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CLINICAL EVIDENCE TECHNOLOGIES AND PATIENT CARE

A Dissertation Presented

by

Marianne D. Burke

to

The Faculty of the Graduate College

of

The University of Vermont

In Partial Fulfillment of the Requirements for the Degree of Doctor of Philosophy Specializing in Clinical and Translational Science

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Defense Date: March 18, 2019 Dissertation Examination Committee:

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ABSTRACT

Clinical evidence technologies (CETs) are information sources derived from medical research literature that may assist health care providers in continued learning, decision-making, and patient care. Examples of CETs include: MEDLINE/PubMed and Cochrane Reviews, research journal literature, print and electronic medical texts, clinical topic summaries, guidelines, and interactive decision tools. Clinicians utilize CETs to find answers to questions that arise during patient care. However, it was unclear if CETs had a measurable impact on provider practice or patient outcomes.

A literature review identified twenty-two articles evaluating CETs' impact. Study designs included surveys, observational studies, randomized controlled trials and quasi-experimental methods. The review revealed mixed evidence of CET impact on provider-level outcomes such as improved diagnoses and treatments, and on patient level outcomes such as length of hospital stay and mortality. Additional research was needed to determine whether certain CETs or CET types have impact on patient care outcomes in clinically targeted areas.

We conducted a cluster-randomized controlled trial (CRCT) to evaluate the effect of a dermatology-focused CET (VisualDx) when used by primary care providers. We found no difference in the patient skin disease outcomes of resolution of symptoms and return visits for the same problem in that trial. Thirty-two PCPs and 433 patients participated. In proportional hazards modelling adjusted for provider clusters, the time from index visit to skin problem resolution was similar in both groups (Hazard Ratio=0.92; 95% Confidence Interval (CI)=0.70, 1.21; P=0.54). Patient follow-up appointments did not differ significantly between groups (Odds Ratio=1.26; CI=0.94, 1.70; P=0.29).

In a follow up mixed-methods study, we sought to understand why VisualDx did not make a difference. All CRCT provider participants were surveyed about their experience in the trial. VisualDx users (intervention arm) were interviewed about their experience using the CET. Ease of access and usefulness for patient communication facilitated successful use while irrelevant search results and use of other sources were barriers. Although PCPs reported benefits, they did not perceive the CET as useful often enough to motivate using it frequently or exclusively, thereby reducing the likelihood of it making a difference in the problem resolution and return appointment outcomes.

There was no difference in skin problem resolution or number of follow-up visits when PCPs used VisualDx. PCPs did not perceive VisualDx as "useful" often enough for to use it frequently, or exclusively, thereby reducing the likelihood of this CET making a difference in patient-level outcomes.



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CHAPTER 1 Effects of Clinical Evidence Technologies on Provider Practice and Patients: A Literature Review

1.1 Abstract

Background: Barriers to utilizing the evidence from research persist in health care. The influence of the evidence-based medicine model and the availability of multiple evidence source types may have reduced barriers to health care providers' use of evidence sources and increased the possibility of their impact on clinical practice and patient care outcomes.

Objective: To evaluate the impact of clinical evidence technologies on clinical practice and patient outcomes.

Methods: Research evaluating a variety of clinical evidence technologies was identified through iterative searches in MEDLINE, Google Scholar, and reference lists. Studies involving clinical evidence technologies (CETs) and measuring an impact on clinician practice and patient outcomes were eligible for inclusion.

Results: Four clinical evidence technology types were identified in 22 studies that investigated the impact of clinical evidence technologies on clinical practice and patient outcomes. Technology types included multiple CETs in combination, multiple CETs searched by an intermediary, single CETs, and education in CET use. No consistent pattern of results was found across the studies. Positive results were found in randomized controlled trials, quasi-experimental studies of single CETs, and observational studies utilizing large data sets. Other quasi-experimental and randomized trials were negative.



Discussion: Serious design flaws were noted in several studies. There is conflicting evidence that CETS either individually or collectively improve provider-level or patient-level health care outcomes.

Conclusion: There is mixed evidence supporting an association of CET use with improved patient care. Research with rigorous study designs is needed to determine the effect of clinical evidence technologies on clinical practice and patient-level outcomes.



1.2 Introduction

The information needs and information seeking behaviors of clinicians are well documented. A 2007 literature review of 36 studies of clinical information needs of physicians covered literature from 1999-2005. The review summarized their reported information needs as diagnosis related questions 10-40%, treatment information 14 -60%, and drug therapy 15-60% of information needed [1]. A 2013 review of 24 peerreviewed studies on information needs and information-seeking behavior found similar proportions of need for diagnosis information, drug information, and general treatment information needs. The same review confirmed that clinicians utilize diverse information sources including databases, textbooks, journal articles, the internet, and technologies integrated within the electronic health record [2]. These systematic reviews also support the notion that clinicians, especially primary care providers, seek information regularly to support patient care. Obstacles to answering clinical questions and information acquisition have been reported for decades. Poor technology access, lack of available information sources, lack of relevant evidence in chosen source, time constraints, and lack of institutional support are reported as reasons for clinicians' failure to use evidence sources in patient care [3-6].

With the emergence of evidence sources that may reduce time and access barriers such as point-of-care clinical summaries, optimized citation databases, and open access journal literature, it is reasonable to consider if they have a positive impact on clinical practice and patient care outcomes. We sought to identify research on the impact of clinical evidence technologies (CETs) use to improve clinical practice and patient



outcomes, and to assess the quality and findings of the research identified.

1.2.1 Clinical Evidence Technologies Definition

We use the term "clinical evidence technologies (CETs)" in this review to apply to information sources derived from the medical research literature that may assist health care providers in their continued learning, decision-making, and patient care. We define the term "evidence" as "Grounds for belief;...the available body of facts or information indicating whether a belief or proposition is true or valid" [7]. Evidence in this context emphasizes the medical/ scientific knowledge-base and the authority it is based upon. We use "technology" in the sense of the application of knowledge for practical purposes [7]. In recent decades, technology has been thought of as pertaining to electronic devices only, but any device with practical purpose is a technology, so we considered printed and electronic materials, content and citation databases, educational programs, and literature search interventions as technologies.

Other terms have been used in the health care literature for similar or overlapping health care related technologies. "Knowledge-based information" (KBI) is the term used by the Joint Commission on Accreditations of Health Organizations. The 2018 Comprehensive Accreditation Manual for Hospitals standard (IM.03.01.01) requires that knowledge-based information resources be "available, current, and authoritative" [8]. The manual has described knowledge-based information as that "found in the clinical, scientific, and management literature" [9].

Examples of CETs include citation databases, such as MEDLINE/PUBMED and Cochrane reviews, the published research journal literature, print and electronic medical



texts, clinical topic summaries, and technologies that incorporate clinical reference topics with diagnostic tools. While some CETS, such as decision-support and point-of-care summaries, may be oriented toward patient care episodes, others have more diverse goals and uses such as promulgation of research, professional clinical education, and life-long learning. CETs may include use of a singles CET or multiple CETs in combination such as the variety of resources available from a hospital medical library or accessed from an institutional website.

1.2.2 Provider-Practice Level vs. Patient-Level Outcomes Definitions

This review identifies the impact of CETs on health care outcomes at the provider practice and patient levels. Provider-level outcomes are the intermediate steps of management, *i.e.* diagnosis or treatment decisions, safety measures adopted, or the avoidance of adverse events [10].

Patient-level outcomes are those outcomes that are the result of care from the patient perspective including mortality, symptoms, health status, impact on activity, perceived benefit, and costs to the patient such as length of hospital stay and charges for care. [11].

Several literature reviews have focused on health information technologies in general in health care [12], medical librarian services [13], and clinical decision support systems [14], but none have focused on the spectrum of literature-derived CETs and their impact on provider practice and patient-level outcomes. Therefore, we sought to identify research evaluating CETs and to assess it for quality and validity of evidence of impact on clinical management and patients.



1.3 Objectives

This review aims to identify research studies and assess evidence on the impact of clinical evidence technologies, as used by clinicians, on clinical management and patient outcomes. The specific objectives are to identify and assess research on 1) the impact of use of CETs on provider management of patients and 2) the impact of CETs on patient-level outcomes.

1.4 Methods

We identified peer-reviewed journal articles in which an impact of clinical evidence technologies on clinical management or patient outcomes was evaluated.

1.4.1 Literature Search Methods

We searched MEDLINE/PubMed and Google Scholar for peer-reviewed articles encompassing the impact of knowledge-based information sources and services (CETs) on practice and patient outcomes. Two concepts were combined in the searches: 1) terms to identify clinical evidence technologies and 2) terms to identify impacts on patient care outcomes at the provider practice and patient levels.

Subject headings or terms employed to retrieve the articles on clinical evidence technologies in MEDLINE included "Databases, Bibliographic", or "Databases, Factual, or "Information Services" or "Library Services" or "Libraries, Medical" OR "Information Storage and Retrieval/utilization" or "Hospital Information Systems" or "Decision Support Systems, Clinical"

Subject headings and terms employed to identify impacts on clinician level



practice outcomes and patient-level outcomes included: "Physician's Practice Patterns" or "Information-Seeking Behavior" or "Evidence-Based Medicine/Methods" or "Patient Care" or "Diagnostic Accuracy" or "Quality of Health Care", or "Quality Assurance" or "Referral patterns" or "Guideline Adherence" or "Hospital Mortality" or "Length of Stay", or "Referral" or "Treatment Outcomes".

Articles were also identified by manual review of reference lists of identified articles and literature reviews on related topics. Additional searches were conducted in MEDLINE and Google Scholar using terms that described articles identified in manual reviews. The subject terms "Outcomes and Process Assessment", "Diagnostic Errors", and "Patient Readmission" did not yield additional articles.

1.4.2 Study Selection

We did not limit inclusion to a particular study design, such as randomized trials, but were open to various study designs, including surveys, observational, interrupted time series (before and after), randomized, cohort, case control, and comparative effectiveness studies. Data were obtained from provider or patient selfreport, patient records, and insurance claims if a practice or patient level outcome was measured. Studies with clinicians of any type, including physicians, nurses or trainees, who were involved in patient care, were included.

Articles were excluded if they 1) made no reference to a medical knowledgebased or literature-derived evidence source or content, 2) focused on undergraduate medical students alone, (3) reported provider knowledge, attitude, behavior, or satisfaction outcomes only, or 4) presented no data measuring clinically-relevant



outcomes.

1.4.3 Data Extraction and Analysis

Details from the studies were extracted and appraised by the first author. A second reviewer assisted with the appraisal of study designs, outcomes, and findings. We extracted the following data from each included article: 1) Study first author and date of publication, 2) Study design and method, 3) Participants and sample size, 4) Setting, 5) Data source, 6) CET(s) assessed, 7) Outcomes measured, and, 8) Findings. The author reviewed the articles and judged inclusion and exclusion based on the pre-set criteria. We planned a descriptive synthesis of the data extracted, rather than statistical analysis because of the expected heterogeneity of study designs, CETs, and outcomes measured in the reviewed articles.

1.5 Results

An initial MEDLINE literature search returned 72 articles that warranted abstract review or full reading to determine eligibility. Eleven articles from that search were retained and included in this review. Of the excluded articles, about one-third were excluded because they lacked provider or patient outcomes, one-third lacked an evaluation of a literature derived CET, and others reported no data on primary outcomes. Five were literature reviews whose reference lists were examined. The additional eleven included articles were identified through the reference lists of relevant articles and related literature reviews, keyword and natural language searches in Google Scholar, and the recommendation of colleagues. Twenty-two articles evaluating four CET types met all inclusion criteria, including:



- Two that assessed clinician use of multiple-evidence sources [15, 16];
- Five that evaluated expert literature search services accessing multiple evidence sources [17-21];
- Two that assessed education in EBM methods (acquiring and appraising CET evidence) interventions [22, 23];
- Nine studies of a single commercially published or researcher developed product [24-33]; and
- Three studies that compared effectiveness of two CETs, or one CET and a decision support tool [34-36].

Studies were further analyzed by outcome and data source categories including clinician-reported impact of CETs, impact of CETs on provider practice with independent data sources, and impact on patient-level outcomes also with independent data sources.

1.5.1 Provider-Reported Outcomes of CETs

Nine studies measured clinician perception of the evidence retrieved from CETs on their practice. Study designs include large sample cross-sectional surveys, pre- and post- surveys, and randomized trials. Provider-level outcomes included diagnosis, and treatment impacts, perceived overall impact on patient care, and time saved.

(See Table 1.1)

1.5.1.1 Multiple CETs Used by Clinicians

Two multi-site cross-sectional clinician surveys evaluated the impact of multiple medical library-provided CETs on patient care. Marshall *et al*, surveyed over 16,000



health care providers, including physicians, residents, advanced practice nurses and others, employed at 118 hospitals. Participants were asked to recall a recent patient care incident and to answer questions about how use of library provided information sources had (or had not) affected patient care in that event [15]. Seventy-five percent of the respondents indicated that patient care was definitely or probably handled differently due to an evidence source used. In addition, avoidance of patient misunderstanding was reported by 23%, and avoidance of additional tests by 19%. Misdiagnoses were avoided by 13%, and mortality avoided by 6% in the recalled incident.

Another cross-sectional multi-institutional study surveyed 328 health care providers, including 203 physicians, in four hospitals in Colorado and Missouri of varying size (Sievert, 2011) [16]. In that study, 87% of attending physicians, 91% of residents and physician assistants, and 67% of nurses reported they had changed management of a patient with use of library-sourced CETs. More than four-fifths of the physician sub-group confirmed decision (84%), changed advice to patients (36%), and at least 70% modified diagnosis, therapy, and tests ordered.

1.5.1.2 Multiple CETs Searched by Intermediary

Three studies evaluated the impact of multiple CETs on provider practice outcomes when an intermediary literature search by an expert (such as a medical librarian) was performed.

A randomized controlled trial by McGowan *et al.* (2008) compared the effectiveness of a search by a medical librarian consult service, called JIT (Just-in-Time), to primary care providers (PCPs) self-search for answers to their clinical questions. [17].



PCPs' queries were randomized to the librarian search or self-search when the physician posed a clinical question to the central service. The 88 participants presented 1,889 queries and rated each query's results. The utility of evidence found for clinical decision-making and the time to complete the search were the outcomes measured. Twenty percent of librarian searches resulted in improved practice and decision-making, compared to 5% of physician self-searches. The librarian searches answered questions in an average of 13.7 minutes compared to 20.3 minutes (95% CI 18.7, 21.86) for the self-search. In this study, evidence searches conducted by medical librarians produced more patient-care relevant results in less time compared to physician searches. When a question was randomized to provider self-search, the PCPs conducted searches for only 40% of the questions.

Mulvaney (2008) conducted a randomized controlled trial in which clinician consult requests from four inpatient services were randomly assigned to a Clinical Informatics Consult Service (CICS) staffed by trained clinical librarians, or no CICS service [18]. Impacts on clinician actions regarding diagnoses and treatments were measured. Different or new treatments resulted from 14.9% of requests to CICS consult vs. 4.8% with no CICS, (OR 8.2 95% CI 1.04, 64.0). There were no significant differences in diagnosis related actions. CICS librarians spent more time on the evidence search, and presentation, 4 hours average, compared to clinicians who spent an average of 1.6 hours. Though the CICS service undoubtedly saved time of the physicians who did no search themselves, the length of time reported for searching and filtering the literature in both groups was remarkably long compared to the time measured in other studies,



possibly limiting the generalizability of this service model. Also, some clinicians requested a CICS consult but refused randomization. The search was conducted for them, but their results were excluded from analysis, possibly reducing the impact of the CICS intervention on urgent or complex cases.

A cross-over design study (Aitken, 2011) evaluated a librarian search and education intervention with 50 resident participants who rotated through the control and intervention groups [19]. A majority (74%) reported they changed treatment plan and 36% changed diagnoses based on the mediated search information. Although described as a controlled trial, there were no baseline data on pre-intervention patient management with CETs reported. With no outcome comparison with the control group, the value of the outcomes reported with this sample size is limited.

1.5.1.3 Single CETs by Commercial Publisher or Institutional Developer

Five studies evaluated individual commercial publisher or institutionally developed CETs with provider-reported data.

In a study evaluating DynaMed, a clinical topics summary, Alper *et al* (2005) conducted a randomized controlled trial to determine the CETs effect on decisions and time to find answers compared to usual sources [24]. Physicians were randomized per question to use DynaMed or not. Among 46 PCPs, 54% found answers that changed clinical decisions with DynaMed compared to 23% without (P=0.05). Median search time was 4.7 minutes with DynaMed vs. 4.8 minutes with other sources (P=0.64). The first author was the original developer of DynaMed, which is now owned by the commercial publisher EBSCO Health.



Another study evaluated Quick Clinical, an institutionally developed CET comprised of aggregated evidence sources with a single access point. In a 4 month trial of Quick Clinical, 74% of 227 participating PCPs in Australia reported improved patient care after using it an average of 10 times the first month [37]. After a year, usage frequency dropped to three uses per month and reported treatment effects declined [38].

1.5.1.4 Comparative Effectiveness of CETs

Three studies compared effectiveness of variations of clinical evidence technologies on practice outcomes. Grad and Pluye *et al.* compared practice outcomes of a knowledge-based CET called CIRT (Clinical Information Retrieval Technology) that included literature derived content, such as Cochrane reviews and InfoPoems (a clinical topic summary), to a decision-support tool that included calculators and prediction rules [35]. The calculator and reminder type tool was associated with practice improvement in participant surveys more often than the more literature-based CIRT, in 25% vs 12% of searches. When used together, 78% of links retrieved from both source types had a positive practice impact.

A study by Del Fiol *et al.* (2008), compared the effectiveness of two versions of the CET Micromedex in a randomized trial [36]. Both versions were accessed by means of "Infobuttons" within the electronic health record (EHR). The control version included links to the drug prescriber CET (Micromedex) as generally published, and the other provided specific links to topics and performed imbedded searches within the CET. There was no difference in clinical impact of each link type and no difference in time spent. Participants reported high positive clinical impact in all sessions (62%) in both types.



Maviglia studied the use of drug medication information sources embedded in an EHR by providers at 18 outpatient clinics that were randomized to either Micromedex or Skolar MD, both commercially available drug information databases [34]. No difference was reported for decision changes between groups. The CETs combined answered the query in 84% of searches and resulted in a patient care decision change in 15% of searches.

In these provider-reported outcome studies, the overall impact of the information sources on provider decisions was generally positive and, in a few cases, statistically significant. Impacts on care management were reported by 75% or more of participants in cross-sectional and multi-CET search studies. There were smaller effect sizes, i.e. 20% impact on care, with intermediary search vs. about 5% impact with provider self-searches. The difference in impact between variations of similar information sources was generally not significant except compared to a calculator and reminder tool.

1.5.2 Provider Practice-Level Outcomes with Independent Measures

Seven studies measured impacts on provider-level outcomes using independent data from patient records or judged by specialist review. (See Table 1.2) Five studies evaluated single published CETs, and two studies evaluated an EBM methods education intervention. Study designs included before-and-after, and parallel comparisons. Provider outcomes included impact on decision-making, diagnosis impacts, medications and treatments prescribed, referrals or consults, and clinician time spent.



1.5.2.1 Single CET Evaluations with Independent Data

King (2007) evaluated use of a Clinical Evidence module imbedded in a computerized-physician order entry (CPOE) system [28]. Pediatric inpatients diagnosed with bronchiolitis comprised the sample of 147 patients admitted in a 6 month period before, and 187 patients after implementation of the module. Entry of the bronchiolitis diagnosis in the CPOE prompted the appearance of the CET with relevant evidence. Primary outcomes measured were frequency of ordering antibiotics, bronchodilators, and steroids. Length of hospital stay was also measured. In the post-implementation period, 22% of patients received antibiotics with the CET vs. 37% before, a relative decrease of 37% (P= 0.016), in-line with the CET evidence. There were no differences in bronchodilators or steroids ordered and no difference in patient length of stay.

Barbieri (2015) evaluated VisualDx, an interactive diagnostic tool with images and topic summaries [39], for impact on dermatology consults requested for inpatients before and after the CET was implemented [33]. The number of consults requested per month, and the rate of increase in consults were measured. Post-implementation the absolute number of consults decreased non-significantly by median 4.6 per month (P=0.75), and the rate of consults increased at the rate of one consult per month in both periods (P=0.99).

Another evaluation of VisualDx measured inclusion of the correct final diagnosis in the differential diagnosis list for patients initially diagnosed with cellulitis in the emergency department (ED) by resident physicians with and without the CET. [26]. Records of 145 patients admitted to the ED in 2 hospitals were reviewed and, of those, 28



(25%) were deemed misdiagnosed. The correct diagnosis was included in the differential in 18 of 28 cases (64%) when VisualDx was used by a resident *vs*. correct diagnosis included in the differential in only 4 of 28 cases (14%) by the ED admitting team without VisualDx (P=0.003).

Evaluating a dermatology-relevant CET, Gulati assessed a skin cancer information and education toolkit for impact on referral rates by General Practitioners in England [31]. Over 20% of English general practitioners accessed the toolkit online through a national physicians' website in a six month period after it was deployed and marketed. The toolkit included referral guidelines for suspected skin cancer. In the year after toolkit introduction, there was no difference in referrals made to dermatologists by GPs compared to the pre-toolkit year reported in a national referral database. Use of the toolkit did improve GP confidence in skin cancer diagnosis according to a survey of those who used it.

The fifth study evaluating a single CET examined UpToDate [40]. In this study by Shimizu, researchers reviewed charts of 100 patients seen by general practitioners in outpatient clinics of a Tokyo teaching hospital [32]. Of 100 patients, half were seen by general practitioners (GPs) with access to UpToDate and half were seen by GPs without access. Patient records were screened for correct diagnosis at the index visit to ambulatory care. Decision of correct or incorrect diagnosis was determined by two author investigators reviewing cases independently using an algorithm for error identification described by Singh (2007) [41]. They found a 2% error rate in the UpToDate group of patients, compared to the 25% error rate in the control group. It was unclear from the



article how the physicians were equipped or not with UpToDate, how they were enrolled in the study, and if the reviewers were blinded to the group allocation of physicians and patients. While this study had independent validation of practice improvement, it lacked information about randomization and blinding that limits confidence in its findings.

1.5.2.2 Education in EBM Methods

Education in evidence-based medicine methods includes training in retrieving evidence from medical research literature, appraising it for quality, and applying it with patients. Two studies assessed the impact of education in EBM methods on treatments and tests ordered. The model in both was that participants would retrieve and appraise evidence information from CETs to determine the best protocol. Straus *et al.* compared physician orders at a community hospital for treatments before and after the education [22]. After a seven-hour education session in EBM methods, resident physicians ordered significantly more treatments validated with evidence from randomized-controlled trials or meta-analysis evidence than before (42% pre- v.62% post; P=0.016).

Shuval *et al* compared PCP orders for tests and medications for certain conditions pre- and post- a standardized curriculum intervention of five sessions plus individualized practice site teaching [23]. The tests and treatment orders measured were controversial in that the best evidence from the CETs taught in the intervention recommended protocols that were infrequently followed. In this study, there was no statistical difference (increase) in the proportion of evidence-based tests, such as vision screening P=0.67), or medications, such as Lipitor (P=0.87), ordered after the education.

While the education interventions had conflicting results on the provider



outcomes, both were associated with improved knowledge and skills in evidence retrieval.

In the studies of CETs evaluated for impact on provider-level outcomes with independent data sources, the findings were mixed. Four studies had positive results for the primary outcomes measured (King, David, Shimizu, and Straus) and three had negative, *i.e.*, no difference, findings (Barbieri. Gulati, and Shuval).

1.5.3 Patient-Level Outcomes

Seven studies evaluated CETs with patient-level outcome measures. Three evaluated expert intermediary searches of multiple CETs, and four evaluated single commercially published CETs. Study designs included two observational studies, one RCT, and five quasi-experimental study designs. Outcomes including length of stay, mortality, quality indicators, readmission rate, charges, and hospital costs. (See Table 1.3)

1.5.3.1 Intermediary Evidence Search Impact

An intermediary evidence search conducted by an expert librarian or physician was the CET intervention in three studies with patient-level outcomes. In a case-control study by Banks (2007), 55 inpatient cases presented at Medicine morning report were matched with 136 controls from the previous five years of hospital admissions [42]. A medical librarian on the team conducted an evidence search on questions raised by physicians concerning the cases. Cases and controls were matched on age, primary diagnosis, and secondary diagnoses with up to 3 co-morbidities. Length of stay was reduced by an average of two days with the evidence search support (P=0.023). Total



charges for hospitalization were lower, but not significantly different (P=0.24), in the intervention group, with a median difference of \$1,392 between groups. There was no difference in 30-day hospital readmission rate. It's possible that events occurring outside the study influenced the findings. The control group was drawn from patients from 1 – 5 years (2001 to 2006) prior to the cases. The downward trend of length of stay in U.S. hospitals, occurring at the time could have influenced the positive LOS effect. In that period AHRQ data appears to show that US national length of stay had declined among Medicare beneficiaries, between 2006 and 2015 [43].

Similarly, Esparza conducted a study (2013) on the effect of a medical librarian intermediary search on the patient outcomes of length of stay and 30-day readmission rates [21]. The intervention arm included 252 patients admitted and treated by the physician team with medical librarian support. The control arm included 1948 patients treated by a second physician team with no support. This non-randomized study had a parallel design, *i.e.* the intervention and control arms occurred concurrently, reducing the likelihood of secular events influencing the results. However, LOS and hospital readmission rates were actually higher in the intermediary search supported patients. LOS was two days higher (median 6 days vs. 4 (P<0.001). Thirty-day readmission rates were likewise higher, 19% of patients vs. 13%, P<0.001. The re-assignment of patient cases from the intervention team to the control team may have biased the results against the intervention. Patients admitted and treated by the intervention group who did not require an evidence search, were "flipped" to the control group. Since literature searches were usually requested for more complex cases, moving less complex cases to control may



have kept more serious cases in the intervention group leading to longer hospital stays and readmissions.

A third study by Izcovich (2011) evaluated the intermediary search of multiple CETs for questions arising from patient cases with a randomized controlled trial [20]. The mediated searcher in this study was an attending physician informatics specialist. Patients were randomly assigned to a search supported group or an unsupported group for 6 months. Questions that arose in the intervention group patients were supported by an evidence search in available evidence sources. Compiled information was sent to all members of the intervention group team. Outcomes measured from patient record data included mortality or transfer to ICU, readmission, and length of hospital stay. There was a half-day difference in length of stay favoring control, but it was not statistically significant (P=0.24). There were no differences between groups in the other primary outcomes. In this study it appears that all cases stayed within the assigned intervention or control group on the intention to treat principle.

1.5.3.2 Single CET Evaluations with Patient Outcomes

Four studies evaluated the association of single CETs with patient outcomes. UpToDate was evaluated in two observational studies [29, 30]. Others evaluated were DXplain [27] and Clinical Evidence [28]. Some of the Clinical Evidence (King) study findings were reported earlier in the provider-level results. The length of stay outcome in that study is also included here.

Two observational studies evaluated UpToDate by comparing patient outcomes at hospitals with the CET and without it. The earlier (2008) study by Bonis compared



outcomes in 424 hospitals that licensed UpToDate to 309 hospitals that did not license it between 2000 and 2006 [29]. Hospital outcome data was taken from the proprietary Thomson Top 100 Hospitals Survey database. Information on hospital licensees was supplied by UpToDate, Inc. In that study Length of Stay was reduced 0.18 days (P<0.001). Statistically significant differences were found for reduced complications (P=0.048) and AHRQ patient safety indicators (P<0.001). There was no difference in mortality between the hospital groups (P=0.34). Two authors of this research were employed by UpToDate, Inc. (Bonis and Rind) and two others (Pickens and Foster) were employed by Thomson Healthcare, the source of the hospital data and analysis. The study was funded entirely by UpToDate, Inc.

In the second observational study on UpToDate (Isaac *et al*, 2012) patient outcomes in hospitals with licenses to UpToDate were again compared to those without licenses [30]. Outcomes compared were risk-adjusted lengths of stay, mortality rates, and quality performance. Measures were derived from aggregate and individual hospital Medicare and Medicaid insurance claims data. An UpToDate license in a hospital was associated with shorter average length of stay compared to non-UpToDate hospitals (5.6 days versus 5.7 days; P< 0.001). Among six conditions such as stroke or hip fracture the reduction of length of stay was 0.1 to 0.2 days (P<0.001) for each condition. Smaller community hospitals were associated with larger effect sizes than large teaching hospitals. This study was funded by UpToDate, Inc. also, but, according to the disclosure statement, the corporation "had no role on study design, input into analyses presented, or drafting or editing the manuscript."



Two other studies of individual CETs with patient outcomes include trials of DXplain, a decision support system developed at Massachusetts General Hospital, and the Clinical Evidence variant (BMJ Publishing) imbedded in the electronic medical record described earlier. These CETs had interactive elements depending on provider input, such as patient symptoms or lab values, characteristic of clinical decision support systems.

The DXplain trial conducted in 2001-2002, (published in 2010) compared total hospital charges, Medicare Part A charges, and LOS in diagnostically challenging cases admitted before and after implementation of the DXplain tool in a large U.S. teaching hospital [27]. In the intervention period, total charges averaged \$1,281 less per patient, *i.e.*, 10% lower in patients admitted in the DXplain period (95% C I 1.2%, 18.2%, P=0.006). Cost of service was \$990 lower (P=0.001) per admission with intervention. Statistically significant reductions in Medicare Part A charges were also reported. The pre-implementation portion of the study was within one year in advance of the intervention period, arguably reducing the impact of secular events biasing the findings.

The Clinical Evidence study, described earlier for its provider-level outcomes, also measured length of stay [28]. There was no difference in length of hospital stay between groups in that study.

We did not identify additional research articles evaluating an effect of CETs on patient-level outcomes meeting the definition of this review. A systematic review [12] to identify of randomized trials to increase the use of electronic health information by health care practitioners to improve clinical practice and patient outcomes overlapped with



CETs studies as defined here. It found no randomized controlled trials with a positive effect of Health Information Technology on patient outcomes. That review was concerned with electronic health information in general and on various devices. It identified trials comparing information sources, including some CETs, for effectiveness relevant to health care.

In this review, 12 randomized controlled trials or quasi-experimental research studies directly evaluated an effect of CET(s) on provider practice or patient-level outcomes. Of these, eight had a positive result for CET impact, three made no difference on impact, and one had a significant negative effect. (See Table 1.4)

1.6 Discussion

This review identified research evaluating the impact of clinical evidence technologies on provider practice and patient outcomes. Impacts on provider practice and patients were measured on four CET types in 22 studies using multiple study designs with provider-reported and independent data. In the discussion we synthesize the study results on comparable outcomes to evaluate the strength of evidence we have reviewed.

1.6.1 Evidence of Provider Practice Impact with CET Use

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There is some evidence of improved patient care with CET use in the providerreported outcomes studies and in the independent-measures studies. All of the providerreported data studies indicated perceived improvements in patient care with the individual or multiple CETs evaluated. With independent verification of provider practice improvement, the results were mixed.

1.6.1.1 Patient Care Decisions and Time

Overall effectiveness of a CET for impact on patient care decisions and physician time saved was measured in three RCTs in which intervention and control groups were assigned, and participating PCPs evaluated results per question. All three studies found statistically significant positive rating for patient care impact reported in intervention assigned queries compared to the control queries (Alper, McGowan, and Mulvaney)

In terms of provider time saved, a practice improvement that could increase clinician productivity, the average time for the librarian search to answer the question was 13.7 min per question compared to 20.3 minutes with provider search in the McGowan study. In the DynaMed study, there was no difference in time providers spent searching with and without DynaMed. These RCTs employed randomization and provider report per question enhancing the validity of the clinician-report with immediate response rather than longer term recall. These studies were positive for improved practice outcomes but mixed on the provider time saved. Depending on institutional goals and funding, evidence searches by a librarian intermediary for complex patient cases may save provider time and produce better results.

1.6.1.2 Diagnosis, Treatments, Tests, and Referrals

The cross-sectional surveys of hospital clinicians by Marshall and Sievert provided a detailed look at the provider perceived practice improvements [15, 16]. A positive impact of CETs on diagnosis was reported by 25% and 71% of clinicians, on



patient care management by 75% and 88%, on tests ordered by 19% and 78% in Marshall and Sievert respectively.

In accord with the provider survey perceptions on those impacts, there were positive findings for diagnostic accuracy, treatments and tests ordered found in three studies with independent measures. Greater diagnostic accuracy was demonstrated with the clinical topic summary UpToDate [32]. Fewer antibiotics were prescribed for bronchiolitis with the CPOE-imbedded CET DXplain [28], and more evidence-based therapies were prescribed after education in evidence retrieval and CET use (Strauss) [22].

On the other hand, there was no difference in for evidence-based treatments and tests after another CET education intervention [23]. Likewise there was no significant difference in frequency of inpatient dermatology consults with the interactive diagnosis CET, VisualDx [33], and no difference in general practitioners' referrals to dermatologists after introduction of a dermatology reference tool kit [31].

1.6.2 Evidence of CET Impact on Patient-Level Outcomes

In the studies measuring the effect of CETs on patient-level outcomes, there were positive outcomes in two observational studies and one quasi-experimental study and "no difference" or worse findings in an RCT and two quasi-experimental comparison studies. Patient-level outcomes measured in these studies were: length of stay in hospital (LOS), mortality or transfer to ICU, hospital readmission, and costs and charges for care.


1.6.2.1 Length of Stay

Six of the 7 studies with patient-level outcomes measured length of hospital stay (LOS). Of those, three found an improvement *i.e.* reduced length of stay for patients, and three resulted in no difference or worse outcomes. The two observational studies of the clinical topic summary UpToDate found reduced LOS equal to one-tenth to nearly two-tenths of a day associated with hospitals that licensed the CET [29, 30]. The Banks case-control trial found a reduction in LOS by a median of 2.0 days (P=0.023) associated with a librarian intermediary search.

Five other studies found no difference or worse LOS outcomes with the CET intervention. In the RCT on handling difficult patient questions with an informatics expert intermediary search, there was a non-significant half-day increase in LOS in the intervention patients [20]. In the Clinical Evidence study average LOS increased non-significantly from 2.8 to 2.9 days with the intervention [28]. In the Esparza study, LOS increased significantly in the intervention group by two days [21].

1.6.2.2 Mortality

Of three studies that evaluated a CET with a mortality outcome, only one observational study found an association with decreased mortality (Isaac), the others (Bonis and Izcovich) did not.

1.6.2.3 Costs, Charges and Readmission

One study found a significant reduction of total charges and service costs associated with use of the DXplain, the interactive decision support CET. In the Esparza study, there was no reduction of costs, or 30-day readmission in the intervention patients.



1.6.3 Strengths and Limitations of the Review

This review included relevant studies that met inclusion requirements regardless of study design, even if they were flawed in some way. One flawed study design (Esparza) kept cases requiring a librarian search in the intervention group, while transferring cases not requiring a search to the control team. This method of group assignment all but insured that comparatively sicker, and complex cases remained in the intervention group, making the significantly negative result improbable. The positive result of two days reduction in LOS in the Banks study was flawed because of the 1-5 year difference between in observations between the intervention cases vs. controls. For the LOS outcome, only the observational study of UpToDate retains a plausible association with the CET evaluated. While the two large observational studies of UpToDate made adjustments for differences between hospitals and patients, neither adjusted for the availability of other CETs or evidence sources that may have been present. That there were greater effect sizes in community hospitals than in the larger teaching hospitals in the Isaac study could be due to the greater array of CETs usually available in large settings.

In the Shimizu study on diagnostic accuracy with UpToDate, the lack of description concerning the recruitment of physician participants, how case selection was accomplished, and the blinding of the review panel are concerning. These omissions in procedures raise questions concerning bias and validity in that study.

The CETs evaluated in this study were subject to change, making it difficult to generalize about their individual value. Specific CETs and services in every category



have changed or ceased to exist since the original research was published. This fact limits any generalization about a particular CET.

A limitation of this review is that it may not include all relevant articles due to variations in search terms for evidence technologies and patient outcomes, and due to the iterative nature of the searches.

1.6.4 Implications

How might patient care be affected with use of high quality CETs? Elkin suggested that the mechanism of improved patient outcomes and reduced costs may be that use of the CET may broadens the differential diagnosis on first admission so that the determination of the correct diagnosis occurs sooner. A similar argument was put forth by David. It is possible that by following the behavioral steps of the evidence-based medicine model in practice, from asking clinical questions, through acquiring evidence, and applying evidence to patients, providers may improve provider practice and patientlevel outcomes [44, 45], but the evidence for that is limited based on the literature.

Future research is warranted. The provider-reported experience with CETs and the positive outcomes of a few controlled and observational studies indicate that effects of CET use might be demonstrated in randomized hypothesis testing research. Study designs and outcome measurements would need to be carefully chosen to avoid errors that bias the study or mask true effects.

1.7 Conclusion:

There is mixed evidence supporting an association of CET use with improved provider and patient outcomes. Additional research with rigorous study designs, such as



randomized trials, and appropriate patient-level outcome measures may further elucidate impacts of CETs on patient care outcomes, particularly in clinically targeted area.



1.8 Tables

| Table 1.1: Studies on CET impacts with provider reported data | | | | | | | |
|---|--|---|--|---|---|--|---|
| Author and publication date | Study design/methods | Data source(s) | Participants/Sample | Setting | CET(s) evaluated: Name (if any) | Outcomes Measured | Findings |
| Aitken, 2011 | Cross-over design; Residents rotated through intervention and control teams | Post-intervention provider surveys; 6 month period. | 50 Internal medicine residents. | Teaching hospital, Canada | Multiple evidence sources; intermediary librarian search and brief instruction. | % Treatment decision change % Diagnosis decision change; | 88% changed treatment with skills learned and 74% changed treatment plan with mediated search. 44% changed diagnosis with skills, and 36% |
| Alper, 2005 | Randomized Controlled trial; Clinical question by provider randomized per question to DynaMed vs. usual sources | Clinician survey per question asked | 52 Primary care providers; 698 clinical questions | U.S. + 3 hospitals in 3 other countries | Single CET; DynaMed | Questions answered that changed clinical decisions per participant Duration of search | with librarian search. 54% of PCPs found answers that changed clinical decisions with DynaMed vs. 23% without DynaMed, and 17% no decision difference P=0.05 Median search time 4.8 min. vs. 4.9 min. P=0.64. |
| Del Fiol, 2008 | Controlled trial; comparative technology assessment; computer logs and survey | Computer log sessions recorded, and questionnaire presented immediately post- session | 90 Clinicians in matched pairs; 3,729 sessions | U.S. | 2 CETs; Micromedex versions in CPOE system Infobutton prompted | Impact on decision- links to evidence by topics compared to links to named evidence sources | 35% of sessions in control group reported decision enhancement vs. 18 (38%) in topic enhanced group. 41 (36%): no difference |
| Grad, 2005 | Comparative technology assessment; Impact of 2 clinical information retrieval technologies; | Providers surveyed per search session for impact of results; | 26 Family Medicine residents;4946 searches | Canada | 2 CETs; CDSS with prediction rules and calculators vs CIRT, a CET with bibliographic database and topic summaries. | Impact of each information item retrieved from each technology | CDSS associated with practice improvement more 25% vs 12% CIRT |
| Magrabi, 2004 | Post-trial of CET survey; OctNov. 2002 | Computer log of usage per participant; participant survey based on recalled incident during trial. | 227 general practitioners; volunteers from across Australia | Australia | Single CET; Quick Clinical (QC), aggregated evidence sources optimized for clinical queries | Experience of improvement in care. | 25.6% (40) reported experience of QC resulting in improved patient care after using CET. With 6 or more uses, 50% reported improvement |



| Table 1.1 continued | | | | | | | |
|-----------------------------|---|--|---|-------------------------------------|--|---|--|
| Author and publication date | Study design/methods | Data source(s) | Participants/Sample | Setting | CET(s) evaluated: Name (if any) | Outcomes Measured | Findings |
| Marshall, 2013 | Cross-sectional multi-site critical incident survey | Survey responses | 16,122 Physicians, nurses, and other healthcare providers; 118 hospitals served by 56 medical libraries | U.S. | Multiple CETs provided by medical libraries | Impact on: Patient care Patient advice Diagnosis Drug choice Additional tests Medication errors | 75% definitely or probably handled patient care differently; 48% changed advice to patient 25% diagnosis change 23% drug choice 19% additional tests 12% medication errors avoided |
| Maviglia, 2006 | Prospective cohort study; Comparative effectiveness of 2 drug information technologies; randomized | Primary care providers survey | 359 providers; 18 outpatient clinics | U.S. | 2 CETs; Micromedex compared to Skolar MD | Alteration of patient care decisions | No difference in decision changes between groups; the 2 sources combined resulted in patient care decision change in 15% of searches. |
| McGowan, 2008 | Randomized, controlled study; randomized per question | Search log and provider questionnaire: survey | 88 Primary care clinicians, 1889 questions | Canada | Multiple CETs with rapid librarian search service: Just- in-Time service | Impact of search results on clinical decision Librarian search time compared to physician self- search time | 20% of questions to librarian search had a high positive impact on care decisions vs. 5% of physician self- searched questions Avg. librarian search 13.7 min (95% CI 13.3, 13.8) per question vs. 20.29 min. (CI 18.7, 21.86) with provider search |
| Mulvaney, 2008 | Randomized controlled trial; Clinician consult request assigned to consult service or no consult service | Post-consult request CLIC search clinician report and clinician self-search report. | 299 consults; 89 clinicians from 4 inpatient services | Academic Medical Center, U.S. | Multiple CETs with librarian search service: Clinical Informatics Consult Service (CICS) | Actual impact on care; Specific impacts on clinician actions regarding diagnoses and treatments | Different or new treatment 14.9% with CICs consult vs. 4.8% no CICS OR 8.2 (95% CI 1.04 -64.0). No difference in diagnosis related actions |
| Sievert, 2013 | Cross-sectional, multi-site survey | Survey; recall in any incident. | 328 hospital providers and caregivers in 4 hospitals including 203 physicians | 4 hospitals 2 states, US | Multiple CETs; PubMed/Medline; MDConsult (electronic textbooks and journals) plus other Library provided sources | Library CETs: Management impact Decision confirmation Advice to patient | 88% changed management of patient 84% of physicians confirmed decision 84%; changed advice to patient |



| Table 1.2: Studies on impact of CETs on provider practice outcomes | | | | | | | |
|--|--|---|---|---|---|---|---|
| Author and publication date | Study design/methods | Data source(s) | Participants /Sample | Setting | CET Source(s) Type: name (if any) | Outcomes Measured | Findings |
| Barbieri, 2015 | Interrupted time series; 12 months before and 18 months after VisualDx implementation | Patient records; dermatology consults requested | System-wide physicians and patients | Academic Health care system; US | Single CET: VisualDx | Absolute number of consults Rate of increase in | Absolute number of consults decreased by median 4.6, non- significantly P=0.75 Consults increased at a rate of 1 |
| | | | | | | consults before v. rate of increase of consults after | consult per month in both periods P=0.99 |
| David, 2011 | Comparison of correct diagnoses in differential by physicians with VisualDx vs admitting ED physicians without it; | Patient admission records; post- admission review | 145 patients diagnosed with cellulitis in ED; Comparison on 28 misdiagnosed cases | 2 teaching hospitals; U.S. California and New York | Single CET: VisualDx | Inclusion of the correct diagnosis in the differential diagnosis in misdiagnosed cases | Correct diagnosis was included in differential with VisualDx (18/28 64%) vs. the admitting team without Visual Dx had the correct diagnosis in 4/28 cases (14%) P=0.003 |
| Gulati, 2015 | Observational; Comparison of national skin cancer referrals pre and post CET. Cross-sectional survey post-deployment of toolkit | Health service referral database Survey | General practitioners; 20% of General practitioners in England accessed the toolkit in 6 month period 2012 | England | Single CET: Skin cancer educational toolkit | Number of skin cancer referrals | No difference in referrals behavior in national database pre vs. post- toolkit year Improved confidence in diagnosis |
| King, 2007 | Before and after evidence module implemented | Hospital pharmacy and discharge records | 334 Pediatric inpatients with bronchiolitis diagnosis 147 pre- 187 post year following intervention; resident physicians and medical student trainces | Pediatric hospital, Ottawa Canada | Single CET: Clinical Evidence Module | % frequency of antibiotics prescribed Bronchodilators and steroids prescribed | Fewer antibiotics prescribed; 35% to 22%, relative decrease 37% P= 0.016 No difference in bronchodilators and steroids |
| Shimizu, 2017 | Retrospective chart review comparison; "patients randomly selected" | Patient records; initial diagnoses | 100 outpatients of GPs with and without UpToDate; "equipped vs. "non-equipped" GPs | Ambulatory clinics of teaching hospital Tokyo, Japan | Single CET: UpToDate | Diagnostic errors per group | 2% diagnostic error rate in exposure to UpToDate group vs 24% error rate in control. OR 15.2 (95% CI 1.86, 124.4) |
| Shuval, 2007 | Controlled trial; Pre-Post evaluation of education; | HMO patient database for controlled trial; | Primary care clinics; 75 PCPs and 106,349 patient records | HMO clinics; Israel | Education in EBM evidence retrieval and appraisal methods | % adherence to evidence for tests ordered % adherence to evidence for drue utilization | No statistical difference in evidence-based tests ordered such as eye examination (P =0.67) Patient drug utilization such as for stating (P =0.87) after intervantion |
| | | | | | | for drug utilization | status (1 –0.07) and intervention |
| Straus, 2005 | Pre-Post-intervention chart review of discharge summaries | Patient discharge summaries | 47 physicians; 239 patients pre-, 244 post | Single site teaching hospital, UK | Education in EBM evidence retrieval and appraisal methods | Treatments ordered in line with available RCT or systematic review evidence | Proportion of treatments supported by RCT or systematic review increased from pre- 49% to post- intervention 62% (P=0.016) |

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| Author and | Study design/methods | Data source(s) | Particinants/sample | Setting | CET Evaluated | Outcomes | Findings |
|---------------------|---|---|--|--|---|--|---|
| publication date | Study design/methods | Data source(s) | r ai ucipants/sampie | Setting | /Name(if any) | Measured | rinuings |
| Banks, 2007 | Case-control; prospective cases, retrospective controls | Patient records | 55 prospective inpatient cases to 136 matched retrospective controls seen by Medicine residents | US, academic medical center | Multiple CETs with intermediary search and filter by clinical medical librarian. | Length of stay (LOS) (days) Charges for hospitalization 30-day readmissions | LOS reduced 2 days (P=0.023) Total charges lower, median \$1,392, non-significantly P=0.24 No difference in readmission rate |
| Bonis, 2008 | Observational study; Hospitals with and without CET compared; adjustment for size, region, and level of usage of the system | Thompson Top 100 Hospitals Study database; Publisher licensee identification. | Medicare beneficiary inpatients at 3091 U.S. hospitals; 424 hospitals with UpToDate | US | Single CET/UpToDate | LOS (days) Complications Patient safety indicators (AHRQ) Mortality | LOS reduced 0.167 days (P<0.001) Complications -0.378 P=0.048 Patient safety -0.08 P<0.001 Mortality 0.179 P=0.34 |
| Elkin, 2010 | Before and after implementation of evidence support tool; Residents used DXplain; Pt cases identified in DRG groups (all Medicare) | Patient records | Residents; Diagnostically challenging patients:1173 pre- period; 564 post- period | Teaching hospital, Mayo Clinic, Rochester Minn. | Single CET/DXplain | Total charges and cost of service for diagnostically challenging patients | Total charges \$1281 lower P=0.006. Medicare Part A charges \$1032 lower P=.006; Cost of service \$990 lower P=0.001 per admission in intervention (DXplain cases vs. control cases |
| Esparza, 2013 | Prospective matched cases. Data collection 78 weeks 2008-9 | Patient records | 2 physician teams; internal Medline service patients. 252 cases, 1948 controls | Urban Academic Medical Center US | Multiple CETs with intermediary search and filter by clinical medical librarian | LOS (days) % 30-day readmission | LOS, higher median 6 vs. 4 P<0.001 Readmission rates higher 19% vs. 13%, P<0.001 |
| Isaac, 2012 | Observational study; Retrospective comparison of hospitals with vs. without CET. | CMS Medicare data for US hospitals; publisher supplied license status. | Fee-for-service Medicare beneficiaries. 3000 US hospitals; Medicare patients | US | Single CET/UpToDate | Risk-adjusted LOS (days) Mortality rates for 3 conditions | LOS 5.6 vs. 5.7 days P=0.001 (CI -0.2, 0.00) Mortality range -0.1% - 0.6% reduction |
| Izcovich, 2011 | RCT; patients randomly assigned to literature search support for provider questions vs. no support. Intention-to- treat analysis | Patient records | 809 patients admitted to Medicine ward | Academic medical center, Argentina | Multiple CETs with intermediary search and filter by informatics specialist. | LOS (days) Mortality or transfer to ICU, Readmission | LOS 6.5 v 6 days, Mortality or ICU transfer RR 1.09 (95% CI 0.7, 1.6) Readmission RR 1.0 (95%CI 0.7, 1.3) |
| King, 2007 | Before and after evidence module implemented | Patient records | 334 pediatric inpatients with bronchiolitis diagnosis; 147 pre-, 187 post- implementation. | Pediatric hospital, Canada | Clinical Evidence Module (BMJ Clinical Evidence) integrated with CPOE | LOS (days) | Median LOS increased 0.1 day post implementation P=0.125 ER through admission and discharge |



Table 1.4: Twelve randomized controlled trials or quasi-experimental studies that evaluated an effect of CET interventions on provider practice or patient-level outcomes

| First author, year published | Study design; sample size | CET type and/or name | Outcome(s) measured | Effect (intervention v. control) or difference (+ = significant result) |
|---------------------------------|---|--|---|--|
| Alper, 2005 | RCT; 52 PCPs, 698 queries | DynaMed | % changed clinical decisions | (+) 54% vs. 23% <i>P</i> =0.05 |
| Banks, 2007 | Case control; 55 inpatient cases to 136 controls | Multiple/Intermediary evidence search | LOS (days) Hospital charges | (+) 2 days lower (P=0.023); (-) \$1,392 lower P=0.24, |
| Barbieri, 2015 | Interrupted time series; system-wide patients | VisualDx | Change per month in skin consults | (-) 1 consult/mo. increase vs. same P=0.99 |
| Elkin, 2010 | Before and after; 1173 patients pre-, 564 post-intervention | DXplain | Total charges/pt. Cost of service/pt. | (+) \$1281 lower P=0.006. (+) \$990 lower P=0.001 |
| Esparza, 2013 | Prospective case- control; 252 cases, 1948 controls | Multiple/Intermediary evidence search | LOS (days) %Readmission to hospital | (-) 6 vs. 4 P<0.001 (-) 19% v. 13%, P<0.001, |
| Izcovich, 2011 | RCT; 809 patients | Multiple/Intermediary search | LOS (days) Mortality or ICU | (-) 6.5 vs.6 <i>P</i> =0.25 (-) RR 1.09 (95%CI 0.7,1.6) |
| King, 2007 | Before and after; 334 inpatients | Clinical Evidence | % antibiotics prescribed LOS (days) | (+) 22% vs. 35%, P= 0.016 (-) Increased 0.1 day P=0.125 |
| McGowan, 2008 | RCT; 88 PCPs, 1889 queries | Multiple/Intermediary search: JIT | % queries with impact on care decisions | (+) 20% vs. 5% <i>P</i> =NA |
| Mulvaney, 2008 | RCT; 89 physicians; 299 consults | Multiple/Intermediary search: CICS | % different or new treatment | (+) 14.9% vs. 4.8% OR 8.2 (95% CI 1.04, 64.0). |
| Shimizu, 2017 | Parallel "with and without"; 100 patients | UpToDate | % diagnostic errors | (+) 2% vs. 24% OR 15.2 (95% CI 1.86, 124.4) |
| Shuval, 2007 | Controlled trial; 75 PCPs, 106,000 patients | Education in EBM methods | % adherence to evidence for tests | (-) no difference, <i>P</i> =0.67, |
| Straus, 2005 | Before and after; 47 physicians, 483 patients | Education in EBM methods | % adherence to evidence for treatment | (+) 62% vs. 49% (<i>P</i> =0.016) |



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CHAPTER 2 Effect of a Clinical Evidence Technology on Patient Skin Disease Outcomes in Primary Care: A Cluster-Randomized Controlled Trial

2.1 Abstract

Objective: Providers' use of clinical evidence technologies (CETs) improves their diagnosis and treatment decisions. Despite these benefits, few studies have evaluated the impact of CETs on patient outcomes. Investigators evaluated the effect of one CET, VisualDx, on skin problem outcomes in primary care.

Methods: A cluster-randomized controlled pragmatic trial was conducted in outpatient clinics at an academic medical center in the Northeast. Participants were primary care providers (PCPs) and their adult patients seen for skin problems. The intervention was VisualDx as used by PCPs. Outcomes were patient-reported time from index clinic visit to problem resolution, and the number of follow-up visits to any provider for the same problem. PCPs randomly assigned to the intervention agreed to use VisualDx as their primary evidence source for skin problems. Control group PCPs agreed not to use VisualDx. Investigators collected outcome data from patients by phone at 30 day intervals. Cox proportional hazards models assessed time to resolution. Wilcoxon-rank sum tests and logistic regression compared need for return appointments.

Results: Thirty-two PCPs and 433 patients participated. In proportional hazards modelling adjusted for provider clusters, the time from index visit to skin problem resolution was similar in both groups (Hazard Ratio=0.92; 95% Confidence Interval



(CI)=0.70, 1.21; *P*=0.54). Patient follow-up appointments did not differ significantly between groups (Odds Ratio=1.26; CI=0.94, 1.70; *P*=0.29).

Conclusion: This pragmatic trial tested the effectiveness of VisualDx on patient-reported skin disease outcomes in a generalizable clinical setting. There was no difference in skin problem resolution or number of follow-up visits when PCPs used VisualDx.

2.2 Introduction

Health care providers across a spectrum of primary care and specialty domains regularly refer to clinical evidence technologies (CETs) to answer clinical questions [1]. As reported in provider survey and chart review studies, use of CETs such as PubMed/MEDLINE, journal articles, electronic texts, topic summaries, and internet search engines has improved diagnosis and treatment decisions and avoided adverse events [2-6]. Despite these provider reports, few studies have evaluated the impact of CETs on patient-level outcomes. Patient-level outcomes include mortality, relief of symptoms, impact on activity, perceived benefit, and costs to the patient such as length of hospital stay and lost work time [7]. The literature on patient outcomes of CET use is mixed. Only one published study has reported an improvement in patient outcomes. Researchers reviewed insurance claims from hospitals before and after subscribing to UpToDate (a source for comprehensive medical topic summaries). Results showed a modest reduction in morbidity and length of stay in hospitals after subscribing [8].

Hospital libraries and informatics centers acquire and make CETs available to the clinical community on the assumption that these resources have value for education, practice improvement, and the outcomes of care. CET licenses can be expensive. Medical



school libraries associated with teaching hospitals in the US or Canada spent an average of \$US 2 million each in 2015 for medical research journals and clinical information resources [9].While CETs, individually or in combination, have been evaluated for education and practice-level outcomes, they have not undergone the rigorous evaluations with randomized trials for patient outcomes. A 2015 systematic review of electronic health information (EHI), including CETs, found no randomized trials with patient outcomes, such as relief from symptoms or utilization [10].

The broad nature and diverse goals of many CETs may discourage rigorous evaluation. However, skin conditions are a relatively circumscribed domain within the broad field of Primary Care. The clinical goal in many cases can be quantified as time to problem resolution. Likewise, the need for additional medical care after the index visit usually represents a suboptimal and expensive outcome that might be reduced by improved provider knowledge and decision support [11].

Skin problems account for 15% of primary care office visits in the U.S [12] and ten common dermatologic conditions (dermatitis, pyoderma, tinea, benign neoplasms, candida, dermatosis, warts, malignant neoplasm, sebaceous cyst, and acne) account for 77% of skin-related diagnoses in Family Practice. Likewise, many internal conditions manifest themselves on the skin, including malignancies, vascular conditions, anemia, endocrine disorders and pregnancy. Most skin conditions first present, and are often diagnosed and managed, in primary care. Eight percent of all outpatient visits for skin problems result in referrals to dermatologists or return visits to primary care [13]. Limitations in the ability of primary care providers (PCPs) to diagnose skin rashes and



lesions correctly have been noted in the literature [14, 15]. Some studies have indicated that additional dermatology knowledge, training, and diagnostic support could improve practice and patient outcomes. General Practitioners in the UK who used an online skin cancer diagnosis information source increased their diagnostic accuracy and confidence, but did not reduce referrals [16]. Referrals to Dermatology in a VA hospital that lacked a specific diagnosis were reduced by an intervention that trained PCPs. [17]

VisualDx is a CET that presents images and text on a comprehensive range of skin conditions and symptoms whether they are local to the skin or are manifestations of internal conditions [18]. Users may search by diagnosis or by entering patient characteristics and examination findings to generate a differential diagnosis list with images. Individuals, practices, and institutions license VisualDx to support medical education and patient care [19]. VisualDx has been shown to improve diagnostic competency in non-primary care settings. In one study, its use improved the differential diagnosis of cellulitis by Emergency Room physicians [20]. In a pilot study, diagnostic accuracy of dermatology residents and medical students increased after using VisualDx as judged by a consultant dermatologist [21].

Given the prevalence and broad range of skin conditions seen in Primary Care, the need for improved knowledge and competency by PCPs in skin disease, the availability of a dermatology-focused CET (VisualDx) shown to affect clinical competence, and the lack of randomized clinical trials of any CET with patient-level outcomes, we proposed a clinical trial to evaluate use of VisualDx in Primary Care in the domain of skin disease with patient-level outcomes.



Our objective was to evaluate the effect of VisualDx on duration of symptoms and follow-up care for skin problems in a pragmatic randomized clinical trial in primary care. Recognizing that in typical clinical care, the correct diagnosis and therapy are often uncertain, that some problems resolve regardless of whether the management was technically correct, and that some resist even the most insightful management, we were concerned in this study with the net result of each episode of care – the patient outcomes – rather than the intermediate steps of management, *i.e.* diagnosis or treatment decisions.

2.3 Methods

2.3.1 Study Design, Model, and Setting

We designed a cluster-randomized controlled trial (CRCT) to evaluate the outcomes of skin problems in patients whose PCP referred to VisualDx or not (usual care). In this design, PCPs were the subjects of randomization. Patients were clustered within the arm of the provider they saw for the skin problem. The cluster design was appropriate because the intervention is directed to physicians while the outcomes occur within individual patients [22]. With randomization, environmental and provider or subject characteristics (such as years in practice, insurance status, chronicity of the presenting complaint, comorbidities, *etc.*) are distributed at chance levels across both arms of the experiment. The model underlying the design of the experiment asserts that the CET supports the PCP in management (diagnosis, treatment, and referral decisions) and impacts patient-level outcomes, resolution of symptoms and return appointments, when used in a real-world clinical setting. Presumably, use of a valuable CET leads to more correct diagnoses and wiser therapeutic or referral choices. These, in turn, lead to



better patient outcomes (quicker resolution of the presenting problem or reduced need for additional care). To test this model, we performed a pragmatic [23], (*i.e.* not heavily controlled), cluster-randomized controlled trial of the impact of one CET on the outcomes of skin problems presenting to Primary Care

The study was conducted at clinics associated with an academic regional medical center in the Northeast. VisualDx and other CETs were available to medical



Figure 2.1: Model of the cluster-randomized pragmatic design

center clinicians through the hospital Intranet, electronic health record (EHR), and mobile devices. The Institutional Review Board approved the protocol in June 2015.

2.3.2 Provider Subjects

Attending physicians, residents, advanced practice nurses, and physician assistants in outpatient Family Medicine and General Internal Medicine were invited to participate by email or personal contact. Eligible providers 1) were currently seeing patients at a Primary Care site, 2) consented and agreed to comply with the protocol



procedures assigned, and, 3) permitted patients to be informed of the study via a letter sent over their signature. Providers answered a survey concerning resident/attending status, year of clinical degree, sex, specialty, and typical number of times per month they used CETs for patient care. (**See Appendix I**)

We randomly assigned PCPs to intervention or control groups using a sequential numbered envelope method stratified by resident status [24]. We randomized residents independently because of the possibility that they respond differently to the intervention than more experienced providers. PCPs were enrolled in the study when they gave consent, completed the tutorial, provided their signature for patient letters, and reaffirmed their agreement to follow their assigned protocol.

2.3.3 Patient Subjects

Adult patients seen for acute or chronic skin problems, excluding lacerations or burns, were eligible. Patients were excluded if non-English speaking or decisionally impaired. To identify patients, investigators reviewed the appointment records of participating providers for patients seen for a skin problem. We identified patients with any complaint in the broad range of skin disease as noted in the EHR. The Reason for visit, Appointment note, and Clinical summary fields provided patient complaint information such as "rash", "redness", "lump", "itch", "wart", "mole", or "sore". ICD codes were also used to identify potential cases. Per the institutionally-approved protocol, personal health information from the patient record such as reason for visit, phone number, and address could be used for identification and recruitment but not to ascertain patient characteristics or outcomes.



We sent each identified patient a letter signed by their PCP describing the study and informing them that the study team would call to invite their participation. The letter also stated how to opt out of any contact.

2.3.4 Intervention

The intervention was VisualDx as used by PCPs treating patients with skin problems. Providers received email notification of their experimental group status with a link to a self-paced slide tutorial specific to their group. (See Appendix II and III) For the Active group, the 5-10-minute tutorial included the direction to use VisualDx when needed in treating a patient skin problem, and how to access and use it. For Control providers, the tutorial included the direction <u>not</u> to use VisualDx, and a general orientation to information sources available through the Medical Library. A study team member contacted participating providers by email, phone, and letter at intervals during the study to remind them of their assigned protocol, and to re-confirm their continued participation.

2.3.5 Measurements

The primary predictor (independent variable) was the randomized group status of the provider: Active (use of VisualDx) or Control (non-use). Patient subjects were assigned to the group of the provider they saw. The primary outcome variables reported by the patients were: 1) time to resolution of the skin problem from presentation at the primary care office visit and 2) number of follow up visits (to any provider) for the same problem.



About 30 days after the index visit, an investigator phoned each eligible patient (except those who had opted out) and, following verbal consent, proceeded with the interview questions. If the patient reported their presenting skin problem resolved, *i.e.* "All better", their participation in the study was concluded. Patients whose presenting complaint had not resolved were re-interviewed at 60 days and, if still unresolved, again at 90 days. The 30-60-90 day phone call schedule was specified in the protocol to balance the requirements to reach many people while preserving patient recall [25]. At the first interview, patients reported their age, sex, and whether the PCP seen was their usual provider (See Appendix IV). We ascertained the status of the skin problem as "All better", "Improved," Unchanged", or "Worse", each time we interviewed the patient. If "All better" at any interview, we asked them to recall the number of days from the index visit date or the date when they realized the problem was resolved. If necessary, we asked questions to aid more exact recall. This determined the "days to resolution" outcome data. If the problem was not resolved by the first interview, we interviewed the patients at 60 days, and if still not resolved, at 90 days. The final problem status at the last completed interview was determined for analysis.

For the number of follow-up appointments, at the first interview, we asked how many appointments the patient had for the same problem since the index visit. If there was a second or third phone interview, we asked how many appointments they had since the last call and added that number to any previously reported appointments, if any. The total number of appointments reported comprised the variable.



2.3.6 Data Collection

Trained research assistants using standardized scripts conducted patient interviews by telephone. Study data were collected and managed using REDCap (Research Electronic Data Capture) secure tools hosted by the researchers' institution.

2.3.7 Blinding

By necessity, providers knew their own intervention or control group status. Investigators were blind to providers' and patients' group while conducting patient interviews. Patients were blind to the group assignment of their provider.

2.3.8 Analysis

We used Cox proportional hazards models to assess time to resolution and Wilcoxon-rank sum tests and logistic regression to compare return appointments between groups. Logistic and proportional hazards models were adjusted for clustering. Data analyses were performed using Stata 14 statistical software [24]. We sought an adequate sample size to detect a moderate-to-large effect of the intervention, on the order of 0.4 standard deviations. Given the broad range of skin problems presenting in Primary Care, we expected significant variability in the time to resolution. Therefore, we chose a target of 8 days in time to resolution with a standard deviation of 20 days. The effect of clustering within PCP was not known, but we used estimates from other primary care settings that suggested an intra-cluster correlation of approximately 0.025 [20]. Assuming alpha=0.05, beta=0.80, 10 patients per provider, and a two-sided t-test, we estimated the study needed 26 PCPs and 260 patients.



2.4 Results

We enrolled 31 physicians and 1 nurse practitioner. We identified 989 eligible patients with a skin problem visit to a participating PCP between November 2015 and August 2016. 433 patients consented and provided data.



Figure 2.2: Flow of participants through stages of the cluster-randomized controlled trial The active and control groups were similar at baseline except for the median number of subjects per PCP (6 in the active group *vs.* 15 in the control group; P=0.045). Seven PCPs (22%) reported use of VisualDx prior to the study including 4 (27%) in the Control group who agreed not to use it during the trial.



| • | All | Active | Control | P^* |
|---|-------------|-----------------|-----------------|-------|
| Primary Care Providers, n | 32 | 17 | 15 | |
| Residents | 13 (41%) | 8 (47%) | 5 (33%) | 0.43 |
| Sex (male) | 17 (53%) | 10 (59%) | 7 (47%) | 0.49 |
| Family Medicine (vs. Internal Medicine) | 14 (45%) | 6 (35%) | 8 (53%) | 0.30 |
| Year graduated, median (range) | 2010 | 2012 | 2002 | 0.44 |
| | (1976-2015) | (1976- 2015) | (1977- 2015) | |
| Study patients per provider, median (range) | 13.5 (1-34) | 6 (1-32) | 15 (1-34) | 0.045 |
| Used any CET > 10 times prior month | 27 (84%) | 13 (77%) | 14 (93%) | 0.19 |
| Used VisualDx prior month (yes) | 7 (22%) | 3 (18%) | 4 (27%) | 0.54 |
| <u>Patients</u> , n | 433 | 158 | 275 | |
| Age in years, median (range), 431 obs. | 58 (19-94) | 58 (20-91) | 58 (19-94) | 0.73 |
| Sex (male), 431 obs. | 214 (49%) | 77 (49%) | 137 (50%) | 0.54 |
| Completed all protocol | 360 (83%) | 126 (80%) | 234 (85%) | 0.15 |

Table 2.1: Characteristics of primary care providers and patients

Unless noted, all cells contain n and (%). **P*-value comparing Active and Control groups from X^2 tests for categorical variables (proportions) and Wilcoxon Rank-Sum tests for ordinal and continuous variables.

2.4.1 Problem Resolution

48% of all patients in the study considered their skin problem resolved ("All better") by the final contact, including 46% in the active group and 49% in the control group (P=0.48). Active and control patients were similar in terms of whether they were "All better", "Improved", "Unchanged" or "Worse" at their final interview (P=0.88).



| | All subjects | Active | Control | P^* |
|---|--------------|-------------|-------------|-------|
| Patients, n | 433 | 158 | 275 | |
| Final skin status | | | | 0.88 |
| Resolved | 207 (48%) | 72 (46%) | 135 (49%) | |
| Improved | 104 (24%) | 41 (26%) | 63 (23%) | |
| Unchanged | 108 (25%) | 40 (25%) | 68 (25%) | |
| Worse | 14 (3%) | 5 (3%) | 9 (3%) | |
| Return visits | | | | |
| Return visits per patient, mean (standard deviation) | 0.59 (1.07) | 0.65 (1.10) | 0.55 (1.05) | 0.19 |
| Any return visits (vs. none) | 148 (34%) | 59 (37%) | 89 (32%) | 0.29 |

Table 2.2: Problem resolution and return visit outcomes

Unless noted, all cells contain n and (%). **P*-value comparing Active and Control groups from X^2 tests for categorical variables (proportions) and Wilcoxon Rank-Sum test for number of visits.

Time to resolution was similar in the two groups throughout the observation period of up



to 120 days (P=0.56 by log-rank test).

Figure 2.3: Proportion of patients whose skin problems remained unresolved over time



In univariable Cox proportional hazards modelling, with standard errors adjusted for provider clusters, the days from index visit to resolution were similar in both groups (Hazard Ratio (HR)=0.92; 95% Confidence Interval (CI)=0.70, 1.21; P = 0.54). Tests for potential confounding by patient age and sex, PCP status (as resident and as patient's regular provider), PCP time since graduation, number of subjects per provider, and time of the year, indicated no potential confounding. Therefore, these variables were not included in the analysis.

2.4.2 Return Appointments

Active group patients had a mean of 0.65 return appointments compared to 0.55 in the control group (P=0.19). The median was 0 return appointments in both groups.



Figure 2.4: Return appointments for 433 skin patients by experimental group



Thirty-seven percent of active patients had one or more follow-up appointments for the index problem *vs.* 32 % of control, P=0.29.

When analyzed as a binary variable (any follow-up visits *vs*. none) in clusteradjusted logistic regression, the odds of a return visit in active group patients were higher than in the control group (Odds Ratio (OR) =1.25; CI =0.93, 1.67; P=0.15) but were not statistically significant. Tests for potential confounding by patient characteristics (age and sex), PCP characteristics (as resident, as patient's regular provider, and time since graduation) or time of the year indicated no confounding. Therefore, these variables were not included in the model. However, the number of patients per provider was associated with both the use of any follow-up visits (P=0.066) and group assignment (P=.065) raising the possibility of confounding and was included in the final logistic regression model. The odds of any follow-up visits remained higher in the active group than the control group when adjusting for clustering and the number of subjects per provider (OR=1.14; CI=0.84, 1.56; P=0.39), but was not statistically significant. The intra-cluster correlation coefficient for both outcome measures was <0.00001 with an upper 95% confidence limit of 0.039.

2.5 Discussion

Patients with skin problems whose PCPs used the CET VisualDx experienced similar rates of problem resolution and similar time to resolution as patients whose providers did not use it. There was no difference in the number of follow-up visits to any health-care provider for the index skin problem.



The goal of this study was to assess effectiveness of a CET as used in a generalizable clinical setting, rather than to determine its mechanism of action or efficacy under ideal conditions. Therefore, we designed a "pragmatic trial" in a clinical environment in which day-to-day factors were not highly controlled. Pragmatic trials seek to answer the question "Does this intervention work under usual conditions?" [23]. Intervention PCPs had flexibility in how they followed their assigned protocol to reference VisualDx when a patient care uncertainty arose. They could have searched within VisualDx by diagnosis terms, as opposed to using the differential diagnosis support tool. They could also decide that assistance was not needed with some patients and opt not to employ the CET. They could seek advice from additional sources after consulting VisualDx.

We obtained data for the primary outcomes from patient reports because we sought to understand the outcomes of care as the patients experienced it. Patient-reported outcome measures complement other health care indicators such as provider-reported outcomes, chart review, and insurance data. They are appropriate measures in research when the intervention is incorporated into treatment [26, 27]. They are frequently used in clinical trials of medical products, drugs, and in health-related quality of life studies [28]. We did not evaluate whether the diagnosis or treatment decided upon by the PCP was correct by an objective standard, such as expert dermatologist review. Likewise, we did not distinguish appropriate follow-up appointments or referrals from unnecessary or avoidable ones, recording only that a follow-up occurred.



Physician-reported benefits of referring to CETs, such as correct diagnosis, treatment, and avoidance of adverse events have been noted previously. Marshall *et al.* in multi-institutional survey of physicians (n=4,906) and residents (n=1,290) in 118 hospitals, found that 36% of physicians and 42% of residents changed a diagnosis after referring to a clinical evidence source in a recent recalled incident. Physicians (29%) and residents (32%) also reported avoidance of unnecessary procedures or tests because of the information they used in the incident [5].

Likewise, use of VisualDx may improve diagnostic skills. A team including the developer of VisualDx reported that among 28 cases initially misdiagnosed as cellulitis in the Emergency Room, VisualDx included the correct diagnosis in its differential diagnosis list more often than the admitting medical resident (64% *vs.* 14%; P=0.003). In a pilot study by Chou, clinical diagnoses of 13 patients were made by 13 dermatology residents and 51 medical students before and after using VisualDx. Diagnostic accuracy increased from 63% to 81% (P <0.01) as judged by a consultant dermatologist [23]. Despite these positive intermediate effects, the published literature, including the study reported here, provides no evidence of better patient outcomes.

Why did use of VisualDx, a technologically sophisticated, well-designed, stateof-the-art CET, fail to influence the tested outcomes for skin disease? Some potential reasons for the negative results in this trial, such as bias due to uneven distribution of patient or provider characteristics, were minimized by the randomized design of the study. Another reason we found no difference between groups could be that the VisualDx users had insufficient knowledge of the resource to use it effectively. However, active



group PCPs were made aware of the resource, what it was meant to do, and how to access it. They received more training on its features, via an online tutorial, than is usually available in clinical practice. Although the VisualDx interface appears intuitive and easy to use compared to other CETs (PubMed/MEDLINE for example), it is possible that PCPs found it difficult to find the information they needed. The specific content and interactive diagnosis tool of VisualDx, written largely by specialists, could be too complex or time-consuming in the Primary Care setting. This may have contributed to busy clinicians bypassing VisualDx at times, resulting in suboptimal management.

Even if the content acquired by the PCPs was correct from a biomedical pointof-view, the PCPs were not obligated to follow it. Indeed, local availability of certain procedures, prescriptions, and specialty referrals may make it unreasonable or impractical to follow the advice of the CET, leading to the "no difference" result.

Finally, it is possible that many skin problems presenting in Primary Care are inherently resistant to improvement no matter how well-managed. They will resolve (or not) at their own pace regardless of the diagnosis and therapy offered. Nonetheless, one supposes that return appointments and referrals to dermatology could be reduced with optimal Primary Care management.

This study tested the effectiveness of VisualDx for problem resolution and return visit frequency, not for other outcomes such as improved diagnosis, or satisfaction with care. This was not a comprehensive multi-attribute assessment of the CET. Likewise, ease of use and usefulness were also beyond the scope of this evaluation.



VisualDx is costly, and this study may help health care organizations determine whether that cost is appropriate for their local institutional goals and settings.

2.5.1 Strengths and Limitations

The cluster-randomized parallel design reduced the likelihood of bias due to differences in the provider and patient subjects. Secular events occurring outside the study, such as seasonal changes in skin-related appointments, affected providers and patients in the intervention and control groups equally because of the randomized, parallel design.

The study took place in one large academic medical center, possibly reducing generalizability to other settings. However, the patients of the study institution are similar to populations in rural regions of the United States in terms of age, race, poverty rates and other factors.

Although this is the largest randomized study of a CET with patient outcomes to date, the power to detect a potential effect was limited. Given the sample size of 433 patients, a control resolution rate of 49% within 90 days, and assuming α =0.05, the study had 80% power to detect a resolution rate of at least 63% in the active group using Chi-square analysis. The observed rate was 46% and therefore not significantly different from control. In the Cox model, the observed Hazard Ratio of 0.92 (favoring control) was well under the minimum detectable HR of 1.24. Likewise, the study had 80% power to detect a difference of 0.30 return visits per patient. The observed rate was 0.10 higher in the Active group. Given that all analyses showed a trend towards worse outcomes, *i.e.* longer



time to resolution and more return visits in the Active Group, it highly unlikely that a larger study would have demonstrated a statistically significant beneficial effect. The study relied on provider adherence to the protocol based on their agreement to do so (which was confirmed periodically). We did not have independent confirmation of their adherence. There may also have been contamination between provider subjects since there were both active and control providers in some clinics. While the active group PCPs used VisualDx as their primary resource for skin-related uncertainty and the control group did not, both groups could use other CETs and resources available in the information-rich environment of the academic medical center. This access could have masked a positive effect of using VisualDx.

We had limited ability to independently measure participant usage of VisualDx prior to the study. However, at baseline, 22% of PCPs reported use of VisualDx in a prior month with no significant difference between groups. We did not measure VisualDx use during the study. Nevertheless, we did encourage provider adherence to the protocol. When contacted, all providers confirmed they were staying within their assigned protocol, to use VisualDx as a reference or not.

The study relied upon the memory of patients which could have been faulty. However, the first patient interviews followed the index visit by approximately thirty days, a relatively short time span [25]. Only one patient who consented could not remember the skin problem visit at all.

This study included patients with acute and chronic conditions reflecting the usual variety of skin conditions seen in primary care. It is possible that a study of only



acute skin conditions, or a study in an inpatient setting, might have had a different outcome.

2.5.2 Implications

While this CET did not make a difference in the patient outcomes studied, it may have value for other goals such as medical knowledge, decision confirmation, and diagnostic confidence. The pragmatic study design with patient-level outcomes proved to be feasible, and could be extended to evaluate other clinical evidence source technologies relevant to health care.

2.6 Conclusion

The study showed no difference in resolution of symptoms and return visits in

patients of doctors who referenced VisualDx. Although VisualDx and other CETs may

support institutional missions of medical knowledge and practice improvement, VisualDx

does not appear to improve patient outcomes for skin problems managed in Primary Care.

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MB conducted participant recruitment and data collection, MB and BL analyzed the data,

interpreted it, and wrote and approved the final manuscript.



CHAPTER 3 Barriers and Facilitators to Using Clinical Evidence Technology in the Assessment of Skin Problems in Primary Care

3.1 Abstract

Background: A previous cluster-randomized controlled trial tested the effectiveness of a clinical evidence technology (CET), VisualDx, for skin problems seen by primary care providers (PCPs). Based on patient report, there was no effect on time to problem resolution or return appointments.

Objective: The objective of this investigation was to explain, from the provider perspective, why the CET did not make a difference in the clinical trial and to identify barriers and facilitators to successful use of VisualDx.

Methods: We used a mixed methods study design. Providers from both arms completed a survey about their use of VisualDx and information-seeking during and after the trial. Active arm providers participated in interviews to explore their opinions and experiences using VisualDx. Behavioral steps of the evidence-based medicine (EBM) paradigm framed the analyses. The survey and interviews were conducted concurrently.

Results: PCPs found VisualDx easy to use (median 3 on a 1-4 scale), but found it only somewhat useful (median 2 on a 1-4 scale). PCPs with fewer years in practice used it more often and found it easier to use. Interviews identified facilitators and barriers to using VisualDx. Facilitators included diagnostic uncertainty, positive attitude, ease of access, utility for diagnosis and therapy decisions, and utility for patient communication. Barriers included PCP confidence in dermatology, preference for other sources, interface



difficulty, and retrieval of irrelevant diagnoses and images. Some PCPs reported positive impacts on patient treatment and fewer referrals; others saw no difference.

PCPs found VisualDx easy to access, but some found the interface difficult to use. They found it useful and relevant at times, but also frustrating and time-consuming. They used other sources in addition to, or instead of, VisualDx.

Conclusion: PCPs did not perceive VisualDx as "useful" often enough for them to use it frequently or exclusively, thereby reducing the likelihood of it making a difference in patient-level outcomes such as problem resolution and return appointments.

3.2 Background

Studies show that clinicians who use clinical evidence technologies (CETs) to answer clinical questions perceive that they change or confirm diagnoses and treatment decisions, avoid medical errors, and improve their practice [1-3]. Obstacles to answering clinical questions and information acquisition with CETs are also reported. Poor technology access, lack of available evidence sources, lack of relevant evidence in chosen source, time constraints, and lack of institutional support are described as reasons for clinicians' failure to use CETs in patient care [4-6].

Evidence-based medicine (EBM), defined as "the integration of best research evidence with clinical expertise and patient values [7]" endorses the use of researchbased evidence found in medical journals, databases, and clinical topic summaries. In practice, EBM outlines basic steps that clinicians must take to effectively find and apply evidence. These steps may need to be executed quickly, often in a patient visit. The behavioral steps outlined for EBM in practice are 1) Ask a clinical question, 2) Acquire



available evidence, 3) Appraise and interpret it, and 4) Apply evidence with patient values and preferences [8, 9].

3.3 Previous Study

VisualDx is a factual knowledge database and diagnostic tool that matches patient symptoms with images to suggest likely diagnoses and management strategies [10]. Research suggests that its use improved ER physicians' knowledge and accuracy of diagnosis for cellulitis [11], and diagnoses by dermatology residents and medical students for other skin conditions [11, 12].

Use of VisualDx, a CET, by primary care providers (PCPs) was the intervention in a 2016 cluster-randomized controlled trial (CRCT) [13]. In the CRCT, PCPs were randomly assigned to use VisualDx or not. Their patients with skin complaints were interviewed about the outcome of the care they received. The CET did not affect time to resolution of symptoms or need for return appointments for the same problem in that study.

3.4 Objective

The objective of this investigation was to 1) learn why VisualDx did not make a difference in patient-level outcomes from the perspective of the clinicians, and 2), to identify barriers and facilitators to the use of the CET as experienced by VisualDx users.

3.5 Study Design

We used a convergent, parallel, mixed methods design with a quantitative survey and qualitative interviews. [14]. We combined data types to realize a more complete analysis and interpretation when exploring the experiences and perspectives of

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the PCPS who used VisualDx, and to interpret their experience through a behavioral steps model adapted from the EBM in practice steps.

3.6 Methods

The methods of the current study included a survey of all participant PCPs (users and non-users of the CET VisualDx), and semi-structured interviews of PCPs in the active arm (VisualDx users). PCPs from both arms completed a closed answer survey on paper or online. Interview participants included only the active arm PCPs *i.e.* those assigned to use the CET. The original trial and the current investigation took place at the University of Vermont Medical Center [13]. The subjects included faculty and residents in Family Medicine and Internal Medicine primary care clinics.

The behavioral steps of the EBM paradigm were used as a reference framework to inform the data analyses and evaluate the success and failure of the CET as used by PCPs. To realize a more in-depth understanding, we developed a six-step model of how clinicians seek evidence, use a CET to answer patient care questions, and apply evidence learned to patients. Thus, the model behavioral steps, for the current study were: (S1) Recognize a clinical uncertainty, (S2) Decide to seek information, (S3) Navigate access technologies, (S4) Use the CET interface and features, (S5) Appraise the information found for relevance and quality, and (S6) Apply the evidence to and with the patient. In this model, difficulty at any step could block proceeding to the next, thereby reducing the likelihood of finding relevant, applicable information in the CET, and preventing an impact on patient care. (See Figure 3.1.)





Figure 3.1: Model of behavioral steps to use a CET for patient care

We organized results from the survey and interviews with the Steps model to illustrate the barriers, and facilitators of CET use that the PCPs encountered.

3.6.1 Quantitative Data and Analysis

PCP demographic data and CET usage patterns were available from the CRCT baseline survey. In the post-trial survey, PCPs answered questions based on their arm during the trial. Questions specific to the VisualDx user arm included: frequency of VisualDx use, proportion of skin patients for whom they referred to VisualDx, ease of use, and usefulness. Control PCPs were asked if they had used VisualDx or other CETs at all during the trial. All were asked if they had used VisualDx after the trial and which CET resources, if any, they had used for skin problems in a recent month. (See Figure 3.2)



Primary Care Provider Survey

VisualDx user Arm

During the study, how many times did you refer to VisualDx? In what percent of skin problem patients did you refer to it? How useful was VisualDx in diagnosing and treating patients? Scale 1-4, 1. Not at all, 2. Occasionally, 3. Usually, 4. Always How easy or difficult was it to find information you needed? Scale 1-4, 1. Very difficult, 2. Somewhat difficult, 3. Somewhat easy 4. Very easy **Non-VisualDx user (Control) Arm**

During the study participation period (ending July 31 2016), did you refer to VisualDx?

Yes/No

Both arms

How often have you referred to VisualDx since the trial ended? In the last month, how many times did you see a patient for a skin problem? In last month, how many times did you look for additional information to support care for a patient skin problem. In those times, what sources did you use? [Check box] DynaMed, Google, Journal articles, PubMed/Medline, UpToDate, Textbooks (electronic or print), VisualDx, Wikipedia, Not sure,

Other. If other, please list.

Figure 3.2: Questions in post-trial surveys of trial participants

The survey questions on perceived usefulness and ease of use were informed by the

Technology Acceptance model [16] All survey data were recorded with REDCap

electronic data capture tools [17], and analyzed with descriptive statistics in Stata version

14.2 [18]. The University of Vermont Institutional Review Board approved both the

original clinical trial and the current investigation.



3.6.2 Qualitative Data and Analysis

The principal investigator (MB) conducted semi-structured in-person interviews

of active group PCPs to ascertain their experiences and opinions about using the CET

during and since the CRCT. (See Figure 3.3)

The interviews and surveys were conducted concurrently in February and March 2018.

Semi-structured Interview Outline

Please describe your experience of being (participating) in the study. What was your experience like using VisualDx? (Your opinion of it?) (Prompt: how useful? hard/easy to use? How did you usually access VisualDx? (Prompt: Such as device/network/portal, EHR, mobile) How did you find your usual method? (Prompt hard/easy, fast, slow? What difference did VisualDx make in an aspect of patient care? Could you describe a time when it did make a difference or perhaps when you hoped it would and it didn't? Do you use VisualDx now? What prompts you to use it or not? What other information resources did you use then or do you use now for evidence for skin problems? What else you would like to tell me about using clinical information resources relevant to dermatology or skin problems?

Figure 3.3: Semi-structured interviews outline

The interviews were recorded, transcribed, and coded using NVivo version 12 qualitative

analysis software [19]. The PI and two independent coders identified themes from the

interviews. Results were discussed and themes derived from the interview statements by

three reviewers. Final themes were decided by the PI with reviewer consensus. Themes

were organized for relevance within the behavioral steps model (Figure 3.1).



3.7 Results

3.7.1 Quantitative Survey Results

Twenty-one (66%) of 32 PCPs from the original trial participated in the survey: 13 of 17 from the active group, and 8 of 15 from control group (See Table 3.1).

Table 3.1: Characteristics of 21 post-trial survey participants

| | All | Active | Control |
|---|----------|-----------|---------|
| N | 21 | 13 | 8 |
| Sex (Male), n (%) | 10 (47%) | 6 (46%) | 4 (50%) |
| Resident during CRCT (vs. Attending), n (%) | 4 (10%) | 4 (31%) | 0 |
| Family Med (vs. Internal Med), n (%) | 10 (47%) | 5 (38%) | 5 (63%) |
| Provider Education | | | |
| Physician, n (%) | 20 (95%) | 13 (100%) | 7 (88%) |
| Advanced Practice Nurse, n (%) | 1 (5%) | 0 | 1 (12%) |
| Years in Practice | | | |
| Median | 17 | 12 | 18 |
| Range | 1-40 | 1-40 | 2-39 |
| Used VisualDx during CRCT, n (%) | 14 (67%) | 13 (100%) | 1 (12%) |
| Times used VisualDx during CRCT | | | |
| Median | | 10 | |
| Range | | 3-125 | |
| Used VisualDx since CRCT (yes), n (%) | 14 (67%) | 9 (70%) | 5 (63%) |

3.7.1.1 Frequency of VisualDx Use

All active arm survey respondents reported using the CET multiple times during the study, (median 10 times). Seven of eight control arm PCPs did not use it. This response indicated general protocol fidelity, confirming that VisualDx users sought answers in VisualDx, and that the control group, with one exception, did not use it.

Less than half (6 of 13) of VisualDx users reported using it with 50% or more of their skin patients. The rather low median of 10 uses of the CET per provider, coupled with low use per patient, suggests barriers to effectiveness at Steps 1 and 2.



3.7.1.2 Ease of Using of VisualDx

The survey asked, "How easy or difficult was it to find information you needed?" This question did not distinguish ease of getting to the CET (Step 3) from the search and find step in the CET itself (Step 4). Ten respondents (76%) reported that the CET was "somewhat easy" or "very easy" to use compared to three (24%) who found it "somewhat difficult" or "difficult". On balance, PCPs reported the CET relatively easy to use.

3.7.1.3 Usefulness

The survey measured usefulness with the question "How useful was it?" Five PCPs (38%) considered it "Usually useful" (3 on the 1-4 scale) while eight (62%), found it "not at all" or "only occasionally" useful. None found it "Always/ almost always" useful.

Three of seven (42%) in practice 6 or more years found it not at all useful. No one with 5 years or less practice found it "Not at all" useful. Responses to the "how useful" question most closely mapped to behavioral Step 5, Appraisal for quality and relevance and Step 6, Apply to and with patient.

3.7.1.4 Frequency, Ease of Use, and Usefulness

Those who found the CET harder to use used it less often (median 6 times) and those who found it easier to use used it more often (median 15). Those who found it harder to use found it less useful. Those who found it easier to use were divided equally on usefulness: 50% found it never or occasionally useful, 50% found it usually useful.



3.7.1.5 Years in practice

Less experienced PCPs used the CET with at least half of their skin patients more often than older providers (67% vs. 29%). They also used it more often (median 15 vs. 10) and found it easier to use. A higher proportion also found it more useful (50% vs. 29%). However, these differences were not statistically significant (See Table 3.2).

Table 3.2: Results for VisualDx frequency of use, ease of use, and usefulness comparing years in practice

| | All | Practice Years ≤5 | Practice Years >5 | <i>P-</i> Value |
|---|------------|-------------------------|-------------------------|--------------------|
| Ν | 13 | 6 | 7 | |
| Median VisualDx Use in trial, n (range) | 10 (3-125) | 15 (5-30) | 10 (3-125) | 0.29 [§] |
| Used VisualDx with >50% of skin patients, n (%) | 6 (46) | 4 (67) | 2 (29) | 0.62 [¢] |
| Ease of use, n (%) | | | | 0.06^{ϕ} |
| Harder | 3 (23) | 0 (0) | 3 (43) | |
| Easier | 10 (77) | 6 (100) | 4 (57) | |
| Usefulness, n (%) | | | | 0.43 [¢] |
| Less useful | 8 (62) | 3 (50) | 5 (71) | |
| More useful | 5 (38) | 3 (50) | 2 (29) | |

[§] Spearman Rank, [§] Fisher's Exact Test

3.7.1.6 Usage of VisualDx and Other Resources Post-Trial

There was little difference between users and non-users who had referred to VisualDx since the trial. Since the trial, 69% of PCPs in the active arm had used the CET, compared to 63% in the control arm, a small and statistically insignificant difference (P= 0.9 by Fisher's exact test). In a recent recalled month, UpToDate was used by 11, VisualDx by 6, text-books by 6, Google by 4, and Epocrates and DynaMed by one each.



3.7.2 Qualitative Interview Results

Eleven active group PCPs participated in interviews, including three residents and eight attending physicians (See Table 3.3). Two active group PCPs who participated in the post-trial survey did not participate in an interview.

| PCP code | Resident/ Attending | Specialty | Sex | Years in Practice |
|---------------------|---------------------|-----------|--------|-------------------|
| PCP01 | Resident | IM | Female | 1 |
| PCP02 | Attending | FM | Male | 32 |
| PCP03 | Attending | IM | Male | 34 |
| PCP04 | Attending | IM | Female | 17 |
| PCP05 | Attending | FM | Female | 40 |
| PCP06 | Attending | IM | Male | 4 |
| PCP07 | Resident | IM | Female | 3 |
| PCP08 | Resident | IM | Female | 3 |
| PCP09 | Attending | FM | Female | 4 |
| PCP10 | Attending | IM | Male | 22 |
| PCP11 | Attending | FM | Male | 24 |
| PCP98 (survey only) | Attending | FM | Male | 12 |
| PCP99 (survey only) | Resident | IM | Female | 1 |

 Table 3.3: Profile of active group survey and interview participants' status during CRCT

We assigned themes to provider statements and noted where the statement fell in the Steps framework based on the content of the statement. Eleven relevant themes included: dermatology confidence, attitude or intention, time pressure, other sources, access, skills needed, interface difficulty, diagnosis support, irrelevance, patient communication, and impact on patient management. Within themes, facilitators were factors that promoted use of VisualDx, or that had beneficial impact on the PCP practice or the patient. Barriers were defined as inhibitors of use of the CET or deterrents to its usefulness and effectiveness. (See Appendix V)



3.7.2.1 Recognizing Uncertainty in Skin Disease (S1)

This step, recognizing uncertainty when a patient presents with a skin disease problem,

set the PCP on the path to seeking new information. Dermatology, especially diagnosis of

rashes, was recognized by providers as an area of frequent uncertainty in primary care.

The recognition of uncertainty in skin disease care signaled more openness or intention to

seek information; therefore, we considered it a facilitator of VisualDx use.

"There are certain areas, [like dermatology] where internists in particular, don't have as much training and we tend to fall into...less rigorous ways approaching a diagnosis." PCP10

Several interviewees stated that because of their own uncertainty in dermatology,

evidence-based information resources were especially needed in that domain.

"[Dermatology] is way harder because we just don't have the exposure. Also, so much of it is how it looks rather than like a description of symptoms. So, I think something like VisualDx is totally necessary." PCP07

"[Dermatology] is an area that I feel I continue to work towards improvement in versus some other areas where I feel very prepared and skilled..." PCP09

Self-described knowledge or confidence in dermatology was a barrier to information-

seeking because highly confident PCPs recognized uncertainty less often and needed the

CET less. Physicians with 32 and 24 years' experience noted their comfort with existing

knowledge.

"If it's a simple thing that you kind of deal with a lot and you feel like you know what it is and how to treat it, then you obviously wouldn't use the resource in that situation." PCP02

"There were certainly a lot of patients where I felt comfortable with what I thought the problem was" PCP11



3.7.2.2 Decision to Seek Information in VisualDx (S2)

This step encompasses the decision to act on an uncertainty by seeking answers

to patient-related questions. Themes of intention to obtain information and availability of

competing sources were included in this step.

A positive intention toward using VisualDx was a facilitator for continuing use of

the CET throughout the trial. Some PCPs recounted the specifics of their assigned

protocol as evidence of their intention and commitment to use the CET during the trial.

"When I had a patient that had a skin complaint, I was supposed to open VisualDx and use it to come up with a diagnosis or treatment...I tried to be pretty diligent about it." PCP01

"I think I probably used it close to every time I saw a skin problem, unless it was super obvious...But even then, I would look it up and use it to get ideas for treatment recommendations." PCP08

For some, being in the study was a benefit in itself and motivated them to use it. They

saw it a as a learning opportunity that could improve their practice.

"I was glad I was in the intervention arm of the study, because...it was motivation for me to use it [VisualDx] more and see how it changed my practice..." PCP08

PCPs did not always look for answers even with uncertainty present. Time pressure in a

patient visit made pursuit of any information in VisualDx or other CET less likely.

"When you're already 45 minutes behind and you got patients waiting and someone comes in with a goofy-looking rash, it's very easy to say "Well, I think it's this, let's try it, if it doesn't work call me back..." PCP10

Some PCPs anticipated that diagnosis search on the CET would be time consuming, so

they seldom used the differential diagnosis tool but did use the CET to find treatment

options.



"You know, [VisualDx] is time consuming and...you're busy. It's easier to get at treatment than it is to get a differential because it just takes longer. And I was less likely to do that [differential] part." PCP02

Use of other resources instead of VisualDx was also a barrier at Step 2. PCPs felt that

colleagues or other resources would be faster or more convenient and so used them

instead of the CET despite their active arm protocol.

"I was working...next to a skilled, older practitioner. So often times my first recourse would be going to him, asking him to take a look. So that may have decreased my use... Sometimes I just used Google Images" PCP09

Several PCPs reported using VisualDx to reduce diagnosis uncertainty but another source

for treatment or management decisions.

"If I knew what the problem was...but wasn't sure how to manage it, I might use

UpToDate [more]." PCP11

Several providers reported using UpToDate for skin problem questions, even though it is

not specialized for skin problems.

"I used UpToDate quite frequently. And I used Micromedex quite frequently...I don't think my use of VisualDx changed my rates of use of those other resources." PCP08

3.7.2.3 Access to VisualDx (S3)

This step occurred when the PCP navigated the hospital network, medical library website, or a mobile device to reach the CET. Based on the interviews, access through the electronic medical record (EHR) was an important facilitator. All interviewees described the EHR as virtually the only way they used VisualDx. The ubiquity of networked desk-top computers in exam rooms and offices were additional facilitators. The mobile version of the CET was available on smart phones and tablets, but no participant reported using it for patient care.



"I always went to it on a desktop through [EHR]. Never through the hospital intranet. Never used the mobile. When I'm in clinic I don't use my phone. We're always on the computer, writing the notes, or looking at vitals, looking at meds..." PCP01

Easy point-of care access was essential for some to even consider using a CET.

"...It's difficult, for clinicians that are in a fast-paced clinical environment, to be able to stop and reference things if you don't have it immediately at your fingertips." PCP11

One PCP developed problems accessing the resource after one month into the study and

never got back on track using the resource.

"[It was] moderately useful in the beginning but then, I couldn't access it. I asked for help...and maybe I got a response. But maybe I didn't...follow the answer, and I didn't use it again." PCP05

3.7.2.4 VisualDx Interface and Features (S4)

PCPs next step after navigating access was to utilize the CET's interface and

features. Some found it easy to learn and use while others doubted their skill to use it

effectively. A majority stated that they found the CET easy to use, requiring only a slight

learning curve. This confirmed the survey results, particularly among those with 5 or

fewer years in practice.

"...Once I knew what I was doing, it wasn't hard to use." PCP06

"I would say it's fairly easy...There was a small learning curve to...figure out the best way to use it." PCP08

Others found the interface a barrier and found the interactive diagnosis tool difficult or unpredictable. Even though PCPs viewed a brief training tutorial, some felt they lacked the skill to use it effectively and questioned whether they were at fault for not getting better search results.



"I remember staring at it saying, when I was trying to figure out what this rash was, 'Where do I put the information in?'. So, it wasn't as user-friendly for data input." PCP10

"The output is not always coming up with the most common causes...Or the things I'm most likely to think it is...So I'm not sure if I'm just not putting in enough [information]" PCP09

3.7.2.5 Appraise for Quality and Relevance (S5)

In step 5, the PCP evaluated or appraised the evidence presented by the CET for

quality and relevance to their information need. PCPs considered VisualDx as validated

by expert dermatologists and sufficiently reliable to serve as "best available" evidence.

Several noted that it was more reliable than images on an internet search engine.

"I had a lot of confidence that the material was accurate and properly edited or authenticated by experts in the field. I didn't have any concerns about that." PCP03

"The problem with Google Images is [that] anybody...can upload a picture and tag it with a diagnosis. At least VisualDx has been validated by somebody that these pictures are the real deal." PCP10

PCPs, especially those with fewer years in practice, found the CET's' interactive

diagnostic tool useful when they were "starting from scratch" with little idea of the

diagnosis. The ability to broaden the differential [diagnosis] was useful especially to

residents and those newer to practice.

"I did, on a few occasions, have no idea what I was looking at in the patient and used it to try to figure it out." PCP08

"...I would often look at a skin lesion or rash and have an idea...and then I would put information into VisualDx and it would broaden my differential and sometimes completely change my initial opinion." PCP07

"...I had this young woman with...this rash on her back, I...thought maybe psoriasis, and then used VisualDx. Based on what I found, it looked more like *pityriasis rosea* so I went that way instead." PCP08



Even experienced physicians wished to expand the differential diagnosis at times.

"If something is really weird and I'm trying to figure out what are the possibilities here, it certainly helps generate a list of possible conditions." PCP10

Several experienced providers reported that the CET confirmed a diagnosis and enhanced

their diagnostic confidence.

"A niche for VisualDx is when you think you know what it is but you just want to make sure you haven't forgotten something." PCP10

"I can definitely say it helped me feel...more confident about a diagnosis." PCP02

Although fewer PCPs reported using the CET for treatment decisions, those who

did found it current and useful.

"Treatment recommendations? I definitely used it for those. If I had tried the usual things you try in the primary office...it was helpful to see some of the other treatment options...available on there." PCP01

An experienced PCP found the treatment recommendations especially relevant for

updating his usual practice.

"One case was a fungal infection on the nails...There was a new topical treatment option that had recently been FDA-approved and I hadn't used it before." PCP02

On the other hand, the barrier of useless or irrelevant information in the CET

came up frequently.

"Just as frequently as I found that it was helpful, I found that it was not helpful at all...I mostly got a lot of extraneous information and things that...weren't appropriate for what I was looking for...So some of that time using it was wasted" PCP08

Some experienced clinicians felt that broadening the differential was not useful for them.

They preferred a tool that would help them narrow or confirm the diagnosis. VisualDx



was not as useful for that because the diagnoses and images retrieved were excessively

broad.

"So, at least for my level of experience, it didn't offer me a whole lot in terms of narrowing my differential diagnosis. It was a lot more about broadening it, and I'm not sure if that was helpful to me." PCP03

There was often too much or irrelevant information. The information retrieved needed to

be sifted or a new search launched which consumed valuable time.

"If you put basal cell carcinoma into VisualDx, it's a thousand pictures of every possible way a basal cell carcinoma can show up - which can be misleading, because it's not showing you what the typical ones are. So...it's almost too much information." PCP03

I remember getting more hits back...a lot more diagnoses - than I was expecting - some of which didn't even look close to what I described." PCP10

A barrier to this CET making a difference was that PCPs used it as one tool

among others rather than relying in it alone. Some PCPs used VisualDx less because they

preferred other sources.

"I have a favorite dermatology book that I use like I would use VisualDx." PCP10

"If there was something I was worried about or I didn't know, I'd look in VisualDx but then I'd really rely on [a colleague]: Hey do you mind coming to look at this?" PCP07

"...If I thought of something, I'd look it up on UpToDate [also] and see if the pictures and descriptions matched" PCP06

3.7.2.6 Apply to and with Patient (S6)

In this step, the PCP applied the information from VisualDx to the patient.

Applicable themes included patient communication, management, *i.e.* treatment or

referrals, and "no difference" (no impact on management).



Most PCPs found VisualDx useful for communication, decision agreement, and

building rapport with patients. Several said it helped show patients how their condition

had changed or improved. Several PCPs reported that they shared what they learned on

the CET with the patients to help explain their condition.

"[I used it with patients] a couple of times, especially if they had something that went away; then they could say "Oh it did look like that", kind of self-report. [It was helpful for] patient communication and education, absolutely." PCP04

"If you are able to say, "This is really just eczema and this is what eczema looks like on other people, and it's just like yours", it gives you a kind of rapport with them." PCP01

Some reviewed alternative diagnoses and images with patients during the visit to reach

agreement with them.

"I would open it up on the computer in the patient's room oftentimes, and go through it [all] with them." PCP06

"I would look at VisualDx and it would give me four additional ideas. So, then I would talk to the patient more, come up with a diagnosis that I thought was likely enough...to act on." PCP08

The PCPs who used images with patients found them helpful for communication and

understanding.

"...If you can use a visual to show somebody and say, "Oh this looks like really what you have," they gain a little bit more confidence." PCP09

Some PCPs reported that VisualDx influenced therapy and referral decisions,

and advice to patients and caregivers.

"A patient came in and he was pretty convinced he had poison ivy and I was pretty convinced that he didn't...I ended up using [VisualDx], and he was right. I would have treated it differently had I not opened it and used some of the pictures to help." PCP01



Some PCPs stated that using the CET altered their referral patterns, prompting some referrals and avoiding others. Those making fewer referrals cited having more confidence as the reason.

"A lady came in with something strange on her eyes and we couldn't figure out what it was. Based on using VisualDx I came up with something I hadn't considered that was treated quite differently. That did prompt a referral to dermatology." PCP01

"I think it changed my rate of dermatology referrals because I willing to diagnose skin conditions with...more confidence and to act on those diagnoses." PCP08

Despite positive examples of application to the patient and differences in management,

others did not recall any impact that using the CET made.

"Care difference? I would have to say no, that it didn't really offer me a different path forward". PCP03

"I can't think of a particular instance where it clinched it for me or made a clinical decision distinction or difference. It was more of a tool that I used to augment whatever I was looking into otherwise." PCP09

3.8 Discussion

3.8.1 Barriers

This mixed methods study identified facilitators and barriers to effective use of VisualDx and its impact on PCP decisions and patient care management. Although there were facilitators and benefits, PCPs experienced significant barriers to using the CET. Barriers included lack of perceived need, time pressure, use of other resources, difficulty of interface, irrelevance of information retrieved, and low impact on care management. The greatest single barrier to the CET use appears to have been the frequency of retrieving irrelevant information ("about half the time"), and the frustration and wasted time that engendered. Several held the view that the CET had no impact on case



management. In the survey, more PCPs found it "never" or "occasionally" than "usually". Similarly, lack of relevant information retrieved [4, 21] and insufficient time have been described in previous studies [20].

Seeking information from multiple sources is typical information-seeking behavior for clinicians. [1, 21]. In the current study, PCPs also utilized multiple sources, but they preferred CETs easily available from within in the EHR or at the point-of-care including UpToDate, Google Images, and print textbooks. Although there is an intrinsic value to having multiple sources, their presence served as a barrier to the use of VisualDx and, when they are effective, decreases the impact that the CET has on clinical outcomes.

3.8.2 Facilitators and Benefits

Positive intention to use the CET and accessibility via the EHR facilitated use. PCPs did not often use other dermatology-relevant CETs, such as electronic dermatology text-books, MEDLINE and dermatology journals available to them on the medical library website because they were less convenient and took them out of the EHR environment.

Expansion of the -differential diagnosis, and confirmation of diagnostic decisions were benefits expressed in the interviews. Diagnosis support was "occasionally" or "usually" useful. PCPs in practice five years or less, including residents, appreciated the differential diagnostic support more than senior providers. Those in practice longer preferred to narrow or confirm a diagnosis more, but they were sometimes disappointed with excessive results.

Successful use of the CET for patient communication and shared decisionmaking at Step 6 was an unexpected benefit. This benefit could have affected patient



satisfaction with care, an outcome that was not evaluated in this investigation but could be evaluated in future research.

3.8.3 Impact on Patient Management

PCPs recalled cases when use of VisualDx made a difference in care management in terms of treatment and referrals (Step 6). The CET altered referral patterns, though the differences were in both directions: prompting some referrals and avoiding others. Use of the CET may have resulted in more appropriate referrals, but not a reduction in the overall number of return appointments, an outcome measured in the clinical trial. The interviews confirmed that, at least at times, PCPs believed there were practice improvements after using the CET.

According to a large qualitative study of clinicians, efficiency, defined as brief time to find information and the high relevance of information found, was the most important factor in provider satisfaction with CETs at the point of care [22]. By this criterion, the CET studied here could improve efficiency because of its perceived convenient access through the EHR and its perceived ease of use, thus overcoming barriers of time and access to evidence. On the other hand, the need or habit of clinicians to use other resources and the occasions when information retrieved was irrelevant contributed to inefficiency.

3.8.4 Strengths and Limitations of this Study

This investigation extended previous work on one CET's value in the Primary Care dermatology domain. The population studied included PCPs with varying



experience and backgrounds. Mixed methods enriched our understanding of the users' experiences and allowed us to compare results obtained by different methods.

The study took place in one academic health center thereby limiting generalizability to other settings. Outcomes reported were the view of the providers and not verified by patients or other data sources. Although recall errors are possible in any retrospective report, all participants recalled their participation and responded to survey and interview questions without difficulty.

3.9 Conclusions

This mixed methods investigation identified facilitators and barriers to PCPs use of a CET for dermatological problems that may help explain the results of the prior randomized trial. Despite offering high quality information and interactive diagnostic features, VisualDx was not sufficiently easy to use, or consistently useful enough to motivate PCPs to use it frequently or exclusively. Therefore, it did not make a measurable difference in provider acceptance or patient outcomes. This assessment could be used by medical informaticists and medical librarians responsible for acquisition and implementation of dermatology CETs in academic medical center settings.



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APPENDICES

Appendix I : Provider Eligibility and Baseline Survey

This survey was administered to Primary Care Providers through REDCap following

their consent to participate.

Eligibility Screening Questions:

- 1. What is your medical or professional degree?
- o Physician
- Physician Assistant
- Advanced Practice Nurse
- None of the above
- 2. Are you currently seeing patients at a UVMMC Family Medicine or Primary Care Internal Medicine Clinic?
- o Yes
- o No
- 3. Do you agree to adhere to the procedures of the study depending on the group you are randomized to?
- o Yes
- o No
- Not sure. Please call me.

Answers to Q 1. must be Physician, Physician Assistant, or Advanced Practice

Nurse. Answer to Q. 2. must be yes. Answer to Q. 3. must be yes to be enrolled in the

study and continue to baseline survey.

Baseline Survey in the Information for Skin Problems in Primary Care Study.


1. In the last month, how often did you refer to a print or electronic information source to

support patient care?

- \circ None at all
- o 1-3
- o **4-6**
- o **7-9**
- \circ 10 or more times

2. Which information sources did you use to support patient care? (Check all that apply.)

- □ DynaMed
- □ Google
- □ Journal Articles
- \square PubMed/Medline
- □ UpToDate
- □ Textbooks (electronic or print)
- \Box Visual Dx
- \Box Not sure/don't remember
- \Box Other

3A. If other, please specify.

The next three questions refer to when you saw patients for skin problems.

4. In the last month, how many times did you see a patient for a skin problem?

- None at all
- o 1-3
- o **4-6**
- o 7-9
- \circ 10 or more times

5. In the last month, how many times did you look for additional information to support

care for a patient skin problem?

- None at all
- o 1-3



- o **4-6**
- o **7-9**
- \circ 10 or more times

6. Recalling those times when you sought information for a patient skin problem, what

sources did you use? (Select all that apply.)

- □ DynaMed
- □ Google
- □ Journal Articles
- \Box PubMed/Medline
- □ UpToDate
- □ Textbooks (electronic or print)
- \Box Visual Dx
- \Box Not sure/don't remember
- \Box Other

6A. If other please specify: _____

Information About You

7. What year did you graduate from professional school?

- 8. Are you in a residency program?
 - o Yes
 - o No
- 9. Primary Care Specialty
 - o Family Medicine
 - Internal Medicine
 - Other

9A. If other please specify: _____

10. Your usual practice location:

- Family Medicine Berlin
- Family Medicine Colchester
- Family Medicine Hinesburg
- Family Medicine Milton
- Family Medicine South Burlington
- Urgent Care Colchester



- Adult Primary Care South Burlington
- Adult Primary Care Essex
- Adult Primary Care Burlington
- Adult Primary Care Williston
- 11. What is your gender?
 - o Female
 - o Male
 - Other

12. Please let us know here if you have any questions or comments.

We will email you in a few days with an orientation for the procedures for your

randomized group.

End of Provider baseline survey





Appendix II: PCP Active Group Educational Tutorial







What Is VisualDx?

- VisualDx is a clinical knowledge and diagnostic support resource that is licensed by UVM Medical Library to support providers and patient care.
- It contains over 100,000 images of skin and other visible conditions.

How Do I Access VisualDx?

There are 4 main ways:

- PRISM
- UVMMC Intranet Desktop
- Dana Medical Library website
- Your Mobile Device (app)

The next few slides will provide instruction on each access method.





















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|--------|--|--|---|
| | Other Procedures: What Happens After the Patient Visit? | The University of Virmont Aque 13, 2015 Kindyn Paper 13 Hauptifel Trime Belauge, YT 1948 | |
| | PI identifies your eligible patients in PRISM. | Due Kallijn Peper, Two way meester het in der seine son Augen 1, 2011 et Budingene Primers (2m för a sån prosport verste kallen av eller stratigt av er skillt prosport etter at kallen etter stratigt av prosport etter anderen. Aus dyra sen kennet etter son son son kallen stratigt av etter at stratigt av etter at stratigt son der son | |
| | Study team sends each patient a letter over your name informing them of the study. | The performance part would anow the duct of approximately subpleme. It would have a but matters in the performance of the perfo | |
| | We ask that you provide your signature to include on the letters to your patients. | surver, Breynnis Wheelong, MD Berynnis, Umrteng U.D. | |
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Appendix III: PCP Control Group Educational Tutorial

Welcome

Thank you for agreeing to participate in this research.

This learning module will help you participate in the study in an efficient and effective way.

The module will take about 5 minutes to review.









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Additional Information about the PCP Role

- Both PCPs and patients are subjects in this study.
- 30 or more providers and 300 patients, an average of 10 patients per provider, will participate.
- We will contact you every 2 weeks by email or phone to update you on the progress of the study and answer any questions.
- We will notify you when we have recruited enough patients so that you no longer need to follow the protocol.
- Anticipated duration of your involvement is 6 12 weeks.



Access to Clinical Knowledge Resources

Dana Medical Library provides access to electronic clinical knowledge resources to support evidence-based patient care:

- Medical research journals.
- Medical e-text books in primary care and specialties.
- · PubMed database with links to full text journal articles
- Mobile clinical apps.

You can access these resources from many different locations.

FYI: How to Access Clinical Information Sources

There are 3 main ways:

- PRISM
- UVMMC Intranet Desktop
- Dana Medical Library website

The next few slides will provide instruction on each access method















Appendix IV: Patient Interview Data Collection Instruments

Patient telephone interview/Questionnaire at ~30 days after index visit for the skin

problem. Study team investigators including trained research assistants reached identified eligible patients by telephone 30 days or after post the index visit for the skin problem. After review of the lay summary, and verbal consent from the patient, the following interview was conducted.

1. Our records show that you saw (provider name) for a skin problem about (date of

visit). Does that sound right?

- \circ Yes Go to question 2
- No If patient cannot recall the problem or the visit, call is ended and patient is ineligible (dis-enrolled).

2. Is (provider name) your usual primary care doctor?

- o Yes
- o No

3. Since you saw (provider name) for the skin problem last month have you gone back to

him/her or to any other doctor for a follow-up appointment for this same problem?

- \circ Yes Go to question 4
- $\circ \quad No-Go \ to \ question \ 6$

3A. How many other appointments did you have?

3B. What kind of doctor did you see for the follow up appointment?

- □ Primary Care
- \Box Dermatologist
- \Box Other

3C. If other, what kind?

4. Since that visit with (provider name), would you say the skin problem is:





- All Better If all better Go to 4A, 4B, 4C,4D
- \circ Improved GO to 5
- \circ Unchanged GO to 5
- \circ Worse GO to 5

4A. About how long after that visit did it take to be all better?

4B. How many days or weeks after the appointment was it all better?

4C. Would you say that this time frame is exact or approximate?

o exact

 \circ approximate

4D. If it's easier, thinking back from today, how many days or weeks ago

did you think the problem was all better? [Answer could be in days, weeks, or

a date.]

After patient answers 4A, or 4B, or 4C with enough clarity to determine

number of days - Go to Question 6.

5. Do you plan to see a provider (of any kind) again for this same skin problem?

Yes-GO to 5A

No - GO to 6

5A. What type of doctor will you see?

- □ Primary Care
- \Box Dermatologist
- \Box Other

5B. If other, what type?

6. Thank you. Now, I'd like to ask a couple of questions about you.



How old are you? _____

7. What is your sex?

- o male
- o female
- o other

After Question 7, Go to End call 1 or End call 2 depending on problem status.

End call 1: Patients who were "All Better"

Thank you for helping with this research. I have all I need and won't need to call you again. Do you have any questions or comments? (Record if any)_____ Thank you for your participation. Goodbye.

End call 2: Patients who were improved unchanged or worse.

We're coming to the end of questions today. I'll call you again in about 4 weeks to see if

anything about the skin problem has changed. Thank you for your participation.

60 Day or Second Patient Telephone Interview

1. Hello (patient's first name) (patient's last name). This is (caller name) from the UVM Medical Center research on skin problems. We spoke with you a month ago about a skin problem you saw Dr. (provider name) for. Do you remember talking with us?

o No

2. When we spoke with you before, you described the problem as (problem status:

Improved, Unchanged or Worse). Does that sound right?



o Yes

YesNo

3. Since I (or team member name) spoke with you before on (date of call) about the skin problem visit, have you gone back to Dr. (provider name) or any other provider for this same problem?

- Yes --- GO 3A and 3B
- \circ No Go to 4

3A. Since we spoke with you last time, how many appointments have you had for this

same problem? _____

3B. What type of doctor did you see for this appointment(s)?

- □ Primary Care
- □ Dermatologist
- \Box Other

If other, what type?

4. Since that (First) visit with Dr. (provider name) and our conversation last month would

you say the condition is:

- All Better --- If all better, go to 4A,4B, or 4C,4D
- Improved ---Go to 5
- Unchanged ---Go to 5
- Worse ---Go to 5

4A. When did you realize the skin problem was all better? (Look at calendar try to

approximate days after call.)

4B. Looking at a calendar, that was about (day/date) about ____(days Time) after we talked



4C. If it's easier, thinking back from today, can you recall how long ago you realized

the problem was all better? When was that?

4D. Would you say that number of days is exact or approximate?

- Exact number of days
- Approximate number of days

After determining the days since index visit or date (all better), GO to End Call 1

- 5. Do you plan to see a doctor or health care provider again for this condition?
 - \circ Yes Go to 5A
 - No Go to End Call 2

5A. What type of doctor are you planning to see next?

- □ Primary Care
- □ Dermatologist
- \Box Other

If other, what type?

Go to End Call 2

End Call 1: Thank you for helping with this research.

I have all I need and won't need to call you again. Do you have any questions or

comments?

End Call 2: We're coming to the end of questions today. I'll call you again in about 4

weeks to see if anything about the skin problem has changed.

90 Day (Final) Patient Questionnaire



Hello (patient's first name) I'm calling from the University of Vermont Medical Center about the skin problems study.

I (or one of my team members called you about (3 or 4) weeks ago with questions about what happened with a skin problem you saw doctor (provider name) for.

1. Do you remember?

o Yes

o No

2. When we spoke with you before said the problem was... INTERVIEWER SAYS

WHICH (improved, unchanged, or worse) Does that sound right?

- o Yes
- o No

3. Since I (my team member) spoke with you before (4 weeks ago) (date of call) about

your skin problem visit, have you gone back to any other doctor or provider for this same

problem?

- Yes -- GO to 3A-C
- \circ No -- GO to 4

3A. How many follow up appointments?

3B. What type of doctor did you see for this appointment(s)?

- □ Primary Care
- □ Dermatologist
- \Box Other

3C. If other, what type?

4. I'm going to ask you how the skin problem is doing.

Since that first visit with Dr. (provider name) and our conversation last

month would you say the condition is:



- All Better GO to 4A-D
- Improved –GO to 5
- \circ Unchanged GO to 5
- \circ Worse GO to 5

4A. So about when did you realize the skin problem was all better?

4B. Looking at a calendar, that was about (suggest day/date) That was about

____(Time) after we talked.

4C. If it's easier, thinking back from today, can you recall how long ago you

realized the problem was all better? When was that?

4D. Would you say that number of days is exact or approximate?

- o exact
- o approximate

GO to 5 End Call

5. End Call (All):

We have come to the end of the call and your participation in the study. Thank you so

much for your help. Do you have any questions or comments before we end the call?

(Record comments if any)_____

Again, thank you very much. Goodbye



Appendix V: Schema of Themes with Exemplar Quotations and Relevant Behavioral Step and Barrier or Facilitator Effect

| Theme | PCP Exemplar Quotations (Years in Practice) | Step#: Effect |
|--------------------------------------|--|---------------------------------|
| Knowledge confidence | "There were a lot of patients where I felt comfortable with what the problem was." PCP11 (24 yrs.) | S1: Barrier |
| Attitude and Intention | "I think I used it close to every time I saw a skin problem, unless it was super obviousBut even then, I would use it to get treatment recommendations. PCP08 (3 yrs.) | S2: Facilitator |
| Time | "When you are already 45 minutes behind schedule and someone comes in with an [odd] rash, "It's easy to say, I think it's this, try it, if it doesn't work call me back". PCP10 (22 yrs.) | S1, S2 Barrier |
| Other sources | "I was next to a skilled older practitioner so my first recourse might be to go to him. So that may have decreased my use" PCP09 (4 yrs.) | S2: Barrier |
| Other sources | "I have a favorite dermatology book I use like I would use VisualDx." PCP10 (22 yrs.) | S5: Barrier |
| Other sources | "If I knew what the [diagnosis] was but didn't know how to manage it, I might use UpToDate [more]." PCP11 (24 yrs.) | S5: Barrier |
| Technology: EMR access | "If I'm seeing patients, I'm already in the EMR, and VisualDx is there. It's easy to find. 99% of the time that's what I'd do." PCP11 (24yrs.) | S3: Facilitator |
| Technology: CET interface | "I remember staring at it saying, "Where do I put the information in?" So it wasn't as user friendly for data input" PCP10 (22yrs.) | S4: Barrier |
| Diagnosis: expand differential | "I did, on a few occasions have no idea what I was looking at in a patient, and used [VisualDx]to figure it out" PCP08 (3 yrs.) | S5: Facilitator (Benefit) |
| Diagnosis: confirm | "I can definitely say it helped me feel more confident about a diagnosis." PCP02 (32 yrs.) | S5: Facilitator (Benefit) |
| Usefulness: Irrelevance | "If you put basal cell carcinoma in VisualDx, it's a thousand pictures of every possible way it can show up. It's not showing the typical ones" PCP03 (34 yrs.) | S5 Barrier |
| Patient communication | "I used it with patients, especially if they had something that went away; then they could say," Oh, it did look like that". Helpful for patient communication? Absolutely." PCP04 (17 yrs.) | S6 (Facilitator) Benefit |
| Patient agreement | "I would open it up in the patient room oftentimes, and go through it [all] with them." PCP06 (4yrs.) | S6 (Facilitator) Benefit |
| Usefulness: No Difference | I can't think of a particular instance where it clinched it for me or made a clinical decision distinction or difference. It was more of a tool that I used to augment whatever I was looking into." PCP09 (4 yrs.) | S5, S6 Barrier |

