



**Development and validation of a clinically
practical patient assessment:
Engagement, Literacy and Adherence**

P-ELA

Support

- This program is made possible by support from the National Center for Research Resources and the National Center for Advancing Translational Sciences, NIH, UL1TR000117. (though UK's CCTS Small Grants Program PI: R. Cardarelli)



Other PELA Team Members

- **Roberto Cardarelli, DO, MPH** (PI: UK Department of Family & Community Medicine - Lexington)
- **Christina Studts, PhD** (UK College of Public Health)
- **Kimberly G. Fulda, DrPH** (U. North Texas Health Science Center)
- **Carol Hustedde, PhD** (UK Department of Family & Community Medicine - Lexington)
- **Anna Espinoza, MD** (U. North Texas Health Science Center)
- **Sam Crocker, BA** (UK Department of Family & Community Medicine - Lexington)
- **Derek Combs** (UK Center of Excellence in Rural Health - Hazard)
- **Jennifer Schilling, MPH** (UK Department of Family & Community Medicine - Lexington)

Faculty Disclosures

- Speakers do not have any relevant financial relationships with any commercial interests.

Rationale for Project

- The healthcare environment has changed significantly
 - More oversight
 - Less time with patients
 - More paperwork
 - More rules
 - Less satisfaction
- Demands on providers and their staff have become increasingly more challenging

Rationale for Project

- Patient population seems to be getting sicker
 - More chronic disease
 - Diabetes, smoking-related disease, obesity
 - More co-morbidities
- Need a practical and effective tool to help providers identify a baseline for their patients
 - Adapt communication, educational materials, help overcome barriers to adherence, understand how they want to interact

Rationale for Project

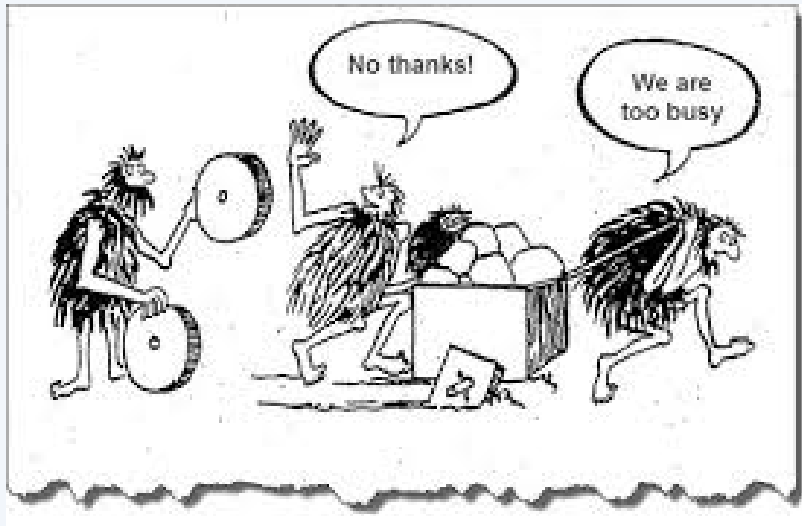
- Research suggests that a fuller understanding of the patient can be obtained by using various assessments (measures) in conjunction with physical exams and interviews
- There are lots of Patient-Reported Measures (PROMs), measuring lots of things: *attitudes, behaviors, intentions, depression, self-efficacy, knowledge, etc.*

Rationale for Project

- How do you decide what is most important to know?
 - Social support? Compliance? Health literacy? Depression? Attitudes? Engagement? Intentions?
- What information would be most relevant to patient care and health outcomes?
 - Which measures should you use?
 - How do you incorporate them into your practice?

Reasons patient assessments don't make it to clinical practice

- Practical
- Methodological
- Attitudinal



Can we tackle these first two?

Practical, Methodological ?'s

- While it would be beneficial to give patients a variety of instruments, it's not always practical or easy to implement
 - Even a few instruments can take a long time to administer
 - Then, you have to score and interpret them
 - And then what do you do with the information?
 - How do you make sense of it for your practice and your patients?

The Plan

- 3 areas that have been identified as important to the medical visit and improving health outcomes
 - Health literacy
 - Patient engagement
 - Medical adherence
- Develop, validate a short and easy to use Patient-Reported Measure (PROM) that measures these factors



The End-Goals...

- Help providers meet their patients where they are
- Build a more activated and empowered patient
- Increase satisfaction with healthcare providers and services
- Improve care monitoring and improve management of chronic conditions



Engagement

“Involving patients in their care.”¹

- Patients fall on a continuum regarding interest in the level of involvement in their care
 - Some will relinquish all control and decisions to their provider
 - Others will want to be a partner
 - Still others will want to drive the direction of their care

¹James, Hibbard, Agres, Lott, Dentzer, *Health Affairs*, 2013



Health Literacy

“people's knowledge, motivation and competences to access, understand, appraise, and apply health information.”²

Two main types of health literacy

- Oral
 - Most information during medical visit is oral
 - Complicated information (i.e., managing a chronic disease) hard to process and implement
- Numeracy
 - Multiple medicines, dosage amounts, reading labels on food can be challenging



Adherence

“The extent to which a person's behavior – taking medication, following a diet and/or executing lifestyle changes, corresponds with recommendations from a health care provider.”³

- Some medical recommendations are easier to follow than others
- Some patients are more adherent than others
 - Environment
 - Health literacy
 - Financial status

³World Health Organization (WHO). Adherence to Long-Term Therapies: Evidence for Action. Geneva: WHO; 2003.



Objectives

- Administer validated instruments on health literacy, medication adherence, and patient engagement
- Select a subset of items that may comprise an ultra-brief Patient-ELA assessment tool for use in primary care settings



Methods

- **Recruited in clinic waiting area**
 - Lexington, Kentucky: 50
 - Hazard, Kentucky: 50
 - Fort Worth, Texas: 100
- **Inclusion Criterion:** 18 years or older, fluent in speaking/reading English, at least 2 prescription medications
- **Convenience sampling**, but sought equal representation of males and females, and persons of all ethnicities.

Demographic, Clinical Characteristics of Respondents

| <u>Characteristics</u> | <u>Range (Mean \pm SD) or Number (%)</u> |
|------------------------|---|
| Age (Mean \pm SD) | 18–88 (49 \pm 14) |
| Sex | |
| Male | 50 (25%) |
| Female | 150 (75%) |
| Marital status | |
| Married | 73 (36.5%) |
| Separated/divorced | 42 (26.5%) |
| Widowed | 19 (9.5%) |
| Never Married | 37 (18.5%) |
| In a relationship | 16 (8%) |
| Refused | 2 (1%) |

Demographic, Clinical Characteristics of Respondents

| <u>Characteristics</u> | <u>Range (Mean \pm SD) or Number (%)</u> |
|------------------------|---|
| Ethnicity | |
| Black/African American | 59 (29.5%) |
| Caucasian | 112 (56%) |
| Hispanic | 21 (10.5%) |
| Other or Refused | 8 (4%) |

Characteristics

Number (%)

Education level

| | |
|-----------------------------|------------|
| No high school | 10 (5%) |
| Some high school | 34 (17%) |
| High school graduate or GED | 59 (29.5%) |
| Some College | 75 (37.5%) |

Household Income

| | |
|-----------------------|-------------|
| Below 20K | 101 (50.5%) |
| 20K to less than 50K | 52 (26%) |
| 50K to less than 100K | 21 (14%) |
| Over 100K | 14 (7%) |
| Refused | 19 (9.5%) |

Characteristics

Number (%)

General Health

Excellent or Very Good

34 (17%)

Good

64 (32%)

Fair

69 (34.5%)

Poor

27 (13.5%)

Smoking

Every Day

34 (17%)

Some Days

64 (32%)

Not at all

69 (34.5%)

Refused/Don't know

6 (3%)

| BMI | Weight Status | <u>Number (%)</u> |
|----------------|----------------------|--------------------------|
| Below 18.5 | Underweight | 3 (1.5%) |
| 18.5 – 24.9 | Normal | 27 (14%) |
| 25.0 – 29.9 | Overweight | 48 (25%) |
| 30.0 and Above | Obese | 115 (59.5%) |

Methods

- **Informed Consent**
- **Demographics Form**
- **7 Instruments** (*given in 3 random orders*)
 - 2 for Engagement
 - 2 for Literacy
 - 3 for Adherence
- **\$10** Walmart gift card



Item response theory, or “IRT” Analysis

- Models the probability of agreeing to an item as a function of the 'amount' of the underlying trait in the respondent (how engaged, literate, or adherent they are)
- Modeling provides:
 - Difficulty level (what level of the trait the item targets)
 - Discrimination (how well does it differentiate people at that level of the trait)



Item response theory, or “IRT” Analysis

- Good questions will maximally target the level of the construct that you care about for your purpose, and discriminate between people within that level
- **PURPOSE!:** Economize test administration by adaptively using only the discriminative items.

Health Care Empowerment Inventory (HCEI)

Instructions: These questions ask about your involvement in your health care. Please indicate how much you agree or disagree with each of the following statements.

I prefer to get as much information as possible about treatment options. (ICCE)

I try to get my health care providers to listen to my preferences for my treatment. (ICCE)

I am very active in my health care. (ICCE)

I take my commitment to my treatment seriously. (ICCE)

~~I accept that the future of my health condition is unknown even if I do everything I can. (TU)~~

~~I recognize that there will likely be setbacks and uncertainty in my health care treatment. (TU)~~

~~I am comfortable with the idea that there may be setbacks in my treatment. (TU)~~

~~I have learned to live with the uncertainty of my health condition. (TU)~~

- | | | |
|---|---|----------------------------|
| 1 | = | Strongly Disagree |
| 2 | = | Disagree |
| 3 | = | Neither Agree Nor Disagree |
| 4 | = | Agree |
| 5 | = | Strongly Agree |

*Measure too
different from HCEI
information
subscale*

Note: ICCE = Informed, Committed, Collaborative, Engaged subscale; TU = Tolerance of Uncertainty subscale

Health Care Empowerment Inventory (HCEI)

Instructions: These questions ask about your involvement in your health care. Please indicate how much you agree or disagree with each of the following statements.

I prefer to get as much information as possible about treatment options. (ICCE)

I try to get my health care providers to listen to my preferences for my treatment. (ICCE)

I am very active in my health care. (ICCE)

I take my commitment to my treatment seriously. (ICCE)

I accept that the future of my health condition is unknown even if I do everything I can. (TU)

I recognize that there will likely be setbacks and uncertainty in my health care treatment. (TU)

I am comfortable with the idea that there may be setbacks in my treatment. (TU)

I have learned to live with the uncertainty of my health condition. (TU)

- | | | |
|----------|---|----------------------------|
| 1 | = | Strongly Disagree |
| 2 | = | Disagree |
| 3 | = | Neither Agree Nor Disagree |
| 4 | = | Agree |
| 5 | = | Strongly Agree |

Note: ICCE = Informed, Committed, Collaborative, Engaged subscale; TU = Tolerance of Uncertainty subscale

HEALTH OPINION SURVEY

The following questions ask for your opinions about different kinds of health care. For each statement below, decide whether you AGREE or DISAGREE and circle the answer which best fits your opinion. Each person is different, so there are no "right" or "wrong" answers. Please try to circle an answer for each question, and don't leave any blank. Even if you find you don't completely agree or disagree with a statement, choose the one answer that comes closest to what you believe.

Your answers are confidential and will be used for research purposes only. Thank you for your assistance.

For each question, circle only one answer that comes CLOSEST to what you believe:

Measure too different from HCEI information subscale

- | | | | | | |
|--|-------|----------|--|-------|----------|
| 1. I usually don't ask the doctor or nurse many questions about what they're doing during a medical exam. | AGREE | DISAGREE | 8. I usually ask the doctor or nurse lots of questions about the procedures during a medical exam. | AGREE | DISAGREE |
| 2. Except for serious illness, it's generally better to take care of your <u>own</u> health than to seek professional help. | AGREE | DISAGREE | 9. It's almost always better to seek professional help than to try to treat yourself. | AGREE | DISAGREE |
| 3. I'd rather have doctors and nurses make the decisions about what's best than for them to give me a whole lot of choices. | AGREE | DISAGREE | 10. It is better to trust the doctor or nurse in charge of a medical procedure than to question what they are doing. | AGREE | DISAGREE |
| 4. Instead of waiting for them to tell me, I usually ask the doctor or nurse immediately after an exam about my health. | AGREE | DISAGREE | 11. Learning how to cure some of your illness without contacting a physician may create more harm than good. | AGREE | DISAGREE |
| 5. It is better to rely on the judgments of doctors (who are experts) than to rely on "common sense" in taking care of your own body. | AGREE | DISAGREE | 12. Recovery is usually quicker under the care of a doctor or nurse than when patients take care of themselves. | AGREE | DISAGREE |
| 6. Clinics and hospitals are good places to go for help <u>since it's best for medical experts to take responsibility</u> for health care. | AGREE | DISAGREE | 13. If it costs the same, I'd rather have a doctor or nurse give me treatments than to do the same treatments myself. | AGREE | DISAGREE |
| 7. Learning how to cure some of your illness without contacting a physician is a good idea. | AGREE | DISAGREE | 14. It is better to rely less on physicians and more on your own common sense when it comes to caring for your body. | AGREE | DISAGREE |
| | | | 15. I usually wait for the doctor or nurse to tell me about the results of a medical exam rather than asking them immediately. | AGREE | DISAGREE |
| | | | 16. I'd rather be given many choices about what's best for my health than to have the doctor make the decisions for me. | AGREE | DISAGREE |

REALM-R

Count a word as correct if the word is pronounced correctly and no additions or deletions have been made to the beginning or ending of the word. For example: “jaundiced” would not receive credit for the word “jaundice”. Fat, Flu, and Pill are not scored.

fat

flu

pill

allergic

jaundice

anemia

fatigue

directed

colitis

constipation

osteoporosis

Score Sheet for the Newest Vital Sign Questions and Answers

READ TO SUBJECT:

This information is on the back of a container of a pint of ice cream.

1. If you eat the entire container, how many calories will you eat?
Answer: 1,000 is the only correct answer
2. If you are allowed to eat 60 grams of carbohydrates as a snack, how much ice cream could you have?
Answer: Any of the following is correct: 1 cup (or any amount up to 1 cup), half the container. Note: If patient answers "two servings," ask "How much ice cream would that be if you were to measure it into a bowl?"
3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?
Answer: 33 is the only correct answer
4. If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?
Answer: 10% is the only correct answer

READ TO SUBJECT:

Pretend that you are allergic to the following substances: penicillin, peanuts, latex gloves, and bee stings.

5. Is it safe for you to eat this ice cream?
Answer: No
6. (Ask only if the patient responds "no" to question 5): Why not?
Answer: Because it has peanut oil.

ANSWER CORRECT?

| yes | no |
|-----|----|
| | |
| | |
| | |
| | |
| | |
| | |
| | |

Number of correct answers:

Interpretation

Score of 0-1 suggests high likelihood (50% or more) of limited literacy.

Score of 2-3 indicates the possibility of limited literacy. Of

Score of 4-6 almost always indicates adequate literacy. Da

If you are allowed to eat 60 grams of carbohydrates as a snack, how much ice cream could you have?

Morisky 8-Item Medication Adherence Questionnaire

| Question | Patient Answer (Yes/No) | Score Y=1; N=0 |
|--|-------------------------|-------------------|
| Do you sometimes forget to take your medicine? | | |
| People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past 2 weeks, were there any days when you did not take your medicine? | | |
| Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it? | | |
| When you travel or leave home, do you sometimes forget to bring along your medicine? | | |
| Did you take all your medicines yesterday? | | |
| When you feel like your symptoms are under control, do you sometimes stop taking your medicine? | | |
| Taking medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan? | | |
| How often do you have difficulty remembering to take all your medicine? | | A = 0; B-E = 1 |
| <input type="checkbox"/> A. Never/rarely | | |
| <input type="checkbox"/> B. Once in a while | | |
| <input type="checkbox"/> C. Sometimes | | |
| <input type="checkbox"/> D. Usually | | |
| <input type="checkbox"/> E. All the time | | |
| Total score | | |

Scores: >2 = low adherence
1 or 2 = medium adherence
0 = high adherence

Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. *Med Care.* 1986;24:67-74.

Morisky 8-Item Medication Adherence Questionnaire

| Question | Patient Answer (Yes/No) | Score Y=1; N=0 |
|--|-------------------------|----------------------|
| Do you sometimes forget to take your medicine? | | |

Table 1: Medical Outcomes Study General Adherence Items

How often was each of the following statements true for you during the past 4 weeks?

(Circle One Number on Each Line)

| | None of the time | A little of the time | Some of the time | A good bit of the time | Most of the time | All of the time |
|--|------------------|----------------------|------------------|------------------------|------------------|-----------------|
| 1. I had a hard time doing what the doctor suggested I do . . . | 1 | 2 | 3 | 4 | 5 | 6 |
| 2. I followed my doctor's suggestions exactly . . . | 1 | 2 | 3 | 4 | 5 | 6 |
| 3. I was unable to do what was necessary to follow my doctor's treatment plans . . . | 1 | 2 | 3 | 4 | 5 | 6 |
| 4. I found it easy to do the things my doctor suggested I do . . . | 1 | 2 | 3 | 4 | 5 | 6 |

5. Generally speaking, how often during the past 4 weeks were you able to do what the doctor told you?

(Circle One)

- None of the time..... 1
- A little of the time..... 2
- Some of the time 3
- A good bit of the time..... 4
- Most of the time..... 5
- All of the time..... 6



Taking Medicine—What Gets in the Way?

Think about all of the medicines you take. Mark one answer for each item below.

INCONVENIENCE/ FORGETFULNESS

Lifestyles



| | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree |
|---|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 1 I just forget to take my medicines some of the time. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 2 I run out of my medicine because I don't get refills on time. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 3 Taking medicines more than once a day is inconvenient. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

TREATMENT BELIEFS

Attitudes and Beliefs



| | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree |
|--|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 4 I feel confident that each one of my medicines will help me. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 5 I know if I am reaching my health goals. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Help From Others



| | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree |
|--|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 6 I have someone I can call with questions about my medicines. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Talking With Healthcare Team



| | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree |
|--|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 7 My doctor/nurse and I work together to make decisions. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

BEHAVIOR

Taking Medicines



| Have You... | In the last week | In the last month | In the last 3 months | More than 3 months | Never |
|---|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 8 Taken a medicine more or less often than prescribe? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9 Skipped or stopped taking a medicine because you didn't think it was working? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 10 Skipped or stopped taking a medicine because it made you feel bad? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 11 Skipped, stopped, not refilled, or taken less medicine because of the cost? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 12 Not had medicine with you when it was time to take it? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

If you checked any answers in the darker blue boxes, talk with your doctor or other healthcare provider.

Measure too different from the other Adherence scales



IRT Yield

- **1 engagement item**
 - “I prefer to get as much information as possible about treatment options”
- **3 Literacy items**
 - 2 REALM pronunciations: colitis, osteoporosis
 - 1 newest vital sign item: “If you are allowed to eat x grams carbohydrates, how much ice cream?”
- **3 Adherence items**
 - Morisky: “Do you sometimes forget to take your medicine?”
 - MOS: “I had a hard time doing what the doctor suggested”; “I was unable to do what was necessary to follow my doctor’s treatment plans”

Next Steps

- Sample Size small for IRT analysis
 - *Increase sample size for increased confidence in our analysis*
- Cross-validate the analysis
 - *See if the same 7 items from this model hold up with a new sample*
- Obtain more broadly representative sample
 - *See if items discriminate with respect to other characteristics (gender, ethnicity and socio-economic status)*

Special Thanks

Special thanks to the clinics, staff, and providers that allowed us to work in their clinic settings:

- UK Family Medicine Center, Lexington, KY
- North Fork Valley CHC, Hazard, KY
- NorTex member clinics, Fort Worth, TX