Using Integrated Health Plan EMR Data to Evaluate Outcomes Associated with Clinical Services for the Treatment of Non-Malignant Chronic Pain

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Kaiser Permanente Center for Health Research
Agenda

• Utilizing EMR Data for Clinical Research
  • Types of data / variables available
  • Ascertaining data quality and comparability across health care systems: the role of the HMORN Virtual Data Warehouse

• The Opioid Use Improvement Project at KP-Northwest: an approach to enhance responsible prescribing and clinical care
  • Instituting the Regional Opioid Treatment Plan
  • Centrality of the Panel Support Tool

• PPACT – using health plan tools to conduct a pragmatic trial
  • Study design and use of EMR and related clinical tools
  • The special case of Patient Reported Outcomes

• Summary of Additional EMR-based Opioid Studies Underway
EMR Data from Integrated Health Plans: Advantages for Clinical Research

- Practice based (not just claims data but details of care)
- Defined populations (known denominator)
- Integrated health care systems: Most medical care is obtained within our systems
- Automated case identification (facilitates recruitment)
- Diverse provider base (enables studies of relationships between provider behaviors and outcomes)
- Same EMR system across all Kaiser sites yet system differences (facilitates natural experiments and internal replication)
Data Resources: Virtual Data Warehouse (VDW)

- Set of Common Data Standards: Variable names, definitions, formats, data structures
- “Virtual” = data are maintained at each participating site*; “Distributed” may be an equally appropriate description
- Source data (EMRs, other clinical and administrative databases) may differ from Site to Site
- SAS and Oracle databases

* Kaiser Permanente Research Centers in Northwest, Hawaii, Northern California, Southern California, Colorado, Georgia, and MidAtlantic), Group Health Cooperative, Health Partners, Harvard Pilgrim, Geisinger, Henry Ford, Maccabi Institute (Israel), Marshfield, Essentia Institute of Rural Health, Meyers Primary Care Institute, Scott and White Research, Palo Alto Medical Foundation Research Institute
The Virtual Data Warehouse: A method for standardizing and pooling electronic health data for multi-site research

Individual Health Care Systems
Administrative and claims data

Advance Work
Enormous gains in efficiencies and data quality are made through investments in advance work.

Research centers convert relevant local data to VDW format

Lessons learned

Research Projects

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# Kaiser Permanente Research

## Demographics
- Person ID
- Birth date
- Gender
- Race
- Ethnicity

## Enrollment
- Person ID
- Start and end dates
- Outside utilization flag
- Insurance plan and type
- Drug coverage
- Primary care clinic
- Primary care provider

## Language
- Person ID
- Language
- Primary language Y/N
- Spoken/written

## Social History
- Encounter ID
- Person ID
- Date
- Education
- Drug history
- Alcohol history
- Sexual history
- Tobacco history

## Tumors
- Person ID
- Diagnosis date
- Tumor type variables
- Tumor stage variables
- Treatment variables

## Vital Signs
- Person ID
- Encounter ID
- Measurement date
- Blood pressure, pulse
- Height, weight
- Head circumference

## Utilization

**Encounters**
- Person ID
- Encounter ID
- Case of service
- Provider ID
- Encounter type
- Facility
- Department
- DRG

**Diagnoses**
- Person ID
- Encounter ID
- Encounter type
- Date
- Diagnosis code
- Diagnosis type
- Primary diag.
- Flag
- Principal diag.
- Flag
- Provider ID

**Procedures**
- Person ID
- Encounter ID
- Date of service
- Procedure type
- Procedure code
- Encounter type
- Provider ID

**Providers**
- Provider ID
- Specialty
- Birth year
- Gender
- Race
- Year graduated

This set of four tables incorporates data for all medical encounters.

## Labs

**Lab Results**
- Person ID
- Order date
- Collection date
- Result date
- Test immediacy
- Test location
- LOINC code
- Test result and unit
- Normal result range
- Ordering provider
- Department
- Facility
- Row ID

**Lab Notes**
- Row ID
- Result note
- Note type
- Line

## Pharmacy

**Pharmacy (Rx fills)**
- Person ID
- Dispensing date
- Dispensing MD
- NDC
- Days supply
- Amount dispensed

**Eversource**
- NDC
- Generic names
- Brand names
- HIV code
- CIF code

## Death

**Cause of Death**
- Person ID
- Date of death
- Type of cause
- Source
- Confidence

**Deaths**
- Person ID
- Geocode
- Location start date
- Location end date

## Census

**Census Location**
- Person ID
- Geocode
- Census year
- Census source
- Race
- Ethnicity
- Education
- Household income

**Census Demographics**
- Person ID
- Gaecode

## Medication Orders

**Medication Orders**
- Person ID
- Encounter ID
- Order ID
- Prescription ID
- Medication ID
- Order date
- SIG
- Simple generic name

**Medication Orders Diagnoses**
- Order ID
- Order diagnosis
- Order Rx code type

**Medication Lookup**
- Medication ID
- Medication name
- Medication route
- Generic name
- Therapeutic class
- Pharmacological class
- Controlled substance Y/N

## Personal Health Records (PHR)

**PHR Registration**
- Person ID
- Message ID
- Thread ID
- Message date
- Sending provider

**PHR Activity**
- Person ID
- Access date
- Type of activity

**PHR Test**
- Person ID
- Access date
- Type of test

**PHR Messages**
- Person ID
- Message ID
- Thread ID
- Message date
- Sending provider

**PHR Proxy**
- Person ID
- Proxy person ID
- Proxy relationship
- Proxy start date
- Proxy end date
Clinical Context: KPNW Operational Response to Opioid Use

Motivating factors for systematic clinical response (safety & efficacy concerns):
- High dose opioid prescribing
- Primary care in need of assistance
- Opioid Use Improvement Project (OUI)

Objectives:
- Improve patient safety
- Improve provider and team support
- Improve outcomes with chronic pain management

Identification of high risk patients:
- High daily MEQ
- Suicide Attempts
- Pharmacy Concerns (multiple and/or early refills)
- Substance Abuse
- Dose Escalations
Care Management Tools

- Opioid Therapy Plans (OTP)
- Care flags added to Patient Support Tool (PST)
- Brief Pain Inventory (BPI)
  - Back office staff trained to enter data
  - Clinicians trained to track functional improvements
- Best Practices Alerts (BPA)
## Opioid Therapy Plan (OTP) Operational Criteria

<table>
<thead>
<tr>
<th>PATIENT CRITERIA</th>
<th>BASIC GREEN</th>
<th>COMPLEX YELLOW</th>
<th>COMPLEX RED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follows plan reliably</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No history of opioid abuse</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No history of other substance abuse within past 2 years</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No current behaviors indicating drug misuse</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current behaviors raise questions about the ability to follow the OTP</td>
<td>X</td>
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<tr>
<td>Calculated overall opioid dosing level at 180mg morphine equivalent or higher</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Have demonstrated repeated problems following the OTP (e.g., unexpected UDS)</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Active substance abuse</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Have current behaviors which raise concerns about possibility of diversion</td>
<td></td>
<td></td>
<td>X</td>
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</table>

### PCP REQUIREMENTS

<table>
<thead>
<tr>
<th>PCP REQUIREMENTS</th>
<th>BASIC GREEN</th>
<th>COMPLEX YELLOW</th>
<th>COMPLEX RED</th>
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</thead>
<tbody>
<tr>
<td>Office visit frequency (minimum)</td>
<td>Semi-annually (1 may be TAY)</td>
<td>Quarterly (2 may be TAVs)</td>
<td>Quarterly (no TAYs)</td>
</tr>
<tr>
<td>Office visit required for any dosing changes</td>
<td>No</td>
<td>Yes</td>
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<td>Brief Pain Inventory (BPI) completed (minimum)</td>
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<td><a href="#">Recommended to be administered at every office visit</a></td>
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<tr>
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<td>UDS ordered and resulted (minimum)</td>
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<tr>
<td>Confirm random pill counts completed</td>
<td>PRN</td>
<td>2x/Year &amp; PRN</td>
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<td>Create AVS or send letter with patient’s dosing and instructions after dosing change</td>
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PPACT: Building Upon Regional Actions & Data Capabilities

PAIN PROGRAM FOR ACTIVE COPING & TRAINING

- Principle Investigator: Lynn DeBar, PhD MPH Kaiser Permanente NW Center for Health Research
- Sites: KP Northwest, KP Southeast, KP Hawaii
- Pragmatic Clinical Trial Sponsored by:
  - National Institutes of Health Common Fund
  - National Institute of Neurological Diseases and Stroke
  - National Institute of Drug Abuse
  - Administered by the National Center for Complementary and Alternative Medicine
PPACT: Building Upon Regional Actions & Data Capabilities

Coordinate and integrate services for helping patients adopt self-management skills for managing chronic pain, limit use of opioid medications, and identify exacerbating factors amenable to treatment that is feasible and sustainable within the primary care setting.

- Implemented across KPNW, KP-Georgia, and KP-Hawaii regions
- Involves 1,200–2,000 patients with chronic pain on opioids (600–1,000 receiving study-supported active care)
- Prioritized recruitment based on operationally identified need:
  - MEQ ≥ 120mg
  - Concurrent opioid and benzodiazepine use
  - High utilization of primary care services
Trial Design

- Cluster-randomized pragmatic clinical trial
- ≥ 350 PCPs will be randomized
- More than 1,000 patients
PPACT Recruitment & Randomization

1. Approach Particular Clinic
   - EMR Identification of all PPACT eligible patients paneled to IM / FP PCP's.

2. Each PCP in clinic receives Epic message with comprehensive list of PPACT eligible patients on their panel.

3. PCP responds to EPIC message identifying any patients on list that are NOT appropriate for PPACT or patients who ARE appropriate for PPACT, but are not on the list.

4. Invitation to participate in PPACT initiative sent to eligible patients under PCP signature.

5. Study staff will contact patients from the randomly sorted list of patients selected by PCPs. Call will describe goal of project and participant responsibilities. Verbal consent will be obtained.

6. PCPs' lists of patients revised to restrict to consented participants.

7. PCP clusters & their associated patients randomized to TAU or Intervention.
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### Outcome Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Analytic Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Pain Inventory (BPI) (Severity &amp; Interference)</td>
<td>Primary Outcome</td>
</tr>
<tr>
<td>Opioids Dispensed (in morphine equivalents)</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Pain related treatment or diagnostic procedures</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Use of emergency / urgent care services</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Use of primary care services</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Use of specialty care services</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Total health service use &amp; cost</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Comorbidities (Depression, anxiety, disability, chronic disease burden, sleep difficulties)</td>
<td>Covariates</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td>Secondary Outcome</td>
</tr>
<tr>
<td>Exercise as Vital Sign (EVS)</td>
<td>Secondary Outcome</td>
</tr>
</tbody>
</table>

- All data collected in routine clinical care
- Data pulled from electronic medical record (EMR) and administrative data systems
- KP Virtual Data Warehouse provides common EMR to ensure standardization across 3 regions
- BPI completion for patients using opioids:
  - Recommended at every visit, required quarterly to semi-annually
## Ensuring Adequacy of Primary Outcome Data

<table>
<thead>
<tr>
<th></th>
<th>KP Northwest</th>
<th>KP Georgia</th>
<th>KP Hawaii</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine BPI collection</td>
<td>Established</td>
<td>Developing</td>
<td>Champion Driven</td>
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<tr>
<td>Currently established</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>collection methods</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>• Panel Support Tool</td>
<td>• PCP training</td>
<td>• Panel Support Tool</td>
</tr>
<tr>
<td></td>
<td>Care Gap</td>
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<td>Care Gap (not</td>
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<tr>
<td></td>
<td>• Nursing workflow</td>
<td></td>
<td>maximally utilized)</td>
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<tr>
<td></td>
<td>• E-mail (kp.org)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active work with region to</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>establish additional methods</td>
<td>• Ongoing PCP training</td>
<td>• Panel Support Tool</td>
<td>• Pharmacy collection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Care Gap</td>
<td>at point of refill</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Pre-visit documentation</td>
<td></td>
</tr>
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<td></td>
<td>• Nursing workflow</td>
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</table>
Current EHR Primary Outcome Data: Analytic Challenges & Interpretative Concerns

- Administration of BPI linked to Opioid Prescription
  - Frequency of PRO administration linked to opioid dose (morphine equivalent level)
  - Potential loss of follow-up data for those tapering off opioids

- Timing and Amount of Data Variable
  - Heterogeneity across health care providers
  - Potential for more frequent collection of PRO among patients with higher rates of health care utilization (potential bias by medical complexity or pain severity)
KP workflow process of PRO email collection

Available EHR questionnaires include:
- BPI
- PHQ-9
- Audit
- Total Health Assessment

Questions?
Ask doctor a question
### Increased patient health record adoption provides additional opportunities to collect PROs

<table>
<thead>
<tr>
<th></th>
<th>Change between 2008 and 2011</th>
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<tbody>
<tr>
<td>Total visits to kp.org</td>
<td>220% increase (Over 100 million visits in 2011)</td>
</tr>
<tr>
<td>Members registered for secure features</td>
<td>140% increase</td>
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<tr>
<td>Total online prescription refill orders</td>
<td>290% increase</td>
</tr>
<tr>
<td>Total online appointment requests</td>
<td>200% increase</td>
</tr>
<tr>
<td>Total e-mails sent to doctors &amp; other care team members</td>
<td>200% increase</td>
</tr>
<tr>
<td>Total lab-test results view online</td>
<td>180% increase</td>
</tr>
<tr>
<td>Total healthy lifestyle program questionnaires submitted</td>
<td>200% increase</td>
</tr>
</tbody>
</table>
Why is the Clinical Use of PROs Limited?

- Adoption largely driven by “stick” (regulation or safety concerns) rather than “carrot” (clinical utility)
- PRO instruments need to fully meet both clinical and evaluation needs
- Administration not hardwired into work flow so that change over time can be tracked (more frequent use as screening measure or single point in time evaluation)
- Available technology often only partially implemented due to health plan or patient resource constraints and compliance/privacy concerns
- Placement in Clinical Record not convenient/accessible
PRO data entered in separate charting area

Lab data embedded directly into chart note
• Less than ideal interface and data entry
- Variable collection of PROs

<table>
<thead>
<tr>
<th>Flowsheet Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select Flowsheets to View</td>
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<tr>
<td>BRIEF PAIN INVENTORY NATL [167]</td>
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<table>
<thead>
<tr>
<th>BPI</th>
<th>1/18/2012</th>
<th>3/15/2012</th>
<th>1/30/2013</th>
<th>4/18/2013</th>
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<tr>
<td>Worst Pain</td>
<td>5</td>
<td>7</td>
<td>4</td>
<td>8</td>
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<tr>
<td>Least Pain</td>
<td>5</td>
<td>3</td>
<td>3</td>
<td>3</td>
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<tr>
<td>Average Pain</td>
<td>5</td>
<td>4</td>
<td>6</td>
<td>6</td>
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<tr>
<td>Current Pain</td>
<td>5</td>
<td>7</td>
<td>7</td>
<td>7</td>
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<tr>
<td>Percentage of Pain Relief</td>
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<tr>
<td>Activity Interference</td>
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<tr>
<td>Mood Interference</td>
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<td>4</td>
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<tr>
<td>Walking Interference</td>
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<tr>
<td>Work Interference</td>
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<tr>
<td>Enjoyment Interference</td>
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- Less than ideal display when viewing multiple PROs

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<tr>
<td>BRIEF PAIN INVENTORY NATL [167]</td>
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<td>DEPRESSION PHQ9 NATL [164]</td>
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<td>Average Pain</td>
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<td>Current Pain</td>
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<td>Percentage of Pain Relief</td>
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<td>11</td>
<td>15</td>
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<td>PHQ9 Score (Office Visit)</td>
<td>A) 0-4 NONE</td>
<td>D) 15-19 MODERATELY SEVERE</td>
<td>C) 10-14 MODERATE</td>
<td>D) 15-19 MODERATELY SEVERE</td>
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**PRO Instrument Selection**
- Instrument choice
- Psychometrics
- Research focused analysis

**PRO Implementation**
- Data collection
- Health IT / EHRs
- Common data elements
- Integration into clinical care
- Real-time analytics to support clinical processes
- Research with service
Additional EMR-based Opioid Studies Underway…
Opioid Treatment Impact Study

- Funded by the National Institute on Drug Abuse
- Principal Investigator: Benjamin Morasco, PhD; Portland VA Medical Center and Oregon Health & Science University
- Sites: Portland VA & Kaiser Permanente Northwest

Objectives:
- to identify clinician- and patient-level factors that predict which patients will receive an increase in opioid dose
- to evaluate clinical outcomes associated with opioid dose escalation
- to assess factors associated with changes in pain intensity and pain-related function over time
Opioid Treatment Impact Study

- Participants from 2 clinical sites
  - Kaiser Permanente Northwest (n=333)
  - Portland VA Medical Center (n=167)

- Eligibility
  - musculoskeletal pain
  - receiving a stable dose of chronic opioid therapy for 90 consecutive days

- EMR data
  - used to identify eligible participants
  - checked weekly to identify dose increases of > 25% in morphine equivalents among participants

- Structured interviews at baseline, 6, 12, 18, and 24 months, & after dose increases
  - assess pain intensity, functioning, QOL, depression, anxiety, alcohol and substance use, prescription opioid misuse, sleep, sexual function, common side effects of opioids, overdoses
Study of Opioid Overdose & Poisoning Events

Funded by Purdue Pharma, LLP
Principal Investigators:
Carla A. Green, PhD, MPH & Nancy A. Perrin, PhD
Center for Health Research, Kaiser Permanente Northwest

- Objectives
  - To determine the best approaches for identifying opioid overdose and poisoning events (OOP events) using EMR data
  - To assess the effects of Oxycontin® reformulated with abuse deterrent properties on OOP events
  - To understand the circumstances surrounding OOP events, and any changes in circumstances following the introduction of the new formulation
Examines:

- The usefulness of different ICD-9 and ICD-10 codes, alone or in combination, for identifying OOP events
  - validated by chart audits

- Changes in rates of OOP events in the Kaiser Permanente Health System (KP Northwest & KP Northern California) using EMR-identified OOP events
  - Prior to and following the 2010 introduction of the tamper-resistant Oxycontin® formulation
    - Comparing different groups of opioids &
    - Evaluating morphine equivalents

- Changes in the circumstances surrounding OOP events
  - Using in-depth interviews with individuals and families of deceased individuals who experienced events
  - Using chart audits to identify route of opioid administration & how opioids were obtained
Summary

- EMR data improvement over claims data for clinical research but additional quality assurance necessary to ensure validity and usability
- Operational response to opioid-related efficacy and safety concerns can expand data available to study issues more broadly (e.g., pain-related PROs and PST elements)
- Clinical uptake of PRO’s increasing but current data gaps
- Studies of opioid-related practice patterns must be augmented by ancillary data collection
Thanks to the following contributors:

- Lindsay Kindler, PhD, RN, CNS
- LouAnn Thorsness, RPH
- David H Smith, PhD
- Alan Bauck, BS
- Rick Deyo, MD
- Reesa Laws, MS
- Carla Green, PhD MPH
- Nancy Perrin, PhD
- Joan Holup, MS