ENGELBERG CENTER for Health Care Reform at BROOKINGS

Conducting Real-Time Safety Evaluation with Medicare Data: Learnings from the SafeRx Project

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Brookings Roundtable on Active Medical Product Surveillance

Some Initial Housekeeping

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Conducting Real-Time Safety Evaluations with Medicare Data

SafeRx Project:

A Collaboration of CMS, FDA, and the

HHS Assistant Secretary for Planning and Evaluation

October 2010

Disclaimer

The views expressed in this presentation represent the opinions of the authors, and do not necessarily represent the views of the United States Food and Drug Administration, the Centers for Medicare & Medicaid Services, or the United States Department of Health and Human Services.

Launch of the SafeRx Project

- In May 2008, the Medicare Part D prescription benefit data became available for research purposes
- SafeRx evolved as a collaboration between FDA and CMS with early support from the HHS Assistant Secretary for Planning and Evaluation
  - Launched June 2008
- The project expands earlier FDA-CMS collaborations to develop near-real time active surveillance methods and provide opportunities for more formal epidemiological studies of medical product safety issues in the Medicare and Medicaid populations

FDA Groups Participating in SafeRx

- Center for Biologics Evaluation and Research
- Center for Drug Evaluation and Research
  - Office of Biotechnology Products
  - Office of Medical Policy/Sentinel Initiative
  - Office of Surveillance and Epidemiology
  - Safe Use Initiative
- Center for Devices and Radiologic Health

Some Presentations/Publications from SafeRx

- Active surveillance projects
  - Burwen D, Sandhu S, MaCurdy T, et al. Surveillance for Guillain–Barre´ Syndrome after Influenza Vaccination among the Medicare Population, 2009–2010 (abstract). 26th International Conference on Pharmacoepidemiology and Therapeutics, August 2010
  - Sandhu S, Burwen D, MaCurdy T, et al. Comparison of Alpha-Spending Plans for Influenza Vaccine Safety Surveillance (abstract). 25th International Conference on Pharmacoepidemiology and Therapeutics, August 2009
- Epidemiology studies
  - Graham D, Ouellet-Hellstrom R, MaCurdy T, et al. Risk of Acute Myocardial Infarction, Stroke, Heart Failure, and Death in Elderly Medicare Patients Treated With Rosiglitazone or Pioglitazone. *JAMA* 2010; 304(4): 411-18.
  - Kuyateh F, Mehta H, Ouellet-Hellstrom R, et al. A Comparison of Opioid Use Patterns in Medicare, Medicaid, and a National Prescription Tracker Service (abstract). 26th International Conference on Pharmacoepidemiology and Therapeutics, August 2010

Study Context

- Post-market safety surveillance systems are most effective when data can be accessed in near real time
- Existing strategies suffer shortcomings
  - Limited population size in drug development programs
  - Underreporting of adverse events and lack of denominator data in post-market passive surveillance systems
- Administrative claims databases offer an alternative source for conducting safety evaluations
  - Large populations
  - Comprehensive diagnostic and treatment information
- What are potential limitations that would impact the ability to use administrative data in near real time?

Outline

- Overview of Medicare claims data
- Potential data limitations for near real-time surveillance
- Investigation of data limitations
- Conclusions

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- **Overview of Medicare claims data**
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Medicare Claims Data Describe Beneficiaries' Health and Treatment Circumstances

- **Medicare population**
  - US elderly (≥65 years)
  - Disabled, End-Stage Renal Disease (ESRD), or Amyotrophic Lateral Sclerosis (ALS)
- **Claims information**

  Enrollment
  - Demographic characteristics (e.g. age, gender, region)

  Fee-for-Service (FFS) – Part A and Part B
  - Utilization of inpatient hospital care, outpatient institutional care, and doctor visits, co-morbidities, procedures, occurrence of laboratory tests, physician information, payments

  Part D
  - Prescription drugs, quantity dispensed, days supplied, prescriber information, payment

Outline

- Overview of Medicare claims data
- **Potential data limitations for near real-time surveillance**
  - **Claims adjudication**
  - **Claim delay**
- Investigation of data limitations
- Conclusions

Claims Adjudication May Introduce Instability into Weekly/Monthly-Updated Data

Standard Analytical File (SAF)

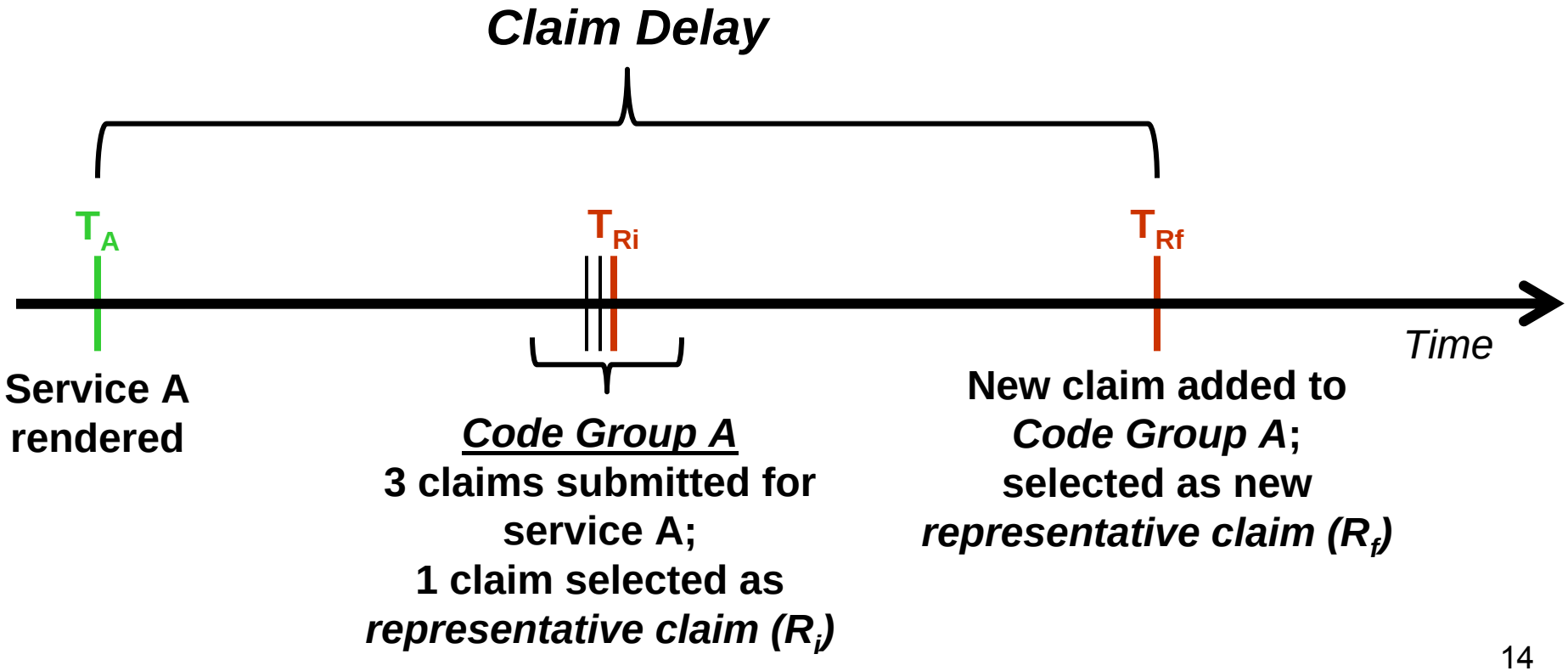
- Annually-updated database of adjudicated claims for FFS services and prescription drugs available to research community (up to 2 years delay for drug data)

Common Working File (CWF) & Part D

- FFS claims data updated weekly; prescription drug claims updated monthly
- *Claims adjudication* process to reconcile multiple claims for the same set of services/drugs
  - *Group* of all claims seeking payment for the same set of services/drugs
  - *Representative* claim selected from group as most accurate
- Dynamic composition of claim groups → changes in representative claim over time

Claim Delay May Limit Near Real-Time Surveillance

- Time between the date the of the most recent *representative claim* and the date of the associated service



Outline

- Overview of Medicare claims data
- Potential data limitations for near real-time surveillance
- **Investigation of data limitations**
  - **Quantifying the impact of claims adjudication**
  - **Summarizing the claim delay**
- Conclusions

Quantifying the Impact of Claims Adjudication

- ***Question***: How stable is the clinical information in claims data over time?
- ***Measurement***: Proportion of groups whose representative claims contained different health/treatment information across time
  - Medicare FFS claims from 2006 with changes in procedure or diagnosis fields in provider settings observed by May 2009
    - Inpatient hospital
    - Outpatient institutional
    - Physician's office
  - Part D prescription drug claims from 2007 with changes in National Drug Code (NDC), dosage, and days supply observed by May 2009

Claims Adjudication Has Little Impact on Stability of Clinical Information

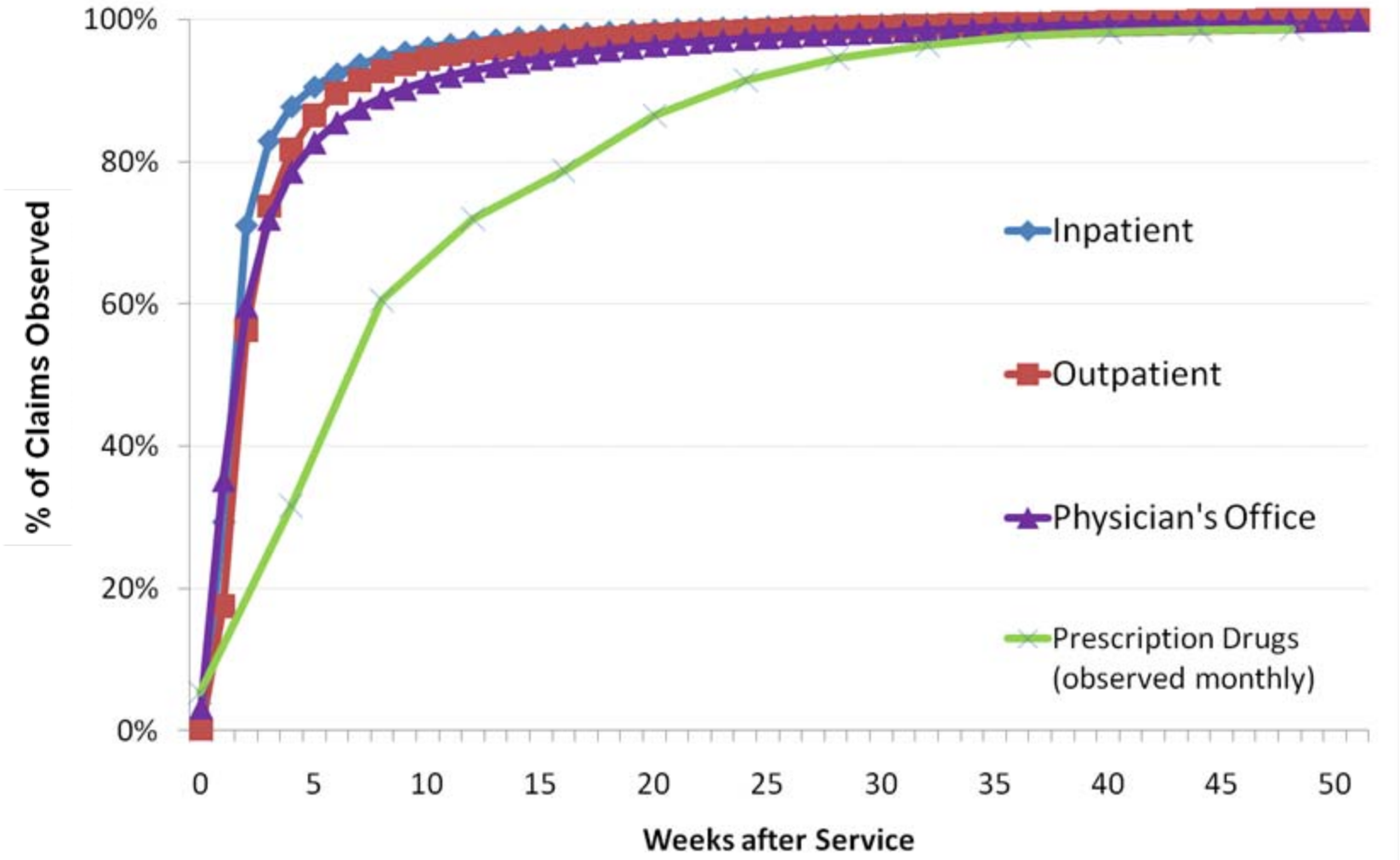
Claim Setting	Number of Claims Groups (% of groups in claim setting)	% of Updated Groups
Total Inpatient Claim Groups*	**13,822,164 (100%)**	**N/A**
Claim Information Updated	1,192,590 (8.6%)	**100%**
ICD-9 Diagnosis Updated	55,364 (0.4%)	4.6%
ICD-9 Procedure Updated	18,690 (0.1%)	1.6%
Total Charge	547,250 (4.0%)	45.9%
Total Outpatient Claim Groups*	**141,187,926 (100%)**	**N/A**
Claim Information Updated	11,158,865 (7.9%)	**100%**
ICD-9 Diagnosis Updated	1,331,042 (0.9%)	11.9%
HCPCS/CPT Procedure Updated	1,596,572 (1.1%)	14.3%
Total Charge	3,173,573 (2.2%)	28.4%
Total Physician's Office Claim Groups*	**839,748,362 (100%)**	**N/A**
Claim Information Updated	40,192,877 (4.8%)	**100%**
ICD-9 Diagnosis Updated	555,844 (0.1%)	1.4%
HCPCS/CPT Procedure Updated	1,373,599 (0.2%)	3.4%
Line Allowed Charge Amount	35,667,539 (4.2%)	88.7%
Total Prescription Drug Claim Groups**	**977,432,233 (100%)**	**N/A**
Claim Information Updated	321,554,611 (32.9%)	**100%**
National Drug Code	91,176 (0.0%)	0.0%
Quantity Dispensed	20,696,635 (2.1%)	6.4%
Days Supply	331,989 (0.0%)	0.1%
Ingredient Cost Paid	14,864,703 (1.5%)	4.6%
Part D Plan Paid	52,415,958 (5.4%)	16.3%

* Claims from 2006 observed by May 2009; **Claims from 2007 observed by May 2009

Summarizing the Claim Delay

- ***Question**:* How quickly after a diagnosis, treatment, or prescription are representative claims observed?
- ***Measurement**:* Cumulative proportion of representative claims observed by the number of weeks after service
  - Medicare FFS claims from 2006 in provider settings
    - Inpatient hospital
    - Outpatient institutional
    - Physician's office
  - Part D prescription drug claims from 2007

Representative Claims Accrue Rapidly



Outline

- Overview of CMS claims data
- Potential data limitations for near real-time surveillance
- Investigation of data limitations
- **Conclusions**
  - **Impacts of claims adjudication and claim delay**
  - **Implications for near real-time safety surveillance**

Conclusions

- Overall, claim information was unchanged for over 90% of diagnosis and procedure claim groups and about 70% of drug claim groups
- Among claim groups that did undergo adjudication, there was little impact on clinical information over time
- In all settings, adjudication most frequently updates payment information
- Representative claims accrue rapidly for health services (≥88% of representative claims observed within 2 months of service); Part D claims are slightly more delayed
- Medicare updates provide a rich source of rapidly-available reliable clinical data for active medical product safety surveillance

Study Collaborators

- Abraham G. Hartzema, PharmD, MSPH, PhD
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  - Stanford University and Acumen LLC
- Jonathan M. Gibbs, BA
  - Acumen LLC
- Jeffrey A. Kelman, MD, MMSc
  - Centers for Medicare & Medicaid Services

Roundtable Discussion and Questions

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Remarks from Mini-Sentinel Collaborators

- Jeff Brown, Assistant Professor, Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute
- Jennifer Nelson, Associate Investigator, Biostatistics Unit, Group Health Research Institute, and Affiliate Assistant Professor, Biostatistics, School of Public Health, University of Washington

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