognize that EBM may set the guidelines for optimal treatment for 'standard patients', but that there are many patients, conditions, or situations in which the EBM does not provide all the answers. As one fourth-year medical student put it:

'And so you often . . . take the algorithm, which, you know, [is] based off of clinical and, you know, um, randomized controlled trials and whatnot, evidence-based medicine, and then, you have to kind of make that leap with the patient, wellinformed that 'We know as much as you know now, we have – if you want to pursue it, we can then pursue this,' almost like a benefactor.'

Indeed, we found that the medical students who were about to embark on their internship year were highly conscious of the gap between answers they could find in the literature and the clinical decisions they had to make, feeling that they lacked the experience to confidently make 'that leap with the patient'. Experienced physicians recognize a gap but their confidence in their experience enables them to both be more critical of the EBM literature and less hesitant to make clinical decisions without EBM support or even contrary to EBM recommendations if clinically appropriate. As one senior clinician put it: 'Well, I'd say most of what I do is supported by literature, but how I interpret the literature and how I interpret the guidelines is informed and it's part – basically my experience of what I've learned in the past onwards, but the guideline literature is very broad.'

Physicians recognize that there may be a lag in the EBM so that published guidelines no longer can provide optimal care. Physicians recognized that this is particularly true in guidelines for infectious diseases. One paediatrician offered changing streptococcal resistance patterns as an example.

'Nobody knows why but apparently we have a lot of repeat infections after use of amoxicillin, which is the current gold standard. So we've had so many children who've come back and they're still positive or they come back and in two months they get three strep infections. We're starting to treat it more with the cephalosporins which is not the standard of care but which seem to work better and keep it away for us. Now, there have been many articles published pertaining to that but it certainly has not become the standard of care anywhere in the United States . . . And now this year it's been particularly bad . . . So now we've changed. However, the APP (American Academy of Pediatrics) recommendations have not changed. It is still amoxicillin or penicillin.'

Physicians noted that a gap can emerge between clinical needs based on changing disease patterns and the EBM that is slower to change. They pointed out that resistance patterns are local by their nature and that aside from those working in hospitals which track strain resistance, physicians do not have access to information on local resistance patterns. Some physicians expressed an interest in community networks into which they could report information on strain resistances and out of which they could get information on what patterns other physicians in the area were seeing.

Physicians also reported the opposite kind of gap in which there is a lag between the establishment of new EBM guidelines for optimal care and their implementation. Physicians reported hesitation in prescribing new medications regardless of the literature until they know someone trustworthy who can personally attest to the benefits and side effect experiences with the drug. Other physicians reported that some medical systems have reputations for being conservative in adopting new medications or guidelines. A graduating medical student who did a rotation in community health care commented:

'Kaiser isn't quick to jump on every new paper that's released in New England or Germany . . . and then start using those drugs. They kind of wait a good five to 10 years before [adopting so that] it's been confirmed.'

Physicians identified clinical situations, such as those of public health clinics, in which guideline implementation was not practicable because of a clinic's limited access to medications. Physicians can find themselves placed in situations where they must say to the patient: 'The best medication for you is this, but it's too expensive and you're never going to be able to get it, so we've got to give you this that doesn't really work quite as well.' As one physician noted, when there are only two or three medications available for a particular condition, therapeutic offerings based on the latest EBM might not be an option.

Other physicians remarked that the life situations of patients can also prohibit following EBM. As one physician put it 'Some of the things [that] the evidence says that you should be doing for best practice is, you know, in reality, it's hard to meet all of those just because of, you know, the situation that people are in.' Another physician put it more directly: 'There certainly are cases where I know, empirically, I should do one thing. But because of my population I can't do that, I've got to come up with a different solution. So, one example would be, I have a diabetic patient who should be on insulin but he's homeless and can't refrigerate it. So I can't follow the literature. In that case, I've got, you know, [to] figure out a work-around.' And so physicians figure out a workaround, but without either the published literature or a local database of clinical experience to guide them (in other words, an EF database). Physicians working in limited-resource clinics with limited-resource patients are left to improvise the uncertainty between 'the reality of what's really real versus what you know you should be doing' in providing patients with the best possible care within given constraints. In practice, many physicians reported improvise a 'work-around' by doing, in fact, the first step of EF, that is, using experience to consciously tailor EBM.

What are physicians' reactions to the EF concept?

So how did our informants respond when presented with the full EF concept? The reaction varied by specialty. Physicians who work in fields in which patient care is usually shared among a group of physicians – such as trauma, emergency care and obstetrics – indicated that outcomes in particular practices would be difficult to track because care is handled by so many different people.

However, others noted that EF could be quite helpful. Some suggested that systematically tracking outcomes would enable physicians to measure whether or not their patient outcomes actually match what the literature suggests: 'everybody assumes every (treatment and outcome) follows a general trend. And nobody is paying attention to the few people that are the exceptions, and if that was [information that was readily available] they realize that, 'Hey, we have something different.'

Most physicians expressed confidence in their ability to remember cases precisely, even years after the event, and thus felt they could fully rely on their experiences in making clinical decisions. However, medical students were more circumspect about their confidence in the precision of their memories. One medical student remarked that:

'I can think of times in clinic when the attending would say: "I had a case like this once before." And he would try to figure, "What did I do exactly?" And he might think of it or he might not, and he might say, "Can you go look it up or, but we – if he, if there's no system to easily find out that rare, random, special case that it was like this, then we, we couldn't do anything. But I – I do think it would be useful for you to just be able to say, "Hey. You know, I know I've had this before. Let me just see what I did and I referenced these journals. Hey. This refreshed my memory." And – and – and plus, it might be useful for other – it still might be useful for other physicians to be like, "Hey. Jeff had a case like that before, you know."... And look that up.'

Older physicians, who trust their memories of clinical experience tended to be less troubled by a need to systematically collect data on their treatments and patient outcomes than novice physicians. One graduating medical student commented that: 'Anytime I went through a rotation, I was like "We need to measure this." . . . I just feel really strongly that you need to record what you do and the outcome of that. If I really know that women between 35 and 40 responded to a higher dose of vitamin B12, then I would know to give them that. Or if patients came in and said, "You know, I was only really taking it twice a month instead of every week and that didn't make any difference", if 20 people said that to me, I could use the information my patients were giving me as evidence for prescribing.' Another novice physician said that if he had a way of recording his clinical experience treating people with comorbidities, then 'based on what you've seen before, [you could] weight the different factors of which diseases are going on, and how you can try to treat multiple diseases with one therapeutic move.'

More experienced physicians seem to have what one called an 'algorithm in my head that I'll follow, based on prior patients and my experience with the medicines and where I think the patient fits in with which medicine is needed.' This physician mentioned that with each new medication, he needed to adjust his mental algorithm. None of the senior physicians reported concerns that their memories of clinical experiences might be imperfect.

Another potential benefit that was mentioned was the possibility that with an EF-like system, one could offer relevant outcomes information for identified categories of patients, leading to more informed decision making and better use of resources. One way to do this would be to provide patients with personalized reports of treatment outcomes of patients like them. A physician we spoke with worked with a team that piloted a patient education intervention to aid decision making regarding total knee replacement surgery that used an EF-like personalized arthritis report and an educational video [43]. Personalized reports were generated for patients so that they could compare their physical function and disease severity with others who underwent surgery both pre- and post-operatively. Post-testing demonstrated that subjects' expectations became more accurate after viewing the report and watching the video, suggesting that personalized information might be beneficial for patient decision making. This physician saw a potential clinical benefit to an EF system that could provide patients with easy to comprehend, individualized reports and say 'This is how people like you do' with particular treatment alternatives. Physicians also were excited about the benefit of access for themselves to local reports, particularly consultation reports. So that, as one physician suggested, if he could easily access the consultation reports of, say, the last 10 patients he had sent to a cardiologist who had had symptoms that matched those of the patient-at-hand, he could start the patient on the cardiologist's typical treatment protocol which would avoid delays in treatment and potentially alleviate the need for a referral if the patient responded as expected to the treatment.

Most physicians saw substantial potential benefits in an EF system. One physician commented that physicians already do EF, but it is simply not systemized for the vast majority of physicians,

Discussion

'Evidence from randomized trials is important information, but it is neither sufficient nor necessary for acceptance of a practice.... There will never be complete evidence for everything that must be done in medicine. The prudent alternative is to make reasonable judgments based on the best available evidence combined with successful experiences in health care.' [44]

We found that physicians tend to favour experience, either theirs or that of trusted colleagues, in making clinical decisions, referring to the EBM literature (largely through electronic clinical resources) either for general information about a condition or to double check that a therapy does not have a published negative outcome. Decisions are made with some reference to EBM, but experience weighs more heavily in clinical decision making about therapeutics. Experience certainly is built up with reference to EBM, but the learning of traditions of practice through apprenticeships and learning from one's particular cases seem to be at the heart of clinical practice. Our conversations confirmed that EBM literature is not wholly translatable into realities of particular patients, contexts, or histories, thus leading to poor uptake of new RCT findings for potentially beneficial therapies.

Evidence-based Medicine and RCT are depicted as analytically distinct from local experience by all sides. Our informants know this distinction very well, but our evidence is that they blend the two kinds of evidence together in their explanatory models of science and of their practice. Physicians argue that they are integrating EBM into their practice by using electronic clinical resources and balancing that with clinical judgment. The widespread interest in an EF-type evidence gathering was not considered something different from EBM - it was conceived as an extension of EBM to their local settings. The model of scientific evidence implicitly and explicitly applied by our informants does not draw a sharp distinction between RCT/global exogenous evidence and EF/local endogenous evidence. Our informants suggest quite clearly that they combine RCT evidence and guidelines with their personal, local experience to make modifications in order to provide optimal patient care. It is not news that physicians are doing experimentation: modifying guidelines to fit local constraints, contexts and particular patients. Currently, physicians rely on memory to recall such EBM modification and rely on hallway consultations to share their successful modifications with others. But if an easily implemented and accessible EF system for 'the real world' were available, our evidence is that it would be used. Further research is necessary to learn exactly how such a system could be designed to be most beneficial to and easily integrated within clinical practice.

When local evidence is uncollected, weak and unanalysed, what choice do physicians have for justifying medical decisions other than stated reference to EBM? But if local evidence were collected, strong and analysable, it could provide alternative, scientifically valid and clinically useful knowledge. When both local and global evidence are available but neither is stronger than the other, they

Acknowledgements

This study is supported by a grant from Pfizer (#PG009184, 'Unleashing Clinical Experience through Evidence Farming'; Richard L. Kravitz & Naihua Duan, PI's, Thomas S. Weisner, co-PI). The following people assisted in either the data organization or manuscript preparation: Dr Eli Lieber, Arman Haghighatgoo, Claudia Solari and Nathan Devore.

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