Leveraging Social Networks to Conduct Observational Research: A Paradigm Shift in Methodology

Presented by:
Elisa Cascade, MediGuard/Quintiles
About Elisa Cascade, VP MediGuard/Quintiles

– Assisted in site design/launch, and currently lead Global Operations at MediGuard, Quintiles’ patient community
  • MediGuard.org is a medication monitoring service covering nearly 2.5 million members in the US, UK, France, Germany, Spain, and Australia
  • Members who join the community provide consent to re-contact for research and disease education

– Over the past 2 years, managed the conduct of 200+ patient-centric studies involving over 25,000 patients
  • Patient-centric studies recruit patients directly, rather than relying on physician sites to recruit patients

– Prior to joining MediGuard, served on the Management Team for Quintiles Late Phase group
  • Over 20 years of industry experience in market research, health economics/outcomes research, pricing/reimbursement, and late phase studies
Agenda

– Emergence of online communities
– Retrospective and prospective patient-centric research services enabled by online communities
– Case examples of patient-centric research
– Common concerns about patient-centric research
– Patient-centric research within the context of other observational data collection methods
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:
  • Older consumers becoming more comfortable with the Internet
  • An increase in the number of adults taking one or more medication
  • Health care costs/cost sharing

Internet Growth has Fueled the Emergence of Online Patient Communities

- **General networking sites**
  - Facebook
  - LinkedIn

- **Health-related social networks**
  - WeAre
  - Patientslikeme
  - TalkHealth Partnership

- **General online panels**
  - My points
  - Harris Interactive

- **Online health services**
  - MediGuard.org
  - Microsoft HealthVault (PHR)

**What’s similar:**

Online patient communities often have an ongoing relationship with members (unlike sites that merely post information)

**What’s different:**

Interest in sharing health information and type of patient
Access to Patient Communities Could Transform Current Practice for Observational Research

Observational Research

- **Retrospective** (EMR, Claims)
- **Prospective** (Site-based enrollment)

Patient-Centric Services

<table>
<thead>
<tr>
<th>Retrospective</th>
<th>Prospective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unstructured (e.g., scanning blogs for adverse events)</td>
<td>Cross-sectional (e.g., burden of illness, disease prevalence)</td>
</tr>
<tr>
<td>Structured (e.g., TSQM data)</td>
<td>Longitudinal (e.g., registries)</td>
</tr>
</tbody>
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Patient-centric Research Programs – More than Just Surveys!

**MediGuard = PRO+EMR+Labs**

### 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
- Genomic testing (blood or saliva)
- Sample banking
Patient-Centric Observational Programs: Offering Time and Cost Efficiencies

- Patient community screens and consents patient into registry
- Medical Chart Review to confirm diagnosis and obtain history
- Baseline assessments
  - Questionnaires
  - Laboratory tests
  - Biologic sample
- Subsequent assessments
  - 3 months
  - 6 months
  - 12 months
- Analysis & Reporting
  - Monthly status reports
  - Baseline & interim analyses
  - Final analysis & report
  - Results dissemination

<table>
<thead>
<tr>
<th>PRO+EMR, 6 month follow-up (n=660 pts)</th>
<th>Site-based Registry</th>
<th>Patient-centric Registry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Timeline</td>
<td>18 months</td>
<td>12 months</td>
</tr>
<tr>
<td>Costs: Professional Fees + Direct Expenses</td>
<td>$1.7 million</td>
<td>$0.5 million</td>
</tr>
</tbody>
</table>
Patient-Centric Studies Can Support the Full Spectrum Prospective Observational Research Types

Patient-Centric Study Types

- Cross-sectional Research
- Burden of Illness
- Comparative Effectiveness
- Signal Detection & Validation
- Patient Surveys & Medical Records
- Patient-reported Outcomes Validation
- Patient-centric Laboratory Testing
- Longitudinal Research
- Registries
Patient-Centric Case Example: Longitudinal PRO Diary Study in Menstrual Bleeding

- **Objective:**
  - Examine burden of illness associated with menstrual bleeding

- **Approach:**
  - All women completed a survey that included resource use for bleeding management amongst other questions
  - A subset of women (30%) were asked to complete an online daily dairy to obtain actual information on bleeding management
    - Women were contacted daily to determine the start of their menstrual cycle
    - Once started, women completed a daily diary to record pain and resource use

- **Outcomes:**
  - 65 of 74 women successfully completed (i.e., missed no more than 1 diary day)

**Compliance with Daily Diary (n=74 subjects)**

- Complete, Successful 88%
- Complete, Not Successful 3%
- Lost to follow up 9%
Patient-Centric Case Example: PRO+EMR Asthma Outcomes Assessment

- **Objective:**
  - While EMR data mining provides some insight into patient flow through treatments, FEV rates, and resource use, these analyses lack the “why” behind the outcomes
  - The purpose of this study is to identify factors that influence asthma outcomes

- **Approach (study in start-up):**
  - Extraction of asthma medical records at the Primary Care Trust level
  - Outreach to patients to drive them to an online PRO survey
    - Asthma control (ACT)
    - Treatment satisfaction (TSQM)
    - Compliance (MARS-5)
    - Attitudes towards asthma (AAQ)

- **Outcomes:**
  - EMR+PRO results will provide actionable data for development of disease management and medication adherence programs to:
    - Improve patient quality of life
    - Decrease costs associated with emergency resource use
Patient-Centric Case Example: PRO+Labs
Prevalence of Low-T in Diabetic Males

- **Objective:**
  - Increase awareness of Low-T among healthcare professionals

- **Approach (study in start-up):**
  - Patient consent and symptom survey
  - Lab testing at local lab facility

- **Study endpoints:**
  - Prevalence of Low-T in T2 diabetic men
  - Diagnosed vs. undiagnosed and symptomatic vs. asymptomatic
  - Ability of the ADAM vs. AMS questionnaire to predict Low-T
  - Differences in health status, resource use, and work productivity in T2 diabetic men with and without Low-T

- **Dissemination (forthcoming):**
  - Peer-reviewed publication

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**Process Flow**

- Obtain IRB approval for project
- Targeted email outreach to MediGuard members
- Online screener for age, gender, and conditions; survey of eligible subjects
- Patient consent to participate in Low-T program from interested members
- Subjects download lab prescription and visit a LabCorp facility for testosterone testing
- Lab results available to the patient and sent de-identified, to MediGuard
Common Concerns About Patient Research Communities & Key Questions for Evaluation

<table>
<thead>
<tr>
<th>Concern</th>
<th>Key Questions for Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Representativeness:</strong></td>
<td>• Patient population attracted to the community</td>
</tr>
<tr>
<td>• Biased towards individuals with a negative medication experience?</td>
<td>• Patient motivation for joining community</td>
</tr>
<tr>
<td>• Community demographics?</td>
<td>• Methods for community recruitment</td>
</tr>
<tr>
<td></td>
<td>• Data collection: spontaneous vs. randomized</td>
</tr>
<tr>
<td></td>
<td>• Data on community demographics</td>
</tr>
<tr>
<td></td>
<td>• Ability to stratify and model to market level</td>
</tr>
<tr>
<td><strong>Data Quality:</strong></td>
<td>• Motivation for creating community profile</td>
</tr>
<tr>
<td>• How do we know the patient has the condition that they say they have?</td>
<td>• Research experience in developing non-leading screeners</td>
</tr>
<tr>
<td>• Can patients accurately self-report data?</td>
<td>• Knowledge and use of validated PRO instruments</td>
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<td></td>
<td>• Ability to integrate EMR/Claims, Lab, and physician data</td>
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## Patient-centric Research Within the Context of Other Research Methods

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Site-based</th>
<th>EMR/ Claims</th>
<th>Patient-centric (PRO+EMR+Lab)</th>
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</thead>
<tbody>
<tr>
<td><strong>Data:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Demographics</td>
<td>●</td>
<td></td>
<td>●/</td>
</tr>
<tr>
<td>- Disease history/assessment</td>
<td>●</td>
<td>●/</td>
<td>●</td>
</tr>
<tr>
<td>- PRO</td>
<td>●</td>
<td>▲/</td>
<td>●/</td>
</tr>
<tr>
<td>- Resource use</td>
<td>●</td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>- Laboratory values</td>
<td>●</td>
<td></td>
<td>●</td>
</tr>
<tr>
<td><strong>Efficiencies:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Time</td>
<td>○</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>- Cost</td>
<td>○</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>- Sample size</td>
<td>○</td>
<td>●</td>
<td>?</td>
</tr>
<tr>
<td><strong>Bias:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Selection bias (subjects invited)</td>
<td>○</td>
<td>●</td>
<td>?</td>
</tr>
<tr>
<td>- Response bias (subjects participating)</td>
<td>▲/</td>
<td>●</td>
<td>?</td>
</tr>
<tr>
<td>- Hawthorne effect (observation bias)</td>
<td>○</td>
<td>●</td>
<td>?</td>
</tr>
<tr>
<td><strong>Representativeness</strong></td>
<td>?</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
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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
  • Direct collection of PRO+EMR+Labs through patient-centric studies
  • Approach offers 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
For more information visit:  
[Quintiles Late Phase Solutions](#)  

or contact us at:  
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