



“Real-World” Research to Support Evidence-Based Medicine

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Shifting Landscape in the United States Health Care System:

So What is *Driving* the Change?

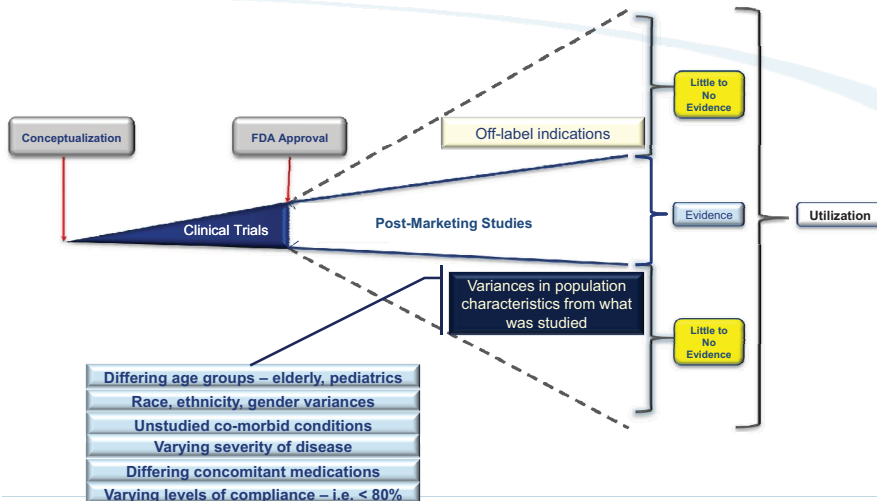
Escalating costs

Disappointing outcomes

Increasing safety concerns

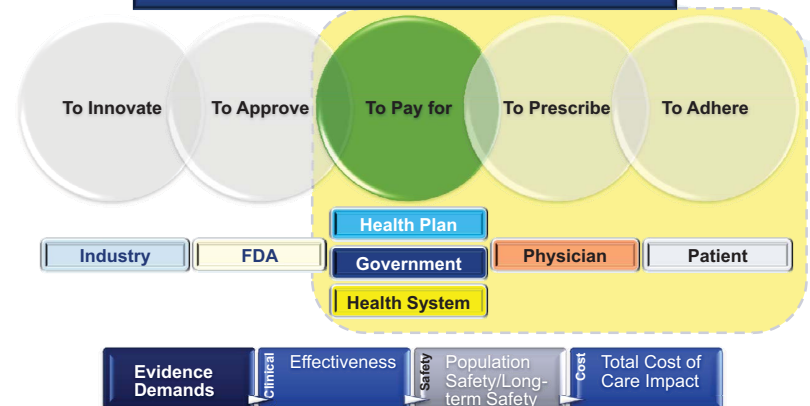


Key Contributors to Evidence Gaps



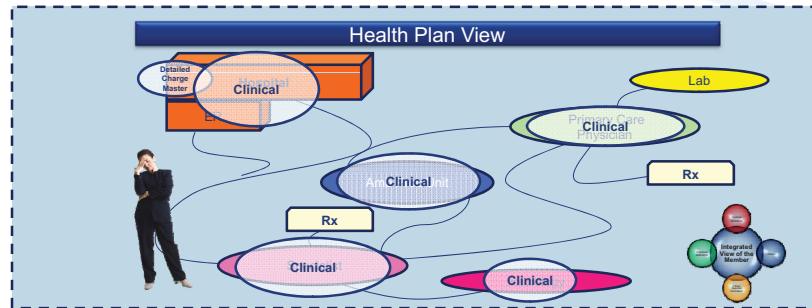
Shifting Landscape in the United States Health Care System

Emergence of the Payor in the Decision-Chain



Prospective Effectiveness Research : Novel Hybrid Study Designs

Use Claims Data as the Starting Point



Claims data provide breadth, but lack depth especially with regard to clinical data necessitating the enrichment with additional data elements especially clinical data

Slide 5

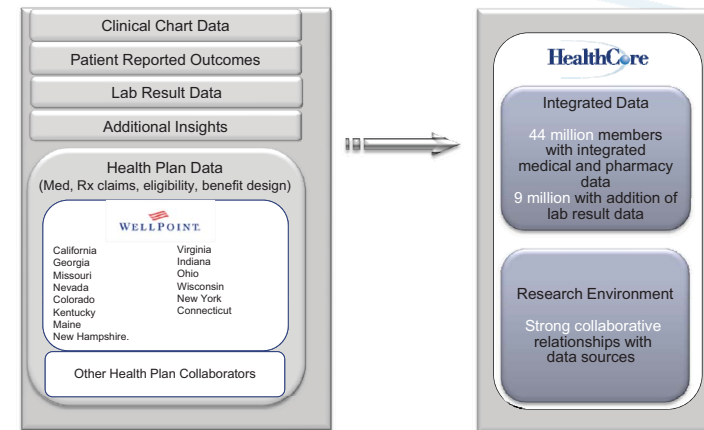
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Data and Research Environment

Disparate Data Sources

Integrated Research



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Data Integration Capability

Specific Patient-Physician-Plan Linkage

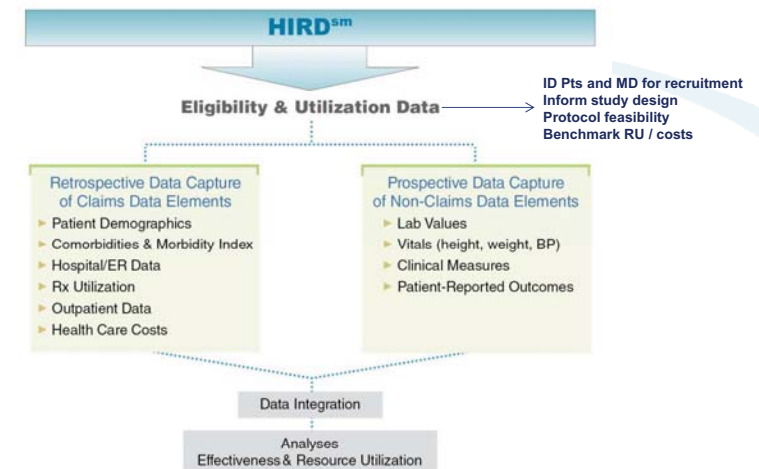
- Administrative Claims Data
 - Medical and pharmacy claims (incl. cost information)
 - Eligibility data (incl. benefit design)
 - Laboratory Result Data (subset of total data set)
- Medical Chart Review
 - Patient demographics, progress notes, radiology, labs, BP, weight, etc.
- Survey Research
 - Patient and physician reported outcomes
 - Response to health plan incentives and restrictions
 - Understand drivers of care-seeking behavior and prescribing choices
 - Link attitudes with actual behavior
- Prospective Clinical Data Collection
 - Point-of-care collection of clinical data, observational research, registries

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HealthCore Experience Study Design: ExOS and ExPAND



ExOS and ExPAND

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ExOS Study Synopsis

| Name of Sponsor | Lilly |
|-------------------|---|
| Study Period | 2006 - 2010 |
| Primary Objective | To examine the effect of exenatide on glycemic control (HbA _{1c}) in a naturalistic clinical practice setting. |
| Study Design | Prospective, multi-center, single-arm observational study designed to collect and report data on the treatment of patients with exenatide in a naturalistic setting. No randomized treatment assignments were made. |

Slide 9

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ExOS Research Approach

- Target and recruit physicians and patients that meet selection criteria using HealthCore's Integrated Research Database (HIRDSM).
- Integrate analysis of retrospective and prospective clinical and treatment experience data to assess real-world effectiveness.
- Augment physician and patient data from the HIRD with prospective data, PRO, and clinician reported outcomes.

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ExOS Research Publications

- Exenatide Observational Study (ExOS): Baseline Population Characteristics and Research Design [^]
- Exenatide Observational Study: Results of 6-Month Primary and Secondary Endpoint Effectiveness Analysis[†]
- Exenatide BID Observational Study: Results for Primary and Secondary Endpoints at 12-months Analysis [‡]
- Exenatide BID Observational Study (ExOS): Results for Primary and Secondary Endpoints of a Prospective Research Study to Evaluate the Clinical Effectiveness of Exenatide BID use in Patients with Type 2 Diabetes in a Real-World Setting^{**}

[^] Current Medical Research and Opinion, December 2010

[†] American Diabetes Association (ADA) 70th Scientific Sessions

[‡] Academy of Managed Care Pharmacy (AMCP), April 2011

^{**} Current Medical Research and Opinion, December 2011

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Examination of Pregabalin Access for Treatment of Indicated Pain Disorders: ExpAND Study

| Name of Sponsor | Pfizer |
|--------------------|--|
| Study Period | 2010 - 2012 |
| Study Design | Prospective, observational, multicenter study to investigate the impact of prior authorization processes for pregabalin in the treatment of pain associated with pDPN and FM in real-world clinical practice. An analysis of pDPN and FM patients will assess resource use, costs and health outcomes in patients pre- and post-initiation of pregabalin or any other therapy initiated at enrollment if not pregabalin using retrospective claims data coupled with prospective site and patient level data capture. |
| Primary Objectives | <ol style="list-style-type: none"> 1. Quantify the between group difference (baseline to 6 months) in direct all-cause medical costs for patients with pDPN and FM in real-world treatment settings with a prior authorization (PA) versus no PA policy in place restricting access to pregabalin. 2. Evaluate the within-group differences in pain alleviation (using the 11 point numerical rating scale [NRS-11] in patients with pDPN and FM in real-world settings with a PA versus no PA policy in place restricting access to pregabalin. |

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ExPAND Study Synopsis

| Name of Sponsor | Pfizer |
|----------------------|---|
| Secondary Objectives | <ol style="list-style-type: none"> Describe how pharmacologic treatment patterns for pDPN or FM differ between groups with PA and without PA in patients being treated in a naturalistic outpatient care setting. Describe non-pharmacologic treatment patterns in pDPN and FM patients in groups with PA versus no PA while being treated in a naturalistic outpatient care setting . For the subset of patients who have at least 6 months pre-study time in the HIRD a within-group costs analysis (all cause) comparing their pre-study healthcare utilization costs for the 6 months pre-baseline with their on-study healthcare utilization costs (baseline to 6 months). Assess changes (baseline through 6 months) in other PRO measures in pDPN and FM patients subject to PA requirements for pregabalin versus those with no PA. Compare the within-group differences (baseline to 6 months) in pain alleviation (using the NRS-11 scale) between groups (PA versus no PA), by condition (pDPN or FM). Quantify the between-group difference (baseline to 6 months) in direct all-cause medical costs for patients with pDPN and FM in real-world treatment settings with a prior authorization (PA) versus no PA policy in place restricting access to pregabalin. Evaluate the within-group differences in pain alleviation in patients with pDPN and FM in real-world settings with a PA versus no PA policy in place restricting access to pregabalin. |

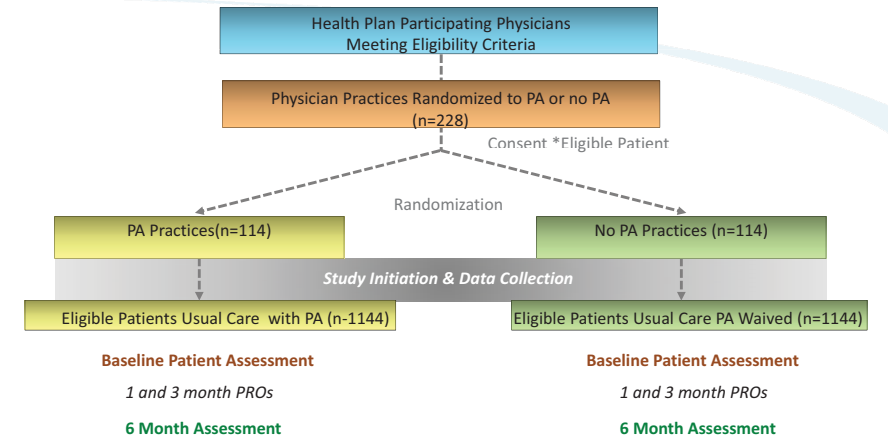
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ExPAND Study Design



*Physician confirmed diagnosis of either pDPN or FM, but not both; Initiation of a medication for pDPN or FM is clinically indicated, either as monotherapy or in combination with other treatments; no prior pregabalin use or pregabalin PA requests; age > 18 years; actively enrolled in a WellPoint health plan.

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Randomized Controlled Evaluation of an Activity Tracking Device with and without Coaching in Increasing Physical Activity

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Study Goals And Metrics

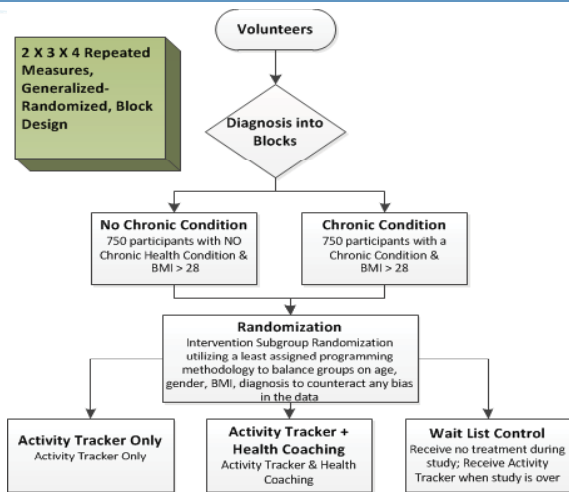
- **Primary Goal** - To determine if use of an activity tracking device with and without coaching helps people be more active:
- **Secondary Goal** - To compare outcomes in the treatment groups above between members with and without chronic health conditions.
- **Metrics:**
 - Self-report questionnaires to assess exercise frequency, weight, quality of life, weight-related symptoms
 - Activity tracking information to assess number of steps per day, distance walked per day, calories burned per day, activity levels per day
 - Health care utilization and costs

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Study Design Part 1

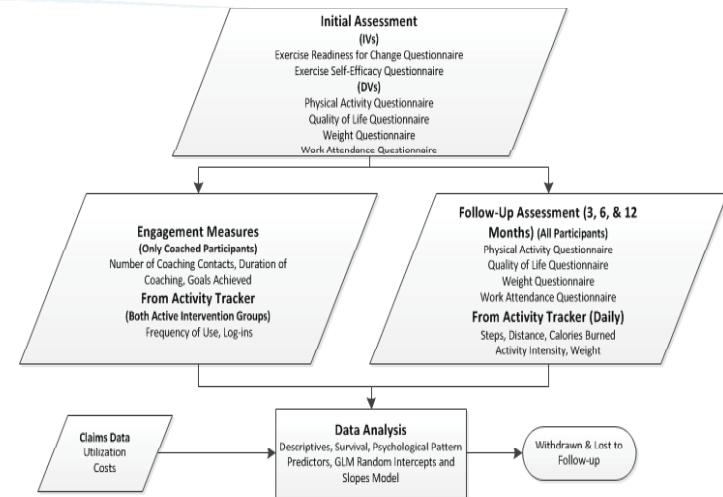


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Study Design Part 2



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