



Integrating Pattern Matching and Active Thinking Support in Information Displays for Clinicians

Introduction - Charlene R. Weir, PhD

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VA Salt Lake City

IDEAS Center

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VA Salt Lake Informatics,
Decision-Enhancement And
Analytic Sciences Center



Defining
EXCELLENCE
in the 21st Century

Theory and Innovation in Cognitive Support for Health Care Decision-Making



VA Salt Lake City Informatics, Decision-Enhancement, and Analytic Sciences (IDEAS) Center



Cyber Seminar Mini-Series

- **Session 1:** "Implicit and Explicit Cognition in Crossing the Consciousness Divide"
- **Session 2:** Today "Integrating Dual Process Implications into Implementation of Cognitive Support Designs in the Clinical Setting"
- **Session 3:** "Integrating Pattern Matching and Active Thinking Support in Information Displays for Clinicians"

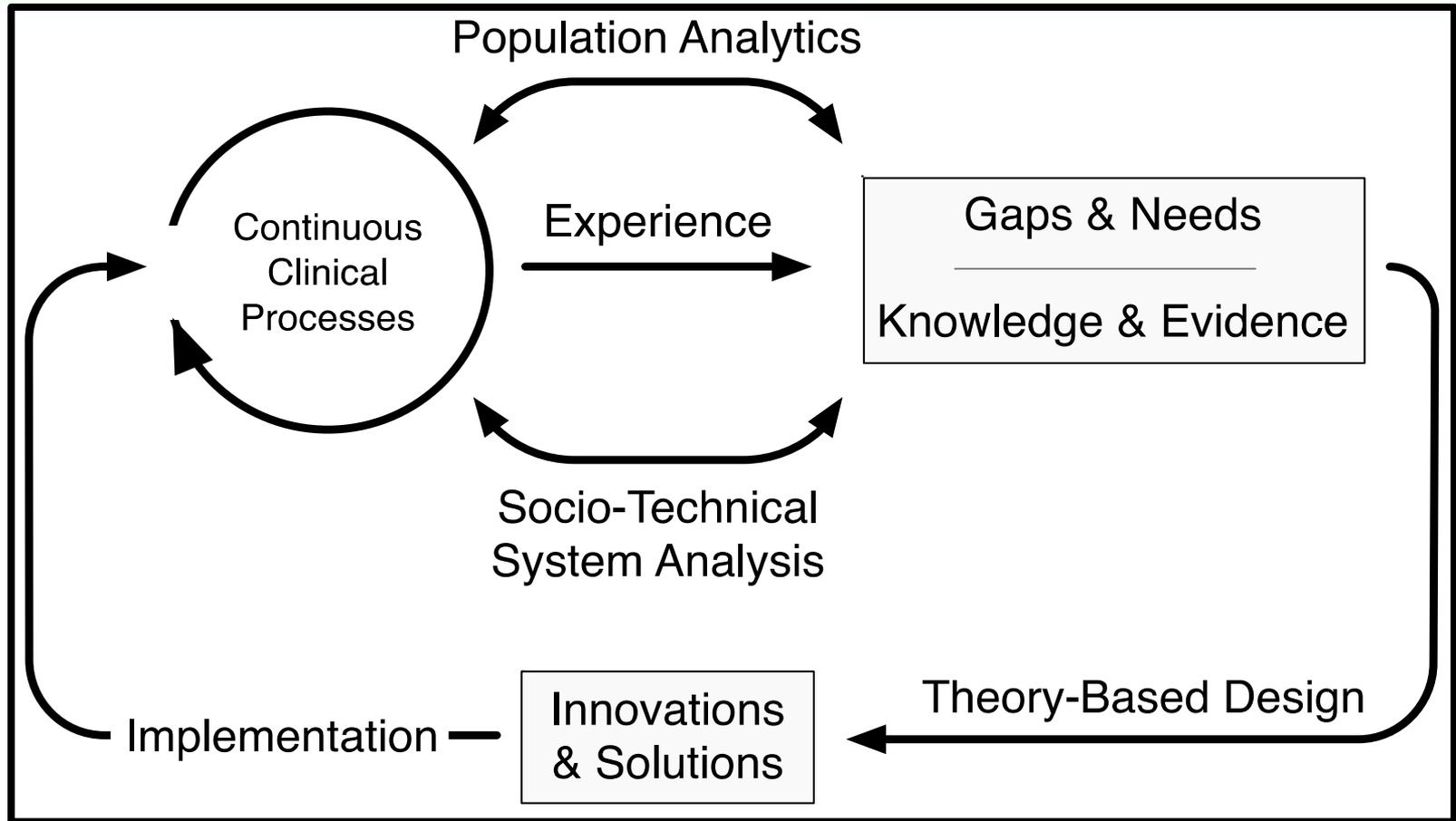
Today's Articles

- ❑ **Translation of Contextual Control Model to chronic disease management: A paradigm to guide design of cognitive support systems.** Molly Leecaster, Charlene Weir, Frank Drews, James Hellewell, Daniel Bolton, Makoto Jones, Jonathan Nebeker
- ❑ **Physicians perception of alternate displays of clinical research evidence for clinical decision support – A study with case vignettes.** Stacie Slager, Charlene Weir, Heejun Kim, Javed Mostafta, Guilherme Del Fiol

Session 3: Integrating Pattern Matching and Active Thinking Support in Displays for Clinicians

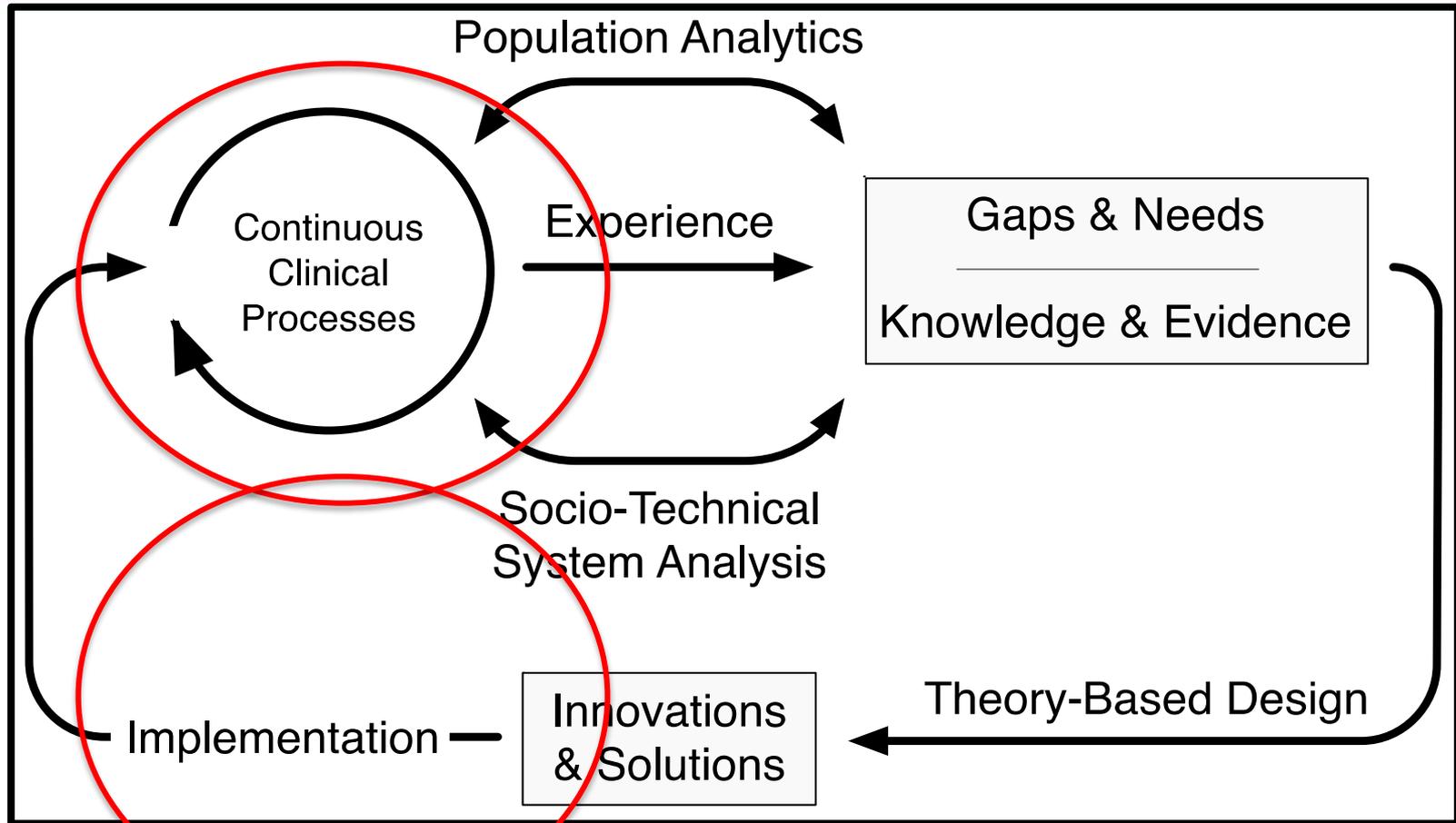
- These two articles are about bridging the gap between the automatic processes of System 1 and the directive efforts of System 2.**
 - Alerting and triggering attention
 - Minimize attention grabbers (interrupters) to time and place
 - Maximize control
- People are continuously regulating and controlling their environment in order to minimize cognitive load – we need to support this effort**

Theory-Inspired Design



Conceptual Framework for IDEAS Research

Theory-Inspired Design



Conceptual Framework for IDEAS Research

JBI Supplement Link

<http://www.sciencedirect.com/science/journal/15320464/71/supp/S>

Journal of Biomedical Informatics

Supplement Articles

1. Modeling the mind: How do we design effective decision-support? ([Editorial](#))
2. Checking the lists: A systematic review of electronic checklist use in health care ([Review](#))
3. Identifying complexity in infectious diseases inpatient settings: An observation study
4. Think twice: A cognitive perspective of an antibiotic timeout intervention to improve antibiotic use
5. Making cognitive decision support work: Facilitating adoption, knowledge and behavior change through QI
6. Detecting the presence of an indwelling urinary catheter and urinary symptoms in hospitalized patients using natural language processing
7. Veterans Like Me: Formative evaluation of a patient decision aid design
8. Physicians' perception of alternative displays of clinical research evidence for clinical decision support – A study with case vignettes
9. Translation of Contextual Control Model to chronic disease management: A paradigm to guide design of cognitive support systems
10. A pilot study of a heuristic algorithm for novel template identification from VA electronic medical record text



Translation of Contextual Control Model to chronic disease management: A paradigm to guide design of cognitive support systems

Jonathan Nebeker, MD, MS

Chief Medical Informatics Officer, VA EHR Modernization
Professor, University of Utah School of Medicine

VA SLC HSR&D Center for Innovation

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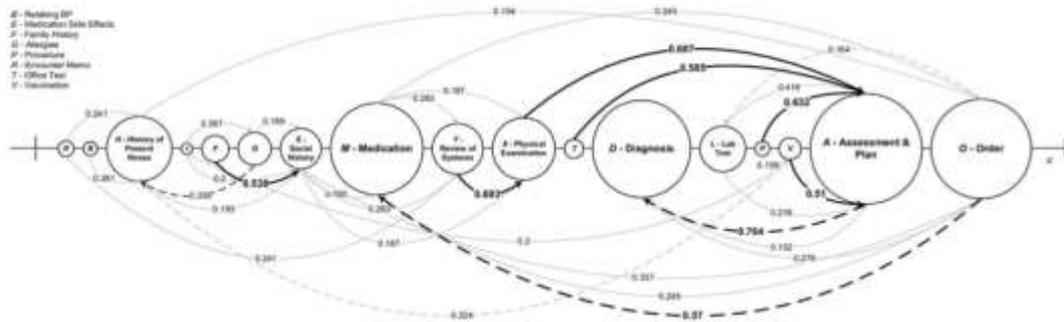


Seamless care and Information system support

- Seamless care is the experience patients and providers have moving from task to task and encounter to encounter within or between organizations such that high-quality decisions form easily and complete care plans execute smoothly.
- Information systems support the seamless-care

234

ZHENG ET AL., Analysis of User Interactions with EHR System



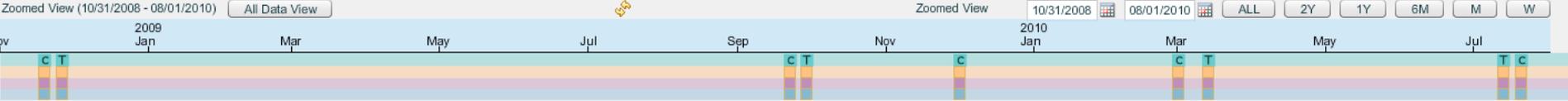
expe
data
asks

rpreting
d managing

IMM Interface

doctor1 | End Sessi... | Preferences | Patient06, Firstname | Id: 00009 | 55 yo F, 2/2/1957 | PCP: doctor1, MD | Alt: doctor2, MD | Current: doctor1, MD | Role: Attending Physician

IMM - Login date 08/01/2010 16:12:26 - THIS DATE IS NOT THE CURRENT DATE - CC: symptomatic hypoglycemia



Relationships | Notes | Notelets | Labs

100%

Interventions + ADE

Sort: Condition

Active Only

- Glyburide 2.5 mg PO daily 20m
- Lisinopril 40 mg PO daily 5m
- Chlorthalidone 25 mg PO ... 5m
- Calcium carbonate 500 m... 20m
- Ergocalciferol 1000 units ... 20m
- Levothyroxine 125 mcg P... 20m
- Venlafaxine 75 mg PO BID 20m
- Simvastatin 80 mg PO daily 20m
- ? Aspirin 81 mg PO daily 20m

Conditions +

Sort: Drag-and-Drop Priori

Active Only

- DM, type II 5m
- HTN** 5m
- Osteopenia 20m
- Hypothyroidism, posto... 5m
- Depression 5m
- Hyperlipidemia 10m

Observations +

Sort: Panel

Active Only

- SBP 128 12d
- DBP 69 12d
- Pulse 70 12d
- POx 97 12d
- Temp 98.6 12d
- RR 14 12d
- Weight 260 12d
- BMI 45 12d
- Glucose 70 12d
- Potassium 5.1 12d
- Creatinine 1.8 12d
- HbA1c 7.1 12d
- Microalbum... 8 12d
- AST 30 12d
- HDL 56 12d
- LDL 58 12d
- TSH 3.2 12d
- Light-head... 0 12d
- PHO-9 1 12d



Poll Question #1

What is your primary role in VA?

- Student, trainee, or fellow
- Clinician
- Researcher
- Administrator, manager or policy-maker
- Other

Outline for Today's Discussion

- What does “cognitive support” mean?
- Models: Dual Process Perspective and Contextual Control Models (COCOM)
- Study Aims and Objectives
- Methods
- Results
- Discussion
- Implications for EHR

What Does “Cognitive Support” Mean?

Pattern-Matching/ Gist /Situation Awareness

- Reorganization/display of data based on task goals
- Summary data over time / event-based data summaries

Attention Regulation

- Risk highlighted
- Tools to control attentional resources (e.g. stickies)

Communication /Coordination

- Shared situation awareness
- Transactional memory (we know what others do)

Support for Action / Behavior

- Specific behavior is automatically elicited by environmental cues
- Tools for action are embedded in workflow and EMR

Poll Question 2

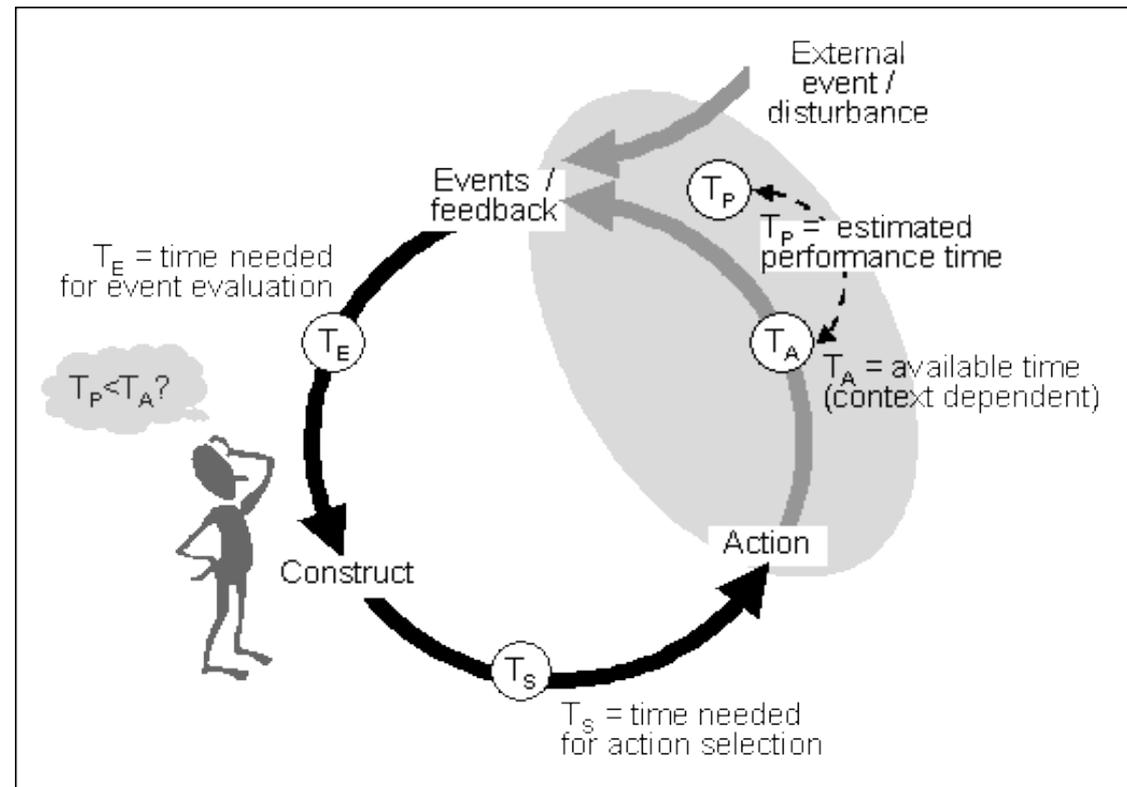
What is your experience with decision support in EHR's?

- I Use EHR's but not familiar with any decision support
- I am aware of algorithms that assist in EHR decision support
- I use links electronic links when using EHR's
- I modify templates to better support my use of EHR's
- I am non Clinical

Hollnagel's Contextual Control Model (COCOM)

Effectiveness in a system is reflected in “orderliness”:

1. Goal integration
2. Broad time horizon
3. Uncertainty management
4. Decision heuristics
5. Customizing action plan to the current situation
6. Iterative Adaptiveness



<http://erikhollnagel.com/ideas/cocom.html>

Contextual Control Model (Adapted)

Aim to discover high-leverage control characteristics

Control Mode	Goal interactions	Time horizon considered	Assessment of uncertainty	Decision heuristics
Strategic	Higher-level goals and interactions considered	Broad into past and future (feed forward)	Recognition and explanation of uncertainty	Adaptation of guidelines to situation, planning, consideration of dependencies
Tactical	Focus on defined, individual goals	Broad into past, minimal projections	Recognition	Guidelines, limited planning
Opportunistic	Poorly defined goals	Present	Limited recognition	Habits, pattern recognition
Scrambled	Lack of consideration	Immediate	None	Random

Aims and Objectives

- To validate a measurement model of COCOM using hypertension management

Hypotheses:

- Emergent Modes of Control = Attributed Modes of Control
- Modes of Control (levels) would be associated with:
 - Time pressures
 - Expertise and familiarity with patient
 - Increased motivation (e.g. deviation from BP control)

METHODS

Settings: Five US VA Medical Centers

Participants: 35 ordering providers seeing a patient with hypertension

Procedures:

- Think-aloud prior to primary care visit
- Observation and audio-taping during visit (counting screen changes)
- Post-visit interview
- Coding of transcripts for level of control
- Coding of transcripts for quality of hypertension management

Measurements:

- Think-aloud prior to primary care visit
- Observation and audio-taping during visit (counting screen changes)
- Post-visit interview

Two forms of assessing Modes of Control: Attributes and Emergent

Emergent mode of control derived from coding of specific control characteristics:

- Deviations from goal
 - Time horizon
 - Uncertainty addressed
 - Model Expectations
 - Goal Interaction
 - Plan specification
- **Attributed mode of control** were generalized control rating of whole visit (Scrambled, Opportunistic, Tactical and Strategic)

ANALYSIS

- Reliability testing for Control Modes coding protocols
- Hypertension deviations from goal (proxy for decision-making difficulty)

Association of Control Characteristics with Control Modes

- With formal coding
- Emergent clustering based on relationships between the data

RESULTS

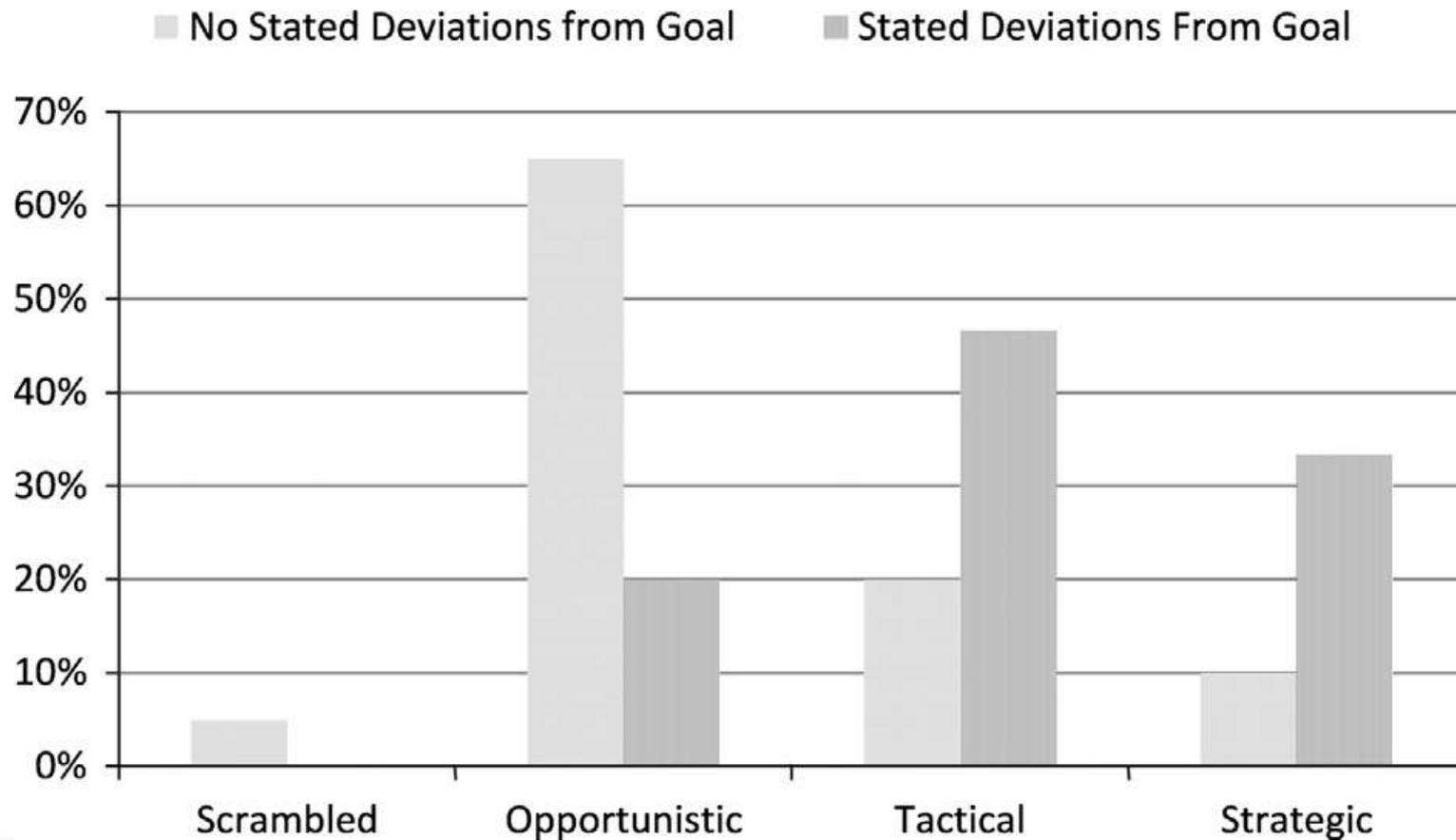
High inter-coder reliability

- Kappa Free 0.78-0.89 for binary items and 0.51-0.81 for scaled items.
- ICC for scaled items 0.79-0.93

Descriptive analysis by

- % **Stated** deviation from hypertension goals – 43%;
- % **No** stated deviation from hypertension goals – 57%
- **Emergent Levels:**
 - Opportunistic
 - Tactical
 - Strategic

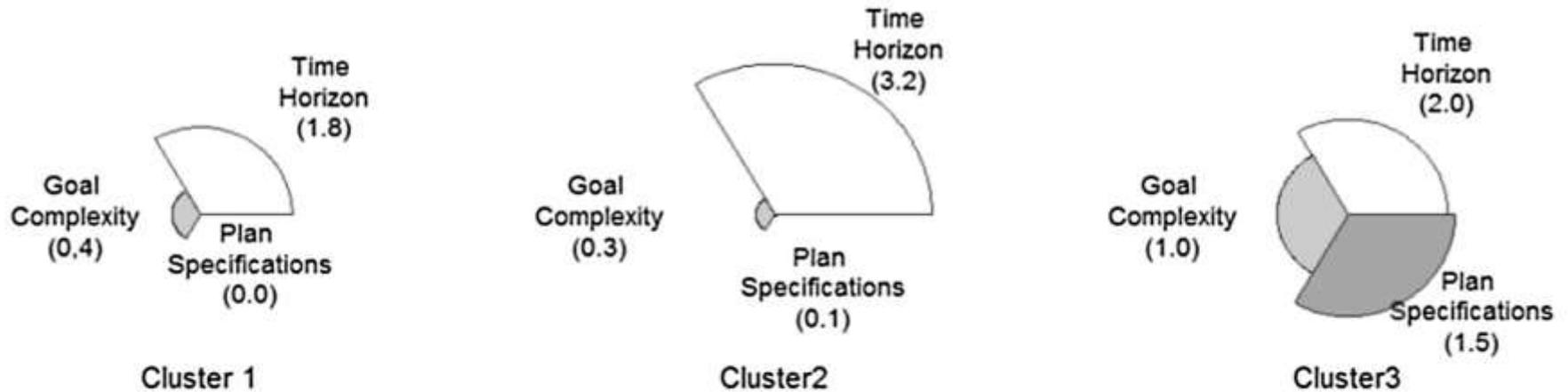
RESULTS



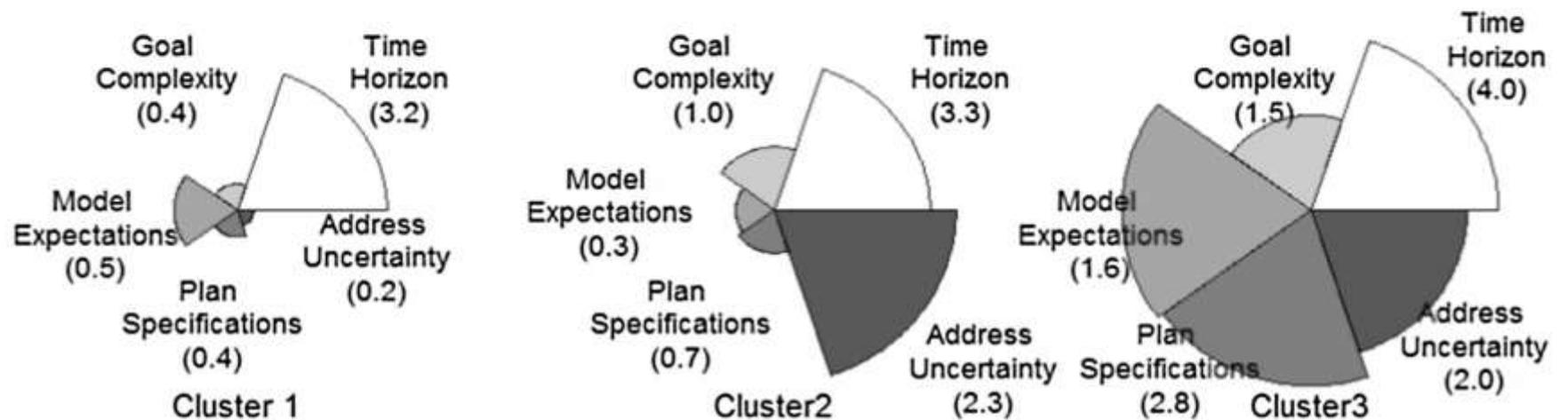
RESULTS: Relationship between visit characteristics and Modes (table 7)

- Nothing to see here
 - Time Pressure
 - Years of Experience
 - Expertise
 - Familiarity
 - Motivation

Encounters without Stated Deviations



Encounters with Stated Deviations



Implications for EHR Design

- Control characteristics are visible with patients who have goal deviations
- Most visits are in the opportunistic or tactical range (not optimal)
- Clinicians need more adaptive control over their information environment for searching, sorting, thinking and linking information across domains
- Current EHR systems constrain these inquiries

Thank you

Translation of Contextual Control Model to chronic disease management: A paradigm to guide design of cognitive support systems Molly Leecaster, Charlene Weir, Frank Drews, James Hellewell, Daniel Bolton, Makoto Jones, Jonathan Nebeker. Journal of Biomedical Informatics July 2017, S60-67.



Physicians' perception of alternative displays of clinical research evidence for clinical decision support

Stacey Slager, MS

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Poll Question #1

- What is your primary role in VA?
 - Student, trainee, or fellow
 - Clinician
 - Researcher
 - Administrator, manager or policy-maker
 - Other

Introduction and Background

- Goal of biomedical research to aid in evidence-based decision making in healthcare
- Clinicians often raise questions that go unanswered
- Large and evolving body of primary medical literature
- Alternate sources that synthesize medical literature may not address problem
- Searching for evidence cognitively tasking and prohibitive
- Research studies are written for researchers, not for clinicians
- Need tools that can improve clinician's ability to scan, identify, and interpret relevant work for specific patients

Decision Support for Information Seeking

- How to best display clinical literature in a way that minimizes cognitive burden and time for clinicians?

Information Foraging Theory

- Humans look for ‘patches’ of information
- We will stay in fruitful information patches and leave barren patches behind
- We adopted two strategies
 - Maximize cues (information scent)
 - Apply information patch enrichment

PICO framework

- PICO (Population, Intervention, Comparison, Outcome) adopted for evidence-based medicine since the 90s
- Clinicians recommended to use PICO for patient-specific clinical questions
- Abstracts in biomedical journals do NOT follow PICO, conflict in mental model

Vernakalant hydrochloride: A novel atrial-selective agent for the cardioversion of recent-onset atrial fibrillation in the emergency department. <i>Acad Emerg Med.</i> 2010.			
Population	Primary Outcome	Study arm/results	Conclusion
Adults with recent-onset AF (> 3 to <= 48 hours) presenting to the ED (n=290)	Conversion to sinus rhythm within 90 minutes	59.4% vernakalant vs. 4.9% placebo	Vernakalant rapidly converted recent-onset AF to sinus rhythm in over half of patients, was well tolerated, and has the potential to offer an important therapeutic option for rhythm control of recent-onset AF in the ED.

Pharmacokinetics of novel atrial-selective antiarrhythmic agent vernakalant hydrochloride injection (RSD1235): influence of CYP2D6 expression and other factors. <i>J Clin Pharmacol.</i> 2009.			
Healthy volunteers and patients with atrial fibrillation or atrial flutter	Maximum plasma concentration	Little difference in vernakalant maximum plasma concentration or area under the plasma concentration-time curve from the start of the first infusion to 90 minutes between CYP2D6 poor metabolizers and extensive metabolizers.	Gender, age, and renal function did not have a clinically significant influence on the pharmacokinetics of vernakalant. An assessment of CYP2D6 expression may not be needed when vernakalant is administered acutely and intravenously to patients with atrial fibrillation.

Usefulness of vernakalant hydrochloride injection for rapid conversion of atrial fibrillation. <i>Am J Cardiol.</i> 2010.			
AF or atrial flutter with arrhythmia duration of >3 hours to <=45 days (n=276)	Conversion of AF to SR	39.8% vernakalant vs. 3.3% placebo (p<0.0001) Transient dysgeusia and sneezing were the most common adverse events.	Vernakalant demonstrated a rapid and high rate of conversion for short-duration AF and was well tolerated.

Effect of dietary fish oil on atrial fibrillation after cardiac surgery. <i>Am J Cardiol.</i> 2011.			
Postsurgical AF after CABG and valve procedures (n=200)	Incidence of AF in the first 6 days after surgery	47 of 97 in the control group vs. 36 of 97 in the fish oil group developed AF (OR 0.63, 95% CI 0.35 to 1.11)	Supplementation with dietary fish oil did not result in a significant decrease in the incidence of postsurgical AF. However, there was a significant decrease in time spent in the intensive care unit.

A randomized active-controlled study comparing the efficacy and safety of vernakalant to amiodarone in recent-onset atrial fibrillation. <i>J Am Coll Cardiol.</i> 2011.			
Adult patients with AF (3 to 48 h duration) eligible for cardioversion (n=254)	Conversion from AF to sinus rhythm within the first 90 min	60 of 116 (51.7%) vernakalant vs. 6 of 116 (5.2%) amiodarone (p < 0.0001).	Vernakalant demonstrated efficacy superior to amiodarone for acute conversion of recent-onset AF. Both vernakalant and amiodarone were safe and well tolerated in this study.

- Presented studies from PubMed's Clinical Queries filter

Clinical Vignettes

- Created three clinical vignettes
 - Atrial fibrillation
 - Heart failure
 - Diabetes mellitus

AFIB

58 year old male with recent onset AFIB who shows at the ED with an acute episode. You are considering vernakalant as an option to cardiovert this patient and would like to review the evidence on its efficacy and safety.

Please click the link below to find the information you need, then return to this survey.

Atrial Fibrillation

Recruitment

- 20 participants invited by email
- Targeted practicing primary care and internal medicine physicians
- 2-25+ years of experience
- Purposive sample, snowball

Methods

- After reading vignette, view information display and complete brief questionnaire in REDCap
- Within-subject design, each participant looked at three displays with one of the vignettes
 - Example
 - Display 1 – PubMed – afib
 - Display 2 – narrative summary - diabetes
 - Diabetes Display 3 - table format - heart failure
- Vignette-display pairs and order of presentation were randomized
- Participants blinded to study goals

Evaluation and Results

- Questions in our survey included some from SUS, rated on a 1-7 Likert scale
 - Self-perceived ability to understand user interface features
 - Quickly scan and determine relevancy
 - Interpret the studies presented
 - Satisfaction
- Usefulness of information contained in PICO table

Table 2

Usefulness of different types of information presented in the PICO tabular display (1 = not at all useful, 5 = very useful).

Item	Mean ± standard deviation
Patient population	4.8 ± 0.4
Patient age	4.6 ± 1.0
Sample size	4.4 ± 1.1
Study arm	4.7 ± 0.6
Primary outcome	4.9 ± 0.3
Primary outcome results	4.9 ± 0.5
Conclusion	4.9 ± 0.4

Results of Display comparisons

- PICO table format most highly rated across all single-item questions

Table 1

Physicians' ratings of the three information displays. All ratings use a Likert scale 1 (strongly disagree) to 7 (strongly agree).

Criteria	PubMed	Narrative summary	PICO table	F score	P value /adjusted (0.05)
	Mean ± standard deviation				
Q1. It was easy to understand the meaning of the information presented.	4.4 ± 1.7	5.8 ± 1.2	5.9 ± 1.2	6.0	0.008/0.05
Q2. I think that I would like to use this product frequently.	3.6 ± 1.76	5.6 ± 1.3	5.9 ± 1.3	16.8	<0.001/0.05
Q3. I was able to scan the information quickly.	3.5 ± 1.8	5.8 ± 1.2	6.0 ± 1.3	18.6	<0.001/0.05
Q4. I was able to quickly determine relevance of the study for my patient.	4.2 ± 1.7	5.3 ± 1.3	6.1 ± 1.1	6.0	0.008/0.05
Q5. It was easy for me to locate the information about the study that I needed.	3.0 ± 1.2	4.6 ± 1.7	5.2 ± 1.6	8.5	0.002/0.05
Q6. I thought that this product was easy to use.	4.1 ± 1.6	6.0 ± 1.4	6.2 ± 1.2	15.9	<0.001/0.05
Q7. I was able to find the pieces of information I needed to understand the study.	4.2 ± 1.8	5.6 ± 1.2	6.2 ± 1.0	19.7	<0.001/0.05
Q8. I would imagine that most people would learn to use this product quickly.	4.9 ± 1.5	5.6 ± 1.5	6.1 ± 1.2	8.0	0.002/0.05
Q9. I was able to quickly grasp the gist of the paper's findings.	3.7 ± 1.9	5.6 ± 1.1	6.1 ± 1.0	13.1	<0.001/0.05
Q10. I found this product very awkward to use. (reversed question)	3.8 ± 1.8	5.4 ± 1.5	5.7 ± 1.4	4.4	0.02/NS
Q11. In general, I am satisfied with the presentation (i.e., format of the display) of the information.	3.7 ± 1.6	5.4 ± 1.3	5.7 ± 1.3	13.9	<0.001/0.05
Average and standard deviation of all items (after reversing the scale of negative criteria)	3.9 ± 0.5	5.4 ± 0.4	5.9 ± 0.3	N/A	N/A

Selected open-ended comments from users

- ***Q: In the tabular display, we have included information on patient population, age, sample size, study arms, outcomes, and conclusions. Is there enough information here for you to be able to make a clinical decision about the patient?***
 - *Yes... It was so much faster*
 - *This is generally enough*
 - *Generally, yes*
 - *There was a lot of information at first. After using it a few times it would probably be quite a bit easier to understand it quickly*

- ***Other types of information that could be included***

Discussion

- By optimizing the information patches using the PICO framework, users were satisfied with the table format
- Table format reduces cognitive effort
- PICO format is widely used and matches clinicians' information-seeking mental model
- Studies have shown clinicians spend only 2-3 minutes looking for information
- Rapid relevance judgement most important design consideration
- Finding the gist of a study an important feature

Poll Question #2

- What do you think are the most critical barriers to clinicians' use of the med literature to help guide patient care decisions (select all that apply)?
 - Clinicians prefer to rely on their own expertise
 - Clinicians' lack of time / busy workflow
 - Perception that evidence is not available
 - Evidence in primary studies is difficult to interpret
 - Med literature format doesn't match clinicians' mental model

Research update

- Evolution to fully interactive prototype
- Formative evaluation with case vignettes
 - P: 20 primary care physicians
 - I&C: RCTcomp vs. PubMed
 - O: efficacy, effort, efficiency, usability
 - Within-subjects design, randomized order and vignette assignment

When comparing the two formats used in the study, I was able to:

		PubMed is much better				Neutral The same				RCTcomp is much better
13)	Scan the information quickly <i>* must provide value</i>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14)	Comprehend the meaning well of the information presented <i>* must provide value</i>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15)	Spend the least degree of mental effort <i>* must provide value</i>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16)	Quickly obtain the gist of the study findings <i>* must provide value</i>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17)	Be satisfied with the presentation (i.e., format of the display) of the information <i>* must provide value</i>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18)	Locate information rapidly <i>* must provide value</i>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19)	Identify relevant information to understand the study <i>* must provide value</i>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20)	Effectively identify relevant RCTs from the search results <i>* must provide value</i>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21)	Interpret individual RCT results quickly <i>* must provide value</i>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

DISPLAY FORMAT: Article list ▾

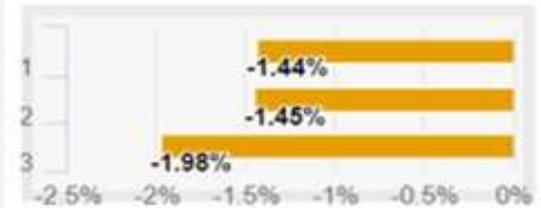
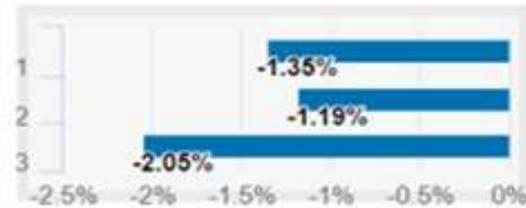
(MAIN MENU)

SELECT	TITLE	POPULATION	STUDY_ARMS
<input checked="" type="checkbox"/>	Efficacy and safety of vildagliptin in patients with type 2 diabetes mellitus inadequately controlled with dual combination of metformin and sulphonylurea.	Type 2 diabetes mellitus (DM2) on Metformin (1500 mg/day or more) plus Glimepiride (4mg/day or more)	<ol style="list-style-type: none"> 1. Placebo 2. Vildagliptin 50 mg Twice Daily + Metformin 1500 mg/day or more + Glimepiride 4 mg/day or more
<input checked="" type="checkbox"/>	Dapagliflozin, Metformin XR, or both: initial pharmacotherapy for Type 2 Diabetes, a randomised control trial (*This study includes two trials)	DM2 with hemoglobin A1c (HbA1c) 7.5-12%	<p>Trial One:</p> <ol style="list-style-type: none"> 1. Metformin 500mg Twice Daily + Placebo 2. Dapagliflozin 5mg Daily + Placebo 3. Dapagliflozin 5mg Daily + Metformin XR <p>Trial Two:</p> <ol style="list-style-type: none"> 1. Metformin 500mg Twice Daily + Placebo 2. Dapagliflozin 10mg Daily + Placebo 3. Dapagliflozin 10mg Daily + Metformin XR
<input checked="" type="checkbox"/>	Twice-daily dapagliflozin co-administered with metformin in type 2 diabetes: a 16-week randomized, placebo-controlled clinical trial	DM2 on Metformin (1500mg/day or more) HbA1c: 6.7 - 10.5%	<ol style="list-style-type: none"> 1. Placebo + Metformin 2. Dapagliflozin 10 mg Daily + Metformin 3. Dapagliflozin 5 mg Twice Daily + Metformin 4. Dapagliflozin 2.5 mg Twice Daily + Metformin
<input type="checkbox"/>	Efficacy and safety of liraglutide versus sitagliptin, both in combination with metformin, in Chinese patients with type 2 diabetes: a 26-week, open-label, randomised, active comparator clinical trial	DM2 on Metformin (1000mg/day or more) HbA1c: 7.0-10.0 %	<ol style="list-style-type: none"> 1. Liraglutide (inj) 1.8 mg Daily + Metformin 2. Sitagliptin 100mg Daily + Metformin
<input type="checkbox"/>	Long-term safety and efficacy of empagliflozin, sitagliptin, and metformin: an active-controlled, parallel-group, randomized, 78-week open-label extension study in patients with type 2 diabetes.	DM2 who completed one of 12 week double blind randomized controlled trial (DBRCT) HbA1c: 7-10 %	<ol style="list-style-type: none"> 1. Metformin 2. Empagliflozin 10 mg + Metformin 3. Empagliflozin 25 mg + Metformin 4. Sitagliptin + Metformin 5. Empagliflozin 10 mg

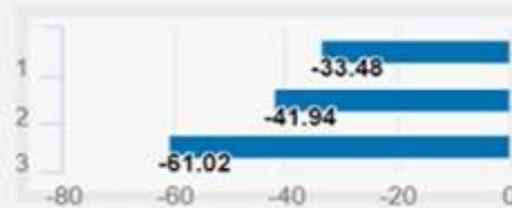
	Efficacy and safety of vildagliptin in patients with type 2 diabetes mellitus inadequately controlled with dual combinat... [Diab Obes Met, 2014]	Dapagliflozin, Metformin XR, or both... [Int Jn Ci Pr, 2012] (*Trial one of this study)	Dapagliflozin, Metformin XR, or both... [Int Jn Ci Pr, 2012] (*Trial two of this study)	Twice-daily dapagliflozin co-administered with metformin in type 2 diabetes... [Diab Obes Met, 2015]
POPULATION				
Inclusion Criteria	Type 2 diabetes mellitus (DM2) on Metformin (1500 mg/day or more) plus Glimepiride (4mg/day or more)	DM2 with hemoglobin A1c (HbA1c) 7.5-12%	DM2 with HbA1c 7.5-12%	DM2 on Metformin (1500mg/day or more) HbA1c: 6.7 - 10.5%
Sample Size (completed/randomized (%))	299/318 (94%)	518/603 (86%)	552/641 (86%)	370/400 (93%)
INTERVENTION				
Arm 1	Placebo	Metformin 500mg Twice Daily + Placebo	Metformin 500mg Twice Daily + Placebo	Placebo + Metformin
Arm 2	Vildagliptin 50 mg Twice Daily + Metformin 1500 mg/day or more + Glimepiride 4 mg/day or more	Dapagliflozin 5mg Daily + Placebo	Dapagliflozin 10mg Daily + Placebo	Dapagliflozin 10 mg Daily + Metformin
Arm 3 more		Dapagliflozin 5mg Daily + Metformin XR	Dapagliflozin 10mg Daily + Metformin XR	Dapagliflozin 5 mg Twice Daily + Metformin
RESULTS (Efficacy Chart)				
HbA1c (%)				
FPG (mg/dl)				
Weight Change (kg)				
Conclusion	Vildagliptin significantly improved glycaemic control in patients with T2DM inadequately controlled with metformin plus glimepiride combination. more	In treatment-naïve patients with T2D, dapagliflozin plus metformin was generally well tolerated and effective in reducing HbA1c, FPG and weight. more	In treatment-naïve patients with T2D, dapagliflozin plus metformin was generally well tolerated and effective in reducing HbA1c, FPG and weight. more	Dapagliflozin 2.5 or 5 mg twice daily added to metformin was effective in reducing glycaemic levels in patients with type 2 diabetes inadequately controlled with metformin alone. more
ADVERSE EFFECTS (Side Effects Chart)				
Overall Adverse Effect (AE) (%)				

RESULTS (Efficacy Chart)

HbA1c (%)



FPG (mg/dl)



Weight Change (kg)



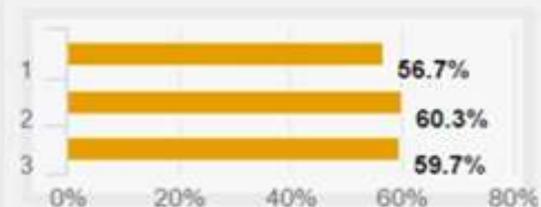
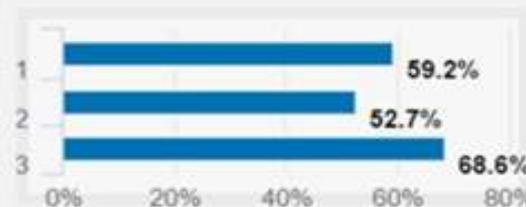
Conclusion

In treatment-naïve patients with T2D, dapagliflozin plus metformin was generally well tolerated and effective in reducing HbA1c, FPG and weight. [more](#)

In treatment-naïve patients with T2D, dapagliflozin plus metformin was generally well tolerated and effective in reducing HbA1c, FPG and weight. [more](#)

ADVERSE EFFECTS (Side Effects Chart)

Overall Adverse Effect (AE) (%)

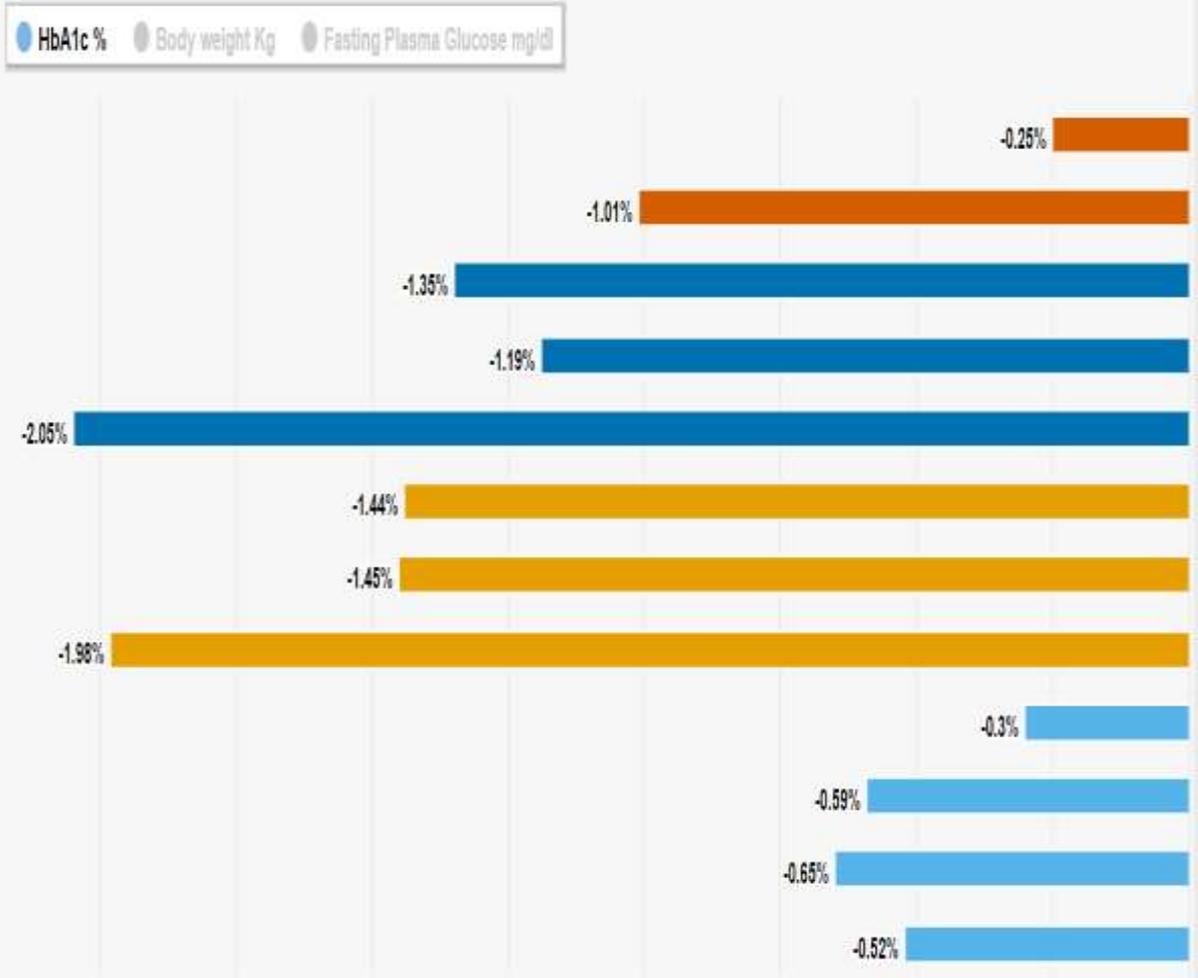


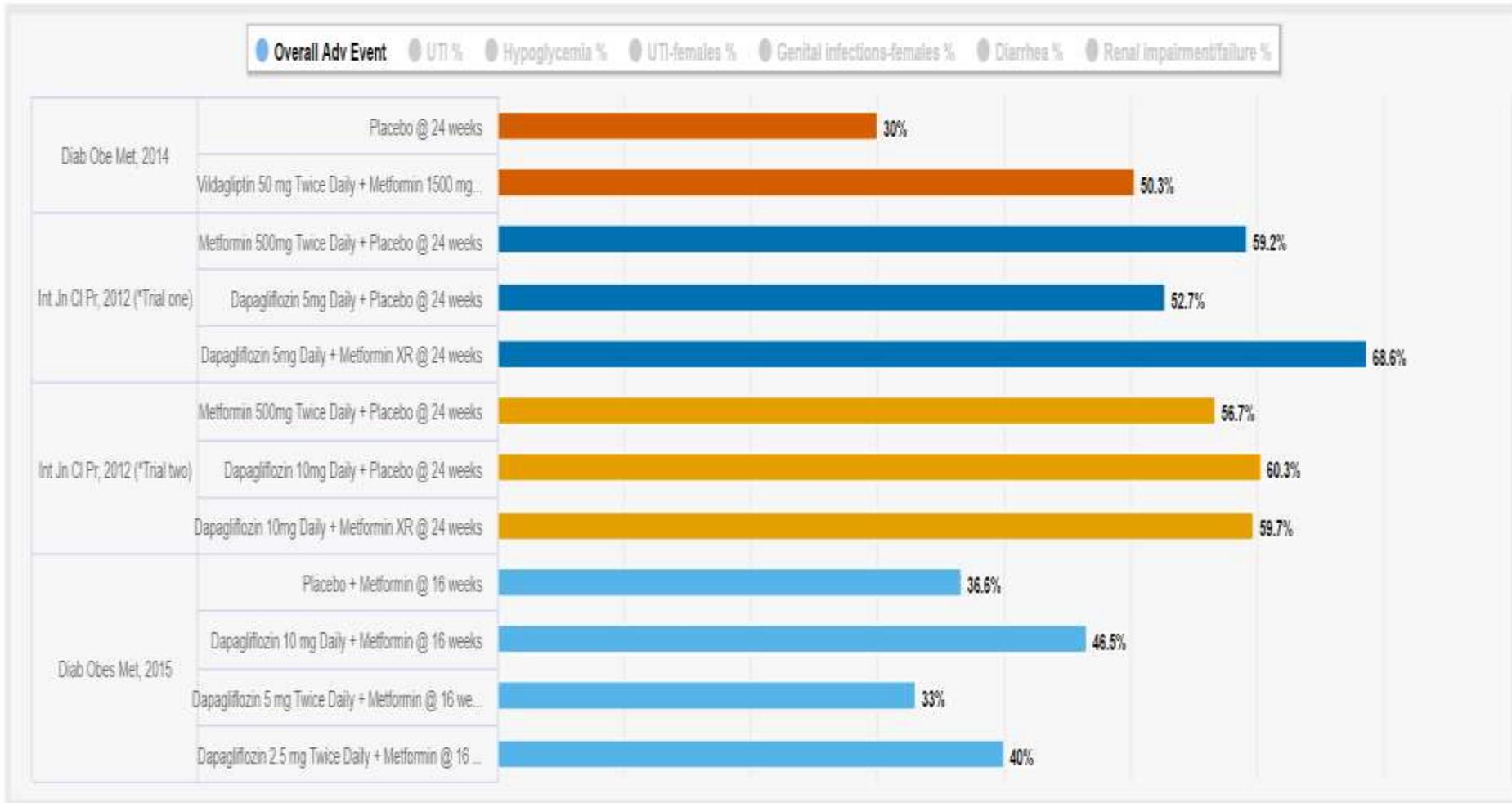
DISPLAY FORMAT: Efficacy graph ▾

(MAIN MENU)

[\(BACK TO TABLE VIEW\)](#)

Diab Obe Met, 2014	Placebo @ 24 weeks
	Vildagliptin 50 mg Twice Daily + Metformin 1500 mg...
Int. Jn Cl Pr, 2012 (*Trial one)	Metformin 500mg Twice Daily + Placebo @ 24 weeks
	Dapagliflozin 5mg Daily + Placebo @ 24 weeks
	Dapagliflozin 5mg Daily + Metformin XR @ 24 weeks
Int. Jn Cl Pr, 2012 (*Trial two)	Metformin 500mg Twice Daily + Placebo @ 24 weeks
	Dapagliflozin 10mg Daily + Placebo @ 24 weeks
	Dapagliflozin 10mg Daily + Metformin XR @ 24 weeks
Diab Obes Met, 2015	Placebo + Metformin @ 16 weeks
	Dapagliflozin 10 mg Daily + Metformin @ 16 weeks
	Dapagliflozin 5 mg Twice Daily + Metformin @ 16 we...
	Dapagliflozin 2.5 mg Twice Daily + Metformin @ 16 ...



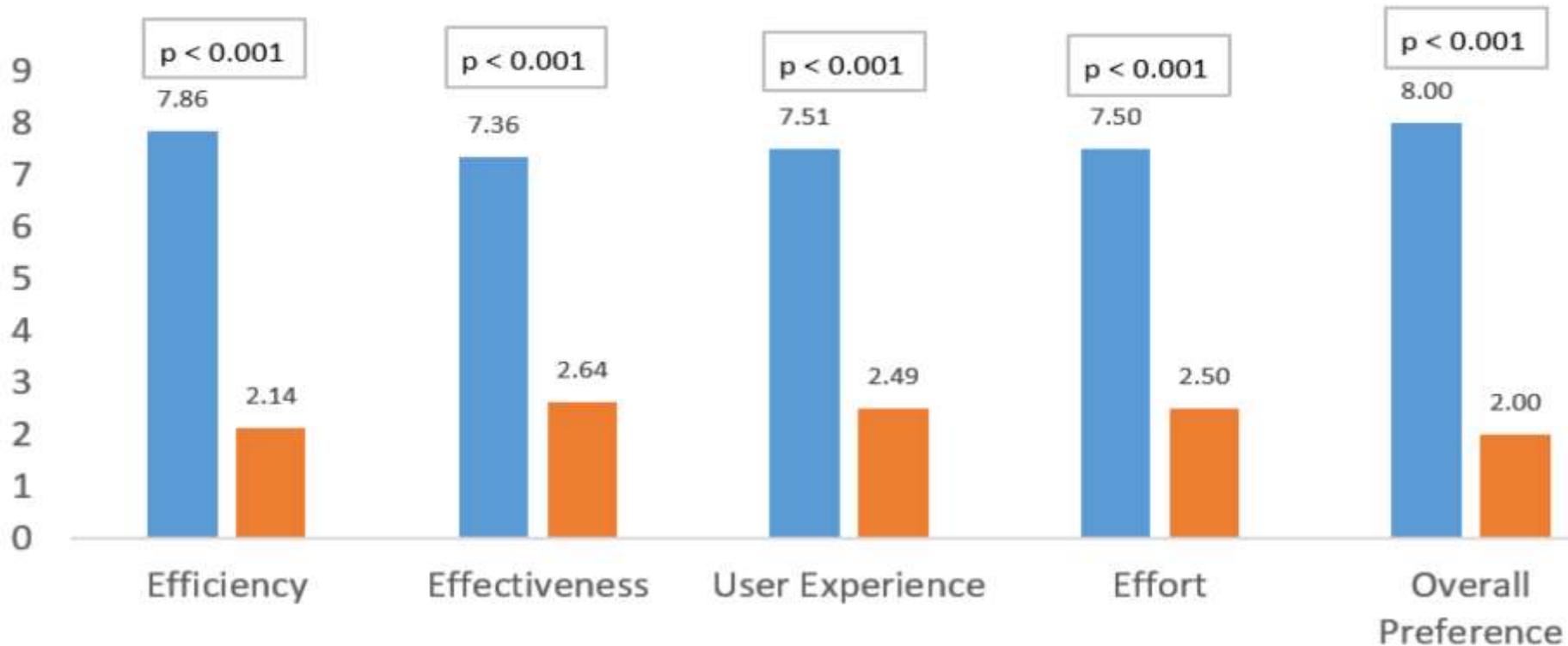


Results

COMPARISON BETWEEN RCTCOMP AND PUBMED®

■ RCTComp

■ PubMed®



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