Research mission is critical to KP - has been and will continue to be so in the future

CESR is a response to a changing world of research and the needs for translation to clinical care
Research Today: A Major Activity

$140 Million budget

3,500 Studies underway

1,200 Clinical trials underway
Kaiser Permanente established the Center for Effectiveness and Safety Research (CESR) to build upon research capabilities

<table>
<thead>
<tr>
<th>Leadership</th>
<th>CESR enables KP a leadership role in a national agenda to evaluate the effectiveness and safety of drugs, devices and biologics.</th>
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<tr>
<td>Resource</td>
<td>CESR is a program-wide resource supported by Kaiser Permanente investment and external funding</td>
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<td>Uniqueness</td>
<td>Builds on the scientific achievements of KP researchers; on a health plan with over 8.7 million diverse members; on a integrated care delivery system that provides comprehensive health care; and on the sophisticated electronic medical record and data infrastructure that captures essentially all health care provided to members across the program.</td>
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<td>Laboratory</td>
<td>This system serves, in turn, as a laboratory that can feed back and translate research findings into practice, both within Kaiser Permanente and more broadly through publication and dissemination.</td>
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Center for Effectiveness & Safety Research

- **Investigator Network** – Investigator Development and Leadership
- **DCC/Data Management Network** – Data Standardization and Management Leadership
- **Administrative Network** – Administrative and Operations Leadership
Center for Effectiveness & Safety Research

- Stable and diverse (racially/ethnically, socio-economically) **membership** of over 8 million individuals, across the United States

- Rich, longitudinal clinical electronic **database** that includes health care delivery, payment, decision-making and behavioral data -- in primary, secondary and tertiary care across inpatient and outpatient settings

- Sufficient number of individuals with **diverse disease conditions**, e.g., asthma, HIV, diabetes, rare conditions, etc.

- Close connection with **delivery system** to pose questions and translate findings

- Expanding database to include **genetic and environmental** exposure
Center for Effectiveness & Safety Research: Capacity for Multi-Site Pediatric Safety Studies

- CardioVascular Research Network (CVRN; 14 HMOs): Use & safety of statins in children
- Cancer Research Network (CRN; 14 HMOs): Preventing errors in the home health care of children with cancer
- Mental Health Research Network (MHRN; 8 HMOs): Comparative effectiveness of commonly used therapies for children with Autism Spectrum Disorder
Center for Effectiveness & Safety Research: Year 1 ‘Demonstration’ Projects

- **H1N1 Infection During Pregnancy:**
  - Impact on pregnancy (eclampsia), developing infant (prematurity), & woman’s health (pneumonia)

- **Glycemic Control & Joint Replacement Surgery**
  - Impact of pre/peri/post operative glucose control on surgical outcomes
Food and Drug Administration (FDA) Mini-Sentinel Initiative
- The Mini-Sentinel Initiative supports the FDA Sentinel Initiative, a Congressional mandate to create an active surveillance system using electronic health data for 100 million people by 2012

National Institutes of Health (NIH) Research Collaboratory
- NIH has proposed a unique research “collaboratory” that would include Kaiser Permanente and other members of the HMO Research Network for CER & other research
Center for Effectiveness & Safety Research (CESR): Outward Facing

- **Food and Drug Administration (FDA) (MEPREP)**
  - Medication Exposure in Pregnancy Risk Evaluation Program
  - Collaborative research program between the FDA, HMO Research Network, Vanderbilt University, and Kaiser Permanente Northern and Southern California
  - Linked data on mothers & infants born 2001-2007
  - Administrative and birth certificate data on over 1,045,373 children linked to mothers
Center for Effectiveness & Safety Research (CESR): Outward Facing

- **International Serious Adverse Events Consortium (SAEC)**
  - Objective: To study patients with drug-related serious AEs and identify genetic underpinnings that place certain patients at risk
  - DILI; SJS; Extreme weight gain on atyp antipsychotics
  - Eventually integrate findings within data systems so as to screen & prevent SAEs in the future
HMO Research Network (HMORN)
Principles of distributed data model:
- Data remain under local control, no central data warehouse.
- Transfer as little data as possible; if stratified summary data, e.g., person-time and events, suffices, only that is transferred for combined analyses.
- If pooled person-level analyses are required, only transfer required fields and maximally de-identify, e.g., use offset dates, age ranges.

Analytic steps:
- Plans extract and transform local data to standard datasets
- Data quality checking led by coordinating center, using standard programs
- Analysis team sends analytic program to each site to run against study datasets.
- Sites run the program and return summary results or limited datasets.
Regional Roadmap Tasks: Regional Data Standardization

- In collaboration with the Data Coordinating Center, the regions identified over 30 Data Standardization Tasks that could be addressed by regional data management teams (distinct from the VDW specialists)
- Virtually all regions addressed/exceeded their expected outcomes for the data standardization tasks
Prior Experience Has Shown…

- Little or no exchange of person-level data is needed to answer many safety, effectiveness, and quality questions.
- A relatively small subset of items in electronic health data systems can answer most safety, effectiveness, and quality questions.
- Essential to have data partner input in interpretation of findings; keep data close to the experts.
- Data partners do not like having their data outside their control.
- Concentrate analytics in a single team.
- Minimize impact on health plan operations.
CESR Guiding Principles:

- Create capacity for KP to participate as a single entity for comparative effectiveness and safety research
- Develop interregional databases as a resource for use
- Have KP National Leadership & Regional commitment to a national research agenda in safety and comparative effectiveness
- Commit to sharing the outcomes of this research to the benefit of our members and patients, and for the public welfare