Realizing the power of real-world oncology evidence:

Cancer registry and life sciences company collaboration

California Cancer Registrars Association 43rd Annual Educational Conference
December 3, 2016
Margaret McCusker, MD, MS, FACPM, Roche Diagnostics Real-World Data
Overview

Defining Real-World Data (RWD)

Cancer registries within the RWD framework

Cancer registry and life sciences company collaboration

Future opportunities
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Defining Real-World Data

Real-world data collected from sources outside of traditional clinical trials – U.S. FDA

"Health care data collected under real life practice circumstances; anything that is not an interventional study"

– International Society for Pharmacoeconomics and Outcomes Research

RWD is any data not collected in conventional RCT. It includes data from existing secondary sources and the collection of new data, both retrospectively and prospectively

– Agency for Healthcare Research and Quality

Analysis of disease diagnoses, biomarker test results, prescribed treatments, clinical outcomes and associated healthcare costs, provides valuable insights about use and impact of diagnostics products in the real-world healthcare setting.
World Data Sources

The variety in coverage, quality and maintenance

**Claims**
- Insurance Payer Data
  - Disease diagnoses
  - Procedures
  - Medications
  - Costs

**EMR**
- Electronic Medical Records
  - Disease diagnoses
  - Biomarker test results
  - Treatments
  - Clinical outcomes

**Registries**
- Linked from Multiple Sources
  - Disease and/or geographic focus
  - Biomarker test results
  - Treatments
  - Long-term outcomes
Evolving RWD landscape with multiple data access models

World Data Sources

Claims

EMR

Registries
<table>
<thead>
<tr>
<th>Benefits of RWD</th>
<th>What RWD can do</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimize Product Development</td>
<td>• Reduce time required for clinical trial data collection by optimizing site selection</td>
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<tr>
<td></td>
<td>• Refine patient selection criteria for clinical trials</td>
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<td></td>
<td>• Support innovative trial designs – historical controls, pragmatic trials</td>
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<tr>
<td>Enhance Market Access</td>
<td>• Provide real-world safety data to confirm benefit-risk profile</td>
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<tr>
<td></td>
<td>• Demonstrate real-world effectiveness required by payers</td>
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<tr>
<td></td>
<td>• Support earlier access with value-based pricing / adaptive licensing</td>
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<tr>
<td>Improve Medical Practice</td>
<td>• Provide evidence to inform treatment guidelines</td>
</tr>
<tr>
<td></td>
<td>• Support continuous benefit/risk evaluations</td>
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<tr>
<td></td>
<td>• Identify and quantify unmet medical needs</td>
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</tbody>
</table>
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World age-standardized cancer incidence rates, 2012*

Sexes, all cancers excluding non-melanoma skin
Global cancer data rely on high-quality national datasets

CR data used to create US cancer estimates for WHO’s GLOBOCAN

DATA & METHODS

must be exercised when interpreting the presented data, given the shortcomings in the quality and completeness of cancer data, particularly in low- and middle-income countries. Our approach is not only to use the collected NPCR data to work alongside national staff to improve local data quality, registry completeness, and analytical capacity. The approach is also to advocate for investment in population-based cancer registration in low- and middle-income countries and to support the Global Initiative for Cancer Registry Development (GICR). The goals of the GICR are to inform cancer control policies, enable tailored improvements in the quality of the data, and support population-based cancer registration data worldwide. Learn more about these global initiatives at the GICR website.

In the United States, the National Program of Cancer Registries (NPCR) maintains a high-quality data set and works to improve the quality of cancer data collected by cancer registries across the country. The NPCR data are used to create the Cancer Statistics Review (CSR), which provides comprehensive cancer statistics for the United States. The data are used to inform public health policies and to monitor trends in cancer incidence, mortality, and survival. The CSR is available online at the National Cancer Institute (NCI) website.

The data sources used to create the CSR include the following:

- **Incidence**
  - Data: High-quality national data or high-quality regional data (coverage greater than 50%).
  - Method: Rates projected to 2012

- **Mortality**
  - Data: High-quality complete vital registration.
  - Method: Rates projected to 2012

The United States of America

**DATA SOURCES AND METHODS (SUMMARY)**

**Incidence**

- Data: High quality national data or high quality regional (coverage greater than 50%)
- Method: Rates projected to 2012

**Mortality**

- Data: High quality complete vital registration.
- Method: Rates projected to 2012

**METHODS (DETAILED)**

**Incidence**

Incidence rates from the National Programme of Cancer Registries (NPCR) public dataset (2000-2009) covering 95% of the US population were projected to 2012 and applied to the 2012 population.

**Mortality**

National mortality rates (2001-2010) were projected to 2012 and applied to 2012 population.
Registry data inform estimates of economic burden of cancer

**Linkage between SEER and Medicare data are a unique source of insights**

Cancer prevalence estimated and projected through 2020 using incidence and survival data from SEER Program and U.S. Census population projections.

Annualized net costs of care estimated using Medicare claims linked to SEER data adjusted to 2010 US dollars.

https://costprojections.cancer.gov/
Examples of RWD studies based on cancer registry data

Understanding of disease burden and treatment patterns

Trends in survival by race for stomach cancer patients from the U.S. SEER cancer registry*

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of patients</th>
<th>Estimated Survival (in months)</th>
<th>% Censored</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treated</td>
<td>5,103</td>
<td>Median (95% CI) 7.5 (7.2-7.7)</td>
<td>0.39</td>
</tr>
<tr>
<td>Untreated</td>
<td>9,421</td>
<td>Mean 2.7 (2.6-2.8)</td>
<td>0.44</td>
</tr>
</tbody>
</table>

10-year landmark survival and characteristics of advanced non-small cell lung cancer long-term survivors*

*McCusker et al, JCOPE Annual Meeting 2016

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2. Median OS (95% confidence interval) in months ethnicity, anatomic site, and time period of stomach cancer.

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Cardia</td>
<td>Noncardia</td>
<td>Cardia</td>
</tr>
<tr>
<td>White</td>
<td>Black</td>
<td>Asian</td>
</tr>
</tbody>
</table>

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Survival Probability

Follow_time

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Examples of RWD studies based on cancer registry data

Real-world safety data to monitor for a rare potential outcome
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Collaboration between CPIC and Genentech

Factors that fostered partnership

- Complementary research interests
- Access to key data unavailable in public-use cancer registry files
- Proximity – close location made in-person meetings easy to arrange
- Pre-existing professional relationship facilitated trust building
Cancer Registry and Life Sciences Collaboration

Key steps in the process

1. Define research interests
2. Establish contractual framework
3. Agree on Scope of Work
4. Collaborate on analyses
5. Communicate Results
Lung cancer epidemiology in U.S. Chinese populations

**IC-Genentech analysis collaboration**

**Issue**

Major need for lung cancer epidemiology data from Chinese populations

- Limited data available from China
- Characterize unmet medical need
- Define product development opportunities

SEER covers ~50% of U.S. Chinese population

- ~75% reside in California
- Opportunity to learn about lung cancer in persons of Chinese descent

**Insights**

- Trends in lung cancer incidence, mortality and survival by patient and tumor characteristics and nativity (birthplace) in the California Chinese population
- Factors associated with survival after lung cancer diagnosis

**Impact:** improved understanding of lung cancer epidemiology in U.S. Chinese populations informed product development and public health research strategies
Lung cancer incidence trends among Chinese Americans, by sex, nativity, and histology, California, 1990-2004*

*Gomez et al. Cancer Epidemiology, Biomarkers and Prevention, 2015
Chinese American Women Diagnosed With Lung Cancer, Survival is Associated With Marital Status and Neighborhood Economic Status

A study in the Journal of Global Oncology (JGO) set out to identify factors associated with survival among Chinese Americans diagnosed with lung cancer. The study, “Lung Cancer Survival Among Chinese Americans, 2000 to 2010,” published online, ahead of print, January 20, found that men and women differed in terms of factors associated with greater survival. Among both men and women, longer survival was associated with receiving care at a National Cancer Institute cancer center and the patient’s cancer histology type. However, among women, living longer was also associated with social factors: The study found that married women lived
Breast Cancer Epidemiology for Hormone Receptor (HR) and HER2-defined Subtypes in California

Issue

Despite approval of Herceptin in 1998 and increased use of HER2 testing post-approval, limited population-based data are available for breast cancer by biomarker-defined subtypes (HR +/- and HER2 +/-). HER2 information is >85% complete for breast cancers diagnosed in years 2005-2011 in California. SEER did not begin collecting HER2 information until 2010.

Insights

- Understanding of breast cancer survival by molecular subtype in a real-world population
- Chemotherapy utilization according to stage at diagnosis, HER2, and HR status

Impact: insights into differences in survival and chemotherapy use based on molecular subtype and race/ethnicity can help identify opportunities for new therapies and inform further research into risk factors associated with increased disease risk.
Racial/ethnic differences in the occurrence of HER2 and hormone receptor-defined breast cancer in California*

* Gomez et al. ASCO Annual Meeting, 2014
Breast Cancer Subtype and Survival in a Large Population-Based Cohort of Patients from California*

* Clarke et al. San Antonio Breast Cancer Symposium, 2015

Early Breast Cancer

Metastatic Breast Cancer
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Future opportunities
Strengths and Limitations of Cancer Registry Data for Life Sciences RWD Research

- Detailed cancer characteristics and follow-up
- Difficult to study new treatments and tests

- Stage at Diagnosis
- Limited treatment data
- Histology
- No information on recurrence
- Long-term survival
- Time lag
- Data quality
Opportunities to enhance collaboration

*Rapid case ascertainment for clinical trial recruitment*

*Virtual biorepositories*

*Medical records linkage to enrich core registry data*
Widespread adoption of electronic pathology reporting increased capability to support rapid case ascertainment for clinical trials

ePath Project Participants as of December 15, 2014

Status

- Data not available
- Using PHINMS for Cancer Reporting
- PHINMS Installation in Progress
- Participating via sFTP or Other Methods
SEER biospecimen repository proposed workflow

Central Processing
- Central Website
- User Registration
- Query de-ID’ed e-Path reports
- Request submission
- Peer review/approval protocol
- Honest Broker Process

Investigator
- Study design: funding, protocols, hypothesis

Path Lab
- Inventory & processing
- Residual & other specimens
- QC

Virtual Tissue Repository

Residual Tissue Repository

De-Identification

SEER Registry
- Work with Honest Broker
- Abstract/Enriched annotation
- Linkages data/specimens
- Interaction with Path Labs & Investigators

One-stop shopping for investigators to identify and request specimens & clinical annotation

Path Lab may ship specimen directly to investigator through registry processes

Note: IRB/MTA/QC issues are relevant to all components of the proposed system

Presented By Lynne Penberthy at 2014 ASCO Quality Care Symposium
Evolving roles for cancer registries

- Comparative effectiveness
- Precision medicine
- Value-based medicine
- Quality improvement

Interoperable digital health systems essential to support transformation
Summary

Cancer registries are an important source of real-world data. Registry data provide vital evidence that enriches pharmaceutical and diagnostics development. Collaborations between cancer registries and life sciences companies provide meaningful opportunities to generate new insights that contribute to cancer research. Opportunities to enhance collaboration through data linkages and other methods that augment core cancer registry data.
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Doing now what patients need next