THEORETICAL DISCUSSION

Evidence-Based Decision-Making (Part 1): Origins and Evolution in the Health Sciences

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Abbreviations:
DALY = disability-adjusted life year
DCP2 = Disease Control Priorities Project
EBM = evidence-based medicine

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Abstract

Evidence is defined as data on which a judgment or conclusion may be based. In the early 1990s, medical clinicians pioneered evidence-based decision-making. The discipline emerged as the use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine required the integration of individual clinical expertise with the best available, external clinical evidence from systematic research and the patient's unique values and circumstances. In this context, evidence acquired a hierarchy of strength based upon the method of data acquisition.

Subsequently, evidence-based decision-making expanded throughout the allied health field. In public health, and particularly for populations in crisis, three major data-gathering tools now dominate: (1) rapid health assessments; (2) population-based surveys; and (3) disease surveillance. Unfortunately, the strength of evidence obtained by these tools is not easily measured by the grading scales of evidence-based medicine. This is complicated by the many purposes for which evidence can be applied in public health—strategic decision-making, program implementation, monitoring, and evaluation. Different applications have different requirements for strength of evidence as well as different time frames for decision-making. Given the challenges of integrating data from multiple sources that are collected by different methods, public health experts have defined best available evidence as the use of all available sources used to provide relevant inputs for decision-making.

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Origins of Evidence-Based Medicine

In 1992, medical researchers at McMaster University in Ontario, Canada first defined evidence-based medicine (EBM) in the biomedical literature.[1] The concept was based on advances in clinical research—clinical trials, clinical epidemiology, and meta-analysis—in which the limits of individual expertise were recognized. It was presented as a "paradigm shift" in medical practice. The prior prevailing paradigm was characterized by numerous assumptions about the knowledge required to guide clinical care:

1. Unsystematic observations from clinical experience are a valid way of building and maintaining one's knowledge about clinical care;
2. Study of basic principles and mechanisms of disease are a sufficient guide to clinical practice; and
3. Traditional medical training and common sense are sufficient to enable evaluation of new tests and treatments.

All these assumptions were found to be flawed. The new goal was to track down the best external evidence with which to answer clinical questions. To this end, the new paradigm was called "evidence-based medicine".[1] Evidence-based medicine became characterized as the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.[2] It encompassed the skills of problem defining, searching, evaluating, and applying original literature. The evidence-based movement stimulated rethinking of a host of professional activities: research studies, submission requirements for

Diagnosis	- Was there an independent, blind comparison with a reference standard? - Did the patient sample include an appropriate spectrum of the sort of patients to whom the diagnostic test will be applied in clinical practice?
Therapy	- Was the assignment of patients to treatments randomized? - Were all of the patients who entered the trial properly accounted for and attributed at its conclusion?
Harm	- Were there clearly identified comparison groups that were similar with respect to important determinants of outcome (other than the one of interest)? - Were outcomes and exposures measured in the same way in the groups being compared?
Practice Guidelines	- Were the options and outcomes clearly specified? - Did the guideline use an explicit process to identify, select, and combine evidence?
Economic Analysis	- Were two or more clearly described alternatives compared? - Were the expected consequences of each alternative based on valid evidence?

Table 1—Key criteria for selecting scientific studies[4]

research articles considered for publication in biomedical journals, new journals focusing on evaluations of evidence, reviews of evidence in existing textbooks, practice guidelines based on rigorous evaluation of published evidence, and the continuing education of health professionals.

Defining a problem was seen as a critical starting point in evidence-based thinking. Precise problem definition was fundamental to the choice of appropriate investigation methods, and retrieval of relevant published research. The ability to ask a well-defined question was critical to the development of an evidence base. The anatomy of a well-defined question was first expressed in 1995.[3] The well-defined question had four components:

1. Patient or problem being addressed;
2. Intervention or exposure being considered;
3. Comparison intervention or exposure, when relevant; and
4. (Clinical) Outcomes of interest.

Questions framed in this way, known as PICO questions, are scientifically testable. It is this testability that leads to the accumulation of authoritative evidence for decision-making.

Scholars found that most of their questions in clinical work arose from a limited number of areas:[3]

1. *Clinical Evidence*—How to gather clinical findings properly and interpret them;
2. *Diagnosis*—How to select and interpret diagnostic tests;
3. *Prognosis*—How to anticipate the patient's likely course;
4. *Therapy*—How to select treatments that do more good than harm;
5. *Prevention*—How to screen and reduce the disease risk; and
6. *Education*—How to teach what is needed to yourself, the patient, and the family.

The research community and the broader evidence-based community have identified key criteria that underpin the quality of different types of studies. These criteria are well characterized in the evidence-based literature[4] and are summarized for selected studies in Table 1.

From its inception in the early 1990s, evidence-based medicine began to influence the entire biomedical enterprise—particularly the domains of biomedical research, medical education, and clinical practice. An extensive bibliography emerged detailing an evidence-based approach to these activities that included a classic series of articles devoted to users guides to the medical literature.[5–36] Among the topics addressed, of special relevance to disaster practitioners, were articles on analyzing variations in outcomes of health services, economic analyses of clinical practice, and the use of electronic health information resources.

The current definition of EBM is:

The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine requires the integration of individual clinical expertise with the best available external clinical evidence from systematic research and our patient's unique values and circumstances.[37]

This practice of EBM explicitly encompasses four cardinal components:

1. External evidence from systematic research—Valid and clinical findings from patient-centered clinical research;
2. Individual clinical expertise—Experience and skills to rapidly identify a patient's health state, diagnosis, risks and benefits of interventions, and their personal expectations;
3. Patient values; and
4. Patient circumstances.

Hierarchy of Evidence

The National Health Service Research and Development Centre for Evidence-Based Medicine at Oxford, England has provided a hierarchy of evidence strength, based upon the method of data acquisition:[38]

1a. Systematic review of randomized, controlled trials;
1b. Individual randomized, control trial;
1c. "All or none" studies (met when all patients died before the therapy, but now some survive, or some patients died before the therapy, but now all survive);
2a. Systematic review of cohort studies;
2b. Individual cohort study or low-quality randomized, controlled trial;
2c. "Outcomes" research;
3a. Systematic review of case-control studies;
3b. Individual case-control study;

Classification of Literature			
Design/Class	Therapy	Diagnosis	Prognosis
1	Randomized, controlled trial (RCT) or meta-analysis of RCTs	Prospective cohort	Population prospective cohort
2	Non-randomized trial	Retrospective observational	Retrospective, cohort, case control
3	Case series, case report, consensus panel, review	Case series, case report, consensus panel, review	Case series, case report, consensus panel, review

Table 2a—Classification of research literature by study design and research objective[39]

	Design/Class		
	1	2	3
None	I	II	III
1 level	II	III	excluded
2 levels	III	excluded	excluded
Fatally flawed	excluded	excluded	excluded

Table 2b—Grades of evidence in research and rules for downgrading evidence[39]

4. Case series and poor quality cohort and case-control studies; and
5. Expert opinion.

The randomized trial and systematic review of such trials are recognized as the "gold standard" for certain studies—e.g., the effectiveness of therapies. However, the evidence base in medicine is not restricted to randomized trials and meta-analyses.

Different professional organizations have developed their own schemes for grading evidence from different study types as well as rules for downgrading flawed evidence. An example from a clinical policy in emergency medicine is presented in Tables 2a and 2b.[39] Table 2a shows how research literature relevant to policy was classified by research objective and study design. Table 2b shows how the research classifications were graded by quality of evidence, and how research flaws downgraded the evidence.

In evidence-based medicine, the most subjective and least authoritative level of evidence remains the "expert". The expert has an explicit role in evidence-based decision-making—particularly in understanding patient values and circumstances and determining the relevance of external evidence to the patient at hand. Nonetheless, in assessing external evidence from systematic research, evidence-based medicine affirms the ascendancy of evidence-based judgments over personal judgments, however *eminence*-based they may be. However, while EBM provides a methodology for assessing the weight of the evidence, and penalizing flaws in that evidence, it does not provide a method for deconflicting evidence from different experts.

Sources of Evidence and Strategies for Obtaining It

As evidence has accumulated, dedicated repositories and refined search strategies have improved access to it. Hierarchal approaches to evidence-based information sources in the biomedical sciences are current best practice.[37,40] One such hierarchal approach is characterized as "4S"—computerized decision-support systems, evidence-based journal abstracts (synopses), evidence-based reviews (syntheses), and original published articles (studies). Rank order in search priority, as well as notional magnitude of the search task, is illustrated in Figure 1. Investigators are encouraged to begin with the highest-level resource available for the problem.

Systems—Evidence-based clinical information systems that link a patient's diagnosis and special circumstances to relevant research evidence about a clinical problem. The goal is to ensure that cumulative research evidence is at hand. Current systems are limited in clinical scope and in adequacy of research integration. Internet-based "aggregators" providing commercial access to evidence-based information serve as current proxies for truly integrated systems.
Examples: *Clinical Evidence, Evidence-Based Medicine Reviews, Up-To-Date*

Synopses—Abstracts of original research with commentary typically all on one page. The title may concisely state the effectiveness of an intervention in positively or negatively worded syntax. In circumstances in which the decision-maker has familiarity with the intervention and alternatives, the title may provide enough information to enable the decision-maker to proceed.
Examples: *ACP Journal Club, Evidence-Based Medicine, Database of Abstracts of Reviews of Evidence (DARE)*

Syntheses—Systematic review of a contentious clinical health issue based on explicit scientific review of relevant studies as well as systematic compilation of the evidence.

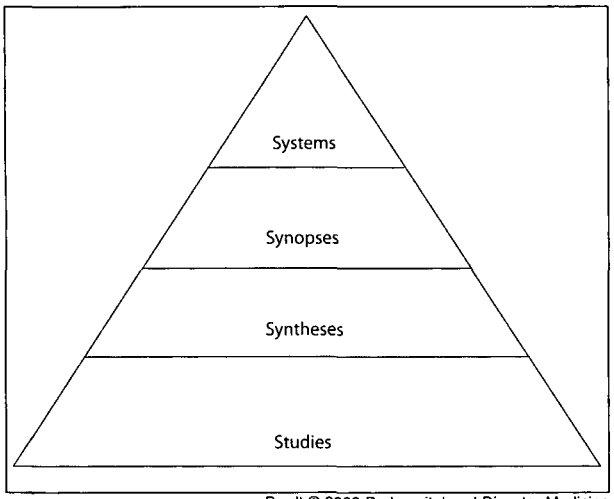

Figure 1—4S Hierarchy of organized evidence
Source: Strauss *et al*[37]

The review is considered a current, comprehensive, and authoritative review of effects of a health intervention.
Examples: *Cochrane Reviews, Clinical Evidence, [US] Centers for Disease Control and Prevention (CDC) Guide to Community Preventive Services*

Studies—Original research from full-text biomedical publishers. Studies offer the most current evidence insofar as systems, synopses and syntheses follow the publication of original articles by at least six months. The most relevant yields from evidence-based search engines come from electronic journal or databases that filter out biomedical publications not meeting appropriate evidence standards.
Examples of electronic journals: *Evidence-Based Healthcare, Evidence-Based Healthcare and Public Health, Evidence-Based Medicine, Evidence-Based Health Policy and Management.*
Examples of databases: *MEDLINE, CINAHL, EMBASE*

Overall, key concepts in evidence-based medicine include PICO questions, criteria for selection of individual studies, hierarchy of evidence, and hierarchy of search strategies.

Evidence-Based Public Health

During the 20th century, the average lifespan of persons in western developed countries increased by more than a generation, and in the US by >30 years. Twenty-five years of that gain have been attributed to improvements in public health.[41] To highlight these achievements, in 1999, the US Centers for Disease Control and Prevention identified 10 great 20th century achievements in public health of the US. These achievements are listed, unranked, in Table 3.[42]

All these achievements are considered extraordinarily successful, and all of these achievements preceded the evidence-based movement *per se*. The first systematic review of research relevant to public health was not published until 2001.[43]

One type of evidence of importance to donors is cost-effectiveness. The understanding of cost-effectiveness in public health took a dramatic leap forward with the advent of an accepted metric for measuring it—cost per disability-adjusted life year (DALY) averted. These metric and associated methodologies enabled global comparisons of interventions to improve health in developing countries. Figure 2 is a simplified graph from a sentinel 1993 publication.[44] The graph shows the number of DALYs increase (averted) versus the costs per intervention. Isobars on the graph refer to log differences in costs per DALY. Overall, the most cost-effective part of the graph remains in the upper right corner. In that corner, small investments yield large payoffs in DALYs averted. By these measures, Vitamin A is clearly shown to be cheap and cost-effective, and is thus exalted in the international health community.

Since the time the World Bank first published these findings, researchers have acquired extensive data on cost-effectiveness of other public health interventions. At present, there are catalogues of evidence-based interventions rank ordered by cost-effectiveness such as those in the Disease Control Priorities Project (DCP2), a project of the US National Institutes of Health, the World Health Organization, and the World Bank.[45] Some highly cost-effective interventions are listed in Table 4. These interventions became public investments with high payoffs in public health. Researchers acknowledge that a population-based intervention implemented in a low prevalence area usually is less cost-effective than the same intervention in a high-prevalence area; that cost-effectiveness data at hand are not varied with the scale of the intervention; and that cost-effectiveness is only one consideration in resource allocation along with epidemiological, medical, political, ethical, cultural, and budgetary factors. Nonetheless, DCP2 underscores the belief that existing cost-effective interventions merit adoption on a global scale.

Evidence-based strategies also have been developed for complex emergencies. These strategies bundle cost-effective health interventions that remain practical under field conditions. In the Democratic Republic of the Congo, a strategy for interventions emerged from a series of meetings in 2001 starting with an informal donor contact group in Geneva, and culminating in a Multi-Agency Consultation in Nairobi. The Nairobi consultation included meetings of health officials from four rebel-controlled areas of Democratic Republic of the Congo. Their consensus approach to health interventions in the acute phase of the complex emergency is illustrated in Figure 3.[46] The strategy boils down to a minimum package of key services for seven main causes of death—malaria, measles, diarrhea, acute respiratory syndrome, malnutrition, childbirth, and HIV/AIDS. Public health policies relying on these strategies are considered informed by the highest possible quality of available evidence and are eminently evidence-based.

Problems with Data

Public health interventions may be seen narrowly as successful individual health interventions applied on a wide scale. Nevertheless, much of the evidence for successful public health interventions relies upon data-gathering tools for population-based research that are different than those used for individual clinical care. In public health, and particularly for populations in crisis, three major data-gathering tools dominate—rapid health assessments, population-based surveys, and disease surveillance.[47] The methodological burdens complicating the use of those data-gathering tools are well-recognized.[48–51]

1. Rapid health assessments are complicated by many different templates and indicators.[48]

- Vaccination
- Motor-vehicle safety
- Safer workplaces
- Control of infectious diseases
- Decline in deaths from coronary heart disease and stroke
- Safer and healthier foods
- Healthier mothers and babies
- Family planning
- Fluoridation of drinking water
- Recognition of tobacco use as a health hazard

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Table 3—Ten great public health achievements—United States, 1900–1999[42]

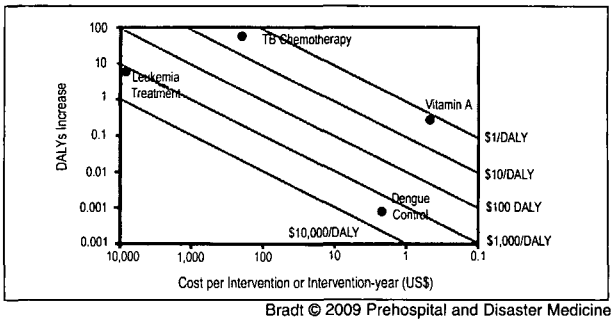

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Figure 2—Benefits and costs of selected health interventions
Source: World Bank[44]

1. Diarrheal disease: hygiene promotion
2. Emergency care: training volunteer paramedics with lay first-responders
3. Malaria: intermittent preventive treatment in pregnancy with drugs other than sulfadoxine-pyrimethamine
4. Tuberculosis, diphtheria-pertussis-tetanus, polio, measles: traditional EPI
5. Malaria: insecticide-treated bed nets
6. Myocardial infarction: acute management with aspirin and β blocker
7. Malaria: residual household spraying
8. Malaria: intermittent preventive treatment in pregnancy with sulfadoxine-pyrimethamine
9. Tobacco addiction: taxation causing 33% price increase
10. HIV/AIDS: peer and education programs for high-risk groups
11. Childhood illness: integrated management of childhood illness
12. Underweight child (0–4 years): child survival programs with nutrition
13. Diarrheal disease: water sector regulation with advocacy where clean water supply is limited
14. HIV/AIDS: voluntary counselling and testing

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Table 4—Cost-effective interventions for high-burden diseases in low-income and middle-income countries. Approximate rank order of most cost-effective[45]

2. Field surveys are complicated by non-compliance with appropriate practices in survey methodology.[49] Interpreting epidemiological reports, particularly mortality reports, remains daunting for non-epidemiologists notwithstanding the availability of primers and checklists to help with the task.[50]
3. Disease surveillance is complicated by incomplete coverage of sentinel sites as well as delays in data processing and information release to guide field actions.[51]

Unfortunately, the strength of evidence obtained by these tools is not easily measured using the grading scales of evidence-based medicine. Moreover, several recurring technical issues further complicate the debate on evidence in public health.[52] These issues include:

1. Unfeasibility of randomized clinical trials to examine the impact of many public health interventions—disaster risk reduction, regulation/legislation for injury prevention through passive restraints or disease prevention through quarantine, tax inducements to modify at-risk behaviors, etc.;
2. Differences between country data provided by established national health authorities and (generally) subnational data obtained by *ad hoc* research prompted by reactive and grant-driven reasons; and
3. Independence of evidence used to monitor critical health issues particularly in the setting of substantial resource flows from external sources (i.e., outside countries) to the beneficiaries at hand.

Overall, evidence-based public health finds many purposes for which evidence can be applied—strategic decision-making, program implementation, monitoring, and evaluation among them. All have different requirements for strength of evidence as well as different timeframes for decision-making. Given the challenges of integrating data from multiple sources that are collected by different methods, public health experts have defined best available evidence as the use of all available sources used to provide relevant inputs for decision-making.[52] The best available evidence places a premium on the attributes of validity, reliability, comparability, inter-agency consultation, and data audit trail.

Critical Distinctions—Evidence-Based vs. Best Available Evidence

Evidence-based decision-making, as defined in evidence-based medicine, relies upon strength of evidence established by the method of data acquisition. Best available evidence, as defined in evidence-based public health, refers to the broad input from all available sources without restriction by hierarchy or grade.

The distinction is important and may be illustrated with a rumor. A rumor of the occurence of disease, such as measles, may be entirely sufficient to trigger a disease outbreak investigation. Rumor investigation is a well-recognized component of information management in communicable disease control.[53] The best available evidence at an early point in the investigation may be only the rumor. While the science of outbreak investigation is "evidence-driven", the outbreak investigation falls out of the spectrum of field activities that may be characterized as "evidence-based" in the jargon of the evidence-based medicine community. That

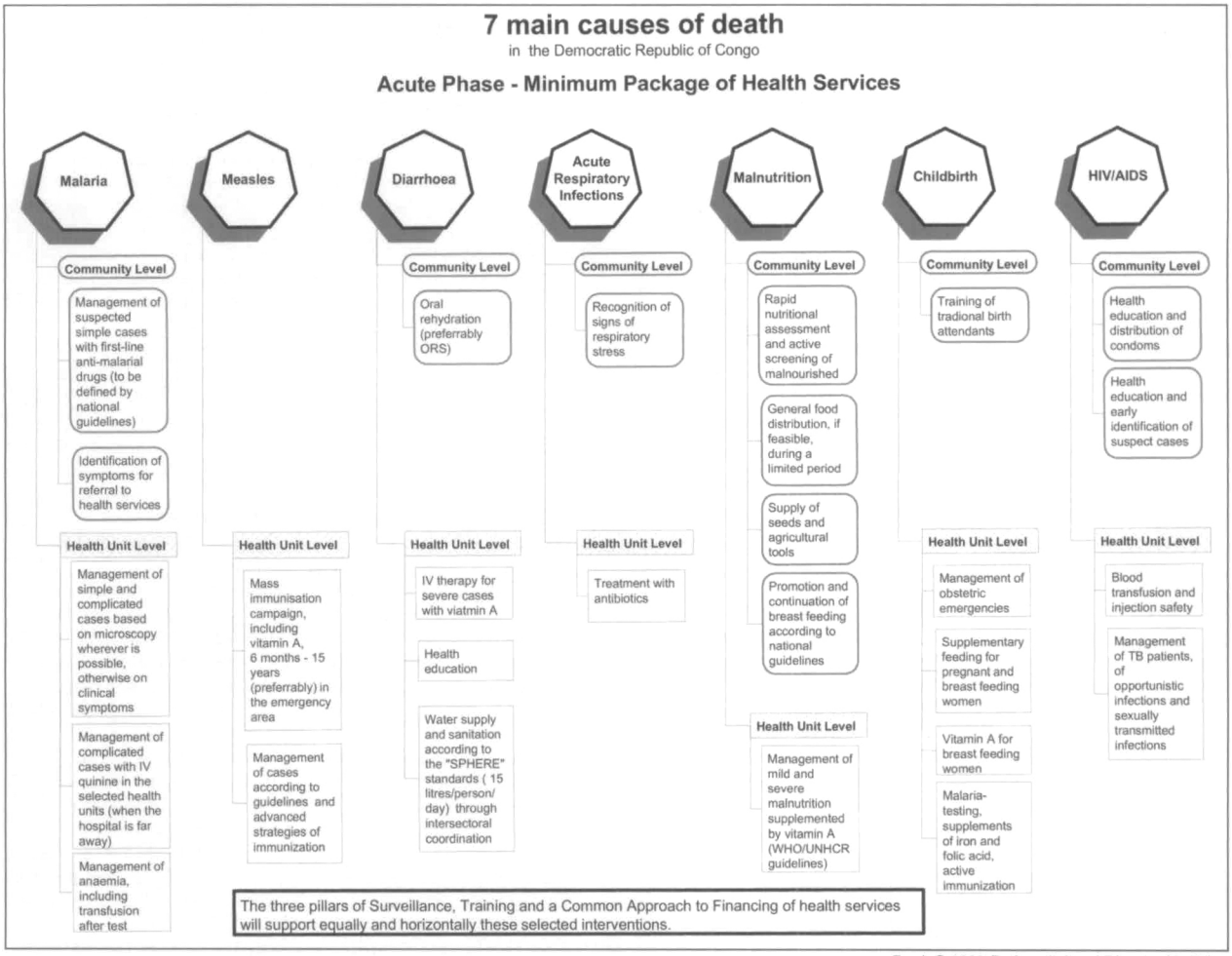

Figure 3—Health interventions in acute phase of a complex emergency *Source:* World Health Organization[46]

does not mean the investigation is not warranted. It simply means the type of evidence informing the action does not rank favorably in a hierarchy of external evidence.

Interveners must be aware of the different nuances of the term "evidence-based" particularly when it is used to (de)legitimize actions and expenses. While individuals and their agencies may be unwilling or unable to engage technical debates on their merits, they have leadership opportunities to enhance the integrity of technical processes that produce evidence. These opportunities include strengthening the independence of groups that produce evidence, fostering transparency in the evidence-production process through data audit trails, and insisting on and paying for competent, external peer review.

Migration Path in Uses of Data

Allied health personnel also must be aware of different nuances of terms along a migration path of data application.[54]

Data Information --> Knowledge --> Wisdom

Terms for different steps on this path are commonly misused. All data are not created equal, and in disasters, there is a premium on data that are relevant for decision-making. In an ideal world, data interpreted in context become information. Information enhanced with understanding of how to proceed becomes knowledge. Knowledge informed by when to use it becomes wisdom. This spectrum is encompassed by the acronym DIKW.

Disaster interveners confront common problems on this migration path. Health data frequently are fragmentary and perishable. Existing data may address issues of process, yet yield little insight into the magnitude of unmet needs. There remains information poverty, overload of data distractors, and reliance on knowledge management systems that do not confer wisdom. While there may not be enough time to do something right the first time, there seems to be enough time to do it over and over with the resulting plethora of contradictory site visits, surveys, and derivative statistical anarchy.[55]

Conclusions

The disciplines of medicine and public health differ in origins, definitions, and tools of evidence-based decision-making. The applications of evidence-based decision making to disaster relief operations add another level of complexity. This complexity is considered in detail in Part 2 of the manuscript.

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