First Fridays Webinar Series:
Medical Education Group (MEG)

Patient-Level Data

February 4, 2011

Webinar Series Goals

- Provide Insights into MEG Operations
- Share Up-To-Date Information
- Share Best Practices
- How Can Pfizer Improve Processes?
- Respond to Outstanding Questions From Providers
Agenda: Patient-Level Data

- Welcome and Review of MEG Operations
- Planning is Everything in the Collection of Patient-Level Data – Sean Hayes, PsyD, Vice President, AXDEV Group, Inc. and Suzanne Murray President & Founder AXDEV Group, Inc.
- Q and A
- Closing Remarks

The Pfizer Grants Portal
Inside the Resource Center

Archived Webinars

Mouse-over goal statements

The MEG 2-Step

Register ➔ Submit ➔ Review ➔ Decide ➔ Notification ➔ Single Event ➔ Pay ➔ Reconcile / Close

Quarterly Review ➔ Multi-step Program ➔ Monitor

Evaluate
### Quarterly Review Schedule 2011

<table>
<thead>
<tr>
<th>Application Period</th>
<th>Date Decision To Be Communicated By</th>
<th>Signed LOA Deadline</th>
<th>Start Date of Program/Activity</th>
</tr>
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<tbody>
<tr>
<td>Dec 1, 2010 – Jan 15, 2011</td>
<td>Mar 4, 2011</td>
<td>Minimum of 2 weeks before start date or the decision will reverse to denied</td>
<td>April 1, 2011 or later</td>
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<tr>
<td>Mar 1, 2011 – April 15, 2011</td>
<td>June 3, 2011</td>
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<td>June 1, 2011 – July 15, 2011</td>
<td>Sept 2, 2011</td>
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<td>Oct 1, 2011 or later</td>
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### It’s All About the Patient

- Patients are in the forefront of our operation
- Addressing performance improvement
- Totally-engaged learners
- Interdisciplinary care for a holistic approach
- Education is an intermediate step to improved patient care
- Needs assessment
- Tools to get there
Planning is Everything in the Collection of Patient-Level Data

Presenters: Suzanne Murray
Sean Hayes

February 4th, 2011

Agenda

<table>
<thead>
<tr>
<th>Agenda Item</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objectives</td>
<td>5 minutes</td>
</tr>
<tr>
<td>Context for patient-level data</td>
<td>5 minutes</td>
</tr>
<tr>
<td>Patient-level data in the educational cycle</td>
<td>5 minutes</td>
</tr>
<tr>
<td>Planning of patient-level data collection</td>
<td>10 minutes</td>
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<tr>
<td>• Linking the impact to the education</td>
<td></td>
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<tr>
<td>• What is done and what could be done</td>
<td></td>
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<tr>
<td>Potential obstacles for patient-level data</td>
<td>5 minutes</td>
</tr>
<tr>
<td>Q &amp; A</td>
<td>10 minutes</td>
</tr>
</tbody>
</table>
Objectives

At the end of this presentation, participants should recognize:

1. The importance of planning for patient-level assessment
2. The value of patient-level data in assessing health care providers’ competence and performance
3. The broad variety of patient-level data sources available
4. Different ways of collecting patient-level data while respecting patients’ privacy, confidentiality and anonymity

Disclosure

Suzanne Murray
President & Founder
AXDEV Group International

Sean Hayes, PsyD
Vice-President
AXDEV Group

The presenters do conduct patient-level research in multiple countries.
**Who we are**

**AXDEV Group** is an international Performance Improvement organization that specializes in assisting healthcare organizations and stakeholders improve professional competencies, interdisciplinary team practices, organizational functioning, and clinical practice efficiency.

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**Agenda**

- Objectives
- **Context for patient-level data**
  - Patient-level data in the educational cycle
  - Planning of patient-level data collection
    - Linking the impact to the education
    - What is done and what could be done
  - Potential obstacles for patient-level data
- Q & A
ACCME Criteria for Evaluation of CME

- Essential Area 3: Evaluation and Improvement
  - Element 2.4: Evaluate the effectiveness of its CME activities in meeting identified educational needs.
  - Element 2.5: Evaluate the effectiveness of its overall CME program and make improvements to the program.

Criteria for Compliance
- C 11. The provider analyzes changes in learners (competence, performance, or patient outcomes) achieved as a result of the overall program's activities/educational interventions
- C 12. The provider gathers data or information and conducts a program-based analysis on the degree to which the CME mission of the provider has been met through the conduct of CME activities/educational interventions.

Performance Improvement in What?

- Health System
  Models / Structures

- Functions
  Family Medicine / Pathology / Clinical practice / Finance / Human resources

- Teams
  Interdisciplinary / Homogenous

- Professionals
  Administrators / Clinicians / Researchers / Support / Technical staff

- Patients/Caregivers
  Compliance / Concordance / Experience of care / Satisfaction
Patient-Level Data in CME

Why do we need patient-level data?

- Patients are the ultimate benefactors of Health Education and Performance Improvement in health care
- Patients are a source of data regarding health care providers’ competence and performance
- Patient-centric model: Patients are a critical part of the health care team
Patient-Level Data in the Educational Cycle

Patient-Level Data in Needs Assessment

PRIMARY CARE PHYSICIAN KNOWLEDGE, ATTITUDE, AND THE THERAPEUTIC RELATIONSHIP IN MENOPAUSE CARE: A GAP ANALYSIS

<table>
<thead>
<tr>
<th>METHODS</th>
<th>SAMPLE</th>
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<tbody>
<tr>
<td>Focus Groups</td>
<td>8</td>
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<tr>
<td>Key Informant Interviews</td>
<td>59</td>
</tr>
<tr>
<td>Regional Locations</td>
<td>East, West, North, South</td>
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<tr>
<td>Sampling</td>
<td>Representative sampling</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>PROVIDER TYPE</th>
<th>Focus Groups</th>
<th>Interviews</th>
<th>TOTAL</th>
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</thead>
<tbody>
<tr>
<td>PCPs</td>
<td>25</td>
<td>33</td>
<td>58</td>
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<tr>
<td>AHPs</td>
<td>6</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>Specialists</td>
<td>4</td>
<td>10</td>
<td>14</td>
</tr>
<tr>
<td>Patients</td>
<td>10</td>
<td>7</td>
<td>17</td>
</tr>
<tr>
<td>TOTAL</td>
<td>45</td>
<td>59</td>
<td>104</td>
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</tbody>
</table>

- Online Survey: 262
Presented at Alliance 2008

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Patients are a valuable source of data regarding participants’ competence and performance.

Don Moore, Vanderbilt University. Planning for and Assessing the Impact of Learning Activities. First Fridays Webinar Series: Medical Education Group (MEG), August 6th, 2010

Agenda

- Objectives
- Context for patient-level data
- Planning of patient-level data collection
  - Linking the impact to the education
  - What is done and what could be done
- Potential obstacles for patient-level data
- Q & A
Linking Impact to Education

CME

Impact on patient outcomes

↑ clinical endpoints: e.g., A1c, BP, CD4 count

Impact on program participants

↑ Knowledge, ↑ Skill, ↑ Competence, ↑ Attitude

Impact on patient outcomes

↑ clinical endpoints: e.g., A1C, blood pressure
Linking Impact to Education

Impact on program participants

Impact on patient outcomes

↑ Competence

↑ Patient-provider relation

↑ Adherence

Performance

CME

What is Generally Done

- Satisfaction questionnaires

  “Is a more satisfied patient a validation of receiving better care?”

- Chart audits

  “Does (electronic) medical records reflect care being given or does it reflect care being documented?”

(NIQIE Annual Meeting meeting, Gabrielle Gaspar, Sutter Physician Services, 2010)
What Could Be Done

- Patient Journey (experience) Mapping
  - Satisfaction questionnaires
  - Self-assessments
  - Surveys
  - Interviews
  - Focus groups
  - Observations
  - Diaries
  - Performance tests
  - Chart audits
  - Patient data registries

![Combinations Diagram]

Patient-Level Data Collection

<table>
<thead>
<tr>
<th>Areas to be evaluated</th>
<th>Patient data collection methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective assessment (e.g. laboratory</td>
<td>• Chart audits</td>
</tr>
<tr>
<td>measures)</td>
<td>• Patient data registries</td>
</tr>
<tr>
<td>Communication</td>
<td>• Interviews</td>
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<tr>
<td></td>
<td>• Focus groups</td>
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<tr>
<td>Concordant goal development</td>
<td>• Observations</td>
</tr>
<tr>
<td></td>
<td>• Diaries</td>
</tr>
<tr>
<td>Subjective assessment (e.g. pain)</td>
<td>• Self-assessments</td>
</tr>
<tr>
<td></td>
<td>• Surveys</td>
</tr>
<tr>
<td>Patient education</td>
<td>• Interviews</td>
</tr>
<tr>
<td></td>
<td>• Focus groups</td>
</tr>
<tr>
<td></td>
<td>• Observations</td>
</tr>
</tbody>
</table>
Patient-Level Data Collection

**Essential questions**

- Why do I need patient data?
- How will it demonstrate the impact of the program?
- What data collection method best fits?
- Do I need protected health information?
- Is the data I will be collecting individually identifiable?
- Do I need the patient’s written permission (Informed Consent Form)?
- Do I need IRB approval to protect the patients’ anonymity, confidentiality and privacy?

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**Agenda**

- Objectives
- Context for patient-level data
- Patient-level data in the educational cycle
- Planning of patient-level data collection
  - Linking the impact to the education
  - What is done and what could be done
- **Potential obstacles for patient-level data**
- Q & A
HIPAA Privacy Rule defines **protected health information** or PHI as individually identifiable health information that is transmitted or maintained in any form or medium (electronic, oral, or paper) by a covered entity or its business associates, excluding certain educational and employment records.

HHS Protection of Human Subjects Regulations Title 45 CFR Part 46: Private information must be **individually identifiable** in order for obtaining the information to constitute research involving human subjects. Individually identifiable means the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

The Privacy Rule allows a covered entity to de-identify data by removing all 18 elements that could be used to identify the individual or the individual's relatives, employers, or household members.

De-identified health information, as described in the Privacy Rule, is not PHI, and thus is not protected by the Privacy Rule.

PHI may be used and disclosed for research with an individual's written permission in the form of an Authorization.

Informed Consent
Institutional Review Boards (IRB)
### Privacy (HIPPA)

1. Names
2. All geographic subdivisions smaller than a state, except under certain condition for the initial three digits of a ZIP Code
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers, serial numbers, license plate numbers
13. Device identifiers/serial numbers
14. Web universal resource locators (URLs)
15. Internet protocol (IP) address numbers
16. Biometric identifiers, including fingerprints and voiceprints
17. Full-face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

### Confidentiality & Anonymity

**Definitions**

- **Confidentiality**: (International Organization for Standardization (ISO), ISO/IEC 17799, Jan 4, 2009)
  
  "ensuring that information is accessible only to those authorized to have access"

- **Anonymity**: (adapted from "anonymous", HIPPA glossary)
  
  "ensuring that information is collected without identifiers, and that is never linked to an individual"

- **Informed consent** (FDA’s guide to informed consent):
  
  "a process of information exchange that may include, in addition to reading and signing the informed consent document, subject recruitment materials, verbal instructions, questions/answers sessions and measures of subject understanding"
Key Messages

• Plan – Plan – Plan
• Identify when you need patient level data
• Identify when you do not
• Map out link between program and patient data collected
• Select appropriate collection method
• Respect of patients’ privacy, confidentiality and anonymity

Q&A
Conclusion

- Patients are a valuable source of data regarding health care providers’ competence and performance
- Good planning of the patient-level data collection process will:
  - Ensure data is collected respecting patients’ privacy, confidentiality and anonymity
  - Guide you in selecting appropriate data collection methods
  - Ensure alignment of data and assessment objectives
  - Increase validity of findings by accessing multiple data sources

Thank you!
• Please join us for our next webinar – Block Grants  
  – Guest Speakers: Bob Addleton, Ed.D. and David Pieper, PhD  
  – Friday, March 4th, 2011  
  – 11am ET

• Next grant window opens March 1, 2011 for activities to occur July 1, 2011 or later

• See what providers are doing to move education forward  
  – PfizerMedEdGrants  
    • Resource Center  
      – Publications