THANK YOU FOR JOINING ISMPP U TODAY!

The program will begin promptly at 11:00 am EDT

September 14, 2016
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QUESTIONS...

- To ask a question, please type your query into the Q&A box
  - To ensure anonymity and that all panelists receive your question, please choose the drop down box option, "Hosts, Presenters and Panelists."
  Otherwise, all audience members will be able to see your submitted question
- We will make every effort to respond to all questions

NOTE: Make sure you send your question to “Host, Presenter and Panelists”
PATIENT INSIGHT, PROS AND PATIENT ENGAGEMENT – WHAT ARE THE OPPORTUNITIES FOR PUBLICATIONS DEVELOPMENT?

Richard White MA PhD
Lizzie Perdeaux MA MPhil PhD
Oxford PharmaGenesis
DONNA SIMCOE
… A BIT ABOUT ME

• Background
  – Managed publications for over 20 years
  – Holds three master’s degrees (in Biomedical Writing, Biotechnology and an MBA)
  – ISMPP Certified Medical Publication Professional™ (CMPP)
  – Active member of AMWA, ISMPP and TIPPA
  – Medical Publications consultant and principal at Simcoe Consultants, Inc., a biomedical company focusing on medical publication development and medical writing.

• Patient
  – Mitral valve prolapse
RICHARD WHITE
... A BIT ABOUT ME

• **Background**
  – MA, PhD Pharmacology (Cambridge)
  – Training in Marketing (INSEAD) and Health Economics (Oxford)
  – Honorary Research Fellow (Oxford Brookes University)

• **Oxford PharmaGenesis**
  – Publication planning for major brand launches
  – Founder of the Value Demonstration Practice
    • Publications, communications and training in HEOR, RWE and PROs
  – Invited presentations on HEOR, RWE and PRO publications at TIPPA and ISMPP

• **Patient**
  – Severe hearing loss and tinnitus (ringing in the ears)
LIZZIE PERDEAUX
... A BIT ABOUT ME

• Background
  – MA, MPhil, PhD Genetics (Cambridge)
  – Post-doctoral Research Fellow
    (Institute of Cancer Research, London)
  – Charity officer at the Myrolytis Trust,
    a patient-support charity

• Oxford PharmaGenesis
  – Medical Writer since January 2015
  – Member of the Patient Engagement Practice

• Patient/carer
  – Robertsonian Translocation t(15;22)(q10;q10)
  – Dad was diagnosed with early-onset Alzheimer’s
    at the age of 58 years
Information presented reflects the personal knowledge and opinion of the presenters and does not necessarily represent the position of their current or past employers or the position of ISMPP.
WHAT YOU SHOULD TAKE AWAY FROM THIS PRESENTATION …

• Not being afraid of the jargon around PROs
• Identifying the publications opportunities provided by PROs
• Understanding what health literacy is, and what patients understand
• Knowing how you can be patient-centric in your role
Describe your current level of confidence in PROs and patient engagement

A. Very confident – high level of experience in this area
B. Quite confident – I’m no expert but I know enough
C. Not very confident – I have some understanding but would like to know more
D. Not confident at all – I really don’t know very much about this area
E. Unsure – this stuff isn’t relevant to my role
WHY PATIENT-REPORTED OUTCOMES (PROS) ARE IMPORTANT
BEING PATIENT-CENTRIC: WHY DO PHYSICIANS TREAT PATIENTS?

• Treatment is offered to patients to:
  – increase longevity
  – prevent future morbidity
  – make them feel better

• ‘Feeling better’ includes avoiding:
  – discomfort (e.g. pain, nausea, breathlessness)
  – disability (i.e. loss of function)
  – distress (i.e. emotional problems)

• ‘Feeling better’ is a subjective assessment that cannot necessarily be measured by a physician using traditional endpoints, such as:
  – clinical status (e.g. peak flow for patients with lung disease)
  – surrogate markers (e.g. bone density for patients prone to fractures)
WHAT IS A PATIENT-REPORTED OUTCOME?

• Food and Drug Administration (FDA) definition of a PRO:

“A measurement based on a report that comes directly from the patient (i.e. study subject) about the status of a patient’s health condition without amendment or interpretation of the patient’s response by a clinician or anyone else”

• PRO measures are usually questionnaires and can be categorized as:

  **Generic HRQoL**
  - SF-36, SF-12
  - EQ-5D
  - HUI-2, HUI-3

  **Symptom-specific**
  - Fatigue Severity Scale

  **Disease-specific**
  - Asthma Quality of Life Questionnaire

• Also clinician-reported outcomes and observer-reported outcomes (out of scope for today)
ALL MAJOR STAKEHOLDERS ARE INCREASINGLY INTERESTED IN PRO DATA

AHA Scientific Statement
Cardiovascular Health: The Importance of Measuring Patient-Reported Health Status

A Scientific Statement From the American Heart Association

John S. Rumsfeld, MD, PhD, FAHA, Chair; Karen P. Alexander, MD, FAHA, Vice Chair; David C. Goff, Jr, MD, PhD, FAHA; Michelle M. Graham, MD; Michael Ho, MD, PhD, FAHA; Frederick A. Masoudi, MD, MSPH, FAHA; Debra K. Moser, DNSc, RN, FAHA; Véronique L. Roger, MD, MPH, FAHA; Mark S. Slaughter, MD, FAHA; Kim G. Smoak, MD, PhD; John A. Spertus, MD, MPH, FAHA; Mark D. Sullivan, MD, PhD; Diane Treat-Jacobson, PhD, RN, FAHA; Julie J. Zerwe, PhD, RN, FAHA; on behalf of the American Heart Association Council on Quality of Care and Outcomes Research, Council on Cardiovascular and Stroke Nursing, Council on Epidemiology and Prevention, Council on Peripheral Vascular Disease, and Stroke Council

JAMA Oncology
Patient-Reported Outcomes in Cancer Drug Development and US Regulatory Review Perspectives From Industry, the Food and Drug Administration, and the Patient

Ethan Ersher, MD, MSK; Cindy Geoghegan, BA; Stephen Joel Coons, PhD; Ari Gnanasakthy, MSc, MBA; Ashley F. Slagle, PhD; Elektra J. Papadopoulos, MD, MPH; Paul O. Kuehler, MD
ALL MAJOR STAKEHOLDERS ARE INCREASINGLY INTERESTED IN PRO DATA

“There is potential to use patient health status as a foundation for shared medical decision-making”"1

“Dozens of studies have shown that patient health status measures are strong, independent predictors of subsequent mortality”"1
ALL MAJOR STAKEHOLDERS ARE INCREASINGLY INTERESTED IN PRO DATA

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“Dozens of studies have shown that patient health status measures are strong, independent predictors of subsequent mortality”¹

“The European Society of Cardiology (ESC) recognizes the importance of advancing PRO research to inform patients, clinicians, payers, and policy-makers”²

“There is potential to use patient health status as a foundation for shared medical decision-making”¹

“Cancer drugs often carry substantial toxicities that may affect how people feel and function … it seems counter-intuitive that PRO end points are not central in the evaluation of cancer drugs”³
IMPORTANCE OF PRO MEASURES (1): THEY PREDICT ‘HARD’ PATIENT OUTCOMES

- FIELD (Fenofibrate Intervention and Event Lowering in Diabetes)
  - 5-year cohort study of 7348 patients with type 2 diabetes, aged 50–75 years
  - Multivariate analysis of baseline predictors of risk in the trial, correcting for multiple factors
  - EQ-5D is a general PRO measure from 0 (death) to 1 (perfect health)

“Index scores derived from the EQ-5D are an independent predictor of the risk of mortality, future vascular events, and other complications in people with type 2 diabetes”

An EQ-5D score 0.1 points higher was associated with:

- 14% rate of all-cause mortality
- 13% risk of complications
- 7% risk of vascular events
IMPORTANCE OF PRO MEASURES (2): THEY PREDICT PATIENT MEDICAL COSTS

- Medical Expenditures Panel Survey (MEPS; n = 20,624) data 2006–2007
- Medical expenditures (prescription medicines, hospital inpatient, ER, out-patient and office-based provider visits) in the 6 months following administration of the SF-12
- SF-12 is a general PRO measure from 0–100, higher scores = better health
- Model effect of physical (PCS) and mental (MCS) component summary scores correcting for age, sex, marital status, comorbidities count and insurance status

A 5-point lower PCS score was associated with an increase in medical expenditures

A 5-point lower MCS score was associated with an increase in medical expenditures

- 22% asthma
- 22% diabetes
- 18% migraine
- 17% depression
- 14% arthritis

- 7% asthma
- 9% diabetes
- 8% migraine
- 4% depression
- 7% arthritis
WHAT ARE PROS AND WHAT DO THEY DO?
GENERIC PRO MEASURES: ‘OFF-THE-SHELF’ TOOLS TO MEASURE HRQOL

- Examples of generic PRO instruments
  - EQ-5D, SF-36, SF-12, HUI-2, HUI-3
- Allow comparisons across:
  - different patient groups
  - different disease types
- Can be used for comparison with data in published studies
- Do not require development and refining before a study can commence
- More familiar to stakeholders
  - EQ-5D (essentially) gives a utility value between 0 and 1
AN EXAMPLE UTILITY CALCULATION USING THE EQ-5D (UK TARIFF)

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Level</th>
<th>Me, today</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobility</td>
<td>1. No problems</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>2. Some problems</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Confined to bed</td>
<td></td>
</tr>
<tr>
<td>Self-care</td>
<td>1. No problems</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>2. Some problems</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Unable to</td>
<td></td>
</tr>
<tr>
<td>Usual activities</td>
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<tr>
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</tr>
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<td><strong>Calculated utility</strong></td>
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<td>0.85</td>
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**Calculated utility**: 0.85, 0.62
DISEASE-SPECIFIC PRO MEASURES:
SOME KEY TERMINOLOGY

- **Conceptual framework**
  - Provides a picture of the relationships between items in a PRO instrument and the concepts measured by that instrument

- **Concept**: what is being measured
  - e.g. arthritis symptoms

- **Domain**: a sub-concept of the overall concept being measured
  - e.g. fine motor skills of the hand

- **Item**: an individual question that is evaluated by the patient
  - e.g. do you have difficulty moving your fingers/making a fist/picking up objects?
## DEVELOPMENT OF A DISEASE-SPECIFIC PRO MEASURE

1. **What do we need to do?**
   - Find out what PRO measures and concepts are already available

2. **How do we do it?**
   - Systematic literature review
### DEVELOPMENT OF A DISEASE-SPECIFIC PRO MEASURE

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# Development of a Disease-Specific PRO Measure

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## DEVELOPMENT OF A DISEASE-SPECIFIC PRO MEASURE

### What do we need to do?  
### How do we do it?

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PATIENT-REPORTED OUTCOMES: THE TERMINOLOGY MADE SIMPLE
COMMUNICATING EFFECTIVELY MEANS EXPLAINING THE TECHNICAL JARGON

WHAT WE SAY

CRONBACH’S ALPHA FACTOR
LOADING RASCH ANALYSIS
CONVERGENT VALIDITY CONSTRUCT
CONCEPTUAL MODEL MINIMUM
CLINICALLY IMPORTANT DIFFERENCE
FACE VALIDITY CONTENT VALIDITY
STANDARDIZED RESPONSE MEAN
LIKERT SCALE TEST-RETEST
COMMUNICATING EFFECTIVELY MEANS
EXPLAINING THE TECHNICAL JARGON

WHAT THEY HEAR

BLAH BLAH BLAH BLAH BLAH
BLAH BLAH BLAH BLAH BLAH BLAH
BLAH BLAH BLAH BLAH BLAH BLAH
BLAH BLAH BLAH BLAH MINIMUM
BLAH BLAH IMPORTANT BLAH
BLAH BLAH CONTENT BLAH BLAH
BLAH BLAH BLAH BLAH BLAH BLAH
BLAH BLAH BLAH BLAH BLAH
PRO SCALES – AN ANALOGY…
• Conceptual model – *a set of domains, as defined by patients and physicians, that determines the overall concept [body weight]*
PRO SCALES – AN ANALOGY… AND A SIMPLE CONCEPTUAL MODEL

- Conceptual model – *a set of domains, as defined by patients and physicians, that determines the overall concept [body weight]*

- Content validity – *does the scale contain everything about the concept [body weight] that is relevant to patients, physicians etc.?*
  - Interviews yield different themes; when no more new themes are uncovered (‘saturation’), content is likely to be valid
WHAT DO WE EXPECT FROM A GOOD SCALE?
RELIABILITY

• Reliability – *does it measure the concept [body weight] in a reproducible way?*
  
    – **Internal consistency**
      
      • Items within a domain should correlate with each other and with the total score
      
      • *Cronbach’s alpha > 0.70 between elements in the same domain indicates internal reliability*
WHAT DO WE EXPECT FROM A GOOD SCALE?

RELIABILITY

- Reliability – *does it measure the concept [body weight] in a reproducible way?*
  
  - **Internal consistency**
    - Items within a domain should correlate with each other and with the total score
    - *Cronbach’s alpha > 0.70 between elements in the same domain indicates internal reliability*
  
  - **Test–retest reliability**
    - Where nothing has changed in the subject, the scale should give the same result over time, when tested and retested after a reasonable interval (e.g. 2 weeks)
    - *Test–retest coefficient > 0.70 indicates good test–retest reliability*
WHAT DO WE EXPECT FROM A GOOD SCALE?

RESPONSIVENESS

- Responsiveness – does it detect meaningful changes [in body weight]?
  - When a meaningful change happens, the scale should be able to detect it

- Effect size (mean difference ÷ SD baseline score)
  - over 0.8 is considered large
  - 0.5–0.8 is considered clinically meaningful
  - 0.2–0.5 is considered small
HOW DO WE KNOW A SCALE IS MEASURING WHAT IT SHOULD? PSYCHOMETRIC VALIDITY

- Construct validity – *does the scale actually measure what it is supposed to* [body weight], and *not something else*?

- **Concurrent validity** – measurements from the scale should agree with other instruments that measure the same concept [body weight]
HOW DO WE KNOW A SCALE IS MEASURING WHAT IT SHOULD? PSYCHOMETRIC VALIDITY

- **Construct validity** – does the scale actually measure what it is supposed to [body weight], and not something else?

- **Concurrent validity** – measurements from the scale should agree with other instruments that measure the same concept [body weight]

- **Known-groups validity** – the scale should show differences [in body weight] between patient groups known to be different

- **Pearson correlation coefficients**
  - over 0.6 indicates a strong correlation
  - 0.3–0.6 indicates a moderate correlation
  - below 0.3 indicates a low correlation
PATIENT-REPORTED OUTCOMES: PUBLICATION OPPORTUNITIES
PRO MEASURES OFFER A WIDE RANGE OF PUBLICATION OPPORTUNITIES (1/5)

1. **What do we need to do?**
   - Find out what PRO measures and concepts are already available

2. **How do we do it?**
   - Systematic literature review

3. **What do we need to do?**
   - Develop conceptual framework and draft PRO measure

4. **How do we do it?**
   - Patient and physician focus groups and cognitive interviews

5. **What do we need to do?**
   - Confirm conceptual framework and assess properties of PRO measure

6. **How do we do it?**
   - Validation study in relevant patient samples

7. **What do we need to do?**
   - Collect, analyze and interpret PRO data in clinical studies

8. **How do we do it?**
   - Use PRO measure in clinical studies alongside other PROs

9. **What do we need to do?**
   - Modify PRO measure for wider usage

10. **How do we do it?**
    - Cultural adaptations, translations, evaluations in related diseases
**PRO MEASURES OFFER A WIDE RANGE OF PUBLICATIONS OPPORTUNITIES (2/5)**

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- Systematic literature review
- Patient and physician focus groups and cognitive interviews
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- Use PRO measure in clinical studies alongside other PROs
- Cultural adaptations, translations, evaluations in related diseases

**Journal of the American Academy of Child & Adolescent Psychiatry**

**RESEARCH ARTICLE**

**Adult ADHD patient experiences of impairment, service provision and clinical management in England: a qualitative study**

Lauren McMahon, Philip Johnson, Jou Chie Wei, Paul Humphreys, Sarah Sayer, Khaled Soare and Sarah Olliff

**Abstract**

Background: There is a limited evidence of the current needs and experiences of adults with Attention Deficit Hyperactivity Disorder (ADHD) in the published scientific literature. This study aimed to explore the experiences of adults with ADHD in England, ADHD symptom scores in diagnostic and treatment service, ADHD-related impairment and to compare experiences between patients diagnosed during adulthood and childhood.

Methods: In this qualitative study, 36 adults with ADHD were recruited through an ADHD charity (n = 25) and two hospital outpatient clinics for adults with ADHD in England (n = 11). Half of the participants were diagnosed with ADHD during childhood or adolescence and the remainder during adulthood. Semi-structured interviews were conducted and data was analysed using a thematic approach based on grounded theory principles.

Results: Patients identified five core themes. An qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, qualitative, 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PRO MEASURES OFFER A WIDE RANGE OF PUBLICATIONS OPPORTUNITIES (3/5)

<table>
<thead>
<tr>
<th>What do we need to do?</th>
<th>How do we do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Find out what PRO measures and concepts are already available</td>
<td>Systematic literature review</td>
</tr>
<tr>
<td>Develop conceptual framework and draft PRO measure</td>
<td>Patient and physician focus groups and cognitive interviews</td>
</tr>
<tr>
<td>Confirm conceptual framework and assess properties of PRO measure</td>
<td>Validation study in relevant patient samples</td>
</tr>
<tr>
<td>Collect, analyze and interpret PRO data in clinical studies</td>
<td>Use PRO measure in clinical studies alongside other PROs</td>
</tr>
<tr>
<td>Modify PRO measure for wider usage</td>
<td>Cultural adaptations, translations, evaluations in related diseases</td>
</tr>
</tbody>
</table>
## PRO MEASURES OFFER A WIDE RANGE OF PUBLICATIONS OPPORTUNITIES (4/5)

<table>
<thead>
<tr>
<th>Step</th>
<th>What do we need to do?</th>
<th>How do we do it?</th>
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# PRO Measures Offer a Wide Range of Publications Opportunities (5/5)

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</tr>
<tr>
<td>5 Modify PRO measure for wider usage</td>
<td>Cultural adaptations, translations evaluations in related diseases</td>
</tr>
</tbody>
</table>
WRITING UP THE STUDIES – MAKING THE MOST OF THE AVAILABLE GUIDANCE

- There is less guidance on the reporting of PRO studies than RCTs
- Reporting standards are available for describing PRO data in an RCT
  - CONSORT PRO
  - ISOQOL
- Regulatory guidance provides a framework for the elements that a PRO validation should cover
  - FDA and EMA guidelines
  - ISPOR PRO Special Interest Group
SIMPLE STEPS TO MAKING PRO ARTICLES EASIER FOR THE NON-SPECIALIST

• How can I convey the meaning to a non-PRO specialist among all this technical detail?

Use the abstract to place the study in a clinical context

Preface each section with one sentence that tells the non-specialist what it means (e.g. what is construct validity)

Use the conclusion to convey how the results might affect healthcare decision-making

Make use of supplementary tables/figures/methods
WHEN TO TARGET MAINSTREAM CLINICAL VERSUS SPECIALIST JOURNALS AND MEETINGS

• Specialist journals for PRO studies exist
  – But most of your key audiences are not PRO or psychometrics specialists
• Effective publication planning is essential
• Mainstream clinical journals and meetings
  – Core PRO papers – can be top-tier specialist journals
• Specialist journals and meetings
  – Technical and methodology papers (e.g. psychometric validation)
COMMUNICATING PATIENT-REPORTED OUTCOME DATA EFFECTIVELY
EFFECTIVE COMMUNICATION OF PRO DATA: APPLY THE ‘SO WHAT?’ FACTOR

• Effective communication involves clearly describing the data and then relating it to relevant measures of patient function

• The QOLRAD domain scores don’t tell us anything about:
  – what the scale relates to in terms of patient outcomes
  – whether this difference in score is clinically meaningful

![QOLRAD dimension: sleep disturbance](chart.png)

- Treatment for acid reflux
- Best possible score: 7
- Worst possible score: 0

Before treatment: 4.7
After treatment: 6.2

p < 0.05
Minimal clinically important difference (MCID) is the smallest difference in score that patients perceive as beneficial and that is significant enough to result in a change to the patient’s management\textsuperscript{1,2}

- When a change in PRO score is less than the MCID it is unlikely to have a meaningful impact on the patient
  - Even if the difference is statistically significant

- Changes and differences in PRO scores should therefore be interpreted relative to the MCID for the instrument
Mean data for the overall PRO measure are often only the starting point.

Consideration should be given to:

- Significant differences in individual domains or items.
- How threshold scores correspond to meaningful patient outcomes.
- Differences across relevant patient subsets (e.g. disease severity).

**QOLRAD dimension: sleep disturbance**

<table>
<thead>
<tr>
<th>Difficulty getting a good night’s sleep</th>
<th>Wakes up at night</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before treatment: 49%</td>
<td>34%</td>
</tr>
<tr>
<td>After treatment: 9%</td>
<td>7%</td>
</tr>
</tbody>
</table>
HELP YOUR AUDIENCES – GO BEYOND THE INITIAL PRO STUDY PUBLICATION

- Most of your internal and external audiences for PRO publications will not understand the technical details of PRO studies
- Develop simple, non-technical tools to accompany PRO publications
  - One-page evidence summaries of key PRO study publications
  - Infographics-driven, visually stimulating interactive slide decks
WHY DO WE CARE ABOUT PATIENT ENGAGEMENT?
WE’RE ON THE CUSP OF CHANGE

• Enhanced Patient Voice in Medicines Lifecycle (IMI2 Call 2)
• The European Patients’ Academy (EUPATI)
• Adapt Smart
• European Medicines Research Training Network (EMTRAIN)
• Patient-Centred Outcomes Research Institute (PCORI)
• International Consortium for Health Outcomes Measurement (ICHOM)
• Patient Focused Medicines Development (PFMD)
• National Health Council (NHC)
• Faster Cures
• Clinical Trials Transformation Initiative (CTTI)
• TransCelerate
• DIA-Tufts initiative on Return on Engagement
UNDERSTANDING WHAT MATTERS TO PATIENTS ACROSS THE DRUG DEVELOPMENT CONTINUUM

- Input on interest in research question
- Provide key insights on unmet needs that matter to patients
- Help to design study protocols (study visits, procedures, eligibility criteria, etc.)
- Advise on and review the development of patient materials (e.g., ICFs) (click here for more information)
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- Address barriers that impede access to care
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The Internal Journey Towards a Better Understanding of Patients

I can think like a patient, so I already understand the patient perspective.
I can think like a patient, so I already understand the patient perspective

I spoke to a patient and I learned something interesting
I can think like a patient, so I already understand the patient perspective

I spoke to a patient and I learned something interesting

I spoke to lots of patients and they all told me something different – how do I know that I’ve understood everything that’s relevant to patients?
I can think like a patient, so I already understand the patient perspective.

I spoke to a patient and I learned something interesting.

I spoke to lots of patients and they all told me something different – how do I know that I’ve understood everything that’s relevant to patients?

Help! I need to talk to our patient engagement team!
UNDERSTANDING HEALTH LITERACY
Health literacy ... entails people’s knowledge, motivation and competences to access, understand, appraise and apply health information in order to make judgements and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life during the life course

World Health Organization Regional Office for Europe
Health literacy report 2013
WHAT DOES HEALTH LITERACY MEAN?
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WHAT DOES HEALTH LITERACY MEAN?

“Health literacy means empowerment”
WHY DOES HEALTH LITERACY MATTER?

- Worse health\(^1\)
- Finds medication difficult to manage\(^1\)
- Higher hospitalization rate\(^1\)
- Higher mortality\(^1\)

- High healthcare costs\(^2\)
What reading age should you write your communications for, if you want > 90% of the public to understand what you’ve written?

A. 5–6 years
B. 7–8 years
C. 9–11 years
D. 12–14 years
E. 15–17 years
WHAT DOES THIS MEAN FOR COMMUNICATORS?

<table>
<thead>
<tr>
<th>Proportion of readers able to understand, %</th>
<th>National Qualifications Framework age equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>93%</td>
<td>9–11 years</td>
</tr>
<tr>
<td>85%</td>
<td>GCSE grades D–G</td>
</tr>
<tr>
<td>57%</td>
<td>GCSE grades A*–C or higher qualifications</td>
</tr>
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</table>
The single biggest problem in communication is the illusion it has taken place

George Bernard Shaw, playwright and author
PATIENT INFORMATION NEEDS TO IMPROVE

- Researchers user-tested leaflets written by charities and the NHS
  - 64 leaflets (50 included numerical information)
  - 4767 UK residents aged 16–65 years, sampled to reflect the socioeconomic demographics of the UK population
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Text-only information

| Could not understand (43%) | Could understand |
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<th>Text-only information</th>
<th>Could not understand (43%)</th>
<th>Could understand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Text and numerical information</td>
<td>Could not understand (61%)</td>
<td>Could understand</td>
</tr>
</tbody>
</table>
• Health literacy varies across Europe

Proportion of public with inadequate or problematic health literacy

- The Netherlands: 29%
- Ireland: 40%
- Greece: 45%
- Germany: 46%
- Poland: 48%
- Austria: 56%
- Spain: 58%
- Bulgaria: 62%
Approximately 36% of adults have limited health literacy\(^1\)

Only 12% of the population has proficient health literacy\(^1\)

“Nearly 9 out of 10 adults have difficulty using the everyday health information that is routinely available in our health care facilities, retail outlets, media and communities”\(^2\)
BRIEF TIPS ON HOW TO WRITE IN A WAY THAT PATIENTS WILL UNDERSTAND

- Simple language
- Short sentences
- Simplify numerical information
- Larger fonts with plenty of white space
- Use **bold lowercase letters** for emphasis (not CAPITALS, *italics* or underlined)
- Left-align rather than fully justify
- Use only pictures that are directly relevant to the text
- User-test everything

Simple Measure of Gobbledygook (SMOG)

http://www.niace.org.uk/misc/SMOG-calculator/smogcalc.php
89% of patients have lung cysts that are visible on CT scans. More than 50% of cysts are located directly under the covering layer of the lung (visceral pleura).

$\text{SMOG} = 16.2$
Lung cysts are a common manifestation of BHD; more than 80% of adults with BHD have the cysts. BHD lung cysts are most often located in the lower half (basal area) of the lungs.

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9 in 10 people with BHD get lung cysts. They are most often found in the lower half of the lungs.

SMOG = 8.1

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**SMOG = 8.1**

Aim for a SMOG score of **12** for patient communications.
BEING PATIENT-CENTRIC AS A PUBLICATIONS PROFESSIONAL
UNDERSTANDING WHAT MATTERS TO PATIENTS ACROSS THE DRUG DEVELOPMENT CONTINUUM

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¹ Ref: Patients have knowledge, perspectives and experiences that are unique and contribute to essential evidence for HTA.
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Can I trust the findings of this health research?

This tool will guide you through a series of questions to help you review health research that you have come across.

Get started
(1) PUBLISH OPEN ACCESS, SO PATIENTS CAN FIND YOUR PAPER

“A doctor asked me if had a medical degree after I explained my diagnosis. I replied: “No, I’m just a patient.”

Jo Goode
(2) PROVIDE A (PATIENT) LAY SUMMARY, WRITTEN AT THE APPROPRIATE LEVEL

- Can be a **standalone** document, or a supplementary file to a published journal article
- **Pitch the document at the correct level**
  - How would you describe the study to your parents?
  - Work from the patient’s perspective and level of understanding
  - Don’t treat a patient like a scientist who doesn’t understand big words
(3) INCLUDE SECONDARY ANALYSES OF KEY PATIENT POPULATIONS IN PUBLICATION PLANNING

- Be clear about the patient population the research relates to
- Clearly communicate information for each group

<table>
<thead>
<tr>
<th>Patient &lt; 50 years</th>
<th>Non-smoker risk</th>
<th>Smoker risk</th>
</tr>
</thead>
<tbody>
<tr>
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<td>. . .</td>
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<tr>
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</tbody>
</table>

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Figure 4. (a) Quality of written English, as assessed by peer reviewers, and (b) time from submission to editorial acceptance for articles with and without acknowledged medical writer support.

A lie will go round the world while the truth is pulling its boots on

C. H. Spurgeon, Gems from Spurgeon (1859)
Phenotype and natural history in 101 individuals with Pitt-Hopkins syndrome through an internet questionnaire system

Channa F. de Winter†, Melanie Baas‡, Emilia K. Bijlsma, John van Heukelingen, Sue Routledge and Raoul C. M. Hennekam*
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BMJ PATIENT PARTNERSHIP STRATEGY

• Report patient involvement in:
  – Choice of research question
  – Study design
  – Outcome measures
  – Dissemination of results

• Patients or carers (caregivers) should be involved as contributors or authors

“In future we are likely to include clinical research papers only if the authors can demonstrate partnership with patients in their study”
And finally…

(6) Thank patients for their contribution

- Clinical study acknowledgments sections routinely thank the investigators, the medical centre staff, the professional medical writer …
- … but in articles published by the BMJ that used patient data, patients were acknowledged only ~50% of the time
- Why not routinely thank patients in any study that involves them?
THANK YOU!
• To ask a question, please type your query into the Q&A box
• To ensure anonymity, before sending please choose the drop-down box option, "Hosts, Presenters and Panelists." Otherwise, ALL audience members will be able to see your submitted question
## UPCOMING ISMPP U'S

<table>
<thead>
<tr>
<th>DATE</th>
<th>TOPIC</th>
<th>FACULTY</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 26</td>
<td>Reproducibility: A Tragedy of Errors</td>
<td>David Allison &amp; Richard Sarver</td>
</tr>
<tr>
<td></td>
<td></td>
<td>University of Alabama at Birmingham</td>
</tr>
<tr>
<td>November 30</td>
<td>Practices and Challenges in Publication Peer Review</td>
<td>Martin Delahunty, Nature Partner Journals</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mary Beth DeYoung, AstraZeneca</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rosamund Snow, BMJ</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ann Davis, Moderator</td>
</tr>
</tbody>
</table>
THANK YOU FOR AttENDING!

• We hope you enjoyed today's presentation. Please check your email for a link to a survey that should take a few minutes to complete. We depend on your feedback and take your comments into account as we develop future educational offerings. Thank you in advance for your participation!