ADDRESSING BARRIERS TO MEDICATION ADHERENCE: AN EVIDENCE-BASED SCREENING INSTRUMENT VALIDATION STUDY

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Donna Washburn DNP, RN, CNS, ACNS-BC, AOCNS

Disclosure

• Authors:

- D. Washburn DNP, RN, CNS, ACNS-BC, AOCNS
 - Director of Professional Clinical Practice at Centra Health
 - Faculty Adjunct for MSN for Liberty University
 - Health Policy and Ethics; Nursing Theory and Advanced Practice
- Ken Thompson PharmD
 - Professor DNP Faculty for Liberty University
 - Chair for this doctoral project

Objectives:

- Recognize rationale for use of an instrument to identify medication adherence barriers
- Explain early development of an evidence-based instrument
- Describe a pilot test used to evaluate the instrument

No Conflict of Interest



Introduction

 Adherence is critical to management of comorbid disease

- Mental illness
- **DM-2**
- HTN/CVD
- Renal Impairment
- COPD



Older Cancer Patients

F

Multiple Comorbidities

+

Chemotherapy Treatment

=

Increased Risk

(Sarfati, Koczwara, & Jackson, 2016).



• Adherence:

"The extent to which a persons' behavior corresponds with agreed recommendations from a healthcare provider" (WHO)



Barriers are real:

- Financial
- Psychological
- Educational
- Medical, and
- Behavioral

Barriers are complicated:

- Intentional
- Unintentional
- Independent
- Intertwined



Healthcare providers need to know:

50% to 60%

of patients

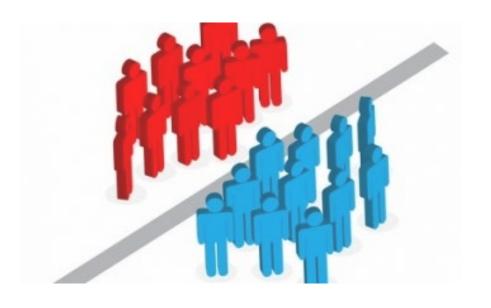
nonadherent

to

prescribed treatment

regimen

(Lam & Fresco, 2015).





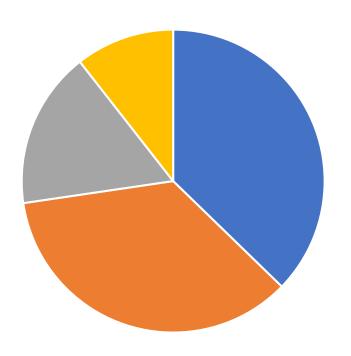
Background

• 42 significant barriers identified in one extensive meta-analysis of research (Irwin & Johnson, 2015).

 Research to address barriers often focuses on a single barrier such as education or finance.

Prescriptions

- •make it to the pharmacy 50% to 70%
- •come out of pharmacy 48% to 66%
- •taken properly 25% to 30%
- •refilled as prescribed 15% to 20%





Problem Statement



Non-adherence leads to uncontrolled comorbid illness and potential for reduced cancer treatment efficacy



Healthcare providers need a valid, efficient evidence-based process to screen for the most impactful barriers



Objective

 develop an evidence-based observational screening instrument

• evaluate its potential for identifying barriers to medication adherence in adult oncology patients.

Method

- Search Literature
- Categorize into five barriers
- Organize into a screening instrument
- Study: A retrospective, quasiexperimental, observational comparison study was used to evaluate retrospective data of patients with co-morbidities.

Search Strategy

Databases:

• CINAHL Plus with Full Text, Cochrane Library, JAMA, Journals@Ovid, MEDLINE, MEDLINE with Full-Text (EBSCO), Nursing and Allied Health, and ProQuest

• Keywords and Phrases:

• readmission, rehospitalizations, cancer, oncology, diabetes type 2, depression, behavior, comorbidities, medication(s), adherence, nonadherence, compliance, noncompliance, barriers, obstacles, challenges, difficulties, issues, stigma, predictors, predicting, causes, drug therapy, polypharmacy, prescriptions, providers, outcomes, quality of life, algorithm, toolkit, questionnaire, assessment, instrument

- Sources reviewed:
 - **990**
- Sources used in project manuscript:
 - 55 (29 research articles and 26 additional sources)

- Melnyk Levels of Evidence used to analyze literature.
 - Priority given to level one systematic reviews, meta-analysis, meta-analysis with triangulation, clinical guidelines based on systematic reviews and meta-analysis

Critical Appraisal

Financial Social

• (AMA, 2018); (Wooldridge, Schnipper, Goggins, Dittus, & Kripalani, 2016); (Hanson, Habibi, Khamo, Abdou & Stubbings, 2014); (NCPA, 2013); (Heath, 2017); (Frakt, 2017); (KFF, 2017); (Kangovi et al., 2012); (Irwin & Johnson, 2015); (Greer et al., 2016).

Depression Distress Anxiety

• (AMA, 2018); (American Family Physician, 2012); (Millionhearts.hhs.gov, 2017); (Greer et al., 2016); (Mausbach, Schwab & Irwin, 2015); (Aikens, Trivedi, Aron, & Piette, 2015); (Spoelstra, & Sansoucie, 2015).

Medical Related Concerns

• (AMA, 2018); (CDC, 2017); (Irwin, & Johnson, 2015); (NCPA, 2013); (Peeters et al., 2015); (Balling, Erstad, & Weibel, 2015); (Lam & Fresco, 2015); (Wooldridge, Schnipper, Goggins, Dittus, & Kripalani, 2016).

Behaviors and Lifestyl

• (NCPA, 2013); (Frakt, 2017); (Millionhearts.hhs.gov, 2017); (Irwin, & Johnson, 2015); (ONS, 2016); (Wooldridge, Schnipper, Goggins, Dittus, & Kripalani, 2016).

Educational Barriers

• (Millionhearts.hhs.gov, 2017); (AMA, 2018); (Spoelstra, & Sansoucie, 2015); (Irwin, & Johnson, 2015); (Cawthon, Mion, Willens, Roumie & Kripalani, 2014); (CDC, 2017); (Heath, 2017); (Parr, 2017); (Boucher, Lucca, Hooper, Pedulla, & Berry, 2015); (Al-Batran, 2015); (Patel, Phuoc, Bachler & Atkinson, 2017); (Tomko et al., 2013); (Kangovi et al., 2012).

1. Financial and Social Barriers

• Cost is reason for not filling prescription 23.5% of the time in project by Wooldridge, Schnipper, Goggins, Dittus, & Kripalani (2016).

• 35% of patients taking four or more pills a day reported taking lower dosage or skipped doses (KFF, 2017).

 Social Support a factor 32% of the time in a metaanalysis with triangulation (Irwin & Johnson, 2015).



Depression/Distress/Anxiety



- In a meta-analysis by Mausbach, Schwab, & Irwin (2015) 17,000 women evaluated for association of depression and adherence to oral anticancer therapy.
 - greater depression = lower adherence.
 - increased mortality
 - worse quality of life
- Depression, anxiety are predictors of poor adherence. (Millionhearts.hhs.gov, 2017).
- Long-term distress may be a predictor of non-adherence (Aikens, Trivedi, Aron, & Piette, 2015).

3. Medical

- Roop & Wu (2014) One of the most frequently identified barriers was adverse effects of medication.
- Greater number of different medications prescribed and higher daily frequency, increases nonadherence (AMA, 2018).
- A meta-analysis of qualitative research with triangulation to quantitative research revealed a 42% frequency of provider relationship as a predictor of adherence (Irwin, & Johnson, 2015).

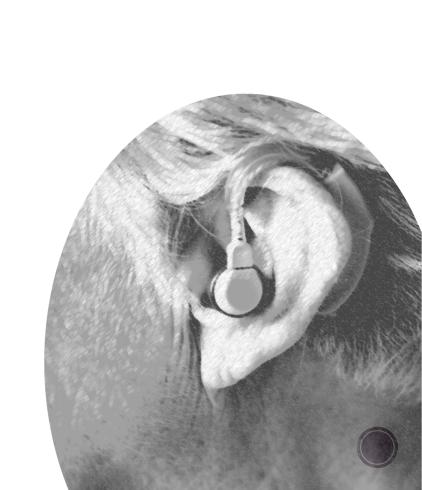
4. Behavior and Lifestyle

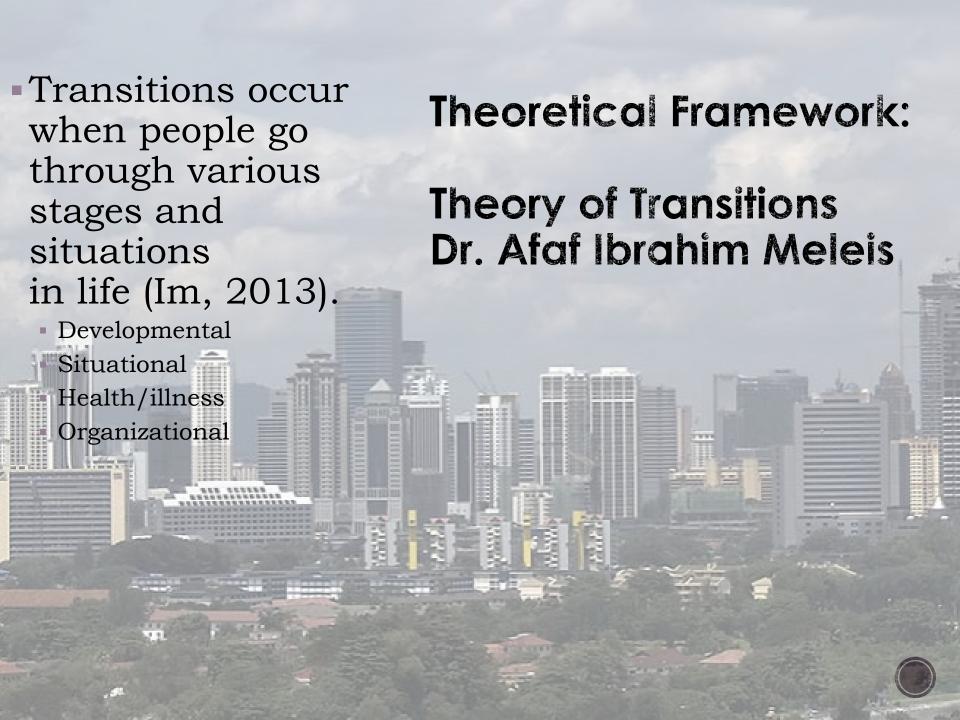
- Forgetting was #1 selfreported reason for nonadherence in a national telephone survey (NCPA, 2013).
 - additional research revealed may not be as large an impact (Frakt, 2017).
- Impact of "doubting necessity" 35% in a meta-analysis of research with triangulation (Irwin, & Johnson, 2015).
- More than 10 medications significantly associated with not filling medications. (Millionhearts.hhs.gov, 2017).



5. Educational

- Medication knowledge was mentioned 25% of the time as a barrier to adherence in an extensive meta-analysis of qualitative studies triangulated with quantitative studies (Irwin, & Johnson, 2015).
- 90 million adults in the United States have low health literacy which is associated with lower rates of preventive care, poorer disease control, and greater mortality, as well as increased health care utilization and costs (Cawthon, Mion, Willens, Roumie & Kripalani, 2014).





Summary

- Comprehensive screening instrument addressing all five categories was not found
- With the Iowa model as a guide, it was decided to develop an evidence-based screening instrument.
 - literature classified into five categories of adherence barriers with accompanying evidence-based warning signs.
 - Result? A one-page, comprehensive screening instrument.
 - Instrument has been titled, "W-BMA"
 (Washburn_Barriers to Medication Adherence risk assessment).



- Alan B. Pearson Comprehensive Cancer Center, Medical Oncology Clinic
- IRB Approval
- Support from key stakeholders
- CMS Oncology Care Model



Design of Study

- The Iowa model guides the researcher to test a change in practice with a pilot study (Iowa Model Collaborative, 2017).
- Retrospective, quasi-experimental, observational comparison study.
- Patient data was reviewed for existing screening methods of financial counseling, depression, distress.
- Then the new screening instrument was used to identify barriers, interventions, uncontrolled illness, and other details.
 - NCCN CTCAE criteria used for grading uncontrolled illnesses.
- Data was evaluated using frequency tables and classification tree which also helped analyze instrument sensitivity.

Population

- Patients enrolled in the OCM program.
 - Medicare recipients.
 - Received chemotherapy treatment
- At least two visits within the previous year
- Sample of 250/759 patients was selected via a report identifying those who met criteria
- Every third person selected to ensure systematic sampling
- OCM patients are managed more closely than typical patients and are more likely to have had all recommended care (reducing potential confounding variables)

Population

- Sample:
 - 250 retrospective samples,
 - seen at least twice in previous year,
 - majority of sample born between 1934 and 1950,
 - 119 male and 131 females,
 - Average number of prescribed medications = 10,
 - With 10% taking over 20 medications each.

Average Subject Profile

- 74-year-old female
- English-speaking
- Social Security with Medicare
- Cancer diagnoses
- Chemotherapy treatments
- DM-2 (elevated blood glucose)
- HTN (stage 2 hypertension)
- Ten medications
- Her medication list that she provides to the oncologist, does not match what she provides to healthcare personnel as an inpatient.
- She lives with her spouse
- ECOG 1



Data Collection

- Data reviewed and recorded financial concerns/counseling, the presence of PHQ-9 depression screen score of 15 or higher and an NCCN Distress score of 4 or higher and any relevant interventions.
- Following that initial comparison assessment, the record was then analyzed with the W-BMA screening instrument and interventions.
 - The W-BMA screening instrument includes the depression and distress screening results as part of the comprehensive review of risk.
- Also noted and recorded were signs and symptoms of uncontrolled illness, symptoms, relationship to medication, and unplanned healthcare visits.
- Data was collected and evaluated with SPSS to measure outcomes:
 - First, to see if there was an increase in percentage of patients identified with actionable barriers to medication adherence compared to those identified in current screening methods alone.
 - Second, to see if there is instrument sensitivity as predicted by analyzing if patients identified also had uncontrolled illness/adverse events.

W-BMA Instrument

Medication Adherence Barrier Identification Tool

Place a check next to each potential barrier identified (If implemented, tool will include instructions to refer to an oncology navigator if any warning signs identified for coordination of interdisciplinary care)

Barrier:	Warning Signs:	Notes:
☐ Financial/Social	Age 65 or higher and one or more of the	(referrals/interventions)
Support	following:	
	Unmarried and/or absence of social support Medicaid eligible	
	Income less than 50,000 dollars/year	
	 Limited pharmacy access (location of residence 	
	related to pharmacy, resides outside of city, lack of transportation)	
☐ Depression/Distress/	PHQ-9 Depression screen Score of 15 or higher	
Anxiety	NCCN Distress Score of 4 or higher	
	Diganoses of anxiety, or on medication for anxiety	
☐ Medical Related	More than 10 medications	Record # of meds here:
Concerns	Uncontolled illness Unexpected side effects and/or lack of expected side	
Related cues: Side	effects	
effects/Effectiveness/Medication	Distressed about side effects	
Reconciliation Issues/relationship	 Prescription not filled or refilled at expected rate 	
with provider/multiple	Late stage of cancer	
comorbidities/ Polypharmacy/	Poor physical status (ECOG 1 or over) Provider relationship strained	
Poor Performance Score (ECOG)/cancer therapy last 6	No show for appointments and reluctance to	
months	reschedule/Requesting a different provider	
	Significant other concerns about not following	
	treatment regimen	
☐ Behavior/Lifestyle	Prescription not refilled at expected intervals	
Palatad awas Favaatting/Dou't	Pill bottle contains more pills than it should based on fill date (If it is the original bottle)	
Related cues: Forgetting/Don't think it's needed/Didn't "agree" to	Taking additional unprescribed herbal or "natural"	
take it/Don't like taking it/ too	substances	
busy/Away from home/no	 Tobacco, ETOH abuse, illegal drug use 	
established routine	Weekly/daily pill box contains unopened/unused	
	pills	
	Reluctance to accept a change in regimen Preference to be "prescription free" or "all natural" or	
	other alternatives	
☐ Educational	English is not first language	
	Reluctance, difficulty, or inability to read and/or	
Related cues: Knowledge deficits	correctly explain written medication instructions (on	
including general	pill bottle or med list) Medication not taken correctly	
knowledge/limited English proficiency/functional/Cognitive/	Identifies medications by color, size, and shape but	
Psychological/Health	unable to explain what medications are, or what they	
literacy/Vision Impairment/Hard	are for.	
of Hearing/Memory	 Has not filled prescription/reductant to answer 	
impairment/misconceptions	questions about compliance with regimen	
/Distrust	Significant other takes care of all paperwork Known memory impairment	
	Known memory impairment	

Chart 1: Age Groups of Subjects

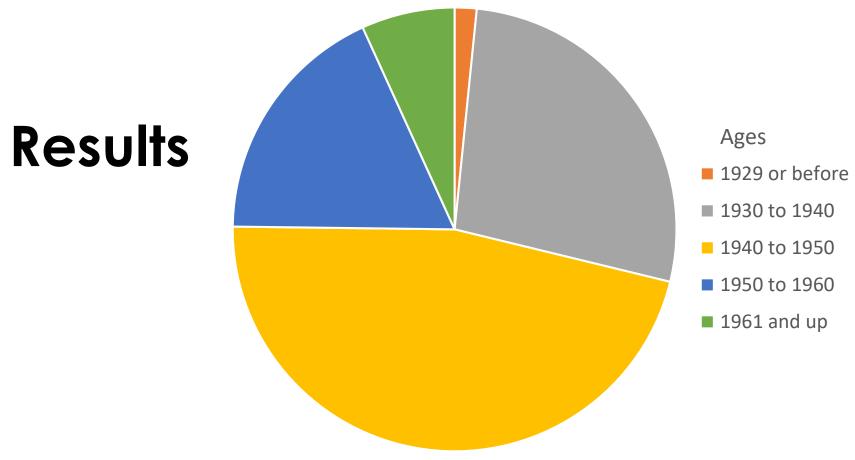
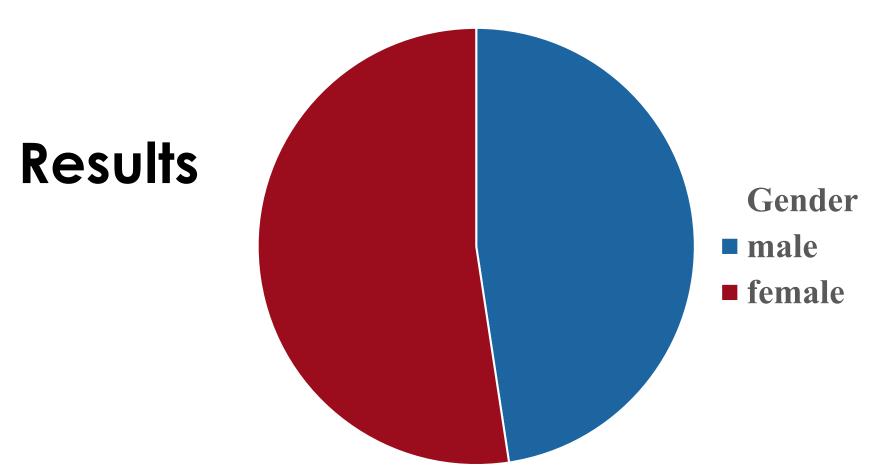




Chart 2: Gender of Subjects





SPSS Frequencies Statistics:

PosCurrentPorNonly

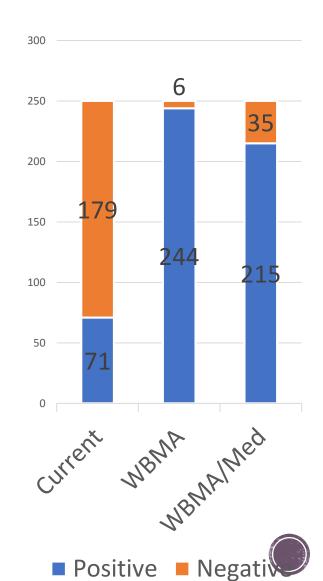
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	71	28.4	28.4	28.4
	no	179	71.6	71.6	100.0
	Total	250	100.0	100.0	

PosWBMA

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	244	97.6	97.6	97.6
	no	6	2.4	2.4	100.0
	Total	250	100.0	100.0	

PosWBMAunaddressed

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	215	86.0	86.0	86.0
	no	35	14.0	14.0	100.0
	Total	250	100.0	100.0	



Results

- Null hypothesis rejected.
 - The current screening method <u>does not</u> identify the same number of patients at risk as the W-BMA.
- In addition, significant numbers of patients with barriers and uncontrolled illness went undetected using the existing screens.
- The Classification Tree further defines the data.



W-BMA Classification Tree Results

- To further evaluate the impact of barriers found by the W-BMA instrument:
 - 56.6% of the time, uncontrolled illness was found in patients prescribed a medication for that disease
 - •62.0% (P < .0002) had undetected medical related barriers.



W-BMA Classification Tree Results

- From the same group of patients with uncontrolled illness related to medication prescriptions 29% (P < .0002) of those individuals had uncontrolled illness possibly related to undetected behavior and lifestyle related barriers. In that case, 80% went undetected.
- As in the first tree, we see 34% lower incidence of uncontrolled illness when barriers are detected and addressed by oncology healthcare personnel.



Results

- SPSS sensitivity test on patients with barriers:
 - 83.2% of patients identified with barriers had an uncontrolled illness. (Chart not shown)
 - 86.2% of patients with barriers had uncontrolled illness related to a prescribed medication.

Observed	.00	1.00	Percent Correct
.00	21	61	25.6%
1.00	5	102	95.3%
Overall Percentage	13.8%	86.2%	65.1%

Implications for practice:

- W-BMA was able to detect a larger group of patients at risk for nonadherence, than the current, existing method.
- Patients found by the W-BMA instrument with undetected barriers had a significantly high rate of uncontrolled illness and adverse events.
- Removing barriers to medication adherence may result in better controlled illness and reduced healthcare costs.



Discussion

Although the research did not focus on the impact of navigation or social work on patient adherence,

the data indicates that there is a strong relationship between lower rates of uncontrolled illness and involvement of these support services to address barriers.



Conclusion

Healthcare systems must make the effort to improve adherence to medication regimens and reduce the incidence of uncontrolled illness and adverse events

The validating evidence from literature, and results of this pilot project, provide impetus to continue further exploration of use of the W-BMA screening instrument as part of a comprehensive adherence program in our most vulnerable patient populations

Questions

Thank you for allowing me to present my scholarly project today.

I'm happy to take any questions.

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