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IN SEARCH OF CLINICAL RELEVANCE AND EVIDENCE-BASED MEDICINE IN HIV

WRITER

Lillian Thiemann
Co-Founder and President,
Visionary Health Concepts
HIV Research Co-Chair,
Women's HIV Collaborative of New York

EDITORS

Daniel R. Kuritzkes, MD
Director of AIDS Research,
Brigham and Women's Hospital
Associate Professor of Medicine,
Harvard Medical School

Jacob Lalezari, MD
Director,
Quest Clinical Research
San Francisco, CA

Charles J. Gonzales, MD, PhD
Assistant Professor of Medicine,
NYU School of Medicine

Dear Healthcare Provider,

- ▶ How can physicians treating HIV-positive patients effectively glean the clinical relevance of the massive amounts of complex and often inconsistent data from HIV trials?
- ▶ How do high-prescribing HIV physicians with large patient bases access, evaluate, and utilize data from clinical trials in their practices?
- ▶ Do physicians need to move as fast as they used to in reacting to data from HIV trials?
- ▶ Can an easily utilized, more comprehensive, tempered approach be applied to the processing of scientific information in HIV care?

This Vital Lines letter stimulates thought about such questions as well other challenges physicians face in evaluating the steady stream of largely non-peer-reviewed HIV data received. To investigate these topics, Visionary Health Concepts recently conducted a survey among 40 HIV specialist physicians to explore their approaches and techniques in this area with the aim of "taking the temperature" of the participants while determining a possible direction for further research and resources. We also stimulated discussion about the relevance of key features of the Evidence-Based Medicine (EBM) model to the particular challenges of HIV. And where possible, we describe preliminary, approximate statistics to indicate trends, preferences, and priorities. (See page 6 for complete Methodology).

The participants

HIV-treating physicians with higher numbers of patients tend to achieve better treatment outcomes.¹ Accordingly, we surveyed within this group (Table 1). The survey results showed that even within this HIV-experienced group of physicians there is a range in approach, as well as several salient similarities in how they access and apply clinical trial information to their practices. How can physicians treating HIV-positive patients

TABLE 1. Survey participants: Indications of extensive experience in treating HIV

	MEDIAN	MINIMUM	MAXIMUM
Number of HIV Patients	325	150	800
Number of Years treating HIV	14	5	22

effectively glean the *clinical relevance* of the massive amounts of complex and often inconsistent HIV trials data available today?

Information-seeking behavior

When asked if they used a formal system for accessing, evaluating, and applying clinical trial data to their HIV practice, *all of our respondents said they did not*. Instead, they discussed various combinations of methods and sources to access data from clinical trials, validate evidence, and determine its relevance to clinical care. The amount of time they spent at this pursuit varied among the participants. On the lower end of the

time-commitment scale, one participant said, "I have one journal per month I am committed to reading, and I go to a local meeting now and then." Another participant demonstrated a much higher level of commitment, which included hours of online research per week, scheduled weekly meetings of providers within his practice for "data discussion," and regular conference attendance.

TABLE 2. Importance of HIV Information Sources

This table summarizes the participants' preferred sources for accessing scientific evidence, rated on a scale of 1 to 5, with 1 being the least important and 5 being the most important.	Percentage of respondents citing a particular degree of importance				MEAN DEGREE OF IMPORTANCE CITED
	5 (HIGH)	4+5 (TOP BOX)	3 (MID)	1+2 (BOTTOM BOX)	
High-use Sources					
Scientific conferences	65%	89%	8%	3%	4.5
Print articles	39%	76%	16%	8%	4.1
CME or other education	37%	79%	18%	3%	4.1
Speaking with colleagues	32%	78%	22%	0%	4.1
Websites	21%	71%	13%	16%	3.7
Moderate-use Sources					
Practices guidelines (e.g. IAS)	13%	50%	24%	26%	3.3
Newsletters	13%	42%	37%	21%	3.3
Patients	16%	49%	16%	35%	3.2
Government advisories	11%	42%	32%	26%	3.1
Government treatment guidelines	6%	56%	8%	36%	3.1
Low-use Sources					
Pharmaceutical reps/detailers	5%	11%	49%	41%	2.7
Email or list serves	5%	16%	32%	53%	2.5

Limited responses from participants on this topic make it impossible for us to quantify time commitment for every activity, but three-quarters of the participants attend at least one of the major scientific conferences each year. These conferences include the Conference on Retroviruses and Opportunistic Infections (CROI) and the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). One of the main

benefits cited for attending personally was the opportunity to discuss the clinical relevance of the latest findings with colleagues and HIV researchers. For any given survey participant, the degree of respect he or she accorded particular information sources, that is, the individual physician’s personal hierarchy of sources, was indicative of that physician’s “style” of information-seeking behavior (Table 2).

The influence of the sources cited becomes more relevant when analyzed in relation to physicians’...

- 1 ability to validate information themselves or through another entity;**
- 2 trust of information sources;**
- 3 decisions to act (or not) in relation to specific evidence;**
- 4 ability to find the applications of newly acquired knowledge that would benefit patients.**

The above four criteria relate directly to our questions probing the relationship and utility of aspects of the Evidence-Based Medicine (EBM) model in HIV with the participants. The EBM model, for those unfamiliar with the term, is formally defined as *“the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research.”*

“Clinical expertise refers to the clinician’s accumulated experience, education, and clinical skills. The patient brings to the encounter his or her own personal and unique concerns, expectations, and values. The best evidence is usually found in clinically relevant research that has been conducted using sound methodology.”²

In the sections that follow, we will provide survey insights, where possible, that relate to the above four criteria.

1. Ability to validate information themselves or through another entity

Although additional research is needed to fully characterize this criterion, our survey’s preliminary results suggest that respondents could be roughly divided into three broad categories.

In the first category, there are those who felt they were not expert in evaluating and applying HIV biostatistics, and who tended to rely on their own clinical experience. They also tended to rely on experts, who they preferred to access at conference updates and at local/regional meetings. Respondents in this group sometimes turned to more experienced colleagues, as well as journals and

pharmaceutical company representatives.

In the second category, there are those who were comfortable relying on their own ability to evaluate research abstracts, the Internet, conference presentations, and local meetings—together with their clinical experience—more than peer-reviewed journal articles or other “slower” sources.

In the third category, there are those who utilize a broad mix of sources, including print publications, Internet-based resources, and personal interactions or meeting attendance.

2. Trust of information sources

All but one participant expressed the need to undertake an internal “de-spin” process when evaluating data presented or primarily supported by the pharmaceutical industry. Although the participants allowed that most studies are sponsored by industry, they indicated that this data can be useful, if they:

- ▶ Determine the sponsor’s likely spin or bias in advance, and accounted for it accordingly.
- ▶ Seek corroboration, that isn’t presented from the trial, unearthing other studies that could question the results.
- ▶ Look for issues that might have been conveniently ignored, as well as instances in which the implications of a legitimate result were extended without adequate justification. Participants suggested it was always good to ask what percentage or types of cases in which a particular result may apply, as compared to those in which it does not.

Trial groups, especially the Adult AIDS Clinical Trials Group, and government-sponsored studies were recognized as “best sources.” Participants tended to scru-

tinize the validity of these studies less than they did industry-sponsored studies, even when a study’s data was considered “important.” American, European, and Australian studies were among those mentioned as garnering more credence than other countries’ studies.

Institutions such as Johns Hopkins and San Francisco General Hospital (which provides a “Warmline”) were cited as trusted sources, and some respondents knew the reputations of several leading researchers, and gave their studies relatively higher credence.

Food and Drug Administration (FDA) “Dear Healthcare Provider” letters (the example of “government advisories” that we provided participants), which are designed for immediate distribution of important information to physicians, received less attention from our participants than the guidelines issued by the U.S. Department of Health and Human Services. This result is interesting because participants who mentioned the Guidelines described them as a *slow* source. For example, one participant said, “By the time information hits the journals or is in the Guidelines, it’s old news.”

3. Decisions to act (or not) in relation to specific evidence

In an effort to move beyond the hypothetical, we explored the responses of our participants to examine if (and how) they differed in process and/or reaction to three very different HIV data-specific scenarios from the exact same informational source. Specifically, we reminded participants of a real-life example they had all experienced in the last few years—FDA Dear Healthcare Provider letters. The letters we described covered three very different topics: (1) a life-threatening adverse event (ddl/d4T),³ (2) an antiviral association to lipodystrophy,⁴ and (3) a report of the discontinuation of a study arm that contained a common regimen (Trizivir® arm of the ACTG 5095 trial) because the trial’s efficacy standard was not met after 16 weeks.⁵

Approximately one-half of the respondents said that by the time an FDA advisory letter has been issued with respect to HIV, they have already learned about the data, evaluated it, discussed it with colleagues, and/or modified their practice for patients to whom

the issue applied. About three-quarters of doctors said their level of response to such letters depends upon the validity and clinical applicability of the evidence upon which the advisory is based.

- ▶ Approximately 65% specified that they review the letter to determine if, and to whom, it applies among their patients.
- ▶ Approximately 70% of respondents said that FDA advisory letters often have little or no effect on their prescription patterns. The only exception was in the case of a life-threatening adverse event, to which most participants paid immediate attention, and in response, often changed their practice.
- ▶ The two other topic examples engendered much less change in practice, either because they had already changed their practices prior to receiving the letter, or because the evidence behind the letter required more validation, or applied to few of their patients.

4. Ability to find applications that are beneficial to patients

Individualization of care and relevance to patient population was a common theme throughout most of the interviews. This section delves into specific questions that illuminate where patients’ needs and preferences may trump changes in practice that were based on other evidence/criteria:

- ▶ Despite the evolving changes in their prescribing patterns, physicians often apply exceptions to the overall pattern. For example, when asked about what they generally do when a patient is virologically suppressed on a drug or regimen the provider has decided he or she will no longer prescribe to other patients for specific reasons, virtually all physicians said, “Usually, if it’s not broken, I don’t fix it.”
- ▶ When we explored the FDA letter scenarios mentioned above in relation to patients’ needs and preferences, we found that at least 65% of respondents said they would prescribe Trizivir® for patients where adherence and pill burden were primary issues because it is a very simple regimen (see the discussion in the preceding section). An additional 15% said they would “consider” this regimen.

When asked about situations in which *patients specifically requested* medications or regimens the physician no longer prescribed in his/her practice, approximately 85% of participants indicated that they would prescribe the requested medicine or regimen for the patient with one caveat: they would first explain to the patient why he or she should avoid the requested drug or regimen. After the explanation, if the patient still wanted it, the physician would prescribe it. (Note: This percentage applied in every scenario except the first, that is, the life-threatening adverse event, where respondents indicated they would be more cautious).

Problem-based approaches to support clinical care

Although the actual value of the EBM model as it relates to supporting better patient outcomes in HIV is unknown, there is some evidence that problem-based approaches to medical education better equip physicians to keep up-to-date with clinical research.⁶

The three main components of EBM are clinical expertise, patient values, and “best” evidence. We asked participants about their general awareness of the EBM model and assessed their opinions about its applicability to their HIV practices (Tables 3 and 4). About one-third said they had extensive exposure to the EBM model, and 40% had a moderate exposure. On the opposite end of the scale, some were unfamiliar that EBM existed as a “formal” model. Overall, the following generalities were noted:

- ▶ Younger participants were more likely to have been well acquainted with the EBM model, through training received at medical school or during residency.
- ▶ Published authors and academically based practitioners on the one hand, and physicians oriented towards family or internal medicine on the other hand, seemed to be the most familiar with EBM.
- ▶ Those least familiar with the EBM model tended to be less oriented towards getting the latest data; and were more dependent, for example, on journal articles than more timely sources.

The following table highlights some of the pros and cons of using the EBM model in HIV, which were identified through the open-ended responses from those (approx. 70%) who were familiar with it.

Challenges to using EBM in HIV	Benefits of using EBM in HIV
Complex regimens: 19 approved medications representing four classes with 78 possible drug regimens that are either “Strongly Recommended” or “Recommended Alternatives”. ⁷ Resistance can quickly cut the choices in half.	Assists physicians in the process of appraising trial data for its validity (closeness to the truth) and applicability (usefulness in clinical practice). Prevents mistakes that may cost patients treatment options.
Complex patient presentation, co-morbidities, side effects & adherence issues; intricate trade-offs involved in long-term regimen sequencing.	Targeted access and evaluation of evidence facilitates the best decision possible in relation to specific patient needs and challenges.
A tradition in HIV of acting upon clinical experience prior to validating it with a normal peer-review process.	Validates “strong” evidence and integrates that knowledge with clinical experience to enhance individualized care.
Huge volumes of new data from clinical trials are available of small size and short duration, at various levels of methodological strength.	When there is no randomized controlled trial or “gold standard” in the literature to address the HIV clinical question, clinicians might use EBM to seek and consider the next best level of evidence.

EBM Process	Survey Insights
The patient 1. Start with the patient — a clinical problem or question arises out of the care of the patient	When physicians were asked what motivates them to seek out specific HIV data, approximately 70% cited specific patient need, vs. approximately 20% for the next highest category, to validate unexpected or questionable results about new trials data.
The question 2. Construct a well-built clinical question derived from the case	Respondents stated HIV patient cases often present quite specific EBM-style clinical questions (for example, a discrete side effect), but that other cases may involve cumbersome multifactorial questions that would be too time consuming for the typical physician to research.
The resource 3. Select the appropriate resource(s) and conduct a search	When researching a clinical or “new data” question, three-quarters of the respondents utilize Web searches (e.g. MEDLINE), about 45% query colleagues, and about one-third look through printed journals. Unfortunately, most respondents also found the available data to be poorly organized, and said they usually must work through huge amounts of trials data to glean the specific insights they seek.
The evaluation 4. Appraise the evidence for its validity (closeness to the truth) and applicability (usefulness in clinical practice)	Many respondents said the “trials validity grades” that some websites supply are extremely helpful. The most commonly cited “intrinsic” factors for assessing evidence validity were the integrity and reliability of the source, size of study, study methodology (prospective vs. retrospective, blinding, etc.), length of the trial, relevance of the study’s sample to the physician’s patient base.
The patient 5. Return to the patient — integrate that evidence with clinical expertise, patient preferences and apply it to practice	The vast majority of leading HIV physicians we surveyed utilized an <i>extremely</i> “individualized care” approach to their patients. The key parameters for choosing treatments included biological factors such as resistance, history, co-morbidities, and side effects, and patient factors and preferences that may affect adherence.

*This table summarizes the information gathered about the first five of the six steps in the EBM process. The sixth step covers self-evaluation; that is, the evaluation by the physician of his or her own performance with the patient.

Can HIV physicians improve on the current model?

The early history of HIV, with its overwhelmingly high morbidity/mortality rates and dearth of evidence and clinical experience, stimulated growth of new structures and techniques that still exist today, over 20 years later. These innovations included a national treatment advocacy that established the “fast tracking” of drug approval; an ethos of formulating HIV treatment strategy based on small trials of short duration (a paradigm unprecedented in other medical specialties); and the empowerment of clinicians on the front lines of the epidemic to lead the way in boldly applying the science, often concurrent to its development.

Many lives were saved utilizing these new structures and techniques, and for many, the words “long-term chronic” replaced “fatal” in describing HIV. However, problems developed that could not be predicted in such a fast-paced model. For example, HIV multi-drug resistance developed for the patients who cycled through treatments with sequential monotherapies. In addition, the emergence of long-term toxicities such as lipodystrophy and increased cardiac risk was observed. Finally, it became apparent that longer-living patients would have to maintain an adherence

level of at least 95% for many years to come.

Participants expressed a strong desire to have reliable and clinically relevant information for themselves and others practicing in HIV. They identified three tools that, if implemented, might assist HIV physicians in achieving a more ideal system of information seeking and analysis:

1. The creation of topical, “Yahoo.com-style” directories for better presentation and targeted access of data rather than the simple keyword searches that generate too much data;
2. Establishment of required standards of HIV education and clinical practice to ensure competent care that minimizes risks and foreclosed options to patients; and
3. The institution of a nonbiased board that reviews all new scientific data—on a more timely and regular basis than the guidelines issued by the U.S. Department of Health and Human Services—and evaluates its validity, distills the results that have clinical relevancy, and publishes them in a user-friendly style.

General conclusions

Our exploratory survey indicates that the results should be considered preliminary until confirmed by more robust research. We base this conclusion on these three factors: (1) the open-ended nature of most of the survey’s questions; (2) the relatively small sample size; and (3) the sample we evaluated was not intended to reflect the diversity of physicians who treat HIV. Approaches that are effective for this highly experienced group of physicians may not work as well for less-experienced physicians, who may be less savvy at accessing HIV-specific information on the Web, who may have less direct access to experts, and who may rely more on guidelines and review articles than on faster sources.

Despite these limitations, many insights and “best practice suggestions” emerged from our collection of highly-experienced participants. The nature of our survey cannot *statistically prove* the efficacy of these suggestions; however, when we consider the source of these suggestions, we propose that they still merit consideration. These suggestions are as follows:

- ▶ Applying the EBM model, or indeed any consistent model, to evaluating and clinically applying the flood of data from HIV trials can be daunting, even for those who regularly work at it while maintaining a busy practice.
- ▶ Although the information flow can be intimidating, once physicians develop a strong base of knowledge in the “ever-expanding literature,” they can keep up to date, for clinical purposes, if they study the literature for one or two hours each week and regularly attend conferences or meetings where validity and clinical application issues are discussed. However, this approach will work only if physicians utilize an efficient process to quickly “filter out” redundant information or data with a weak evidence base.
- ▶ Physicians who treat HIV benefit from regularly seeking input from colleagues and other experts in applying new data from HIV trials.
- ▶ If a physician should lack the knowledge to personally evaluate the validity of data, then finding sources that

provide *trustworthy* evidence is essential. Determining which source is trustworthy is sometimes difficult. (See the “Editors’ Choice” resource list).

- ▶ Once data is evaluated as valid, the question of appropriate clinical application must be answered. Respondents suggested that an ongoing practice with a substantial number of HIV patients is required to evaluate the relevancy and applicability of data from new trials to various types of patients, given their individual needs, adherence abilities, and treatment histories. The respondents varied in the *minimum* number of patients they said were required. This number ranged from 25 to 100 HIV patients.
- ▶ A key unresolved issue raised by the research relates to patient influence in physician treatment decisions. While participants believe in integrating implications of trial results to appropriate patient medical cases, an individual patient’s *psycho-social* needs—including issues of adherence, quality of life, patient satisfaction, and patient-provider relationship—are more influential. Further research is needed to discover how such patient influence can affect clinical outcomes positively or negatively.
- ▶ For those who wish to implement a more EBM-style model, some skills may need improvement, including efficient literature searching. Another important skill is the application of formal rules of evidence in evaluating the clinical literature; if this skill is absent, a substitute skill will be necessary—an aptitude for finding a reliable and readily accessible source that can provide this service.^{8,9}
- ▶ After this survey was completed, we identified questions for which we desired answers. The desired answers, however, could not be obtained within the context of this survey: How do specific information-seeking/evaluation models affect clinical practice and patient outcomes? Without further research into this question, there is no clear way to determine which methods of accessing and evaluating the results of clinical research best serve the needs of patients.

“EDITORS’ CHOICE” RESOURCES

Since virtually all the participants need assistance in data interpretation sometimes, finding a reliable source is important. The more assistance a physician needs, the more important “reliability” becomes. We asked our science editors to identify some “best of” resources for HIV-treating physicians to access information to support the effective evaluation of the clinical applicability of trial evidence:

- ▶ **American Academy of HIV Medicine (AAHIVM):** 310- 278-6380, 866-241-9601 (toll-free)
- ▶ **Adult AIDS Clinical Trials Group (AACTG):** <http://aactg.s-3.com>
- ▶ **International AIDS Society-USA:** www.iasusa.org
- ▶ **HIV Medicine Association, Infectious Diseases Society of America (IDSA):** www.idsociety.org/HIV/toc.htm
- ▶ **National AIDS Treatment Advocacy Project (the “Associated Press” of HIV care):** www.natap.org
- ▶ **HIV Drug Interactions:** www.hiv-druginteractions.org
- ▶ **HIV and Hepatitis.com:** www.hivandhepatitis.com
- ▶ **University of Alabama consultation site:** <http://www.health.uab.edu/4docs/>
- ▶ **Johns Hopkins AIDS Service:** <http://www.hopkins-aids.edu/>
- ▶ **HIV InSite Gateway to HIV and AIDS Knowledge (University of California San Francisco):** <http://hivinsite.ucsf.edu>
- ▶ **Stanford RT and PR Sequence Database (the Stanford Drug Resistance Website):** <http://hivdb.stanford.edu>

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- 6 Shin JH, Haynes RB, Johnston ME. Effect of problem-based, self-directed undergraduate education on life-long learning. *Can. Med. Assoc. J.* 1993;148(6):969–976.
- 7 Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents: <http://aidsinfo.nih.gov>.
- 8 To learn more about searching MEDLINE in OVID, please use the OVID tutorial at <http://www.mclibrary.duke.edu/respub/guides/ovidtut>.
- 9 To learn more about searching MEDLINE in PubMed, go to http://www.nlm.nih.gov/bsd/pubmed_tutorial/m1001.html

- YES, I would like to participate in studies like the one discussed in this program.**
- YES, I would like to receive more updates like this one on similar or related topics.**

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| <input type="checkbox"/> | n/a | Body Changes: The Guide to Lipodystrophy in HIV (secondary provider/patient booklet) |
| <input type="checkbox"/> | <input type="checkbox"/> | Dosing Matters: Getting the Most out of Your HIV Regimen (patient pamphlet) |
| <input type="checkbox"/> | n/a | Explorations in Care: Metabolic Abnormalities in HIV (physician CME monograph—4 credits!) |
| <input type="checkbox"/> | <input type="checkbox"/> | Fat in the Blood (patient pamphlet) |
| <input type="checkbox"/> | <input type="checkbox"/> | Hand in Hand: The User-Friendly Guide to HIV/HCV Co-Infection (secondary provider/patient booklet) |
| <input type="checkbox"/> | n/a | LipoWatch (physician monthly fax or email) <input type="checkbox"/> Fax <input type="checkbox"/> Email (if email, <input type="checkbox"/> HTML <input type="checkbox"/> Text) |
| <input type="checkbox"/> | <input type="checkbox"/> | Look Before You Leap: The Guide to the Ins and Outs of Antiviral Dosing (patient booklet) |
| <input type="checkbox"/> | <input type="checkbox"/> | NUKES! (comic book) |
| <input type="checkbox"/> | n/a | Vital Lines: Clinical Insights into HIV/HCV Co-Infection (physician update letter) |
| <input type="checkbox"/> | <input type="checkbox"/> | What’s New? A User-Friendly Guide to the HIV Guidelines 2003 |

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The more information you can provide us, the better we can serve you and your clients with targeted educational materials.

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 Type of organization (ie, hospital, clinic, private practice) _____
 Total Number of Clients _____ Total HIV+ _____ HCV+ _____ HIV & HCV+ _____
 African American _____% Hispanic _____% White _____% Asian _____% Gay _____% Women _____% Transgender _____%
 Substance Abuser _____% IVDU _____% Other _____%
 What other topics are you interested in? _____
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