Novel approaches to problem solving and designing solutions to medication safety challenges

Noll Campbell, PharmD, MS
Rich Holden, PhD, MS

1/15/21

Regenstrief Institute

PURDUE UNIVERSITY

SCHOOL OF MEDICINE
CENTER FOR AGING RESEARCH

CENTER FOR HEALTH INNOVATION & IMPLEMENTATION SCIENCE

Brain Safety Lab

Conflict of Interest

- Campbell: Paid consultant to Astellas Pharma, US (unrelated)
- Holden: Paid consultant on federal grants (U Wisconsin, Clemson U, Kent State U)

- Research support received from
  - National Institutes of Health/National Institute on Aging (Holden & Campbell)
  - Agency for Healthcare Research and Quality (Holden & Campbell)
  - Healthcare Resources & Services Administration (Campbell)

Objectives:

- Identify multi-step approaches to addressing medication safety challenges in ambulatory care environments.
- Recognize the value gained by combining clinical pharmacy, geriatric, engineering, and social science expertise in a multi-institutional, transdisciplinary learning laboratory.
- Describe federally funded research being conducted by the Brain Safety Laboratory focused on reducing harm from high-risk medications in older adults

Clinical context of personal interest

IDND
FROM DISCOVERY TO DELIVERY

Anticholinergic Cognitive Burden List (ACB)

Developed by the Aging Brain Program at the IU Center for Aging Research

WISHARD
Healthy Aging Brain Center

Drugs with ACB Score of 1

Generic Name	Brand Name
Alverine	Spasmonal™
Alprazolam	Xanax™
Atenolol	Tenormin™
Bupropion	Wellbutrin™, Zyban™
Captopril	Capoten™
Chlorthalidone	Diuril™, Hygroton™
Cimetidine	Tagamet™
Clorazepate	Tranxene™
Codeine	Contin™
Colchicine	Colcrys™
Diazepam	Valium™
Digoxin	Lanoxin™
Dipyridamole	Persantine™
Disopyramide	Norpace™
Fentanyl	Duragesic™, Actiq™
Furosemide	Lasix™
Fluvoxamine	Luvox™
Haloperidol	Haldol™
Hydralazine	Apresoline™
Hydrocortisone	Cortef™, Cortaid™
Isosorbide	Isordil™, Ismo™
Loperamide	Immodium™, others
Metoprolol	Lopressor™, Toprol™
Morphine	MS Contin™, Avinza™
Nifedipine	Procardia™, Adalat™
Prednisone	Deltasone™, Sterapred™
Quinidine	Quinaglute™
Ranitidine	Zantac™
Risperidone	Risperdal™
Theophylline	Theodur™, Uniphyl™
Trazodone	Desyrel™
Triamterene	Dyrenium™
Warfarin	Coumadin™

Drugs with ACB Score of 2

Generic Name	Brand Name
Amantadine	Symmetrel™
Belladonna	Multiple
Carbamazepine	Tegretol™
Cyclobenzaprine	Flexeril™
Cyproheptadine	Periactin™
Loxapine	Loxitane™
Meperidine	Demerol™
Methotrimeprazine	Levoprome™
Molindone	Moban™
Oxcarbazepine	Trileptal™
Pimozide	Orap™

Scoring directions:

- Possible anticholinergics include those listed with a score of 1 in the column to the left
- Definite anticholinergics include those listed with a score of either 2 or 3 in the columns above and to the right

Scoring interpretation:

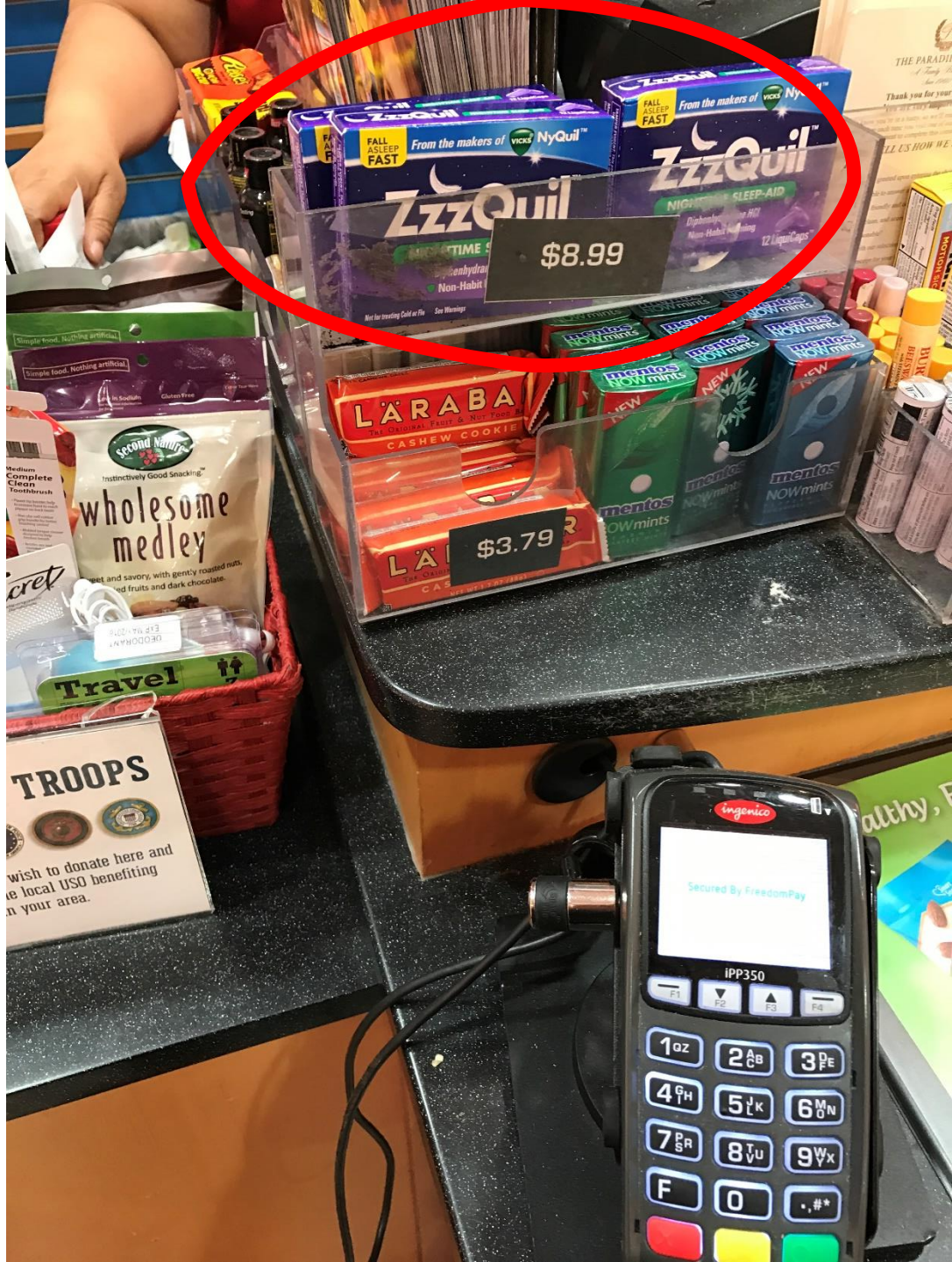
- Each definite anticholinergic may increase the risk of cognitive impairment by 46% over 6 years.[3]
- For each one point increase in the ACB total score, a decline in MMSE of 0.33 points over 2 years has been suggested.[4]
- Additionally, each one point increase in the ACB total score has been correlated with a 26% increase in the risk of death.[4]

COMPLETE REFERENCES:

1. Boustani MA, Campbell NL, Munger S, Maidment I, Fox GC. Impact of anticholinergics on the aging brain: a review and practical application. *Aging Health*. 2008;4(3):311-20.
2. Campbell N, Boustani M, Limbil T, Ott C, et al. The cognitive impact of anticholinergics: a clinical review. *Clinical Interventions in Aging*. 2009;4(1):225-33.
3. Campbell N, Boustani M, Lane K, Gao S, Hendrie H, Khan B, Murrell J, Unverzagt F, Hake A, Smith-Gamble V, Hall K. Use of anticholinergics and the risk of cognitive impairment in an African-American population. *Neurology* 2010;75:152-159.
4. Fox C, Richardson K, Maidment, et al. Anticholinergic medication use and cognitive impairment in the older population: the Medical Research Council Cognitive Function and Ageing Study. *J Am Geriatr Soc* 2011; epub ahead of print.

Drugs with ACB Score of 3

Generic Name	Brand Name
Amitriptyline	Elavil™
Amoxapine	Asendin™
Atropine	Sal-Tropine™
Benztropine	Cogentin™
Brompheniramine	Dimetapp™
Carbinoxamine	Histex™, Carbihist™
Chlorpheniramine	Chlor-Trimeton™
Chlorpromazine	Thorazine™
Clemastine	Tavist™
Clomipramine	Anafranil™
Clozapine	Clozaril™
Darifenacin	Enablex™
Desipramine	Norpramin™
Dicyclomine	Bentyl™
Dimenhydrinate	Dramamine™, others
Diphenhydramine	Benadryl™, others
Doxepin	Sinequan™
Flavoxate	Urispas™
Hydroxyzine	Atarax™, Vistaril™
Hyoscyamine	Anaspaz™, Levsin™
Imipramine	Tofranil™
Meclizine	Antivert™
Methocarbamol	Robaxin™
Nortriptyline	Pamelor™
Olanzapine	Zyprexa™
Orphenadrine	Norflex™
Oxybutynin	Ditropan™
Paroxetine	Paxil™
Perphenazine	Trilafon™
Promethazine	Phenergan™
Propantheline	Pro-Banthine™
Quetiapine	Seroquel™
Scopolamine	Transderm Scop™
Thioridazine	Mellaril™
Tolterodine	Detrol™
Trifluoperazine	Stelazine™
Trihexyphenidyl	Artane™
Trimipramine	Surmontil™



Causality in the Adverse Cognitive Effects of Anticholinergics in older adults

- Association between ACh & **Dementia**
  - Strong ACh over 6 yrs **OR: 1.54 (1.21-1.96)**
    Campbell NL et al. *Neurology.* 2010; 75(2):152-159.
  - Strong ACB total score **OR: 1.36 (1.17-1.58)**
    Campbell NL et al. *Pharmacotherapy.* 2016; 36(2):196-202.
  - Strong ACh for ≥ 3/10 yrs **OR: 1.54 (1.21-1.96)**
    Gray SL et al. *JAMA Intern Med.* 2015; 175(3):401-407.
  - Strong ACh for ≥ 4/20 yrs **OR: 1.40 (1.30-1.50)**
    Richardson K et al. *BMJ.* 2018; 361:k1315.

- Association between ACh & **Delirium**
  - Anticholinergics associated with delirium in 11/13 studies

    Campbell NL et al. *Clin Interv Aging* 2009; 4:225-233.

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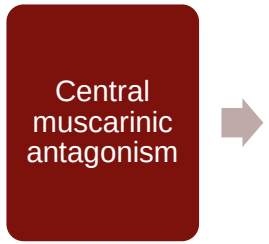
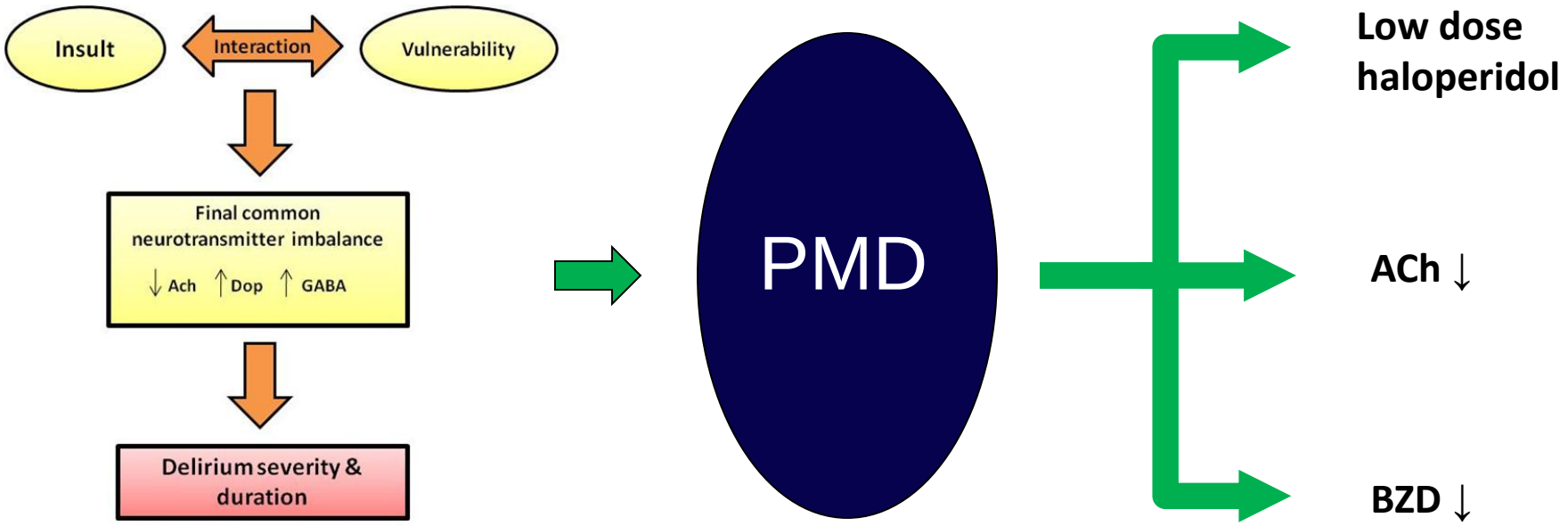


Scheiderer, et al. J Neuroscience 2006; Bierer, et al. J Neurochem 1995; Caccamo, et al. Neuron 2006; Perry, et al. Ann Neurol 2003; Del Pino, et al. ArchToxicol 2016; Risacher, et al. JAMA Neurol 2016.

Clinical trial attempting to reduce anticholinergics: the PMD trial



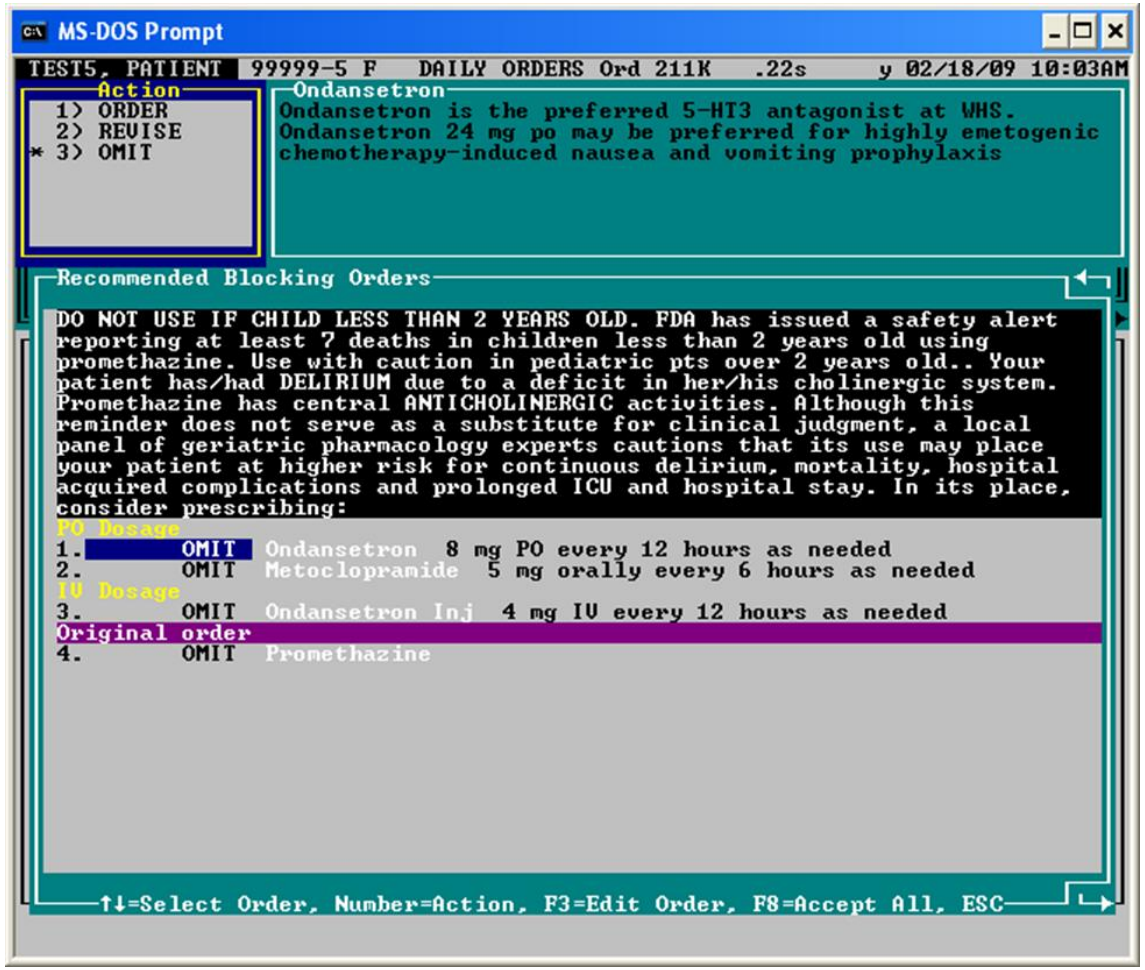
Khan, et al. JAGS 2011

Ach = Acetylchonline
Dop = Dopamine
GABA = Gamma Amino Butyric Acid

PMD Intervention

- PMD: haloperidol 0.5 or 1 mg TID x 7 days
- Anticholinergic reduction:
  - Interruptive alerts in EMR for 20 strong ACB
  - Pharmacist surveillance
- Benzodiazepine reduction
  - Pharmacist surveillance (only)
  - Dose reduction following standard recommendations

Example CDS: Promethazine



CDS did not influence anticholinergic use

	Pre-Randomization			Post-Randomization		
	PMD[a] (N=170)	**Usual Care (N=176)**	**P-value**	**PMD (N=170)**	**Usual Care (N=176)**	**P-value**
Haloperidol						
Exposed[b] n (%)	29 (17.1)	32 (18.2)	0.888	116 (68.2)	56 (31.8)	<0.001
Median daily Dose (IQR)	0 (0-0)	0 (0-0)	0.723	0.5 (0-0.9)	0 (0-0.3)	<0.001
Benzodiazepines[c]						
Exposed[b] n (%)	122 (71.8)	118 (67.0)	0.353	97 (57.1)	116 (65.9)	0.098
Median daily Dose (IQR)	1.3 (0 – 13.1)	1.0 (0-10.5)	0.466	0.1 (0-2.0)	0.3 (0-3.2)	0.079
Anticholinergic Burden[d]						
Exposed[b] n (%)	30 (17.6)	29 (16.5)	0.777	44 (25.9)	54 (30.7)	0.342
Median daily score (IQR)	0 (0-0)	0 (0-0)	0.706	0 (0-0.1)	0 (0-0.2)	0.248

Khan, et al. JAGS 2019
Campbell, et al. JAGS 2019

Trial Experience with Physician alerts

- Neither alerts alone nor accompanied by pharmacist surveillance significantly reduced use of anticholinergics in hospitalized adults
- Acceptance of alerts was poor(ly measured)
- Impact of intervention on outcomes unable to be evaluated

Human-centered design = Making things fit for humans

“Darn these hooves! I hit the wrong switch again! Who designs these instrument panels, raccoons?”

Fits your needs,
Improves performance

Human-centered design ≠ Making humans fit into things

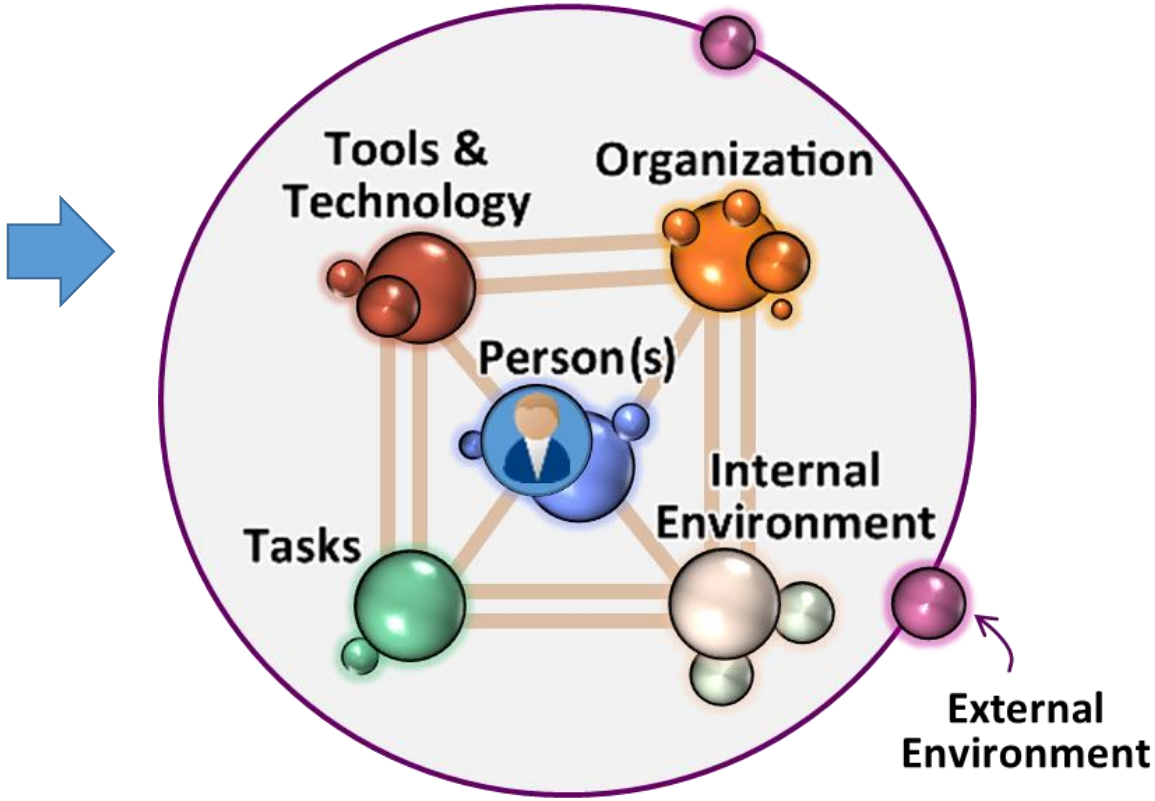
Hole-in-the-wall design:

When a designer comes up with something they think is great, but that requires the user to contort themselves to make it work

Human-centered design ≠ Making humans fit into things

Humans are flexible – to a point – they will contort themselves to fit bad designs, but at the expense of performance!

Humans factors engineering and other disciplines devoted to human-centered design place the human in the center of the system

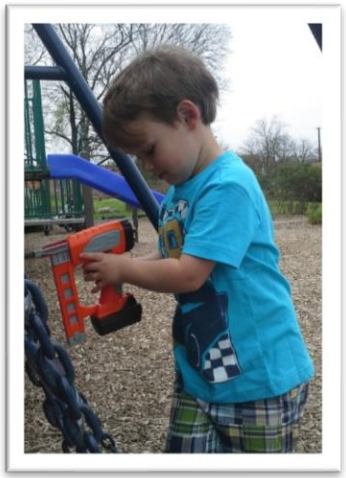


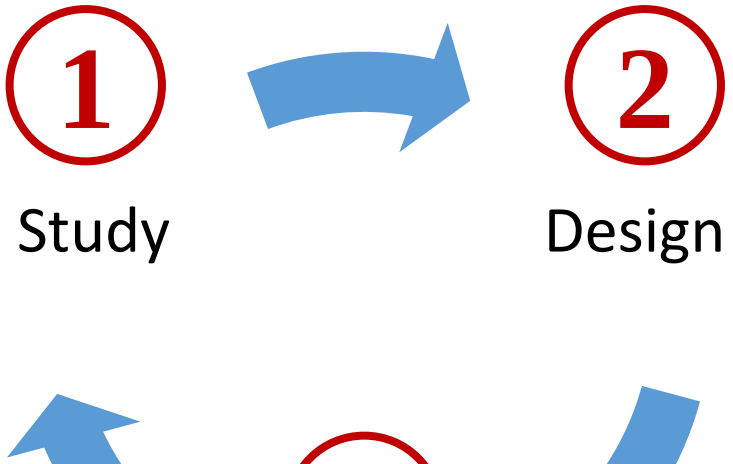
Human factors engineering has been gaining momentum in healthcare as a way to improve performance of:

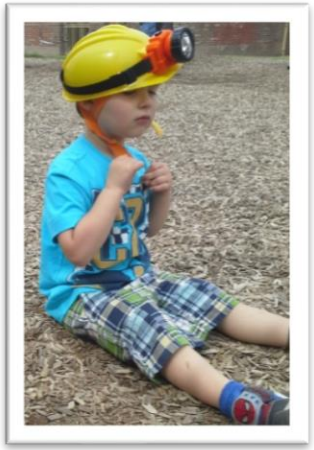
- Healthcare professionals
- Patients and families

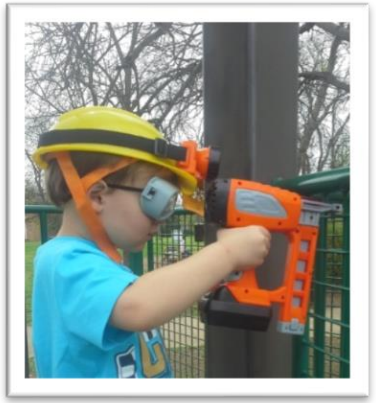
Holden, R. J. et al. (2013). SEIPS 2.0: A human factors framework for studying and improving the work of healthcare professionals and patients. *Ergonomics, 56*(11), 1669-1686.

Human factors engineering / human-centered design cycle









Example of human-centered design: Improving senior brain health

INDIANA UNIVERSITY

IU Newsroom

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IU Newsroom » $4 million grant funds Brain Safety Lab focused on brain health of older adults

$4 million grant funds Brain Safety Lab focused on brain health of older adults

Nov. 17, 2015

INDIANAPOLIS -- Brain health is critical to successful aging. A new four-year $4 million grant from the Agency for Healthcare Research and Quality to the Indiana University Center for Aging Research funds the establishment of the Brain Health Patient Safety Learning Laboratory at Eskenazi Health. It is a collaboration with the IU schools of Medicine, Informatics and Computing, and Nursing; the Purdue University schools of Biomedical and Industrial Engineering; Purdue College of Pharmacy and the Regenstrief Institute.

With the multidisciplinary expertise of more than a dozen faculty members and other key personnel, the new Brain Safety Lab will develop potential brain safety solutions, test prototypes and deploy them in the real-world clinical setting of the Sandra Eskenazi Center for Brain Care Innovation.

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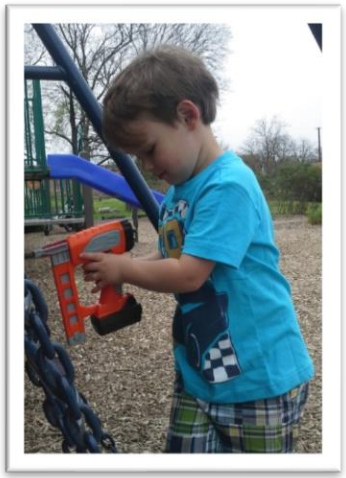
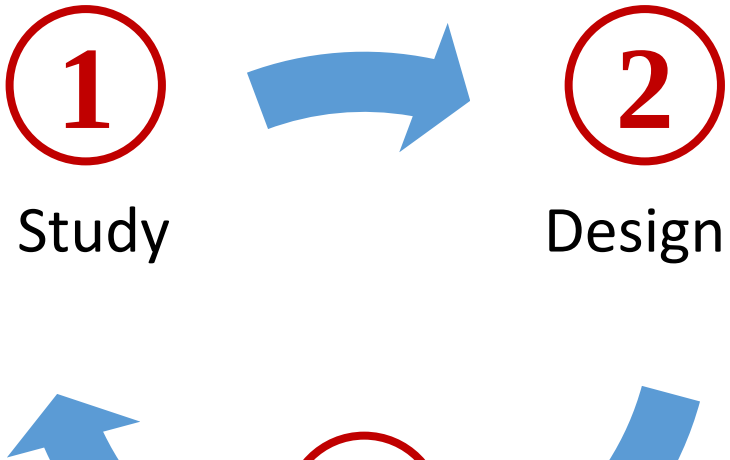
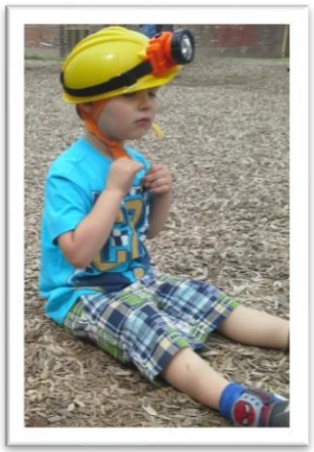
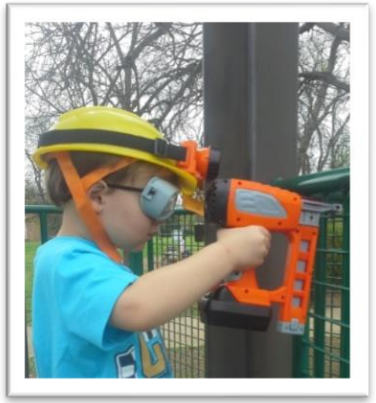
ESKENAZI HEALTH

Human factors engineering / human-centered design cycle





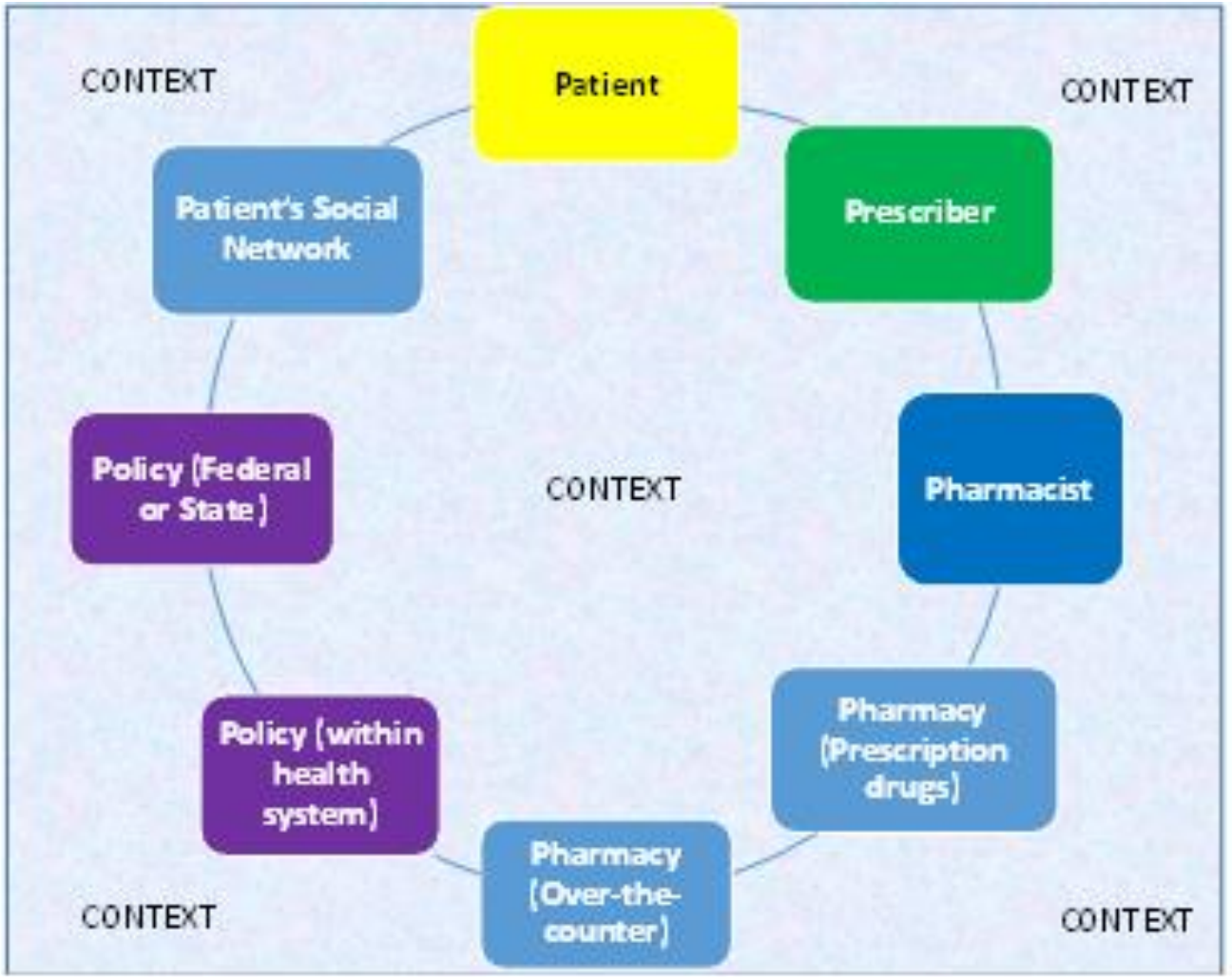




① Study

- Multi-disciplinary team collected data on patients and providers

- Identified multiple agents and targets for safety interventions across the system



a) Interviews with prescription anticholinergic medication users (N=24)

b) Naturalistic in-store shopping observations with contextual inquiry (N=39)

c) Simulated shopping task with think-aloud and post-task interview (N=21)

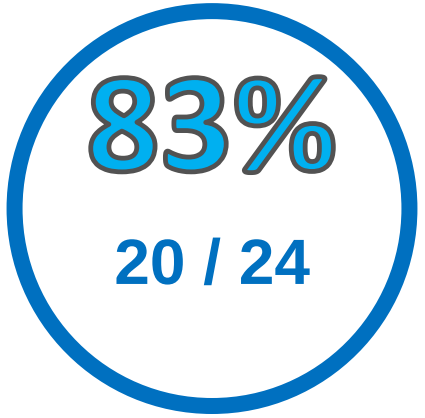
Holden, R. J., Srinivas, P., Campbell, N. L., et al. (2019). *Research in Social and Administrative Pharmacy*, 15(1): 53-60.

Finding 1. Lack of awareness … some willingness to change

anticholinergic users aware of risk

state willingness to consider safer alternatives

Finding 2. Physician often the #1 medication decision maker



consult physicians about OTC + Rx medications

see physician as chief decision maker about medications

(Holden et al 2019)

Finding 3. Safety matters to consumers

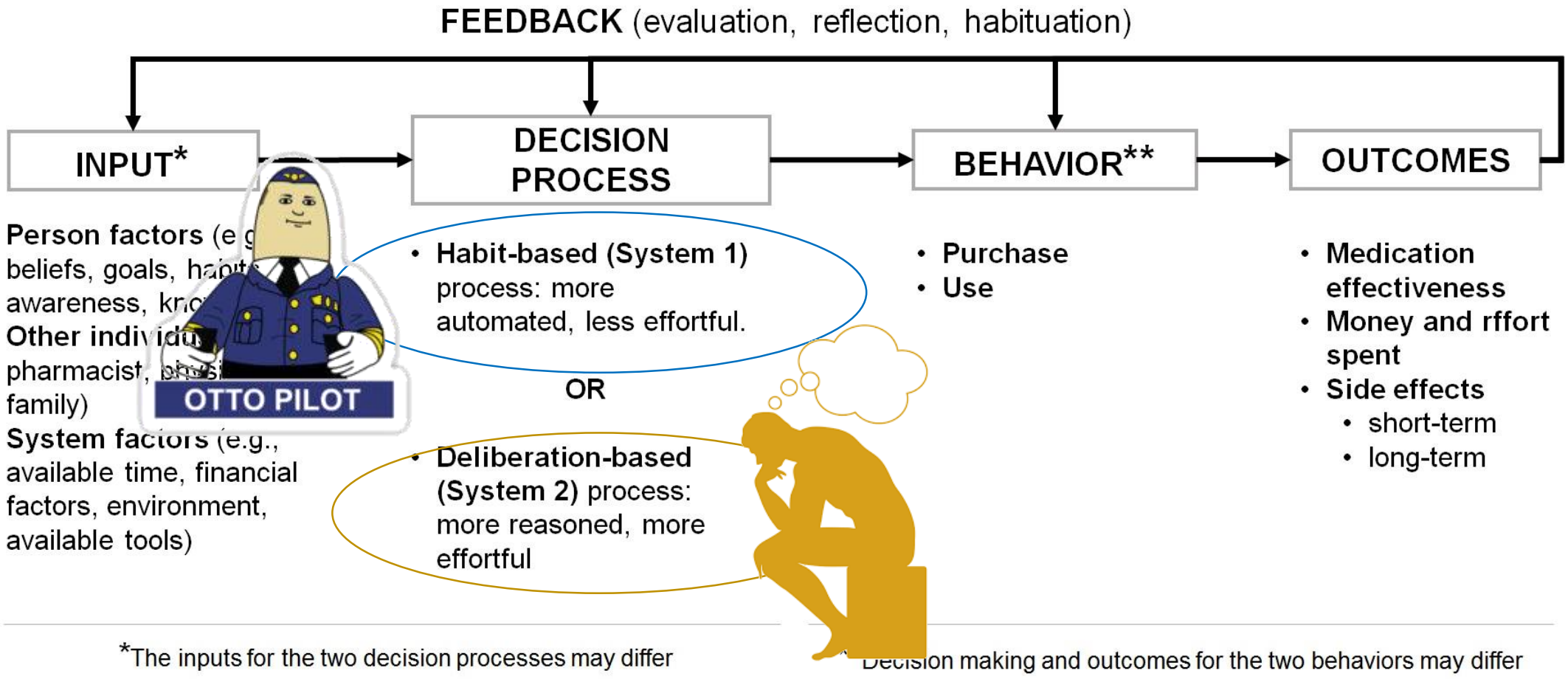
Table 2
Percentage of participants ranking the importance of OTC medication decision criteria in their top 3, middle, and bottom 3.

Decision criteria	Participant rankings of importance of each decision criterion		
	Top 3	Middle	Bottom 3
Effectiveness	**62%**	14%	24%
Health risk/adverse ("side") effects	**48%**	**38%**	14%
Price	**38%**	29%	**33%**
Dosage	24%	**38%**	**38%**
Ingredients	29%	**38%**	**33%**
Quantity	**38%**	14%	**48%**
Habit	**33%**	14%	**52%**
Brand	29%	14%	**57%**

Values ≥ 33% are bolded

(Holden et al 2019)

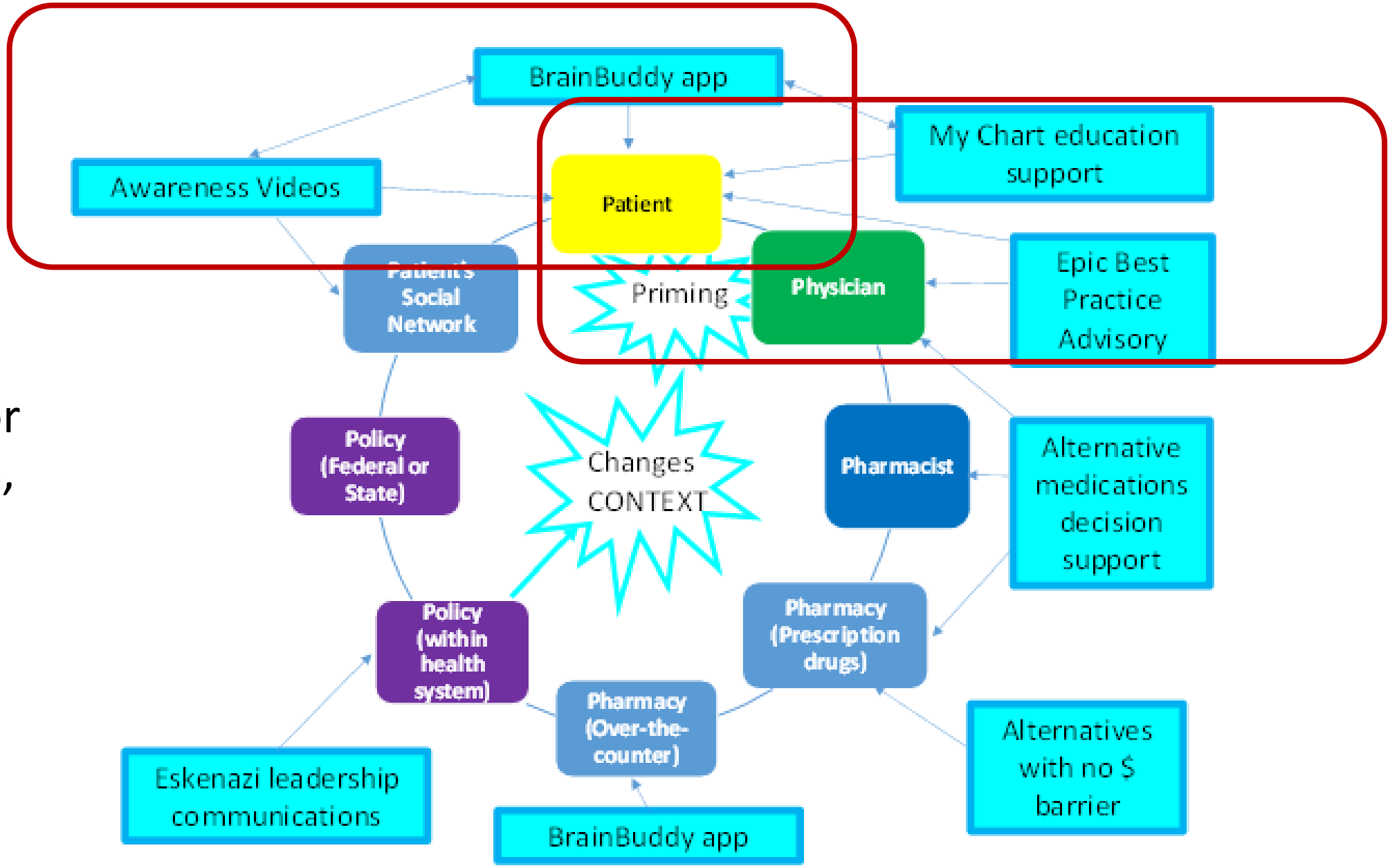
Finding 4. Two personas: Habit- vs. deliberation-based



- Holden, Srinivas, Campbell, et al. (2019). *Research in Social and Administrative Pharmacy*, 15(1): 53-60.
- Stone, Phelan, Holden, et al. 2020. A pilot study of decision factors influencing over-the-counter medication selection and use by older adults. *Research in Social and Administrative Pharmacy, 16*(8), 1117-1120

2 Design

Brainstorm interventions for multiple targets, without constraints



② Design of a patient-facing solution

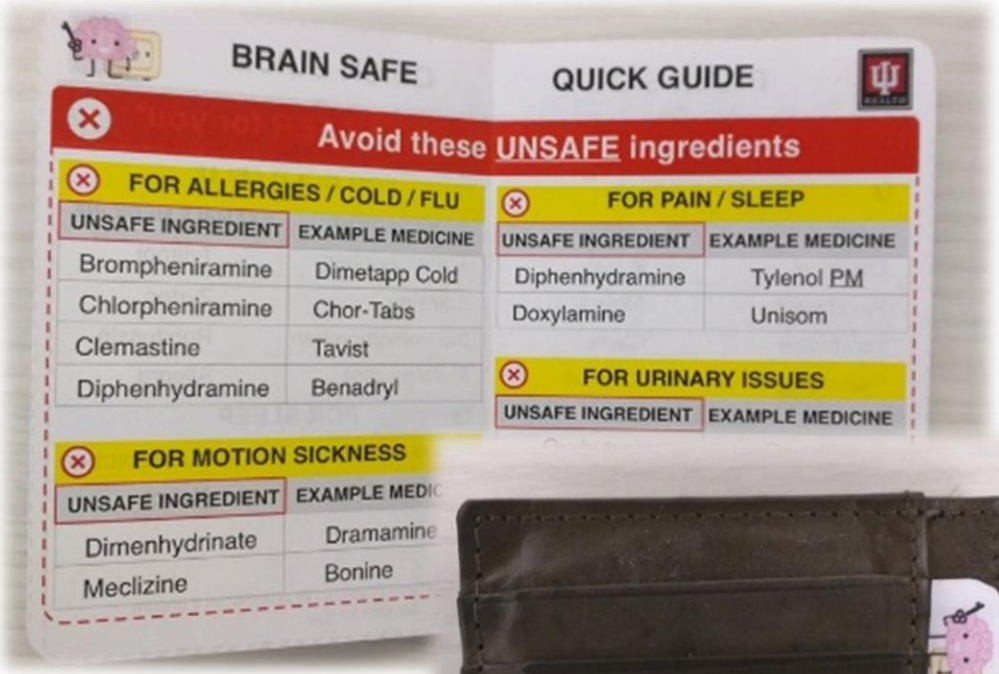
1) Lacking awareness
2) Physician decides
3) Safety matters
4) Habit vs. deliberation based behavior

Design consumer-facing interventions to reduce the use of anticholinergic medications (OTC and Rx)

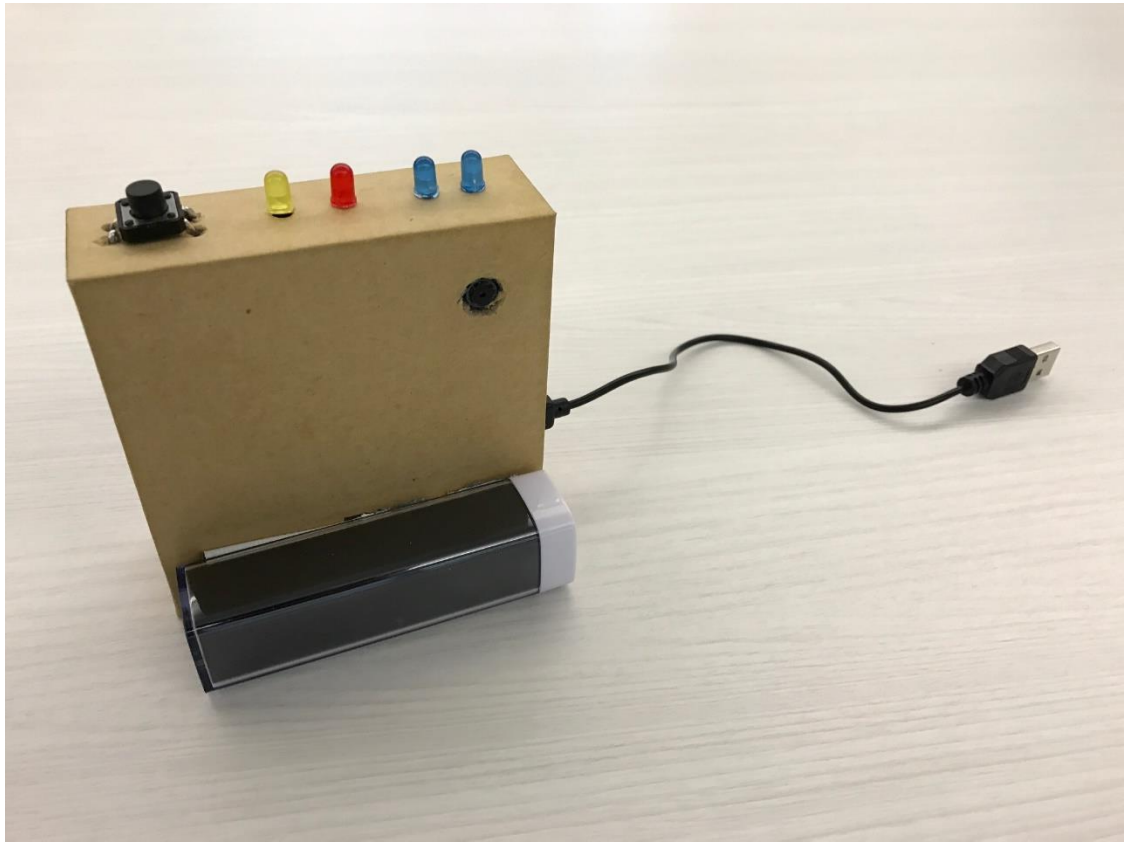
1) Raise awareness
2) Keep physician in the loop
3) Focus on safety information
4) Habit -> Deliberation

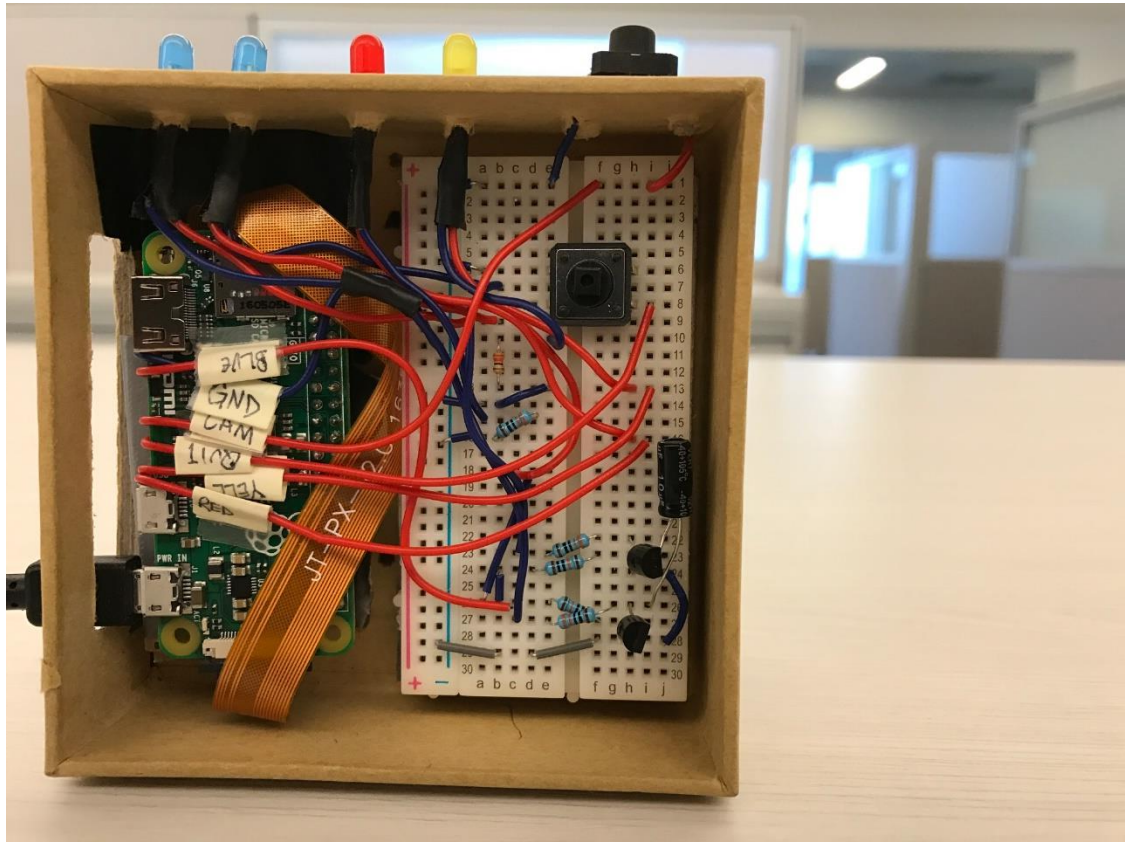
Holden, R. J., Campbell, N. L., Abebe, E., Clark, D. O., Ferguson, D., Bodke, K., ... & Callahan, C. M. (2020). *Research in Social and Administrative Pharmacy*

Lower-tech solutions



Lower-tech solutions





Lower-tech solutions

Reddy, A., Lester, C. A., Stone, J. A., Holden, R. J., Phelan, C. H., & Chui, M. A. (2019). Applying participatory design to a pharmacy system intervention. *Research in Social and Administrative Pharmacy*, *15*(11), 1358-1367

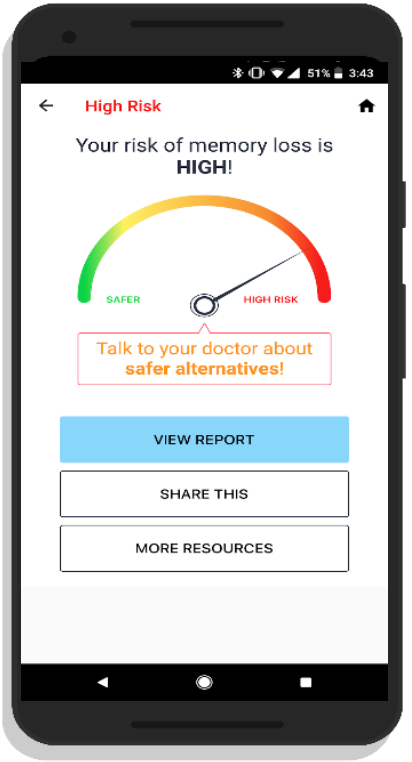
② Design (again!)

Higher-tech solutions

Design consumer-facing interventions to reduce the use of anticholinergic medications (OTC and Rx)

1) Raise awareness
2) Keep physician in the loop
3) Focus on safety information
4) Habit -> Deliberation

+ Make the intervention
  - Scalable
  - Personalized
  - Appealing



Multimedia videos as a scalable, appealing solution

Voice actor auditions

Animated videos

(Holden et al., 2020)

Rapid Prototyping by multidisciplinary team

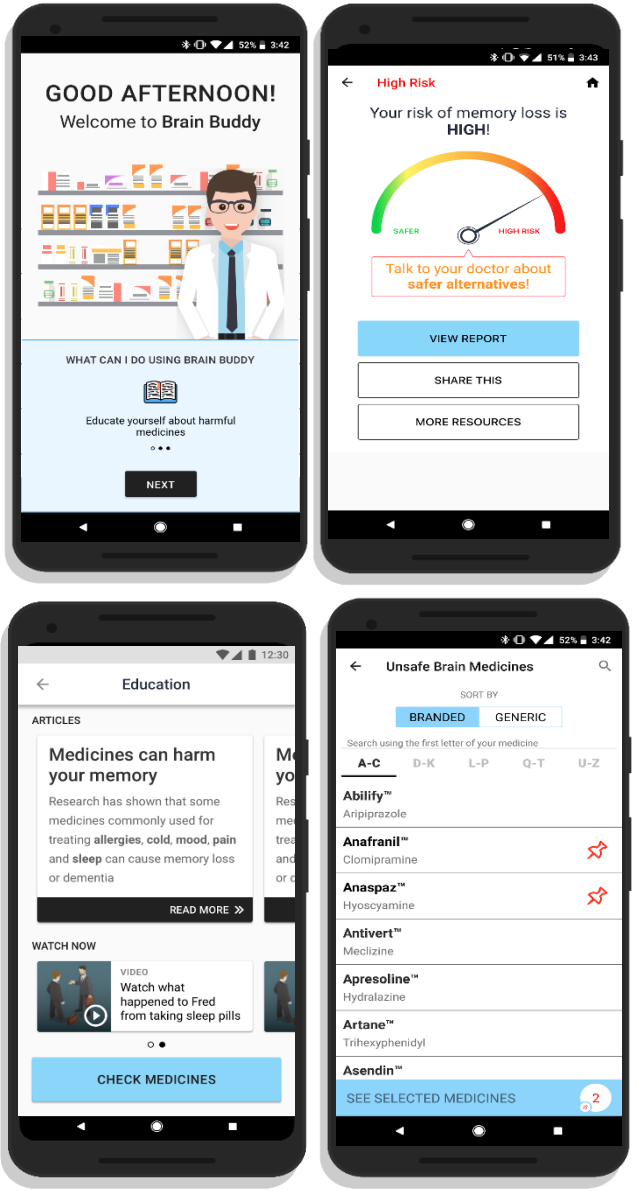
- Pharmacist
- Geriatrician
- Human factors engineer/psychologist
- User experience designer
- Storyteller
- Graphic designer / animator
- Medical sociologist

Holden, R. J. et al. (2020). Usability and feasibility of consumer-facing technology to reduce unsafe medication use by older adults. *Research in Social and Administrative Pharmacy*, *16*(1), 54-61.

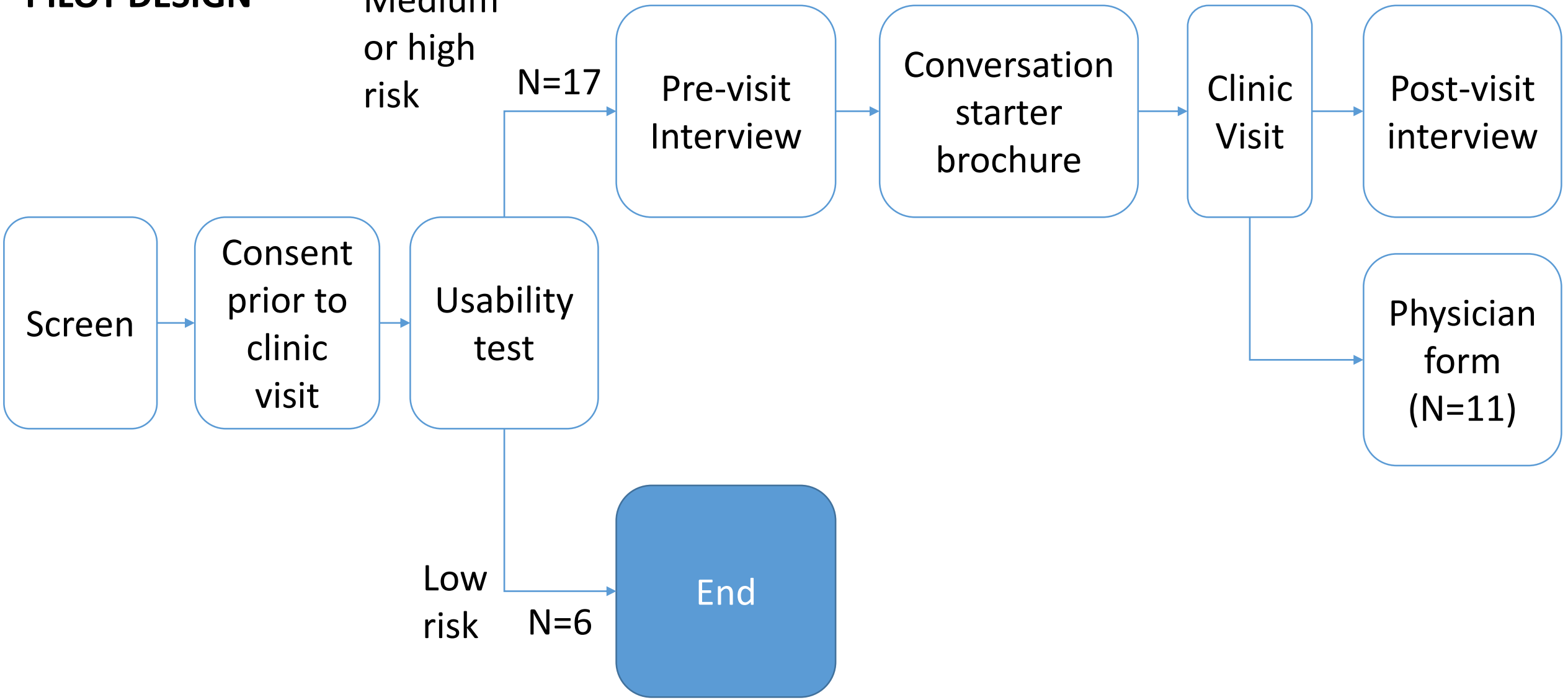
3 Implement (and (1) study)

- Patients aged ≥60 years receiving primary care at Eskenazi Health and prescribed ≥1 strong anticholinergic medication
- Usability testing (N=23)
  - Task-based observation
  - System usability scale (SUS)
- Feasibility of behavior change (N=17 “medium” or “high” risk anticholinergic users)

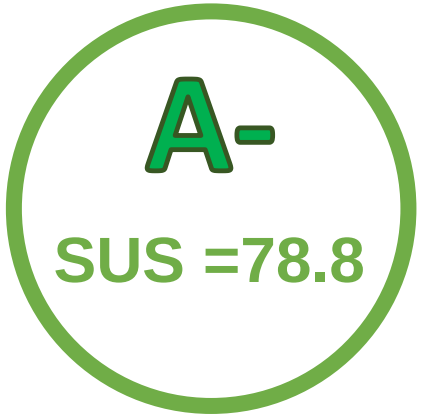
(Holden et al 2020)



PILOT DESIGN



Usability findings



"Good" to **"Excellent"** usability

M = 78.8
Median = 82.5
SD = 15.7
Range = 37.5-97.5

(Holden et al., 2020)

SUS item	% usable
Would use frequently	74%
Easy to use	96%
Parts well integrated	83%
Learning was quick	87%
Felt confident using	83%
Would need help to use	74%
Was confusing for me	91%
Too complex for me	78%
Was hard to use	96%
Would need to learn a lot to use	74%

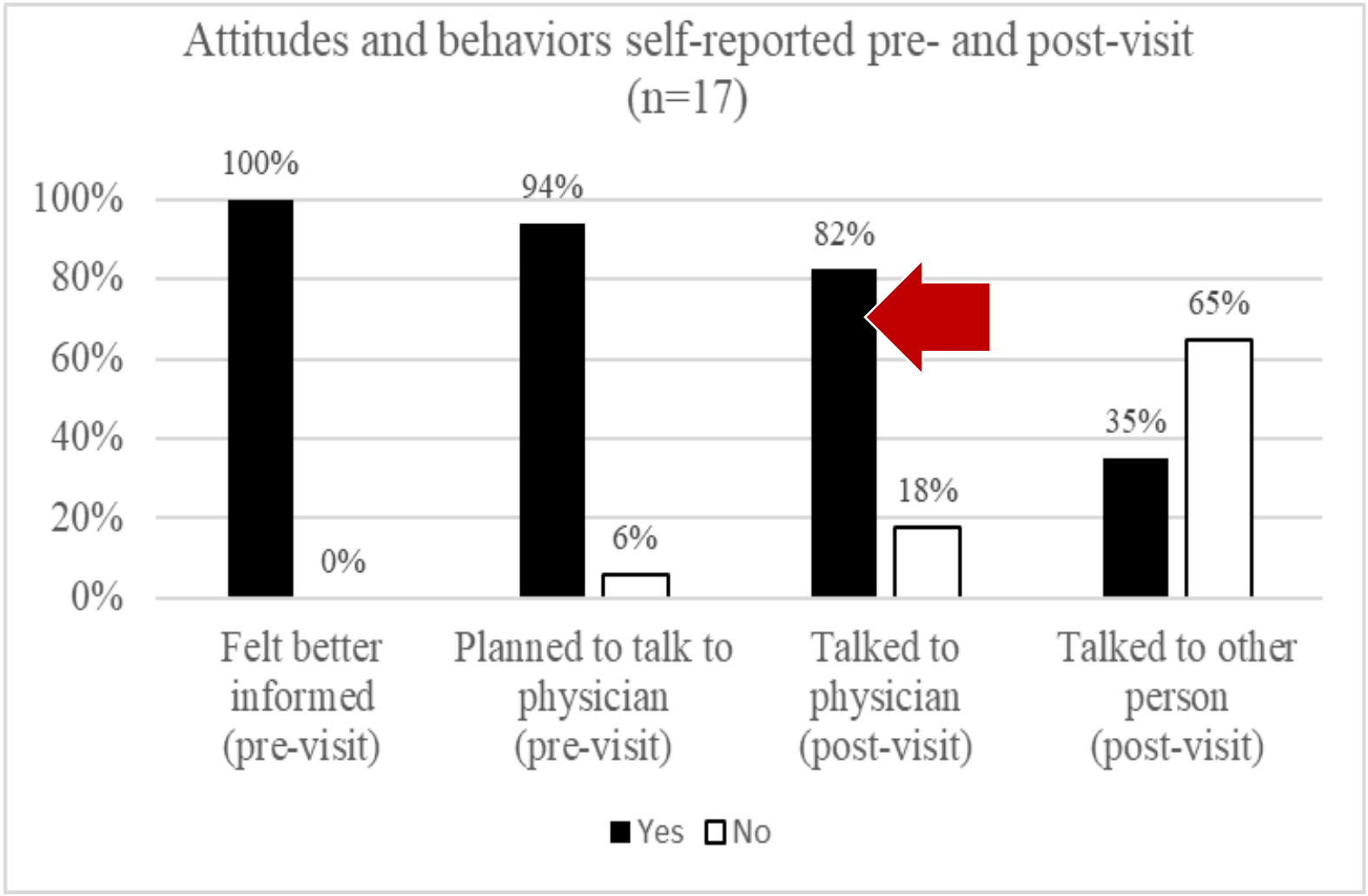
Usability findings

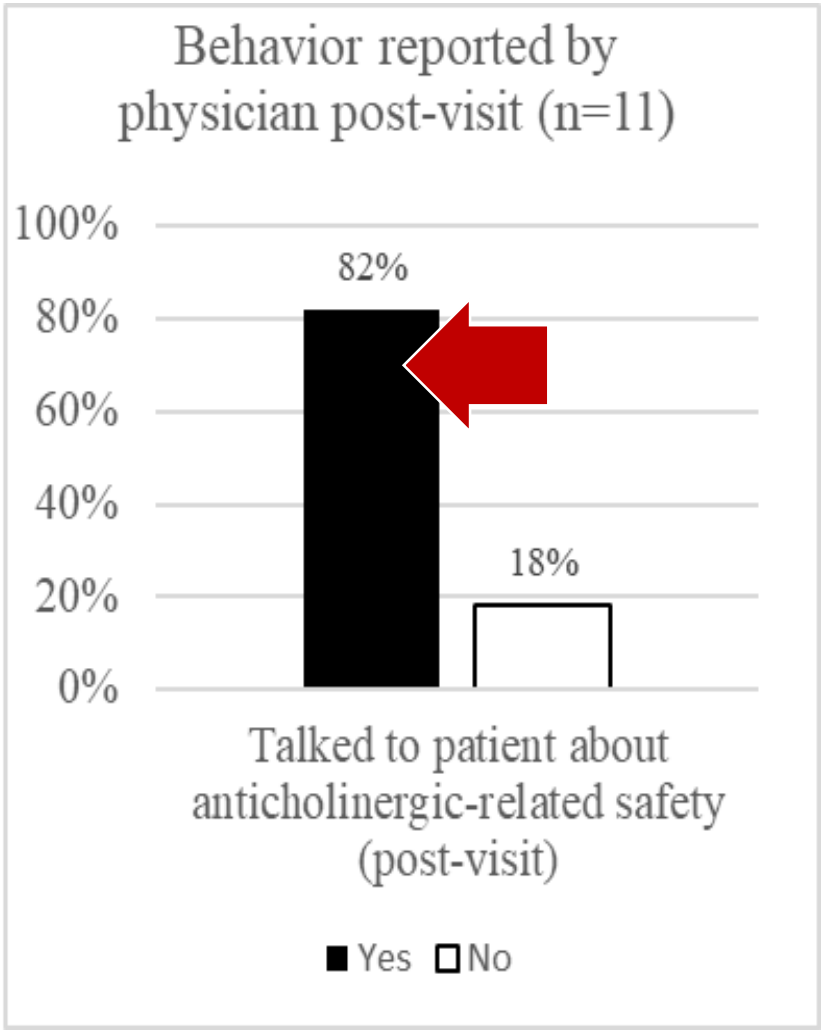
Table 1
Observed usability indicators by task (n = 23).

Usability element, N (%)	Tasks				
	LOG-IN	EDUCATION[a]	SELECT MEDS	ENTER RISK DATA	VIEW RISK SCORE
Completion					
Finished task	23 (100)	8 (100)	23 (100)	23 (100)	23 (100)
Could not do it/gave up	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Mistakes					
No mistakes	21 (91)	6 (75)	13 (54)	16 (70)	22 (96)
Mistakes/had to redo or undo	2 (9)	2 (25)	11 (46)	7 (30)	1 (4)
Efficient use					
Quick/fluid work	22 (96)	6 (75)	14 (61)	15 (65)	21 (91)
Pauses/delays/hesitation	1 (4)	2 (25)	9 (39)	8 (35)	2 (9)
Assistance needed[b]					
None needed	20 (87)	5 (62)	9 (39)	14 (61)	22 (96)
Needed encouragement	3 (13)	2 (25)	6 (26)	5 (22)	1 (4)
Needed more instructions	0 (0)	3 (37)	10 (43)	8 (35)	0 (0)
Needed demonstration	0 (0)	0 (0)	3 (13)	1 (4)	0 (0)
Emotional response[c]					
Satisfied/smiling/nodding	22 (96)	6 (75)	18 (78)	20 (87)	19 (83)
Upset/frustrated/mad	1 (4)	2 (25)	4 (17)	2 (9)	4 (17)

(Holden et al., 2020)

Behavior change feasibility findings

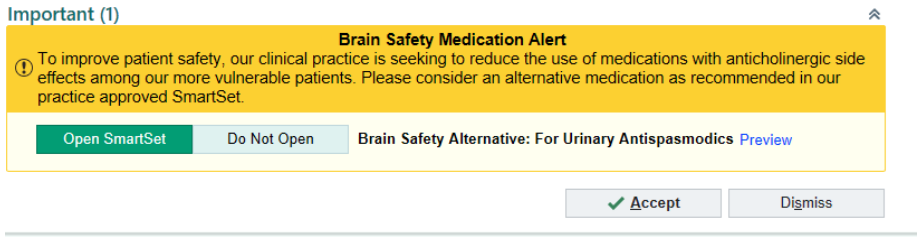




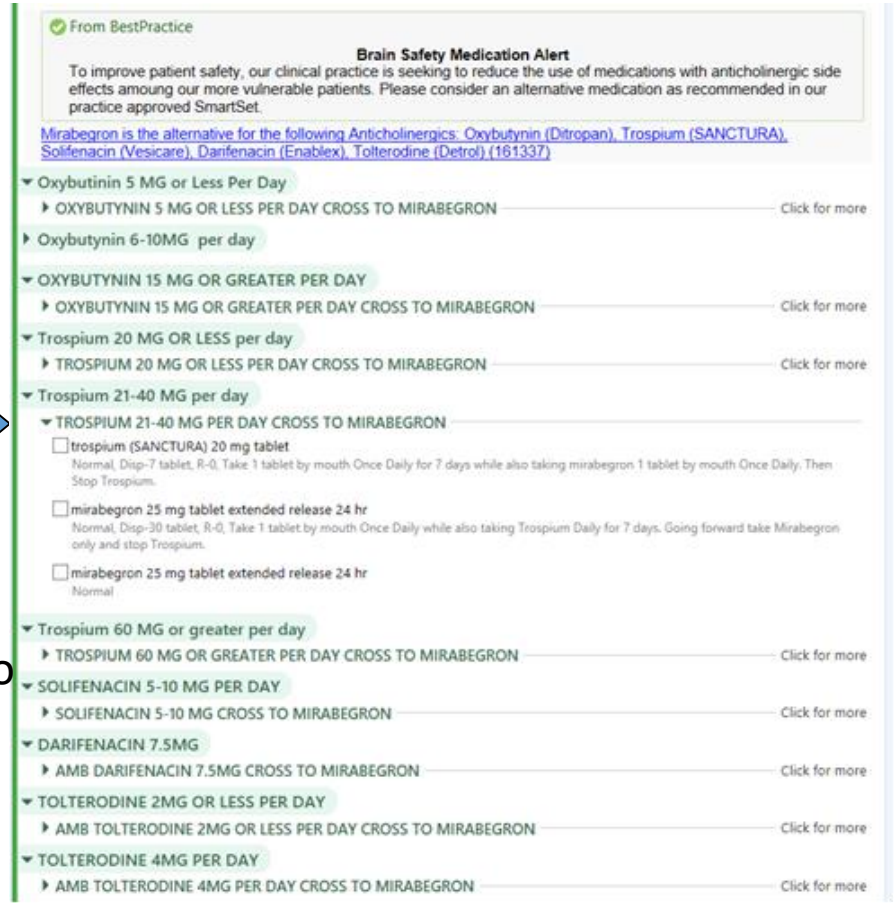
(Holden et al., 2020)

② Design of a provider-facing solution

- Physician/Provider-focused support



1) Identifies risk
2) Indication-specific alternative
3) Auto-populated titration to alternative



- Staff/MA-focused support

③ Implement (and (1) study)

- Cluster-randomized trial of 10 primary care clinics within Eskenazi Health
- Eskenazi Health is one of the nation's largest safety net health systems, and includes 10 FQHC's
- Pre-post comparison by group:
  - Intervention Dates: 4/1/2019-3/31/2020
  - Comparison Dates: 4/1/2018-3/31/2019

	Overall N=552	Intervention N=252	Usual Care N=300	p-value (between-group)
Age, mean (SD)	72.1 (± 6.4)	71.2 (± 5.9)	72.9 (± 6.8)	0.0026
Gender, % female	442 (80.1%)	204 (81.0%)	238 (79.3%)	0.6353
Race				
% African American	250 (45.3%)	132 (52.4%)	118 (39.3%)	<.0001
% Caucasian	232 (42.0%)	79 (31.3%)	153 (51.0%	
% other	70 (12.7%)	41 (16.3%)	29 (9.7%)	
CAD	86 (15.6%)	33 (13.0%)	53 (17.8%)	0.1217
CHF	56 (10.1%)	23 (9.1%)	33 (11.1%)	0.4337
HTN	471 (85.3%)	214 (84.3%)	257 (86.2%)	0.5103
DM	251 (45.5%)	118 (46.5%)	133 (44.6%)	0.6677
Cancer	57 (10.3%)	25 (9.8%)	32 (10.7%)	0.7303
Depression	210 (38.0%)	79 (31.1%)	131 (44.0%)	0.0019
stroke	35 (6.3%)	12 (4.7%)	23 (7.7%)	0.1503
arthritis	172 (31.2%)	79 (31.1%)	93 (31.2%)	0.9787
Liver disease	35 (6.3%)	19 (7.5%)	16 (5.4%)	0.3104
Renal disease	104 (18.8%)	51 (20.1%)	53 (17.8%)	0.4922

Campbell, et al. *Under Review*

Medication Orders by Group and Time

	Order Type*	Intervention	Control	p-value: difference by time
Target Anticholinergics	Number of pre-intervention d/c orders, n (% of all orders)	21 (7.3%)	34 (9.4%)	
	Number of post-intervention d/c orders, n (% of all orders)	23 (7.8%)	29 (8.2%)	
	Change	2	-5	0.7736
Recommended Alternatives	Number of pre-intervention active orders, n (% of all orders)	672 (94.9%)	1019 (93.3%)	
	Number of post-intervention active orders, n (% of all orders)	913 (94.9%)	979 (94.7%)	
	Change	241	-40	0.3066

Campbell, et al. *Under Review*

Prevalence using target medications by group and Time

		Intervention	Control	p-value: difference by time
Target Anticholinergics	Pre-intervention	6.2%	6.6%	0.6983
	Post-intervention	5.1%	7.4%	
Recommended Alternatives	Pre-Intervention	14.0%	17.7%	0.1288
	Post-intervention	14.8%	19.0%	

Campbell, et al. *Under Review*

- Process Measures:
  - 259 alerts directed towards providers
    - **15% opened**
    - **Order changed in 1.2% of all alerts**
    - **NNR = 86**
- 276 alerts directed towards MA
  - **4.7% confirmed action taken**

Interpretation

- Repeated studies with poor acceptability of recommendations from electronic decision support
- Unable to evaluate the combined approach of targeting patients AND providers due to low interaction with interventions
- Multiple disciplines can create better nudge techniques to increase acceptability, functionality of interventions/solutions

Performance of EPIC CDS

Topic	% Compliant	Active	Passive
Missing anticoag d/c instructions	90.9	X	
Foley cath 24-48 hrs w/out order	64.5	X	
No level of care on admit	61.8	X	
No ACE/ARB order for BP 12 h after admission	21.3		X
Suicide Precautions Rec	20.9	X	
Foley without order	20.3	X	
Pressure Ulcer on Admit	12.3		X
Suicide Precautions Rec	7.1		X
Swallow Eval Rec	6.3	X	
No Code 12 hrs after admission	1.9		X
Foley Cath > 48hrs	1.4		X
NPO x 72 hrs	1.2		X

Valvona, et al. *Proc Int Symp Hum Fact Erg Health Care* 2020

More design → more evaluation

Novel app designed to help patients avoid drugs linked to dementia

IU School of Medicine | Jul 15, 2019

+ MORE

Researcher awarded $3.5 million to study effectiveness of technology intervention aimed at older adults

A team of researchers from Indiana University School of Medicine, Regenstrief Institute and Purdue University, led by Richard Holden, PhD, is testing a new app, called Brain Safe,

NEWS RELEASE 28-MAY-2019

First study to see if de-prescribing commonly used drug class prevents or delays dementia

Regenstrief researcher receives $3.3 million NIA award for cause and effect study

REGENSTRIEF INSTITUTE

SHARE PRINT E-MAIL

INDIANAPOLIS - Regenstrief Institute research scientist Noll Campbell, PharmD, M.S. has received a five-year $3.3 million award from the National Institute on Aging (NIA) to conduct the first clinical trial designed to determine if stopping anticholinergic medications results in sustained improvements in cognition.

Anticholinergic medications have been linked to worsening cognition over time, including the diagnosis of dementia, in several prior observational studies. If the

Abebe, E., Campbell, N. L., Clark, D. O., Tu, W., Hill, J. R., Harrington, A. B., ... & Holden, R. J. (2020). Reducing anticholinergic medication exposure among older adults using consumer technology: Protocol for a randomized clinical trial. *Research in Social and Administrative Pharmacy*.

Take-home lessons

Contact Dr. Campbell:
campbenl@iu.edu

Human-centered design = Making things fit for humans

Multiple disciplines working together create better interventions for humans

Human-centered design and evaluation are ongoing, iterative processes

Human behavior (e.g., uptake) is central to solution efficacy

Engineers need friends in the social sciences and healthcare delivery!

Cornet & Holden, 2018; Cornet et al., 2019, 2020