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

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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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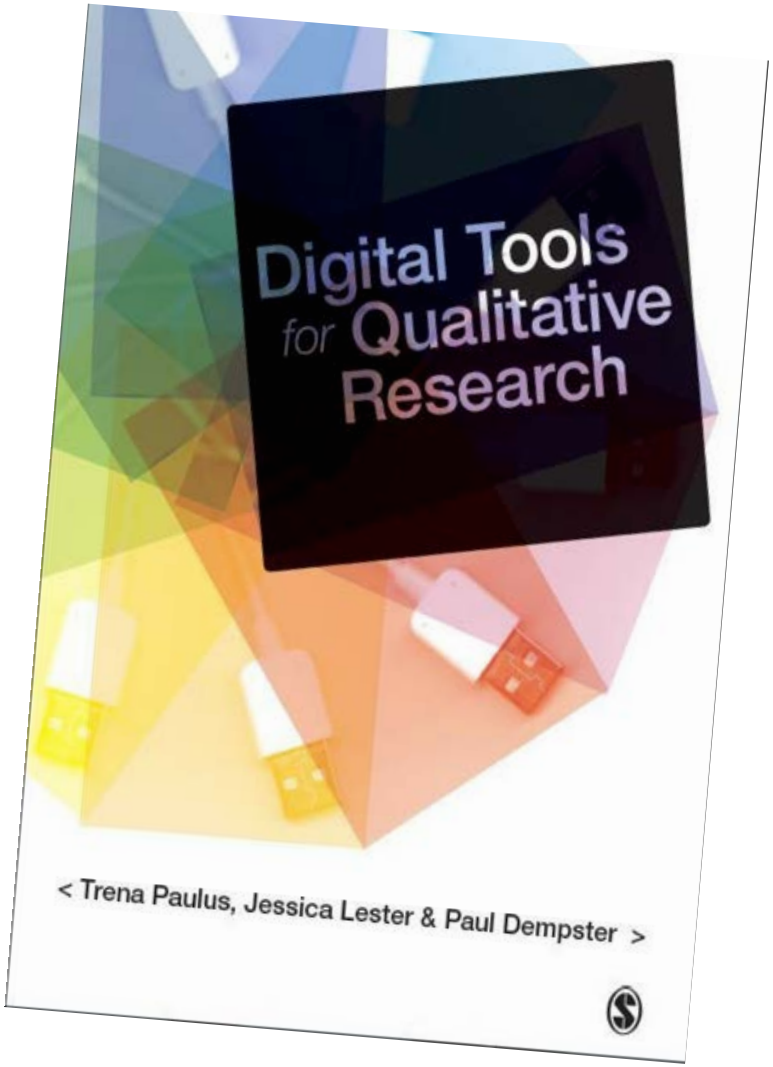
Digital Tools
for Qualitative
Research
< Trena Paulus, Jessica Lester & Paul Dempster >

New technologies & health

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.**

Hayes R. Patient-Reported Outcome (PRO) Instruments as Drug Development Tools (Session III). Consensus Science New Tools and Tactics for Next-Gen Drug Development., Washington, DC: 2011.

New technologies & health

- 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.

S. Fox (Jan 15, 2014) The social life of health information. Pew Research Center.

New technologies & health

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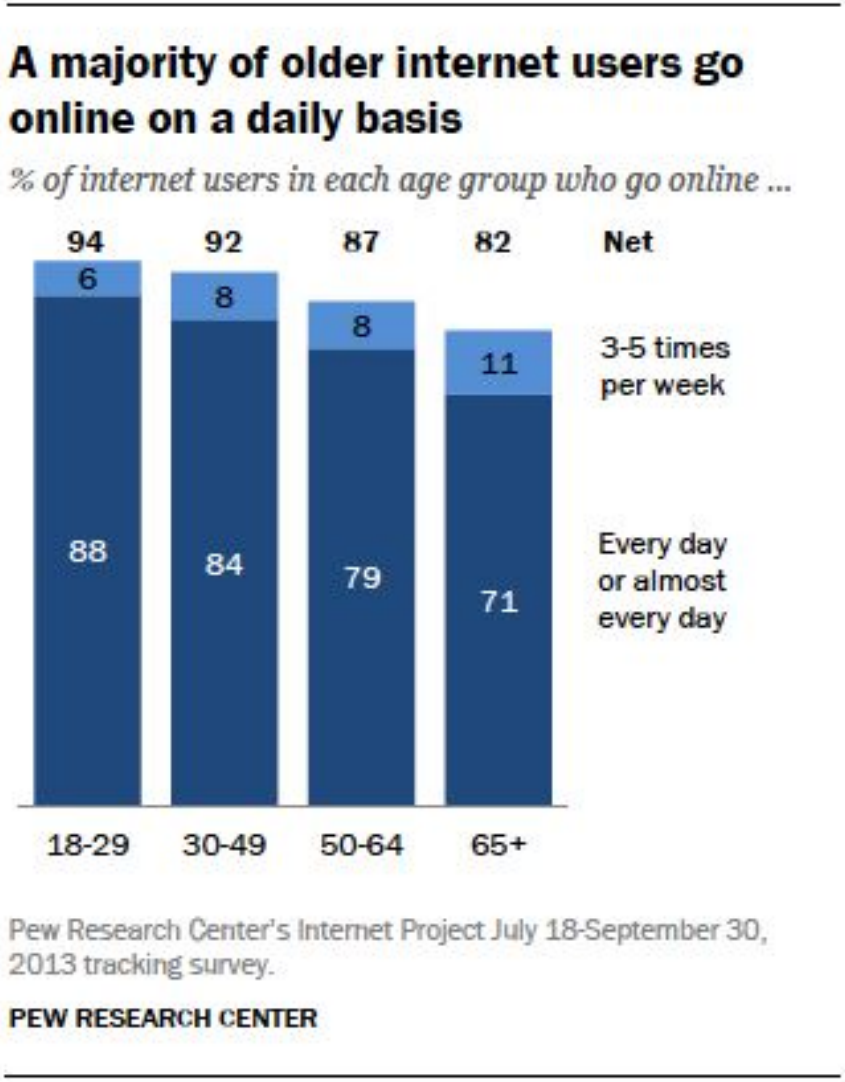

Qualitative data types

- **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

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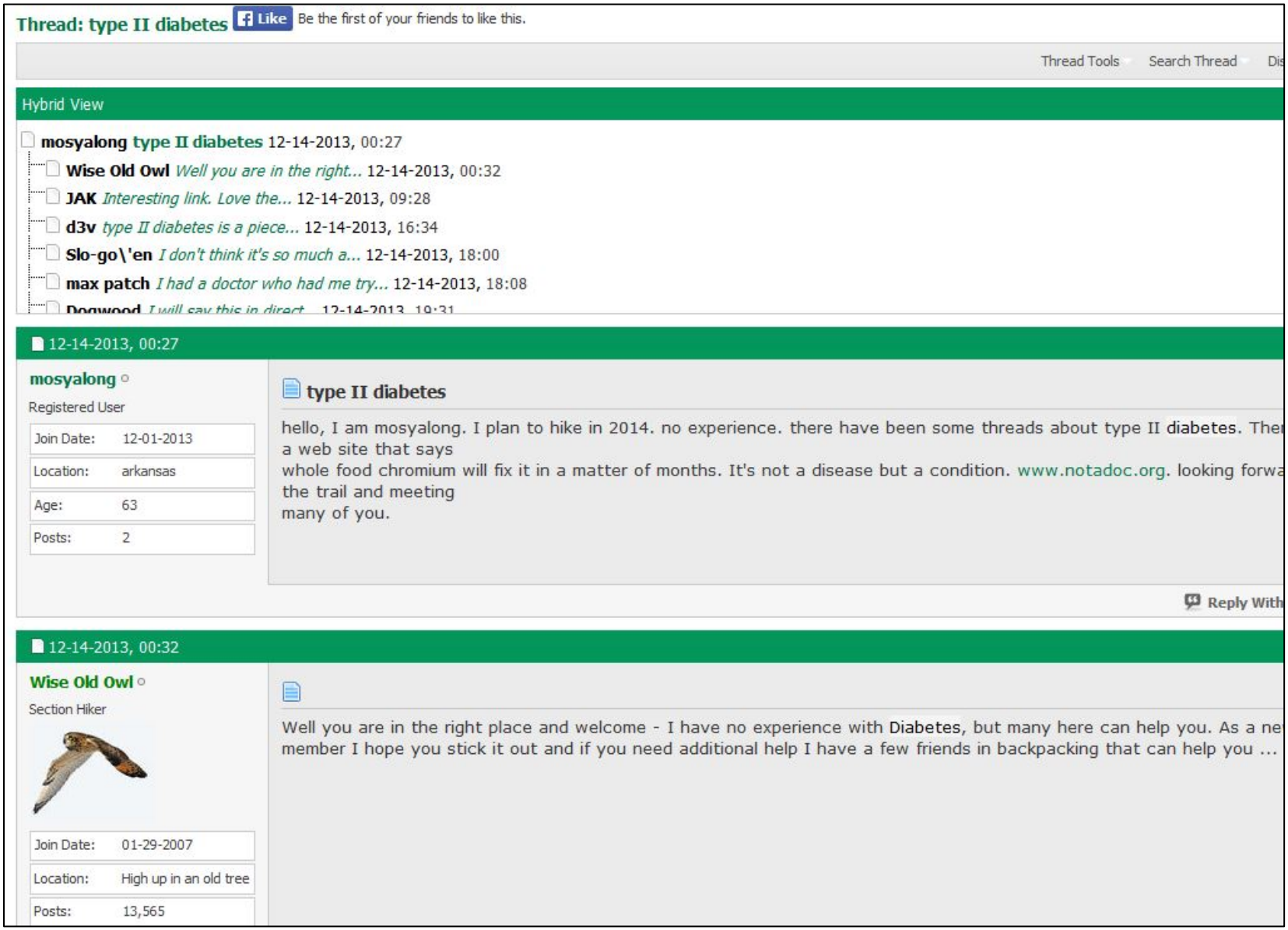


Thread: type II diabetes Like Be the first of your friends to like this.

Thread Tools Search Thread Dis

Hybrid View

mosyalong type II diabetes 12-14-2013, 00:27
- Wise Old Owl *Well you are in the right...* 12-14-2013, 00:32
- JAK *Interesting link. Love the...* 12-14-2013, 09:28
- d3v *type II diabetes is a piece...* 12-14-2013, 16:34
- Slo-go\'en *I don't think it's so much a...* 12-14-2013, 18:00
- max patch *I had a doctor who had me try...* 12-14-2013, 18:08
- Dogwood *I will say this in direct...* 12-14-2013, 19:31

12-14-2013, 00:27

mosyalong
Registered User

Join Date:	12-01-2013
Location:	arkansas
Age:	63
Posts:	2

type II diabetes

hello, I am mosyalong. I plan to hike in 2014. no experience. there have been some threads about type II diabetes. Ther
a web site 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 forwa
the trail and meeting
many of you.

Reply With

12-14-2013, 00:32

Wise Old Owl
Section Hiker

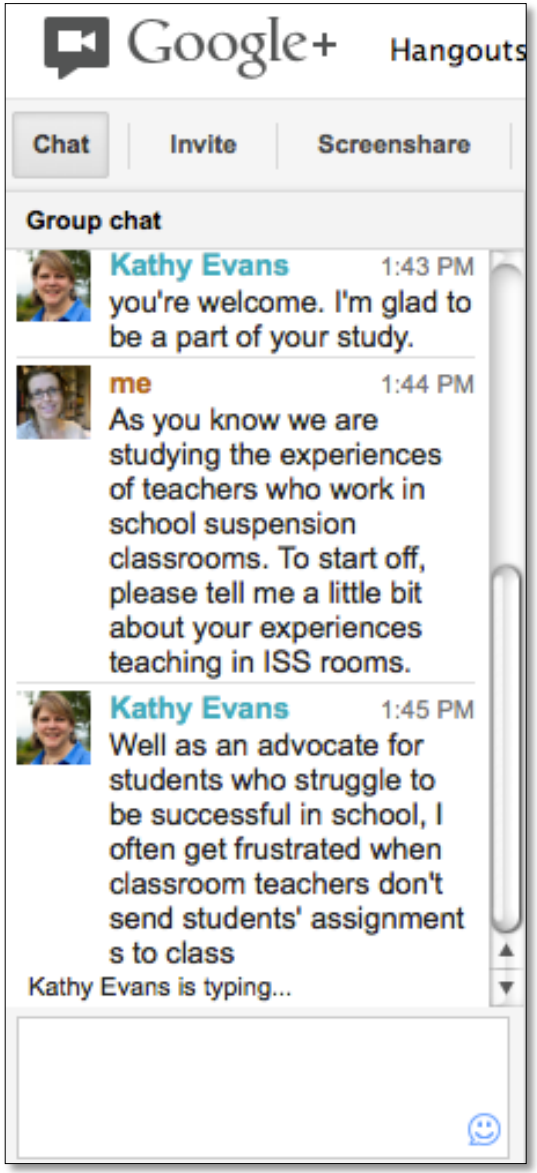
Join Date:	01-29-2007
Location:	High up in an old tree
Posts:	13,565

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

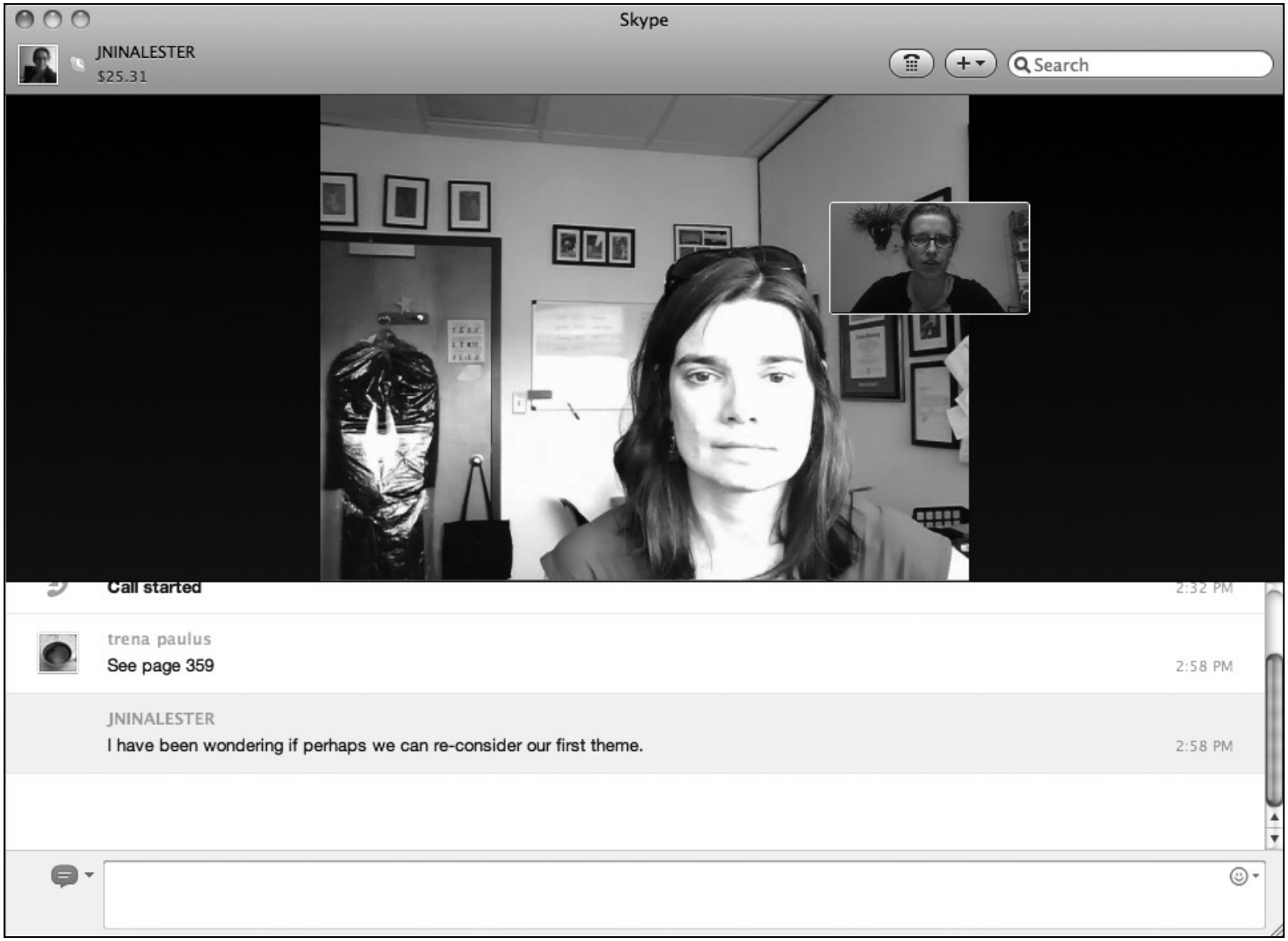
Online interviews & focus groups

- **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



Online interviews & focus groups



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

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

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.

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Online communities & social media

Online communities & social media

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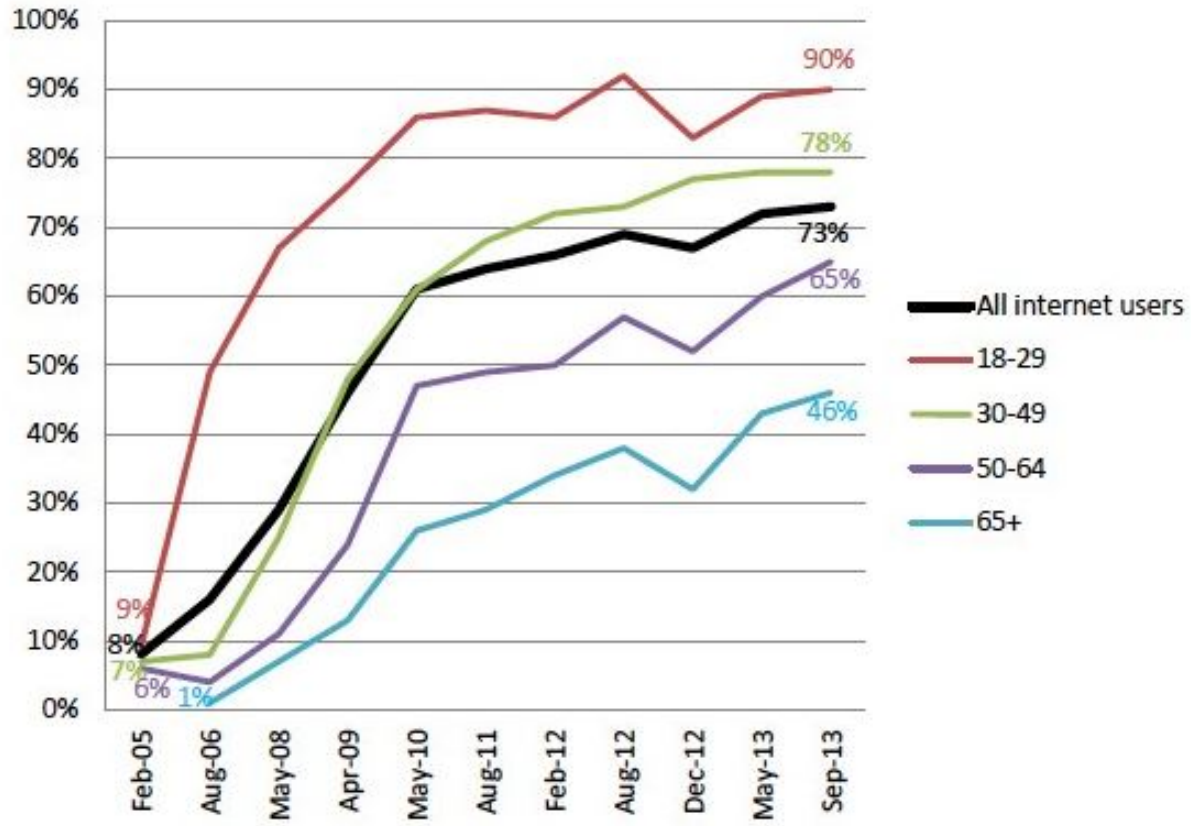
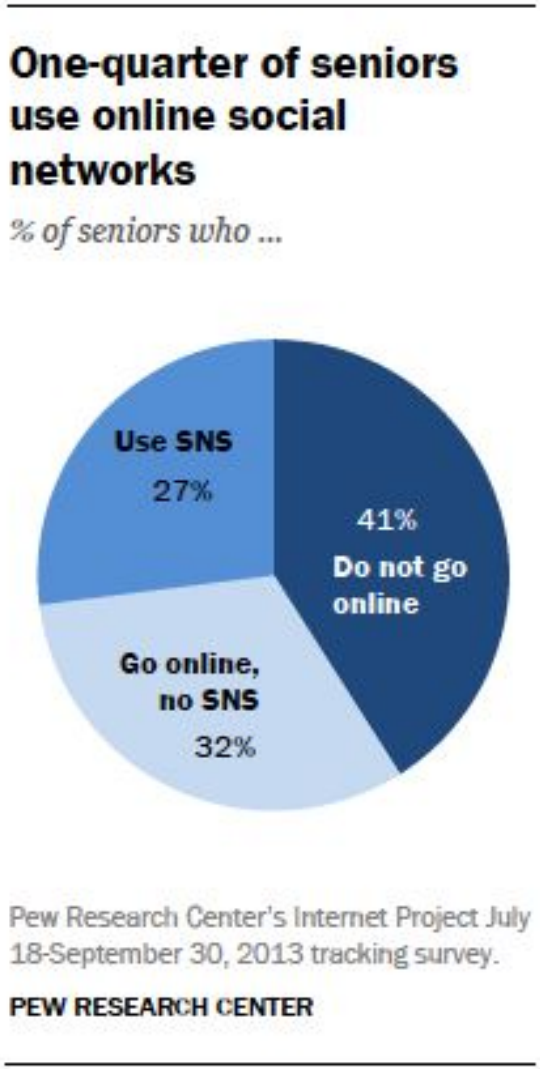
Social networking site use by age group, 2005-2013

% 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.

Online communities & social media



Online communities & social media

- **Spontaneous** (unelicited)
  - WhiteBlaze.net (online hobby group)
  - Facebook
  - SecondLife
  - **Unknown** participants
- **Designed** (elicited)
  - Patients Like Me
  - One Thousand Voices
  - Online support groups (Varga & Paulus, 2014); online educational groups (Paulus & Lester, 2013)
  - **Known** participants

Online communities & social media

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General Discussions

Back to Discussion List

High Glucose reading at Dr. visit

Watch this

Frisc

View More Posts

Ignore

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 cholesteral 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 cholesteral 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 definetly 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 concearned 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

Online communities & social media

Online communities & social media

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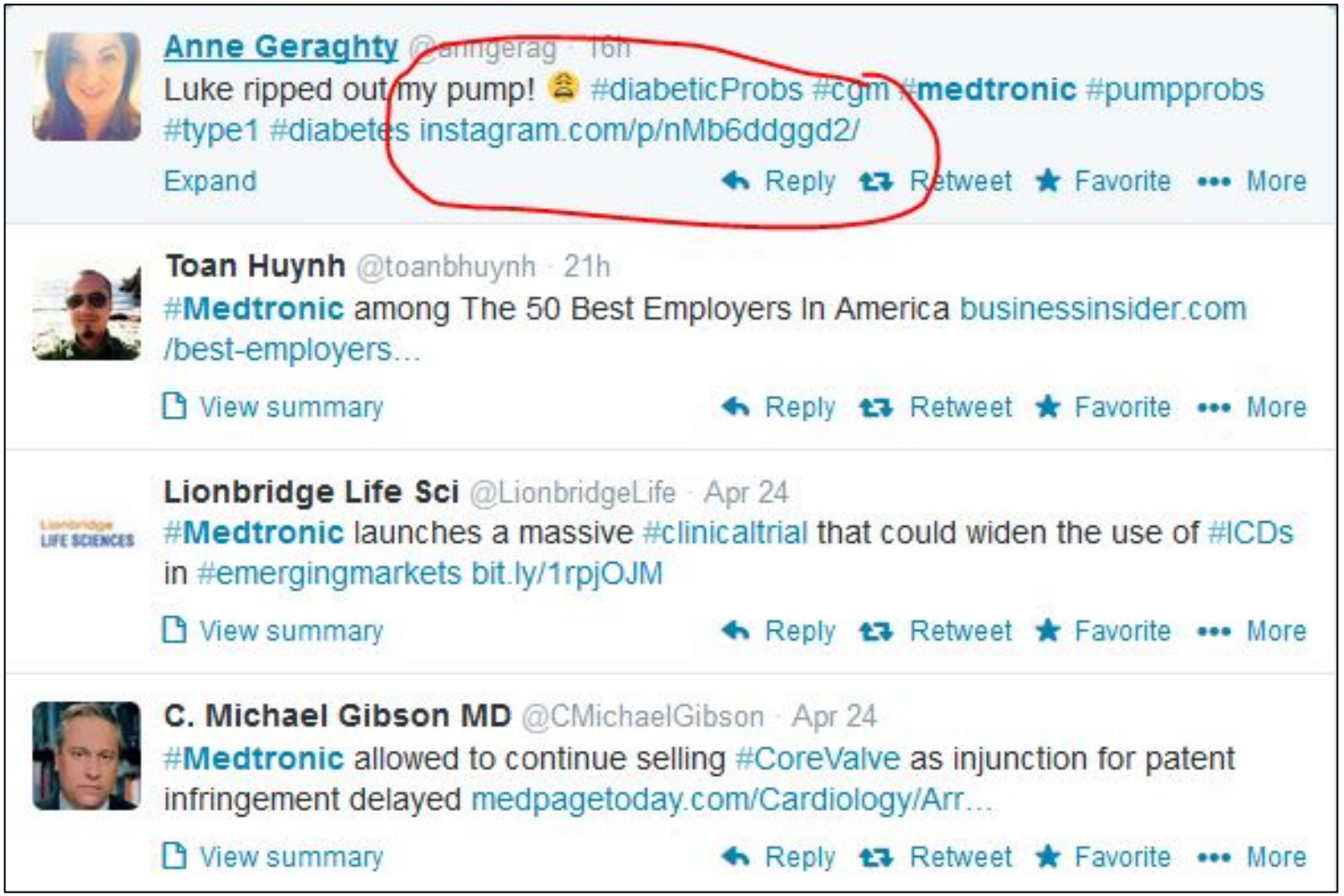
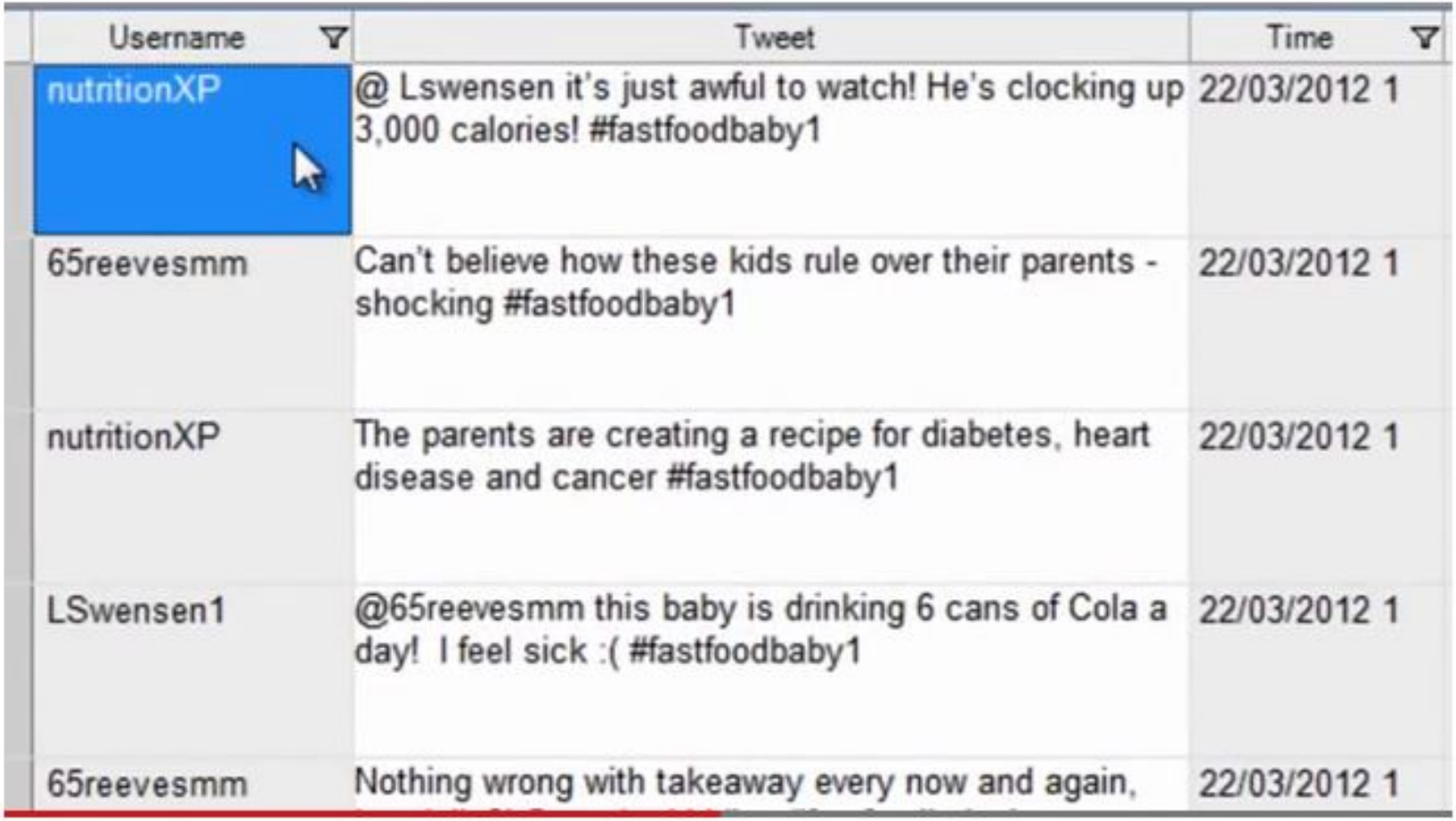


Online communities & social media

- **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



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

QSR Nvivo's Ncapture tool

Issues to consider

Public vs Private	Topic Sensitivity	Degree of Interaction	Subject Vulnerability	Is Consent Necessary?
Private	High	High	High	Likely
↕	↕	↕	↕	↕
Public	Low	Low	Low	Not Likely

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...

81	send or receive text messages
60	access the internet
52	send or receive email
50	download apps
49	get directions, recommendations, or other location-based information
48	listen to music
21	participate in a video call or video chat
8	"check in" or share your location

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

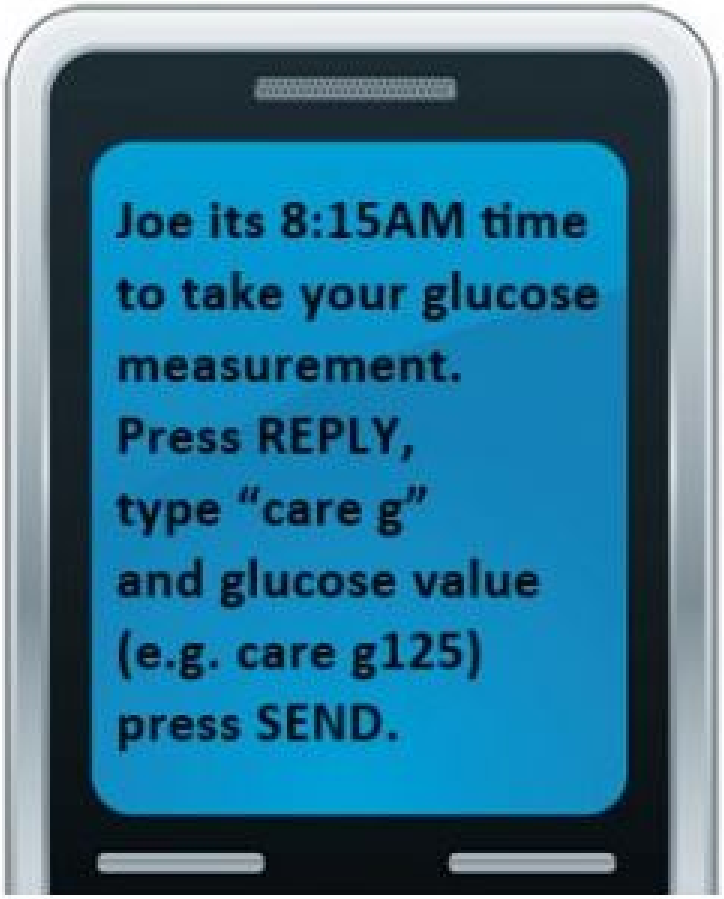


Image: http://mobihealthnews.com/13526/unitedhealth-group-taps-carespeak-for-sms/

Mobile devices

Image: http://journal.frontiersin.org/Journal/10.3389/fpubh.2014.00012/full

Mobile devices

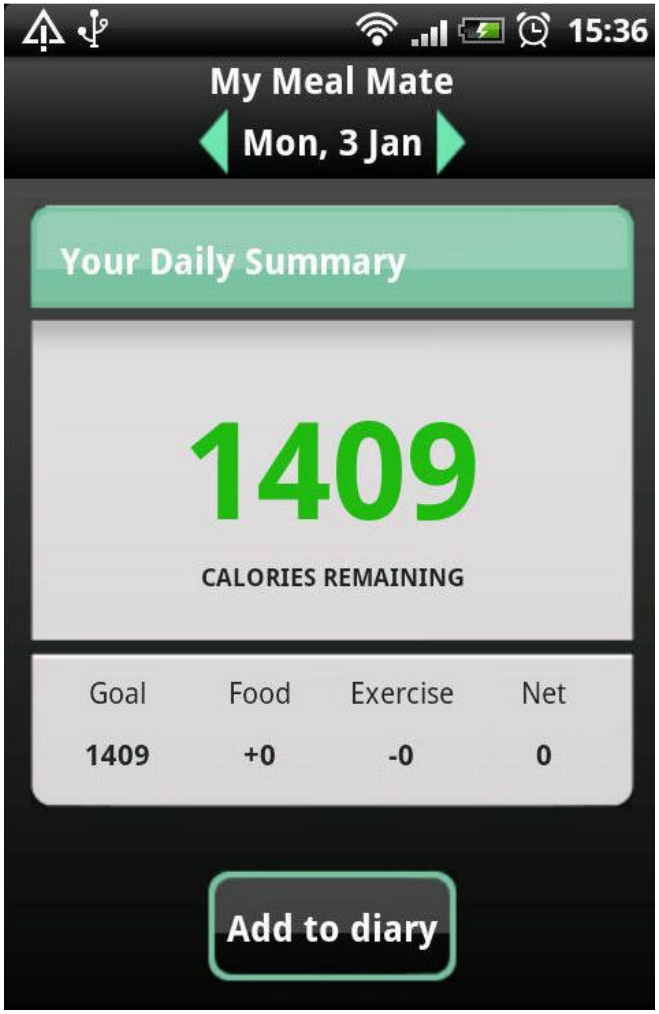


Image: http://www.jmir.org/2013/4/e32/

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

Resources

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- Kozinets, R. (2010) *Netnography*.
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- Salmons, J. (2014) *Qualitative Online Interviews*, 2nd edition.
- 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

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Advances in Online Tools for Accelerating PRO Development

Paul Wicks, PhD
PatientsLikeMe
Vice President of Innovation

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PatientsLikeMe

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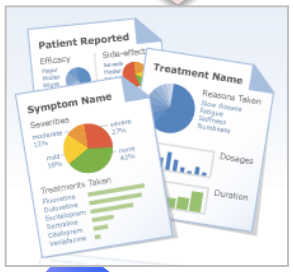
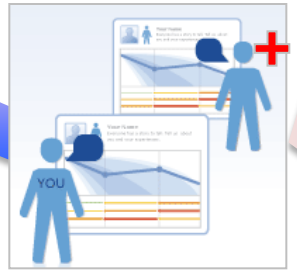
Step 1:
Create/update and share your health profile

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



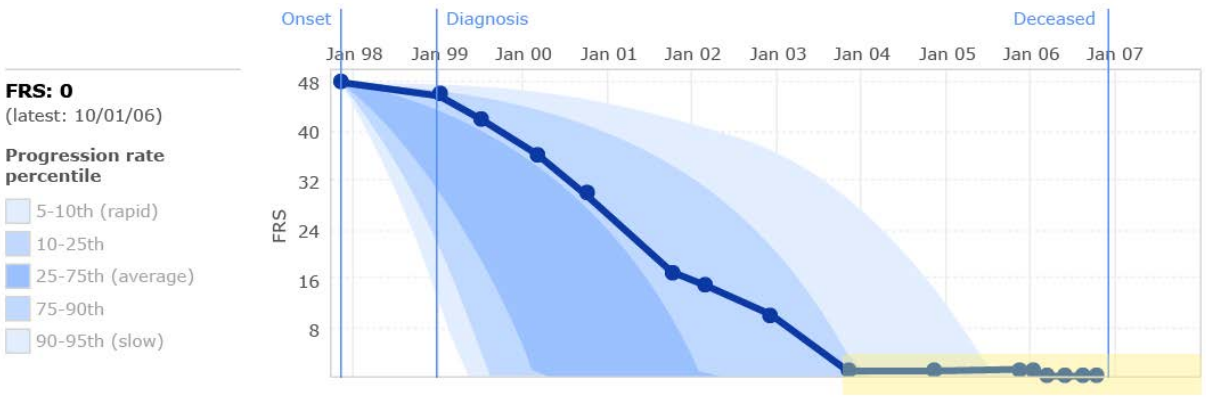
Step 3:
Learn from aggregated community Treatment and Symptom Reports



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

Step 5:
Play an integral part in your own health care

Measuring Advanced ALS



European Journal of Neurology 2009, **16:** 353–359 doi:10.1111/j.1468-1331.2008.02434.x

Measuring function in advanced ALS: validation of ALSFRS-EX extension items

P. Wicks[a], M. P. Massagli[a], C. Wolf[b] and J. Heywood[a]

[a]*PatientsLikeMe Inc., Research & Development, Cambridge, MA, USA; and* [b]*Person living with ALS, patient member of PatientsLikeMe.com*

Keywords:
ALS, ALSFRS-R, clinical rating scale, floor effect

Received 19 August 2008
Accepted 18 November 2008

Background: With the aid of assistive technology, some patients with amyotrophic lateral sclerosis (ALS) are able to live for several years past the lowest measurable level of function on the Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised (ALSFRS-R), a widely used end-point in ALS assessment. There is a research need to monitor patient function at the end of life, particularly in the face of severe impairment or 'locked in syndrome'. *Methods:* We used an online community for people with ALS (PALS) (PatientsLikeMe) to construct and pilot a number of new items to add to the

- 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

Rosen R. Development of Patient Reported Outcome (PRO) Measures: How Feasible is a PRO for Asymptomatic PCa Treatment? FDA Public Workshop Clinical Trial Design Issues Drug and Device Development for Localized Prostate Cancer, 2013.

Hayes R. Patient-Reported Outcome (PRO) Instruments as Drug Development Tools (Session III). Consensus Science New Tools and Tactics for Next-Gen Drug Development., Washington, DC: 2011.

Open source model and PROs

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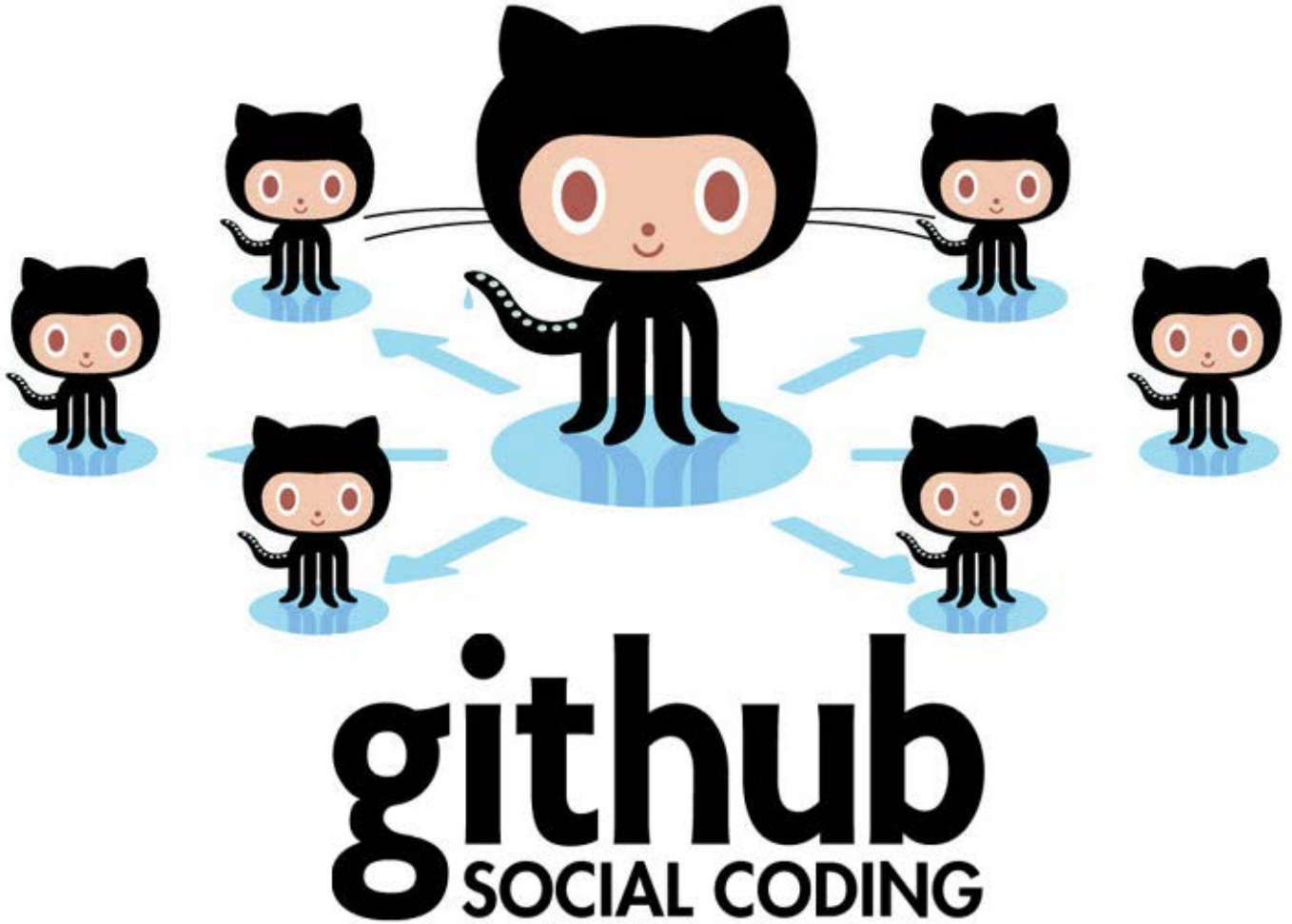

Open Research Exchange (ORE)

- **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

open research exchange
by patientslikeme

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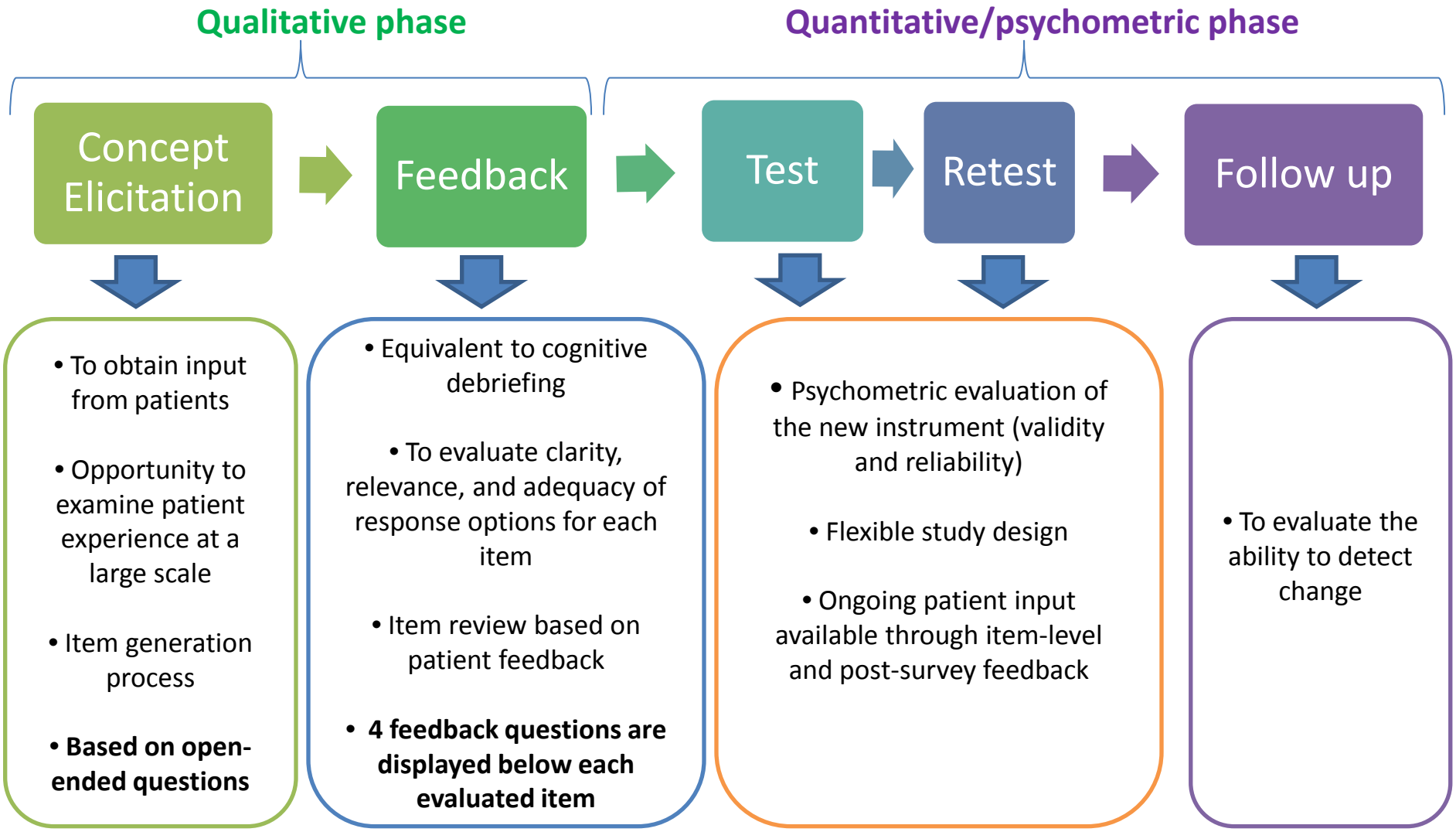
Sara Riggare
PhD student, Karolinska Institutet

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



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

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View results for Study 1 - Test of Psoriasis Survey — Export

Descriptive | Qualitative | Performance & details

N = 357 of 400 invited: Multiple Sclerosis, No Diabetes, Ages 18-65, 207 M / 193 F, USA, MSRS-R 7.0-10.0, Dx Date 3+ yrs

Group Descriptive Results

Show for Layout 1 > New PRO items > All Domains — Print

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

How long have you experienced joint stiffness?

Response option	Code	Freq.	%	Cum. freq.	Cum. %	Avg. time
Less than 1 week	0	228	15.49%	228	15.49%	12 s
Less than one month	1	339	23.02%	795	38.51%	19 s
Less than one year	2	397	26.97%	1192	65.48%	15 s
Less than 5 years	3	254	17.26%	1446	82.74%	15 s
More than 5 years	4	254	17.26%	1700	95.25%	16 s
I prefer to skip	-97	10	2.31%	1710	97.31%	5 s
I don't know	-98	5	1.65%	1715	100.00%	12s
Does not apply	- 99	0	0.00%	0	100.00%	---
Forced skip	- 100	0	0.00%	0	100.00%	---
Did not complete	- 999	0	0.00%	0	100.00%	---

Quantitative Feedback Responses

Does it apply?	Freq.	%
Very well	5	27.7
Reasonably well	8	44.4
A little bit	3	16.7
Not at all	2	11.1

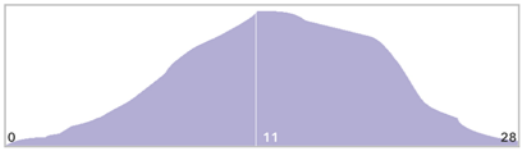
Easy to understand?	Freq.	%
Very easy	5	27.7
Easy	8	44.4
Somewhat easy	3	16.7
Not easy at all	2	11.1

Do responses fit?	Freq.	%
Very well	3	27.7
Reasonably well	9	44.4
A little bit	4	16.7
Not at all	3	11.1

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	Code	Freq.	%	Avg. time
I prefer to skip	-97	10	2.31%	5 s
I don't know	-98	5	1.65%	12s
Does not apply	- 99	0	0.00%	---
Forced skip	- 100	0	0.00%	---
Did not complete	- 999	0	0.00%	---

Quantitative Feedback Responses

Does it apply?	Freq.	%
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Do responses fit?	Freq.	%
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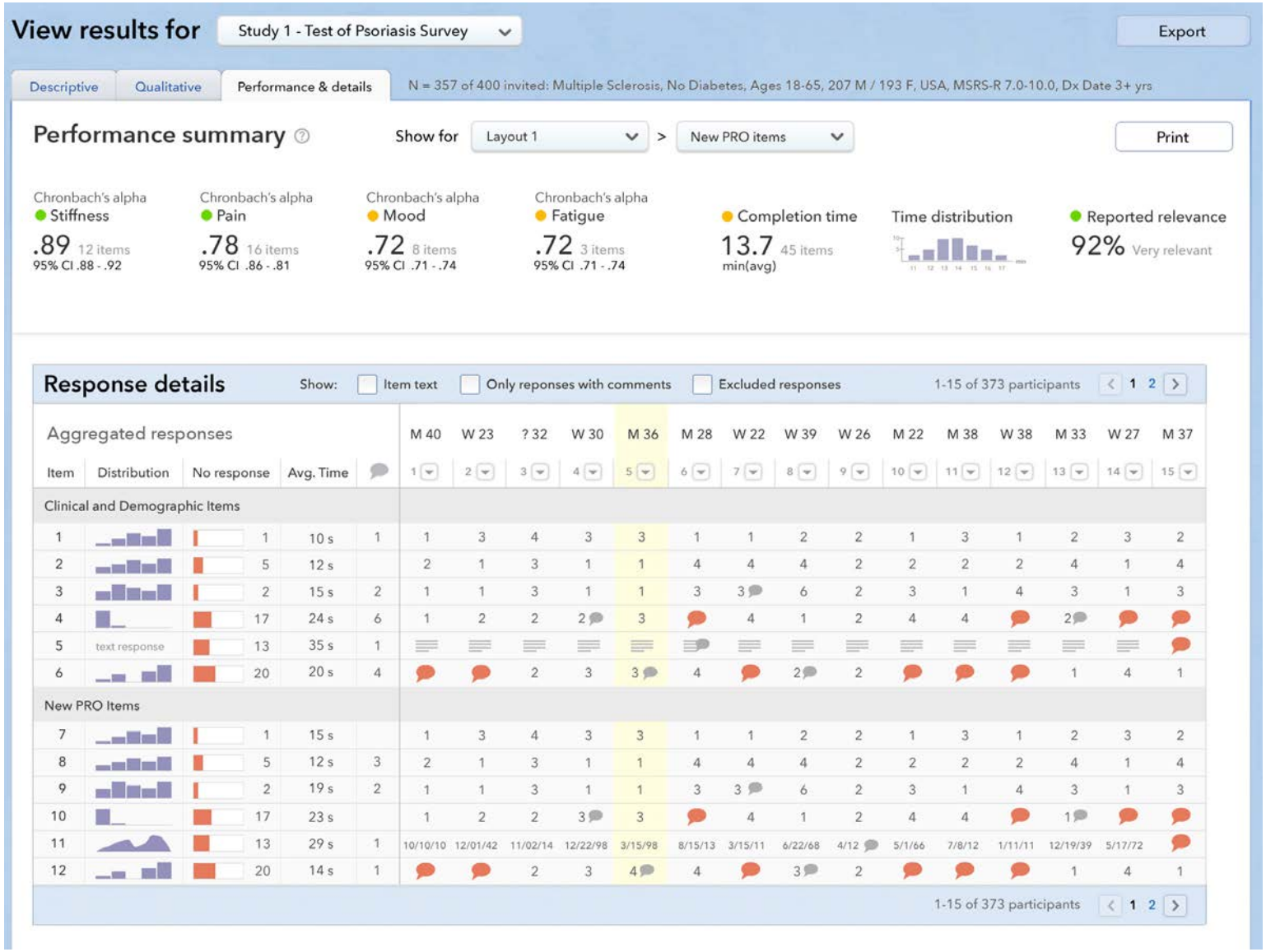
Patient-Level Data Display



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

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- 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?