Overview of Social Networks and Their Role in Direct-to-Patient Research

Presented by:
Elisa Cascade, MediGuard.org

Rapid Adoption of the Internet as a Source of Health Information
- In 2009, 102.3 million U.S. adults went online for prescription drug information; more than 2x the number in 2004 (45.7 million)1
- 30 million people in the UK access the internet every day (60%)
- ~40% seeking health related information
- ~50% of French people go regularly on the web to find medical information
- Each month, 1 out of 3 internet users goes to a website dedicated to health, wellbeing, or nutrition
- Drivers of the rapid growth include:
  - Greater access to the internet
  - Greater adoption, especially amongst older consumers
  - An increase in the number of adults taking one or more medication
  - Health care costs/cost sharing


Nearly 60% of All US Adults Seeking Health Information On-Line (May 2011)

% of All Adults Looking On-line for Health Information

59% | 66% | 71% | 66% | 58% | 29%
--- | --- | --- | --- | --- | ---
Overall | Male | Female | 18-29 | 30-46 | 50-64 | 65+


Despite Increased Information, Level of Misinformation About the Same; Result is Improved Outcomes
Internet Growth has Fueled the Emergence of Online Patient Communities

- General networking sites
  - Facebook
  - LinkedIn
- Health-related social networks
  - WeAre
  - Inspire
  - TalkHealth Partnership
- General online panels
  - My points
  - Harris Interactive
- Online health services
  - MediGuard.org
  - PatientsLikeMe
  - TrialX and ClinicalResearch.com

What’s similar:
- Online patient communities often have an ongoing relationship with members
- Inspire
- TalkHealth Partnership

What’s different:
- Interest in sharing health information and type of patient

Online Communities are Well-positioned for Growth

- Explosive growth set to continue
  - New, untapped study populations
  - Most age groups / demographics have strong representation
  - Unprecedented amounts of clinically relevant data and new patient insights

- Why?
  - Convenience
  - Time
  - Unmet medical need

These online patient communities provide a significant opportunity for direct-to-patient research in clinical, outcomes, and commercial programs

Social Media and Safety Monitoring Requirements

- In Nov. 2010, the MHRA provided the following guidance on Sponsor responsibilities for adverse event monitoring:
  - Sponsors should regularly screen sites under their management or responsibility
  - Sponsors are not expected to screen sites outside of their control
  - However, if a suspected adverse event is spotted on an external site, the Sponsor should review the case and determine whether reporting is warranted

- Guidance from the FDA is expected this year
  - Discussions with US pharmacovigilance experts suggest that the guidance will be similar to the MHRA – monitor sponsored sites

Direct-to-Patient Research with On-line Communities

Clinical Trial Feasibility
- Patient survey to obtain feedback on:
  - UL criteria
  - Barriers to participation
  - Facilitating messages

Clinical Trial Recruitment
- Ensure patients for trial eligibility and provide referrals to local investigators
- Existing members
- Social media outreach

Observational Research
- Direct patient enrollment into observational studies
- Retrospective
- Prospective

Disease Management
- Baseline assessment and consent to recontact
- Satisfaction survey
- Intervention (education, reminders, etc.)
- Subsequent assessments

Access to Patient Communities Could Transform Current Practice for Observational Research

Observational Research
- Retrospective (EMR, Claims)
- Prospective (Site-based enrollment)

Direct-to-Patient Services
- Retrospective
  - Unstructured (e.g., scanning blogs for adverse events)
  - Structured (e.g., TSQM data, treatment experience)
- Prospective
  - Cross-sectional (e.g., PRO for burden of illness)
  - Longitudinal (e.g., registries)

Examples of Patient-reported Data

- Be aware of study limitations related to representativeness and data quality
**Prospective Direct-to-Patient Research – More than Just Surveys!**

**Patient Survey (PRO)**
- Disease status
- Quality of life
- Treatment satisfaction
- Work productivity

**Medical Record (EMR)**
- Diagnosis confirmation
- Comorbid conditions
- Treatments

**Laboratory Testing (Labs)**
- Blood and urine based labs
- Genetic testing (blood or saliva)
- Sample banking

**MediGuard = PRO+EMR+Labs**

**Analysis & Reporting**
- Monthly status reports
- Physician benchmarking
- Patient status reports
- Results dissemination

**Direct-to-Patient Observational Registries: Offering Time and Cost Efficiencies**

**PRO+EMR, 6 month follow-up (n=660 pts)**
- Site-based Registry
- Direct-to-Patient Registry

<table>
<thead>
<tr>
<th>Study Timeline</th>
<th>Site-based Registry</th>
<th>Direct-to-Patient Registry</th>
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<tbody>
<tr>
<td>18 months</td>
<td>12 months</td>
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<table>
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<th>Costs: Professional Fees + Direct Expenses</th>
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<td>$1.7 million</td>
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**Summary**
- Pharmaceutical companies are being asked to do more with less
  - Increase in stakeholder demand for real-world data post-approval
  - Decrease in availability of funds for non-registration research
- Online patient communities have the potential to enable a paradigm shift in the conduct of observational research
  - Retrospective data mining – unstructured and structured
  - Prospective collection of PRO (and in some cases EMR+Labs) through direct-to-patient studies
- Primary benefit is the potential for both time and cost efficiencies
  - Beware of issues related to representativeness and data quality
- While often overlooked as a stakeholder, patients are motivated to participate in observational research
  - Strong desire to help others by participating in research
  - Alignment of incentives from consent through compensation results in high levels of study compliance

**Patient Motivation and Study Limitations**

**Patient Motivation**
- Helping others!!!
- Direct alignment of incentives
  - Patient offered study opportunity
  - Patient consents to participate
  - Patient reports study data
  - Patient receives compensation
- Comprehensive condition monitoring and tracking

**Research Limitations**
- Representativeness?
  - Community demographics
  - Negative research experience
- Data quality?
  - Verification of patient diagnosis
  - Self-reported data
  - Lack of randomization

**For More Information, Please Contact:**
Elisa.Cascade@MediGuard.org