Session 4:
Social/Digital Media: The Future of Qualitative Data Collection in the Context of Labeling

Fifth Annual Patient-Reported Outcome (PRO) Consortium Workshop
April 29 - 30, 2014 ■ Silver Spring, MD

Co-sponsored by

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Session Objectives

• Gain greater understanding of techniques used to conduct qualitative research using digital media
• Provide examples of the implementation of some of these techniques used for concept elicitation with a single social media platform
• Discuss the advantages and disadvantages of using digital media to collect data used in the context of labeling
• Consider how the health care enterprise can move forward with the use of digital media to enhance our understanding of how patients experience their health and treatment.
Session Participants

• Moderator
  – Margaret Rothman, PhD – Senior Director, PRO Group, Janssen Pharmaceutical Companies of Johnson and Johnson

• Presenters and Panelists
  – Trena M. Paulus, PhD - Associate Professor and Coordinator of the Graduate Certificate in Qualitative Research Methods, Department of Educational Psychology and Counseling, University of Tennessee

  – Paul Wicks, PhD – Vice President of Innovation, PatientsLikeMe

  – Elektra Papadopoulos, MD, MPH – Team Leader, Study Endpoints Team, SEALD, OND, CDER, FDA

  – Tara Symonds, PhD – Senior Director and Head, PRO Center of Excellence, Pfizer
Digital tools for qualitative data collection
Trena M. Paulus, Ph.D.
University of Tennessee

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PATIENT-REPORTED OUTCOME (PRO) CONSORTIUM WORKSHOP

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Digital Tools for Qualitative Research

< Trena Paulus, Jessica Lester & Paul Dempster >
Estimates from the New England Research Institutes (NERI) suggest developing a PRO from beginning to end takes at least 24 months and costs between $1m - $5m, while estimates shared at the 2011 C-Path meeting suggest up to 4 years for development and costs between $725k - $2.1m.

• Seven-in-ten (72%) adult internet users say they have searched online for information about a **range of health issues**, the most popular being specific diseases and treatments.

• One-in-four (26%) adult internet users say they have read or watched **someone else’s health experience** about health or medical issues in the past 12 months.

• **16%** of adult internet users in the U.S. have gone online in the past 12 months to **find others who share** the same health concerns.

A majority of older internet users go online on a daily basis

% of internet users in each age group who go online...

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Every day or almost every day</th>
<th>3-5 times per week</th>
<th>Net</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-29</td>
<td>88</td>
<td>8</td>
<td>86</td>
</tr>
<tr>
<td>30-49</td>
<td>84</td>
<td>8</td>
<td>82</td>
</tr>
<tr>
<td>50-64</td>
<td>79</td>
<td>11</td>
<td>71</td>
</tr>
<tr>
<td>65+</td>
<td>71</td>
<td>11</td>
<td></td>
</tr>
</tbody>
</table>

Pew Research Center's Internet Project July 18-September 30, 2013 tracking survey.

PEW RESEARCH CENTER
Qualitative data types

- **Researcher-generated** (technologies as **tools**)
  - Focus groups
  - Interviews
  - Surveys
  - *Online interviews & focus groups
  - *Mobile devices

- **Naturally-occurring** (technologies as **contexts**)
  - Observations
  - Conversations
  - Documents
  - *Online communities & social media interactions
Digital tools & qualitative data

1. Online interviews & focus groups

2. Online communities & social media

3. Mobile devices
Online interviews & focus groups
Online interviews & focus groups

• **Asynchronous** (different place, different time)
  – E-mail
  – Discussion forums
  – Social media (blurs the boundary)

• **Synchronous** (different place, same time)
  – (Phone, SMS/text messages)
  – Facebook chat
  – Skype video (with chat)
  – Google Hangout video (with chat)
  – Video messaging (blurs the boundary)
Online interviews & focus groups

Thread: type II diabetes

mosyalong

Registered User
Join Date: 12-01-2013
Location: arksas
Age: 63
Posts: 2

12-14-2013, 00:27

Hello, I am mosyalong. I plan to hike in 2014. I have no experience. There have been some threads about type II diabetes. There is a website that says whole food chromium will fix it in a matter of months. It's not a disease but a condition. www.notadoc.org. looking forward to the trail and meeting many of you.

Wise Old Owl

Section Hiker

12-14-2013, 00:32

Well you are in the right place and welcome - I have no experience with Diabetes, but many here can help you. As a new member I hope you stick it out and if you need additional help I have a few friends in backpacking that can help you...
Online interviews & focus groups

• **Asynchronous focus groups** (Tates et al., 2009):
  – Access to hard to reach populations
  – Cost & time saving for researchers
  – Accurate & automatic capture of data
  – Participant convenience & comfort
  – Greater self-disclosure
  – Lack of time pressure & greater reflection
  – Selection bias
  – Digital divide
  – Lurkers
  – Lack of visual cues
Online interviews & focus groups

Google+ Hangouts

Group chat

Kathy Evans 1:43 PM
you're welcome. I'm glad to be a part of your study.

me 1:44 PM
As you know we are studying the experiences of teachers who work in school suspension classrooms. To start off, please tell me a little bit about your experiences teaching in ISS rooms.

Kathy Evans 1:45 PM
Well as an advocate for students who struggle to be successful in school, I often get frustrated when classroom teachers don't send students' assignments to class.

Kathy Evans is typing...
Online interviews & focus groups

Call started

2:32 PM

trena paulus
See page 359

2:58 PM

JNIALESTER
I have been wondering if perhaps we can re-consider our first theme.

2:58 PM
Online interviews & focus groups

- **Synchronous focus groups** with young people (Fox et al. 2007)
  - Dynamic, immediate, more similar to talk
  - Emotions conveyed through emoticon use
  - Less threatening to young people
  - Must find common meeting time
  - Requires fast Internet connection
  - Chaotic turn-taking
  - Typing speed = power
  - More than 5 participants requires 2 moderators
## Issues to consider

<table>
<thead>
<tr>
<th></th>
<th>Asynchronous</th>
<th>Synchronous</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technical requirements</strong></td>
<td>Likely familiar technologies</td>
<td>Fast connection, webcam, audio/video, more technical difficulties likely</td>
</tr>
<tr>
<td><strong>Skills</strong></td>
<td>Writing skills</td>
<td>Typing speed, Comfort with video</td>
</tr>
<tr>
<td><strong>Visual cues</strong></td>
<td>Largely absent</td>
<td>Present with video or emoticons or text abbreviations</td>
</tr>
<tr>
<td><strong>Participation</strong></td>
<td>Can ignore messages, Can lurk, Lag time for responses</td>
<td>Chaotic with too many participants</td>
</tr>
<tr>
<td><strong>Response types</strong></td>
<td>Reflective</td>
<td>Spontaneous, can respond to probes</td>
</tr>
</tbody>
</table>

See also Wilkerson et al. (2014). *Recommendations for Internet-based Qualitative Health Research with Hard to Reach Populations.* Qualitative Health Research 4(4), 561-574.
Online communities & social media
Online communities & social media

Social networking site use by age group, 2005-2013
% of internet users in each age group who use social networking sites, over time

Source: Latest data from Pew Research Center’s Internet Project Library Survey, July 18 – September 30, 2013. N=5,112 internet users ages 18+. Interviews were conducted in English and Spanish and on landline and cell phones. The margin of error for results based on internet users is +/- 1.6 percentage points.
One-quarter of seniors use online social networks

% of seniors who ...

- Use SNS: 27%
- Do not go online: 41%
- Go online, no SNS: 32%

Pew Research Center’s Internet Project July 18-September 30, 2013 tracking survey.

PEW RESEARCH CENTER
Online communities & social media

- **Spontaneous** (unelicited)
  - [WhiteBlaze.net](http://www.whiteblaze.net) (online hobby group)
  - Facebook
  - SecondLife
  - **Unknown** participants

- **Designed** (elicited)
  - [Patients Like Me](http://www.patientslikeme.com)
  - [One Thousand Voices](http://www.onethousandvoices.org)
  - Online support groups (Varga & Paulus, 2014); online educational groups (Paulus & Lester, 2013)
  - **Known** participants
I've had high blood pressure and I am on that forum. I'm 40 years old and have a physical job, I'm not obese, but do have the "spare tire" I'm 6 foot 5 and 260lbs. I was dieting last year and was about 230, but fell off the diet wagon and now I'm 260, again, mostly belly fat, which I have read is the worst.

So I went to my family Dr. to re-fill my RX for my blood pressure medicine and he decided to do some blood work. My cholesterol was alittle high so he prescribed 10mg of Lipitor, but the thing that scares me the most was my elevated glucose level. It was 118. The Dr. said it should be between 65 and 105. I now have to go take a 2 hour glucose tolerance test.

I don't have a family history of diabetes. The cholesterol doesn't bother me as much, as I am confident I can change that with my diet. I have already sworn off any fast food, junk food and sweets. All this happened yesterday after my appointment, but it's a real eye opener to me, and with that said, I have the willpower to eat nothing but salads, granola, grilled chicken, grilled salmon, and water.

I'm confused though because I was talking to a friend that has diabetes and has to take shots, and he said 118 wasn't bad. I know I definitly need to loose weight, and although I only started yesterday, I'm on that path and I am going to be eating right from now on. I'm just concerned as to why my Dr. requested I take the 2 hour test. Are there some other issues that can be uncovered in that test?

Any input would be greatly appreciated. I didn't get to talk to the Dr. the lab nurse called me late in the day Friday with the results and news that I needed to take the test. So obviously with this being the weekend, I'm stressing out about it.

Thanks
Posted on 04/19/14, 11:54 am
Another Facebook fan could use your help! She writes: "I was wondering if any fellow pumpers get a lot of infections at the infusion site that requires strong antibiotic or even lancing and packing? How often? I am getting them every 2-3 months. I'm really discouraged."

135 people like this.

Sue Champagne Soulière like
Like · Reply · about an hour ago

Sarah McEwan When I first started on the pump I got infections quite quickly where the cannula was and needed antibiotics, but as long as I change my cannula every 2 days I'm okay now.
Like · Reply · about an hour ago

Crystal Ferril Morris I use omnipod and you have to change it every 3 days. My Medtronic sites use to get irritated when I used it but not with omnipod.
Like · Reply · 2 hours ago

Jackie McDonald Pump for 4 years and never had an infection. Hit a blood vessel once which caused a huge bruise but otherwise no issues.
Like · Reply · 3 · 15 hours ago

Crystal Ferril Morris I have done that before and wow yes huge bruise lol
Like · 2 hours ago
Online communities & social media

Anne Geraghty @arngerag · 16h
Luke ripped out my pump! 😞 diabeticProbs #cgm #medtronic #pumpprobs #type1 #diabetes instagram.com/p/nMb6ddggd2/

Toan Huynh @toanbhuyh · 21h
#Medtronic among The 50 Best Employers In America businessinsider.com/best-employers...

Lionbridge Life Sci @LionbridgeLife · Apr 24
#Medtronic launches a massive #clinicaltrial that could widen the use of #ICDs in #emergingmarkets bit.ly/1rpJ0JM

C. Michael Gibson MD @CMichaelGibson · Apr 24
#Medtronic allowed to continue selling #CoreValve as injunction for patent infringement delayed medpagetoday.com/Cardiology/Arr...
Online communities & social media

- **Detecting** health conditions (Prieto et al 2014)
- **Sharing** treatments and experiences of care (McGregor et al 2014)
- **Recruiting** survey participants (O’Conner et al 2013)
## Issues to consider

<table>
<thead>
<tr>
<th>Username</th>
<th>Tweet</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>nutritionXP</td>
<td>@Lswensen it’s just awful to watch! He’s clocking up 3,000 calories! #fastfoodbaby1</td>
<td>22/03/2012 1</td>
</tr>
<tr>
<td>65reevesmm</td>
<td>Can’t believe how these kids rule over their parents - shocking #fastfoodbaby1</td>
<td>22/03/2012 1</td>
</tr>
<tr>
<td>nutritionXP</td>
<td>The parents are creating a recipe for diabetes, heart disease and cancer #fastfoodbaby1</td>
<td>22/03/2012 1</td>
</tr>
<tr>
<td>LSwensen1</td>
<td>@65reevesmm this baby is drinking 6 cans of Cola a day! I feel sick :( #fastfoodbaby1</td>
<td>22/03/2012 1</td>
</tr>
<tr>
<td>65reevesmm</td>
<td>Nothing wrong with takeaway every now and again,</td>
<td>22/03/2012 1</td>
</tr>
</tbody>
</table>

QSR Nvivo’s [Ncapture](#) tool
### Issues to consider

<table>
<thead>
<tr>
<th>Public vs Private</th>
<th>Topic Sensitivity</th>
<th>Degree of Interaction</th>
<th>Subject Vulnerability</th>
<th>Is Consent Necessary?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Likely</td>
</tr>
<tr>
<td>Public</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Not Likely</td>
</tr>
</tbody>
</table>

*Figure 5.1* Heuristic for making informed consent decisions in Internet research (adapted from McKee and Porter, 2009, p. 88)
Mobile devices
Mobile devices

• 90% of American adults have a cell phone (including 77% of older adults)

• 58% of American adults have a smartphone (including 18% of older adults)

• 32% of American adults own an e-reader

• 42% of American adults own a tablet computer
# Mobile devices

**Cell phone activities**

*The % of cell phone owners who use their cell phone to...*

<table>
<thead>
<tr>
<th>%</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>81</td>
<td>send or receive text messages</td>
</tr>
<tr>
<td>60</td>
<td>access the internet</td>
</tr>
<tr>
<td>52</td>
<td>send or receive email</td>
</tr>
<tr>
<td>50</td>
<td>download apps</td>
</tr>
<tr>
<td>49</td>
<td>get directions, recommendations, or other location-based information</td>
</tr>
<tr>
<td>48</td>
<td>listen to music</td>
</tr>
<tr>
<td>21</td>
<td>participate in a video call or video chat</td>
</tr>
<tr>
<td>8</td>
<td>“check in” or share your location</td>
</tr>
</tbody>
</table>

Source: Pew Research Center's Internet & American Life Project Spring Tracking Survey, April 17 – May 19, 2013. N=2,076 cell phone owners. Interviews were conducted in English and Spanish and on landline and cell phones. The margin of error for results based on all cell phone owners is +/- 2.4 percentage points.
Mobile devices

- Motion sensor to trigger physical activity recall (Dunton et al, 2014)
- Text-message/SMS prompts (Bobrow et al, 2014; Tsai et al, 2007)
- Mobile phone-assisted personal interviewing (van Heerden et al., 2014)
Mobile devices

Image: http://mobihealthnews.com/13526/unitedhealth-group-taps-carespeak-for-sms/
Mobile devices

Mobile devices


**Your Daily Summary**

1409

**CALORIES REMAINING**

<table>
<thead>
<tr>
<th>Goal</th>
<th>Food</th>
<th>Exercise</th>
<th>Net</th>
</tr>
</thead>
<tbody>
<tr>
<td>1409</td>
<td>+0</td>
<td>-0</td>
<td>0</td>
</tr>
</tbody>
</table>
Issues to consider
Your poll will show here

1. Install the app from pollev.com/app
2. Make sure you are in Slide Show mode

Still not working? Get help at pollev.com/app/help
or
Open poll in your web browser
• Special issue of *Health Affairs*: *Early evidence, future promise of connected health* (data security & privacy)
• Bamboo DiRT: *Digital research tools*
• Visualizing data: *Tools for collecting and handling data*


References

Advances in Online Tools for Accelerating PRO Development
Paul Wicks, PhD
PatientsLikeMe
Vice President of Innovation

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Step 1: Create/update and share your health profile

Step 2: Find support from others like you and compare experiences

Step 3: Learn from aggregated community Treatment and Symptom Reports

Step 4: Take profile to your doctor to have an improved treatment conversation

Step 5: Play an integral part in your own health care
ALS patient noticed ALSFRS-R wasn't sensitive enough to capture function in advanced ALS, “floor effect” of measure.

200+ patients participated in study to construct and pilot a new, more sensitive instrument.

3 new items were selected to be included in the new ALSFRS-EX measure.

Being used by the VA biobank and academic studies.
Challenges in PRO Development Today

- Slow (2-4 years) & expensive to develop ($725k-$2.1m)
- Only available in few diseases
- Typically license fee for use
- Many lack patient input in design
- Outdated e.g. home shopping, internet, smartphones


Open source model and PROs
Open Research Exchange (ORE)

- A PRO builder toolset modeled on open source software
- Includes versioning, branching, contributions, feedback
- **Social Architecture** for collaboration, credentialing, credit
- **Automated psychometric statistics** for PRO improvement
- **Database of instruments** and supporting data
- **Scientific support** from experts at PatientsLikeMe & SAB
ORE advisory board

Ethan Basch, M.D.
University of North Carolina School of Medicine, Lineberger Comprehensive Cancer Center

Patricia Brennan, R.N., Ph.D.
University of Wisconsin-Madison School of Nursing and College of Engineering

David Cella, Ph.D.
Northwestern University Feinberg School of Medicine, Department of Medical Social Sciences

Ari Gnanasakthy
Head of Patient Reported Outcomes, Novartis

Hugh Hempel
Co-Founder, Solution Therapeutics and Parent Advocate, The Addi and Cassi Fund

Erin Holve, Ph.D.
Senior Director, AcademyHealth

Bryce Reeve, Ph.D.
University of North Carolina Gillings School of Global Public Health

Sara Riggare
PhD student, Karolinska Institutet

Sharon Terry
President and CEO, Genetic Alliance

John Wilbanks
Chief Commons Officer at Sage Bionetworks; Founder, Consent to Research; Senior Fellow in Entrepreneurship, Ewing Marion Kauffman Foundation
5 Phases of PRO development

**Qualitative phase**

1. **Concept Elicitation**
   - To obtain input from patients
   - Opportunity to examine patient experience at a large scale
   - Item generation process
   - Based on open-ended questions

2. **Feedback**
   - Equivalent to cognitive debriefing
     - To evaluate clarity, relevance, and adequacy of response options for each item
     - Item review based on patient feedback
     - 4 feedback questions are displayed below each evaluated item

3. **Test**
   - Psychometric evaluation of the new instrument (validity and reliability)
     - Flexible study design
     - Ongoing patient input available through item-level and post-survey feedback

4. **Retest**
   - To evaluate the ability to detect change

**Quantitative/psychometric phase**
Online Concept Elicitation (non-ORE)

Ongoing Collaborations (not using ORE)

• Patient-Relevant Concepts in Chronic Lymphocytic Leukemia (Janssen)
  – 50 adults with CLL recruited via PatientsLikeMe
  – 78% reported at least one symptom
  – 369 descriptions of CLL symptoms including fatigue (40%), tiredness (38%), night sweats (38%), swollen lymph nodes (32%)
  – Supplemental telephone interviews included for a subset
  – Concept saturation was achieved using the web-only technique

• Ovarian Cancer – “In your own words” (AstraZeneca)
  – 30 adults with Ovarian cancer recruited via PatientsLikeMe
  – Symptoms leading to diagnosis, patient journey
  – Symptom fluctuations, worst symptom over course
  – Impact of treatment(s) and description of follow-up care
**Item-Level Feedback**

**Quantitative Feedback**
- How well did this question apply to you?
  - Very well, Reasonably well, A little bit, Not at all
- How easy was this question to understand?
  - Very easy, Easy, Somewhat easy, Not easy at all
- How well did the response choices fit the way you think about this question?
  - Very well, Reasonably well, A little bit, Not at all

**Qualitative Feedback**

In the past 4 weeks, how often did you feel restless because of your sleeping problems?
- "Not sure what was meant by 'restless'. Does that mean not being able to fall asleep? Waking up during the night and not being able to get back to sleep? Feeling agitated during the day? 'Restless Legs Syndrome'"

In the past 4 weeks, how often did you feel more emotional than usual because of your sleeping problems?
- "The way this is written makes it seem like it is asking whether I feel more emotional over the last 4 weeks than I did previously. Is that what was intended?"

In the past 4 weeks, how often didn't you feel your best because of your sleeping problems?
- "When I have to read the question 4 times to figure out the question...it was not easy for me to understand"
Feedback: Overall Comments

Did this survey give you any new insights into your own health situation? Please explain.
• “Yes. It showed me how interconnected everything in the body is. My lack of sleep, due to Fibromyalgia, makes my pain, which is constant, even worse than usual. In turn, I nap in the afternoon, so I am wide awake when it's time to go to bed.”

Are there other things missing from this survey that are important for researchers to consider, given your own experience?
• “A question that should be asked is if the individual feels their lack of sleep is due to: meds, depression, illness, etc.”

What, if anything, should we change to improve this survey, make it more relevant to your condition, or make it more understandable?
• “You need to know what illnesses people have other than insomnia, whether they use a CPAP machine, oxygen, sleep alone, if the sleep on a bed or recliner.”

Please add any other comments you may have about the questions used in this survey.
• “I appreciate that I had genuine choices in answering this survey.”
Real-time Psychometric Stats

**Q1: STIFF1**  Domain: Stiffness  Avg. time: 17 s

How long have you experienced joint stiffness?

<table>
<thead>
<tr>
<th>Response option</th>
<th>Code</th>
<th>Freq.</th>
<th>%</th>
<th>Cum. freq.</th>
<th>Cum. %</th>
<th>Avg. time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1 week</td>
<td>0</td>
<td>228</td>
<td>15.49%</td>
<td>228</td>
<td>15.49%</td>
<td>12 s</td>
</tr>
<tr>
<td>Less than one month</td>
<td>1</td>
<td>339</td>
<td>23.02%</td>
<td>767</td>
<td>58.91%</td>
<td>19 s</td>
</tr>
<tr>
<td>Less than one year</td>
<td>2</td>
<td>397</td>
<td>26.97%</td>
<td>1164</td>
<td>85.88%</td>
<td>15 s</td>
</tr>
<tr>
<td>Less than 5 years</td>
<td>3</td>
<td>254</td>
<td>17.26%</td>
<td>1418</td>
<td>100.00%</td>
<td>15 s</td>
</tr>
<tr>
<td>More than 5 years</td>
<td>4</td>
<td>254</td>
<td>17.26%</td>
<td>1700</td>
<td>95.25%</td>
<td>16 s</td>
</tr>
<tr>
<td>I prefer to skip</td>
<td>-97</td>
<td>10</td>
<td>2.31%</td>
<td>1720</td>
<td>97.61%</td>
<td>5 s</td>
</tr>
<tr>
<td>I don't know</td>
<td>-98</td>
<td>5</td>
<td>1.65%</td>
<td>1725</td>
<td>100.00%</td>
<td>12 s</td>
</tr>
<tr>
<td>Does not apply</td>
<td>-99</td>
<td>0</td>
<td>0.00%</td>
<td>0</td>
<td>0.00%</td>
<td>---</td>
</tr>
<tr>
<td>Forced skip</td>
<td>-100</td>
<td>0</td>
<td>0.00%</td>
<td>0</td>
<td>0.00%</td>
<td>---</td>
</tr>
<tr>
<td>Did not complete</td>
<td>-999</td>
<td>0</td>
<td>0.00%</td>
<td>0</td>
<td>0.00%</td>
<td>---</td>
</tr>
</tbody>
</table>

**Quantitative Feedback Responses**

<table>
<thead>
<tr>
<th>Does it apply?</th>
<th>Freq.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very well</td>
<td>5</td>
<td>27.7</td>
</tr>
<tr>
<td>Reasonably well</td>
<td>8</td>
<td>44.4</td>
</tr>
<tr>
<td>A little bit</td>
<td>3</td>
<td>16.7</td>
</tr>
<tr>
<td>Not at all</td>
<td>2</td>
<td>11.1</td>
</tr>
<tr>
<td>Easy to understand?</td>
<td>Freq.</td>
<td>%</td>
</tr>
<tr>
<td>Very easy</td>
<td>5</td>
<td>27.7</td>
</tr>
<tr>
<td>Easy</td>
<td>8</td>
<td>44.4</td>
</tr>
<tr>
<td>Somewhat easy</td>
<td>3</td>
<td>16.7</td>
</tr>
<tr>
<td>Not easy at all</td>
<td>2</td>
<td>11.1</td>
</tr>
</tbody>
</table>

**Q2: SPAS1**  Domain: Spasticity  Avg. time: 17 s

How many times have you experienced severe joint spasticity in the last month?

| Min | 0 |
| Max | 28 |
| Mean | 11.5 |
| Median | 11 |
| Mode | 11 |
| SD | 2.76 |

**Missing Responses**

<table>
<thead>
<tr>
<th>Code</th>
<th>Freq.</th>
<th>%</th>
<th>Avg. time</th>
</tr>
</thead>
<tbody>
<tr>
<td>-97</td>
<td>10</td>
<td>2.31%</td>
<td>5 s</td>
</tr>
<tr>
<td>-98</td>
<td>5</td>
<td>1.65%</td>
<td>12 s</td>
</tr>
<tr>
<td>-99</td>
<td>0</td>
<td>0.00%</td>
<td>---</td>
</tr>
<tr>
<td>-100</td>
<td>0</td>
<td>0.00%</td>
<td>---</td>
</tr>
<tr>
<td>-999</td>
<td>0</td>
<td>0.00%</td>
<td>---</td>
</tr>
</tbody>
</table>

**Quantitative Feedback Responses**

<table>
<thead>
<tr>
<th>Does it apply?</th>
<th>Freq.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very well</td>
<td>5</td>
<td>27.7</td>
</tr>
<tr>
<td>Reasonably well</td>
<td>8</td>
<td>44.4</td>
</tr>
<tr>
<td>A little bit</td>
<td>3</td>
<td>16.7</td>
</tr>
<tr>
<td>Not at all</td>
<td>2</td>
<td>11.1</td>
</tr>
<tr>
<td>Easy to understand?</td>
<td>Freq.</td>
<td>%</td>
</tr>
<tr>
<td>Very easy</td>
<td>5</td>
<td>27.7</td>
</tr>
<tr>
<td>Easy</td>
<td>8</td>
<td>44.4</td>
</tr>
<tr>
<td>Somewhat easy</td>
<td>3</td>
<td>16.7</td>
</tr>
<tr>
<td>Not easy at all</td>
<td>2</td>
<td>11.1</td>
</tr>
</tbody>
</table>

**Do responses fit?**

<table>
<thead>
<tr>
<th>Freq.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very well</td>
<td>3</td>
</tr>
<tr>
<td>Reasonably well</td>
<td>9</td>
</tr>
<tr>
<td>A little bit</td>
<td>4</td>
</tr>
<tr>
<td>Not at all</td>
<td>3</td>
</tr>
</tbody>
</table>
### Performance summary

<table>
<thead>
<tr>
<th>Item</th>
<th>Chronbach's alpha</th>
<th>Completeion time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stiffness</td>
<td>0.89 (0.88 - 0.92)</td>
<td>13.7 min(avg)</td>
</tr>
<tr>
<td>Pain</td>
<td>0.78 (0.76 - 0.81)</td>
<td></td>
</tr>
<tr>
<td>Mood</td>
<td>0.72 (0.71 - 0.74)</td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>0.72 (0.71 - 0.74)</td>
<td></td>
</tr>
</tbody>
</table>

### Response details

<table>
<thead>
<tr>
<th>Item</th>
<th>Distribution</th>
<th>No response</th>
<th>Avg. Time</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical and Demographic Items</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>15</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>17</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>5</td>
<td>13</td>
<td>35</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>20</td>
<td>20</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>New PRO Items</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
</tr>
<tr>
<td>8</td>
</tr>
<tr>
<td>9</td>
</tr>
<tr>
<td>10</td>
</tr>
<tr>
<td>11</td>
</tr>
<tr>
<td>12</td>
</tr>
</tbody>
</table>
Adaptations in response to feedback

- **Patient Verification**
  - 80% of patient asked agreed we could contact their physician
- **Comparative validity**
  - Follow-up over telephone produced highly similar results
- **Representativeness**
  - Use of population weightings and stratified sampling
- **Ease of use**
  - Partnering with patients-led PRO, move to self-service
- **Item Response Theory**
  - Supporting CAT item banks, minimize burden, leverage PROMIS
- **Appropriate Credit & Version control**
  - Work in progress to ensure balance of quality and accessibility
Pros / Cons of Online Research

- Participatory
- Speed
- Anonymity
- Patient-centric
- Global reach
- Longitudinal
- Openness

- High Touch
- Errors propagate
- Validation
- Verification
- Localization
- Attrition
- Security
Panel Discussion
Session Participants

• **Moderator**
  - *Margaret Rothman, PhD* – Senior Director, PRO Group, Janssen Pharmaceutical Companies of Johnson and Johnson

• **Presenters and Panelists**
  - *Trena M. Paulus, PhD* - Associate Professor and Coordinator of the Graduate Certificate in Qualitative Research Methods, Department of Educational Psychology and Counseling, University of Tennessee
  - *Paul Wicks, PhD* – Vice President of Innovation, PatientsLikeMe
  - *Elektra Papadopoulos, MD, MPH* – Team Leader, Study Endpoints Team, SEALD, OND, CDER, FDA
  - *Tara Symonds, PhD* – Senior Director and Head, PRO Center of Excellence, Pfizer
Discussion and/or Questions?