

# Web-based Assessments:

The Internet is an Emerging  
Modality in Patient Reported  
Outcomes

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**PRO Consulting**<sup>®</sup>

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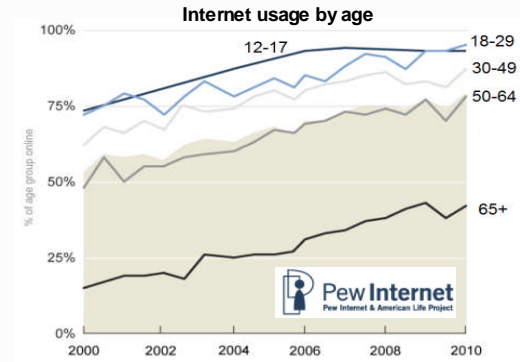
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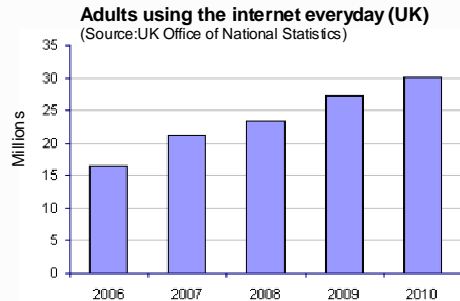
epidemiology Patient  
electronic human Focus Reported  
medical computer group  
record interaction surveys  
self-management  
**Internet**  
cancer blog E-health  
Education support groups  
home monitoring online  
recruitment information search therapy

# The Internet: It ain't slowing down (much)

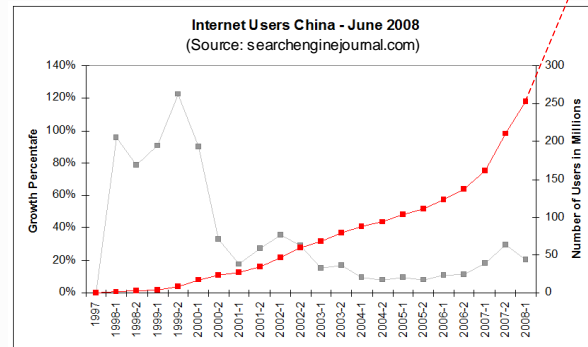
## USA



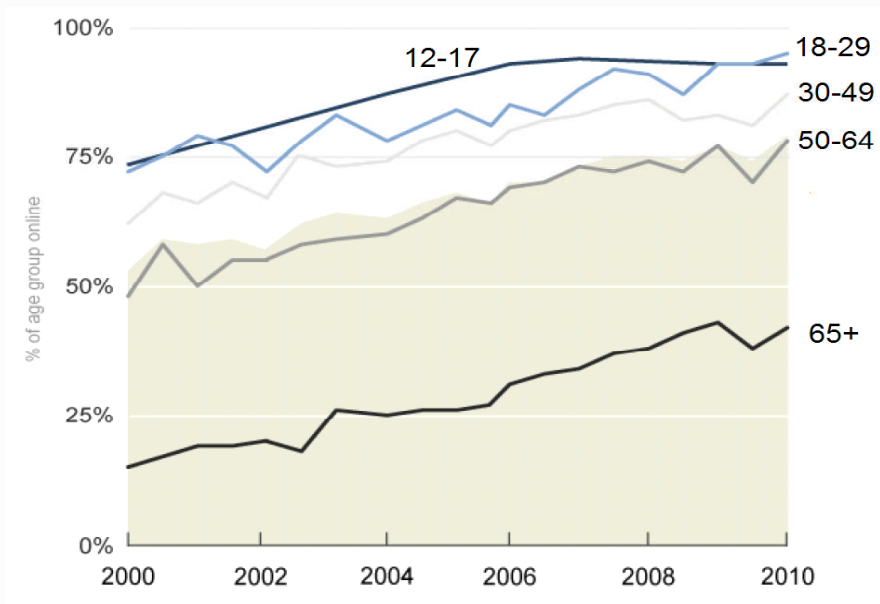
## UK



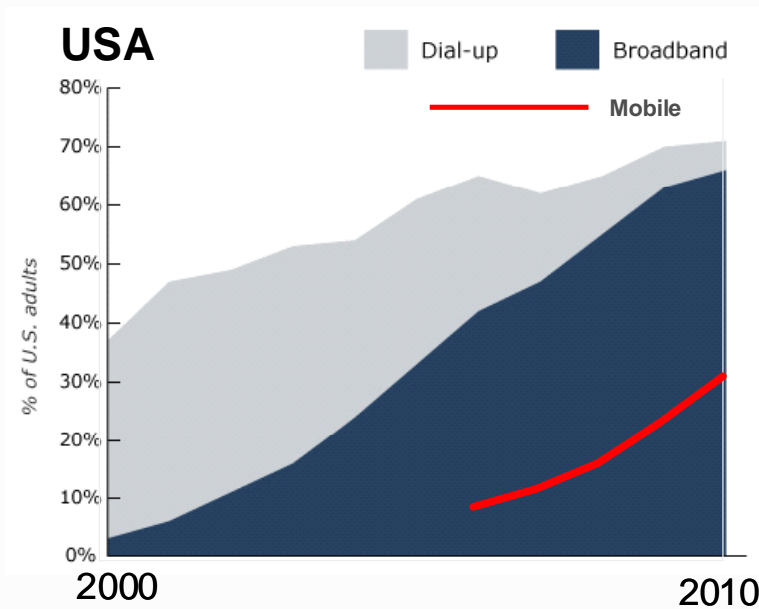
## China



# Internet Usage by Age

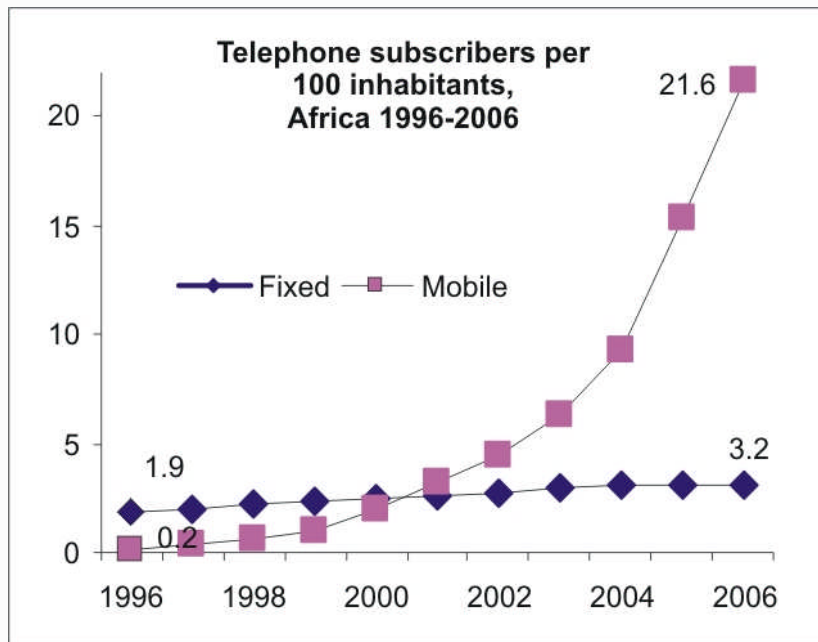


# Internet: Mode of Connection



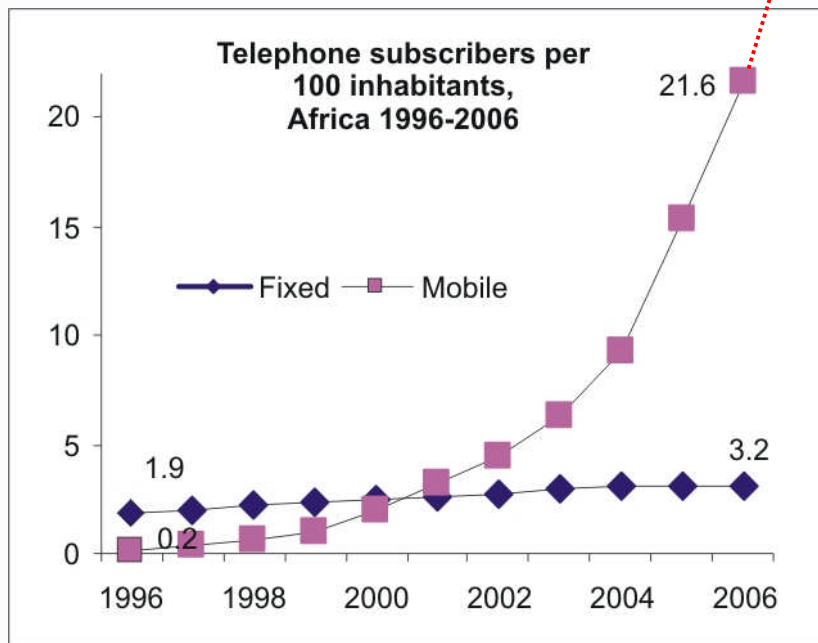
Sources: CircleID &  Pew Internet  
Pew Internet & American Life Project

# Mobile Phones in Africa



# Mobile Phones in Africa

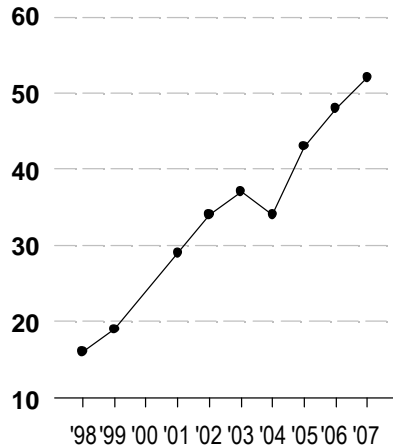
2010:  
Now  
around  
50%





# The Internet for Healthcare

% of adults looking for health information online, 1998-2007



Source: Harris Interactive

- Information Search
- Support Groups
- Surveys
- Personal Monitoring
- Therapy

# Support Groups

- Help in finding relevant information
- Sharing experiences
  - What will it be like?
  - What aren't they telling me?
  - They're telling me too much! What is most important?
- Social support
  - Reduce feelings of isolation and uncertainty
  - Beneficial effects on stress and mood

# Support Groups and Research

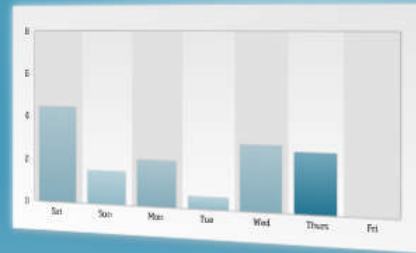
- “What’s it like”
  - Qualitative methods can be used to analyse experience of symptoms and the impact of disease
  - Informing therapeutic research (is your sample representative?)
  - Establishing content validity of PRO instruments (e.g. Wicks et al., 2011)
- Patients description of outcomes
  - Evidence for treatment efficacy and adverse events
  - Useful supplement to Phase IV research (e.g. Frost et. al., 2011)

# Individual Monitoring

- Regular input of data by user
  - Exercise
  - Diet
  - Alcohol consumption
  - Medication adherence
- Feedback from site to user
  - Performance compared to targets
  - Change over time
  - Patterns and associations within data

# Track your drinking over time

Find out how many units are in your favourite drinks. Add them to your diary and see the running total.



# Get personal feedback

See how the units and calories are adding up over days and weeks.



 **MyDrinkaware** for the facts  
drinkaware.co.uk

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# Exercise Monitoring



## Track Progress

Update your progress through web, email, or phone.



## See Results

Get feedback about your progress and learn what influences your behavior.



## Get Encouraged

Receive encouragement from your friends or others with the same

goal!

TrackVille

# Key Features of the Health Internet

- Broadly-based content and participation
  - Web2.0 emphasises user-generated content rather than access to centrally generated material
  - Multiway communication among users and sites
  - An active and autonomous community
- Population often not well-defined
  - Sites are in general open and anonymous
  - Cannot document actual diagnosis or demographics
- Large numbers of patients available

# Telehealth

- Older model, rapidly developing
  - Specialist care of known patients
  - Originally used point-to-point communications, e.g. transmission of ecg data to specialist unit
- Uses a variety of technologies
  - Physiological monitoring
  - Teleconferencing
  - Mobile communications
  - Web-based collection and review of information



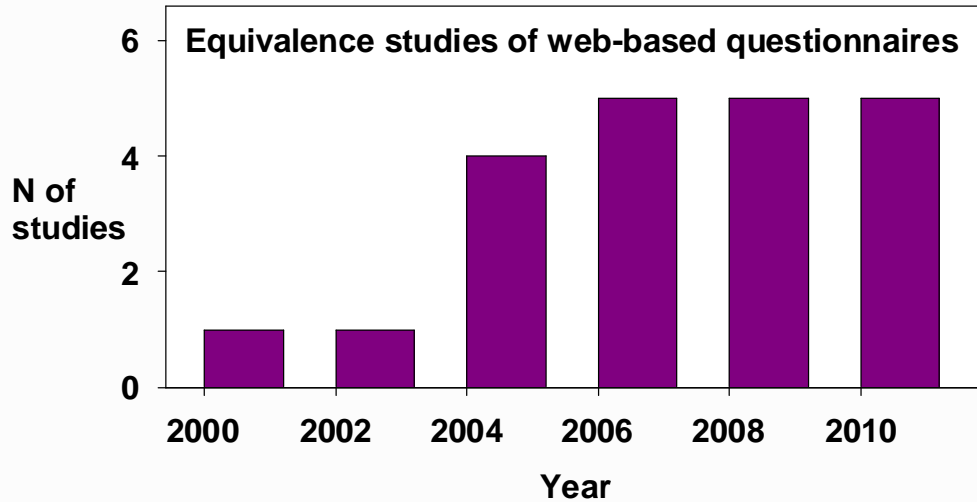
# Potential of the Internet in Clinical Research

- Characterising populations
  - Surveys
  - Content analysis of support sites and blogs
- Instrument development
  - Ensuring content validity of measures
  - Large-scale testing
- Data collection
  - PRO instruments deployed on the web
  - Parallel development of web and other modalities
- Recruitment

# Instrument Development: An example in multiple sclerosis

- Content analysis of PatientsLikeMe.com online community used to develop survey of treatment adherence (MS-TAQ)
- Cognitive interviewing of small face-to-face sample
- Sample recruited from PatientsLikeMe completed survey online
  - 431 complete from 1209 invited
  - Patients had similar sex ratio to those in previous conventional sample, but were slightly younger (47 vs 51), and had disease for slightly shorter time (11 vs 9 yrs)
  - Significant correlations between compliance and “Barriers” (0.50) and “Coping” (-0.30) subscales, supporting scale validity

Source: Wicks et al. (2011)



- Less data available than for device-based ePRO (PC or handheld)
- Good support for mode-equivalence
- No published reports of use in clinical trials

# WHOQOL Equivalence study

- 80 subject randomised crossover, web vs paper
- 1016 subject web validation sample
- No significant differences in scores web vs paper
- ICC in range 0.71-0.85 for scale domain scores
- Cronbach's alpha 0.60-0.83
- Missing data on paper, none from web
- Results similar to those seen from ePRO validation meta-analysis

Sources: Chen et al. (2009), Gwaltney et al. (2008)

# Equivalence Studies on the Web

- Web delivery of in-clinic solutions
  - Supervised setting
  - Equipment specification can be standardised
  - Issues are very similar to conventional ePRO
- Everyday Life Assessment
  - Unsupervised setting
  - Limited information about devices
  - Need to address implications of greater variability



# Safety Monitoring

- iGuard.org is established monitoring site
- Patients enrolled in online survey
- Survey is similar to PRO instruments
- Results published on several CNS medications
- Most adverse events were not reported to patient's doctor

See, e.g. Cascade et al (2010)

# Conclusions

- Web methods clearly applicable to clinical research
- Issues of selection bias need to be considered
  - Web recruitment
  - Availability of internet to all patients?
- Benefits are various
  - Cost, especially when existing infrastructure is used
  - Versatility
  - Ease of distribution
  - Methods familiar to many patients and investigators

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