Defining the treatment

Challenges to identifying the treatment in observational CER

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Outline

1. Challenges in defining what the treatment is in observational CER
2. Where to find data on treatments in observational data (specifically, Medicare data)
3. Challenges in identifying the treatment
4. Recommendations

Defining the treatment in CER

What do we mean by “treatment” in CER?

“Defined interventions compared may include medications, procedures, ...devices, ...diagnostic testing, behavioral change, and delivery system strategies.”

Source: http://effectivehealthcare.ahrq.gov

Potential unobserved confounders

Observed comorbid conditions and other covariates

Demographics

Treatment

Outcomes
Challenges in defining treatment
Variations in treatment that can confound observational CER

1. Treatment history
2. Treatment dose
3. Context or environment in which treatment was delivered
4. Skill of provider of treatment
5. Complex treatments
6. Problems with a “no-treatment” comparison group
7. Timing of treatment
8. Repeated treatments (treatment adherence)

1. Treatment History
Variations in treatment that can confound observational CER

- You identify your study cohort beginning in 2008 but some patients received treatment in 2007
- Problems:
  - Are previously treated no longer eligible for treatment?
  - Do previously treated have different unobserved behaviors because of previous experience with treatment?
    - Example: CABG reduces smoking
  - If so, then some of the “untreated” patients are poor counterfactuals for treated patients.
  - What else?

2. Treatment dose

- Does treatment differ in dose or intensity?
  - Literal dose as in medication, or
- Examples:
  - Dose of an ACEI inhibitor for hypertension versus dose of a diuretic
  - Counseling for smoking cessation
  - What else?
- Problem
  - If Treatment A looks better than treatment B, how do you know it wasn’t do to the fact that treatment B was under-dosed?
3. Context or environment
Variations in treatment that can confound observational CER

- Examples
  Treatment A is given mostly in lousy hospitals and treatment B is given mostly in good hospitals.
  Financially sound clinics adopt electronic health records.
- Problem:
  Difficult to tease out effect of treatment from effect of environment
  RCTs do this by stratified randomization by site (i.e., equal number of A's and B's at each site)
- Potential solutions
  Difference in difference estimation or fixed-effects estimators (more on Wed)

4. Skill of provider
Variations in treatment that can confound observational CER

- Skill of provider may affect estimates of treatment efficacy
- Examples:
  Femoral artery versus trans-radial artery access for PCI
  Robot assisted prostatectomy
- Problem
  What is the counterfactual?
  What would have happened to patient if all cardiologists had switched to trans-radial?
  What would have happened to patient if s/he had switched to an experienced trans-radialis?
- Potential solution
  Stratify by volume or experience

5. Complex treatments

- Treatments can have multiple components
- Examples:
  - Nurse-led disease management
  - Patient Centered Medical Home
- Problem
  - How do you know what part of treatment worked?
  - How do you know whether people received the same treatment?
- Potential solution
  - Conceptual model.
Measure the relationships between each component and the intermediate outcomes specific to that component

Counseling on self-monitoring
- Ptn reports monitoring
- Pin salt intake decreases

Counseling on self-behaviors
- Prescribed meds change

Medication Adjustment
- Visits to social vct, mental helth

Care Coordination
- Hospitalizations
- Death
- Health status (SF-12)

If no change in these visits between tx groups than care coord unlikely to have contributed to the overall success of the tx

6. Untreated comparison group
Variations in treatment that can confound observational CER

- Compare treated to untreated patients
- Examples:
  - Bariatric surgery versus usual care (Matt)
  - Initiation of dialysis in the oldest old.
  - Prostatectomy vs. watchful waiting
- Problems
  - How do you know the untreated folks needed the treatment?
  - When do you start the clock for the untreated patients?
- Potential solution
  - Propensity score matching (Matt)

7. Timing of treatment
Variations in treatment that can confound observational CER

- Compare patients who started treatment early (aggressive) versus late (cautious)
- Examples:
  - Initiation of dialysis before the onset of symptoms?
  - Start steroids in anticipation of lupus flair?
- Problems
  - Lead time bias: if you start the clock when treatment starts, early-start patients will appear to live longer even if treatment is completely ineffective.
- Potential solution
  - Propensity score matching?
  - Statistics appropriate for dynamic regimes (e.g., Cain LE, et al)

8. Repeat treatment
Variations in treatment that can confound observational CER

- Patient receives the same treatment repeatedly over time, but skips or discontinues treatment
- Examples:
  - Chronic disease medications
  - Veterans who switch back and forth between VA and Medicare. What is the effect of VA care on costs and outcomes?
- Problems
  - Time-varying confounding.
- Potential solution (not covered this week)
  - Marginal structural models
  - G-estimation
  - Instrumental variables

Challenges in defining treatment
Variations in treatment that can confound observational CER

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1. Challenges in defining what the treatment is in observational CER
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Types of treatments available in Medicare data?

- Medications
- Procedures and diagnostic testing
- Devices
- Delivery system strategies

Overview of where to find treatments in Medicare data

<table>
<thead>
<tr>
<th>Data file</th>
<th>Medications</th>
<th>Procedures</th>
<th>Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carrier</td>
<td>HCPCS codes</td>
<td>HCPCS codes</td>
<td></td>
</tr>
<tr>
<td>Nonhospital or inpatient</td>
<td>Revenue Center codes</td>
<td>DRG codes</td>
<td>ICD Proc codes</td>
</tr>
<tr>
<td>Part B</td>
<td>NDC-11 codes</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Outpatient hospital</td>
<td>APC codes</td>
<td>HCPCS codes</td>
<td>APC codes</td>
</tr>
<tr>
<td>DME</td>
<td>--</td>
<td>--</td>
<td>HCPCS codes</td>
</tr>
<tr>
<td>Home health file</td>
<td>--</td>
<td>Revenue Center codes</td>
<td>HCPCS</td>
</tr>
</tbody>
</table>

NDC-11: National Drug Classification - 11 characters
HCPCS: Healthcare Common Procedure Coding System
APC: Ambulatory Payment Classification
ICD Proc: International Classification of Disease- Clinical Modification
9th edition Procedure codes

Medications- Part B

Medicare has paid for specific drugs under Part B
- Generally, drugs that are administered in physician or other offices, used as part of infusion devices
- Some oral drugs used following organ transplant.
- Most (40% in 2001) are oncology drugs identified by HCPCS codes starting with ‘J’ on DME claims.

<table>
<thead>
<tr>
<th>Drug name</th>
<th>% of Part B drug costs in 2001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythropoietin (anemia)</td>
<td>12.1%</td>
</tr>
<tr>
<td>Lupron (prostate Cancer)</td>
<td>10.4%</td>
</tr>
<tr>
<td>Ipratropium bromide (Asthma)</td>
<td>7.3%</td>
</tr>
<tr>
<td>Zolodex (prostate cancer)</td>
<td>6.8%</td>
</tr>
<tr>
<td>Albuterol (Asthma)</td>
<td>5.5%</td>
</tr>
</tbody>
</table>

Medicare Part D data

- Part D files
  - Enrollment data (Beneficiary Summary File)
  - Prescription Drug Event (PDE) data
  - Characteristics files
- Available to researchers
  - Via ResDAC
  - From Chronic Conditions Warehouse (CCW) of Buccaneer Computer Systems and Software, Inc.

Important elements in the Part D PDE file

**Beneficiary information**
- Beneficiary ID
- Age, demographics (from enrollment file)

**Drug information**
- NDC 11 code to identify medication (called the "product service ID" in the Part D event file)
- Days Supplied

**Prescriber Information**
- Unique provider, eventually linked to a Prescriber Characteristic File
- Maybe Useful for Instrumental Variable (later)

National Drug Classification (NDC) codes

- Three segments to each NDC code
  - Labeler code – 4 or 5 digits
  - Product code- 3 or 4 digits
  - Packaging code- 2 or 1 digit
- Always 10 digits of information, but not always the same format
  - Eg., the segments lengths could be (4-4-2) (5-3-2) or (5-4-1)
- Medicare/HIPAA solution: NDC 11
Example: Ramipril (Altace)

<table>
<thead>
<tr>
<th>Labeler</th>
<th>Product</th>
<th>Packaging</th>
<th>NDC</th>
<th>NDC-11</th>
</tr>
</thead>
<tbody>
<tr>
<td>61570</td>
<td>110</td>
<td>02</td>
<td>6157011001</td>
<td>6157011001</td>
</tr>
<tr>
<td>61570</td>
<td>111</td>
<td>05</td>
<td>6157011101</td>
<td>6157011101</td>
</tr>
<tr>
<td>61570</td>
<td>111</td>
<td>05</td>
<td>6157011105</td>
<td>6157011105</td>
</tr>
</tbody>
</table>

Different product codes for 1.25 mg vs 2.5 mg
Different packaging code for 100 versus 500 capsules
NDC-11 inserts a leading “0” so the product code is 4 digits and the format is always 5-4-2

Medications
Use Medi-Span/First Data

- In sum: NDC codes are a tragedy to use
  Organized by labeler (i.e., the firm marketing the product) not by type of drug.
  May need to type in hundreds of NDC codes to find all doses, delivery modes (i.e., capsule, tablet, suppository, etc.), container sizes, etc.
- Potential Solution: Buy a subscription to Medi-Span or First Data Bank drug information databases
  www.medispan.com
  www.firstdatabank.com

Medications
Medispan’s Therapeutic Classification System

- Each drug is given a code (a GPI), that consists of a hierarchy of information.
  Drug group (e.g., Diuretics)
  Drug class (e.g., Loop)
  Drug name (e.g., "Furosemide")
  Dosage form (e.g., tablet)
  Dosage strength (20 mg)
- GPIs are linked to NDC codes so you can find you drugs using GPIs and merge with Part D data to identify medication users
### Medications
Identifying medications using Medispan databases

<table>
<thead>
<tr>
<th>GPI code</th>
<th>Medication</th>
</tr>
</thead>
<tbody>
<tr>
<td>37 00-00-00</td>
<td>Diuretics</td>
</tr>
<tr>
<td>37 00-00-00</td>
<td>Loop diuretics</td>
</tr>
<tr>
<td>37 00-00-00</td>
<td>Furosemide</td>
</tr>
<tr>
<td>37 00-00-00</td>
<td>Furosemide Tab 20</td>
</tr>
<tr>
<td>37 00-00-00</td>
<td>Furosemide Tab 40</td>
</tr>
<tr>
<td>37 00-00-00</td>
<td>Furosemide Inj 10 MG/ML</td>
</tr>
</tbody>
</table>

#### Recommendations: Medispan/First Data Bank
- Medispan and First Data Banks subscriptions cost about $5k per year.
- This might be a time saver if you are using CMS Part D data to investigate a large number of different drug categories.
Types of treatments available in Medicare data?

- Medications
- Procedures and diagnostic testing
- Devices
- Delivery system strategies

Outpatient procedures and diagnostic tests

- Defined by HCPCS in Carrier file (see earlier slides on HCPCS codes)
- Billed by physicians or other “non-institutional” providers therefore appear on non-institutional (i.e., Carrier) claims
- However, the physician component of in-patient procedures also appear on Carrier claims
  
  Eg., an in-patient surgery generates both a Carrier claim from the surgeon and a MedPAR or Inpatient record. Both the HCPCS code and the place of service indicator on Carrier claims can be used to identify outpatient settings.

Level 1 HCPCS or CPT Codes Examples

00100 - 01999 Anesthesia
10040 - 69990 Surgery
70010 - 79999 Radiology
80049 - 89399 Pathology and Laboratory
90281 - 99199 Medicine*
99201 - 99499 Evaluation and Management

* Injection of medicine, such as vaccination, immune globulin, antitoxins, etc
Medicare Leading Part B Procedure Codes Ranked by Allowed Charges (2008)

<table>
<thead>
<tr>
<th>HCPC Code</th>
<th>Description</th>
<th>Allowed Charges ($)</th>
<th>% of total allowed charges</th>
</tr>
</thead>
<tbody>
<tr>
<td>99214</td>
<td>Office/outpatient visit, est</td>
<td>6,031,239,662</td>
<td>5.3</td>
</tr>
<tr>
<td>99213</td>
<td>Office/outpatient visit, est</td>
<td>5,910,130,389</td>
<td>5.2</td>
</tr>
<tr>
<td>99232</td>
<td>Subsequent hospital care</td>
<td>3,241,618,814</td>
<td>2.6</td>
</tr>
<tr>
<td>99233</td>
<td>Subsequent hospital care</td>
<td>2,072,478,375</td>
<td>1.8</td>
</tr>
<tr>
<td>99285</td>
<td>Emergency room visit</td>
<td>1,311,734,269</td>
<td>1.1</td>
</tr>
<tr>
<td>70405</td>
<td>Heart image (angioplasty)</td>
<td>1,097,124,017</td>
<td>0.9</td>
</tr>
<tr>
<td>70404</td>
<td>Office consultation</td>
<td>1,082,579,794</td>
<td>1.0</td>
</tr>
<tr>
<td>99215</td>
<td>Office/outpatient visit, est</td>
<td>1,017,088,079</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Examples: Place of service codes from Carrier file

- 04 = Homeless Shelter
- 11 = Office
- 12 = Home
- 13 = Assisted Living Facility
- 20 = Urgent Care Facility
- 21 = Inpatient hospital
- 22 = Outpatient hospital
- 23 = Emergency room - hospital
- 24 = Ambulatory surgical center
- 32 = Nursing facility

Note: The place of service is specific to the HCPCS that appears on the same line-item

Procedures performed in hospital

Procedures performed in hospital also generate a bill from the hospital—that is an institutional Inpatient claim or MedPAR stay record

Identified by ICD-9 Procedure codes:

- Up to 6 per claim. First listed is the “primary” procedure
- Four digits of the form XX.XX with leading zero
Examples ICD procedure codes

35.0 Operations on valves and sept of the heart
35.1 Closed heart valvotomy
35.2 Replacement of heart valve
35.3 Operations on structures adjacent to heart valve
35.4 Production of septal defect in heart
35.5 Repair of atrial and ventricular septa with prosthesis
35.6 Repair of atrial and ventricular septa with tissue patch
35.7 Other and unspecified repair of atrial and ventricular septa
35.8 Other operations on valves and septa of heart
35.84 Creation of conduit between aorta and pulmonary artery

Revenue Center Codes

- Institutional hospital (i.e., MedPAR, Inpatient file) claims also have revenue center codes
- A little tricky to use
  - Up to 450 codes per hospital stay
  - Associated with each code is a number of unit and total charge
  - E.g., The cost center (e.g., ICU), the number of units (e.g., 2 days), and total charges ($)
- Provides additional information on what was done to a patient, but are not very specific.
  - E.g., In the MedPAR file, the revenue center group records charges for:
    - Pharmacy (9 specific types, no information on what specific drugs given)
    - ICU (8 specific types), coronary care unit (5 specific types), radiology/oncology, diagnostic radiology, therapeutic radiology, CT scan, other radiological procedures, nuclear medicine.
  - Important: the Inpatient file (but not the MedPAR) can contain HCPCS codes, but rarely populated

Types of treatments available in Medicare data?

- Medications
- Procedures and diagnostic testing
- Devices
- Delivery system strategies
Medical devices delivered as part of an in-patient procedure

- The charges for some devices are included in the hospital’s payment for the procedure, so look for them using DRG or ICD-9 procedure codes on MedPAR or Inpatient file
  - E.g., Identifying coronary stents
    - DRG: 246 Percutaneous cardiovascular proc w drug-eluting stent w MCC
    - ICD 36.07 Insertion of drug-eluting coronary artery stent(s)

Medical devices in outpatient settings

Surgical implantation of devices conducted in an outpatient hospital setting, look at the Hospital Outpatient file

Hospital Outpatient SAF contains facility charges for outpatient services
  - The physician charges for an encounter with a Medicare beneficiary appear in Carrier file
  - The hospital clinic charges for that encounter appear in the Outpatient SAF
  - The hospital reimbursement has been based on prospective Ambulatory Payment Classifications (APCs).
  - Costs of devices are built in to some APCs

For example, placement of a drug eluting stents in outpatient generates:
  - Hospital outpatient SAF claims.
    - APC 0656: Transcatheter Placement of Drug-Eluting Coronary Stents
    - HCPCS G0290 Transcatheter placement of a drug eluting intracoronary stent(s)
  - Carrier file claims
    - HCPCS 92980 Transcatheter placement of an intracoronary stent(s)

Durable Medical Equipment (DME)

- Durable equipment identified in the DME file
- DME file contains diagnoses, HCPCS codes, charges and and beneficiary information
- Equipment is identified by level 2 HCPCS codes
  - E.g., HCPCS K0800: Power operated vehicle, group 1 standard, patient weight capacity up to and including 300 pounds
Types of treatments available in Medicare data?

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Opportunities for CER on delivery system strategies using Medicare data

Fee-for-service versus managed care
- Limited because encounter level data are not available for Medicare Advantage enrollees
- Death date and month of enrollment and disenrollment are available

E.g., Atherly A, Hebert PL, Maciejewski ML. An Analysis of Disenrollment From Medicare Managed Care Plans by Medicare Beneficiaries With Diabetes. Medical Care 2005;43(1):500-506.

Volume-Outcome analyses
- Compare outcomes for high volume versus low volume providers of a procedure


Opportunities for CER on delivery system strategies continued

Comparisons of outcomes by hospital characteristics
- Link hospital provider ID on Inpatient or MedPAR records to the Hospital Cost Report Information System (HCRIS)
- HCRIS has information for each hospital on
  - Bed size
  - Graduate medical education
  - Disproportionate share payments
  - Profit status (13 categories of nonprofit, proprietary, religious, government, etc...)
CER on delivery system strategies
continued

- Care provided by specialist versus generalist
  Carrier claims contain a field for the specialty of the
  provider of the associated HCPCS procedure
  UPIN/NPI on Inpatient file can be used to identify
  specialty of admitting physician
  Eg. C D Frances, et al Does physician specialty affect the survival of elderly
  patients with myocardial infarction? Health Serv Res. 2000
  December; 35(S Pt 2): 1093–1116.

- Special-topics databases
  Dialysis Facility Compare
  Profit status and quality information for dialysis facilities
  OSCAR: Data from surveys of long-term care facilities

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How accurate are the codes?
Challenges in identifying the treatment

- Generally, pretty good
  Final action claims
  Things that result in payment (like procedures) are
  audited and therefore more accurate
  No comprehensive studies since early 1990s, but
  recent studies suggest codes are reasonably
  accurate

Du, L.M.S.P., et al., External Validation of Medicare Claims for Breast Cancer Chemotherapy Compared
Shahian, D.M., et al., Comparison of Clinical and Administrative Data Sources for Hospital Coronary-Artery
Codes are generally pretty good, however
Challenges to identifying the treatment, continued

- Fraud (especially durable medical equipment) and DRG Creep exists
- Variation in coding by Carrier and provider
  Some treatments that seem relatively easy to find are in fact quite complex.
  For example, Murphy et al, (2004) required multiple combinations of diagnoses and procedure codes to identify patients who got a renal artery angiogram or stent during a coronary artery procedure (i.e., a “drive-by” renal angiography)

Challenges to identifying the treatment using Medicare claims

- How specific are the codes?
- How complete are they?
  - For new technologies, coverage decisions vary by Carrier*
  - Coding rules are complex, and there are many ways to code for some procedures (see right panel)

    Options for coding drug eluding stents on outpatient claims

    In Transmittal A-03-051, CR 2771, CMS implemented payment under APC 0656, Transcatheter Placement of Drug-Eluting Coronary Stents, for two HCPCS codes that describe drug eluting coronary stents. However, CMS indicated that hospitals could conduct reimbursement for the drug-eluting stent in one of two ways:

    1. CMS also indicated that, alternatively, hospitals could bill separately for the drug eluting stent by using HCPCS code C1874, Stent, coated/covered, with delivery system. This option requires that the provider or hospital use HCPCS code C1874 to report charges for the drug-eluting stent.
    2. As of January 1, 2004, CMS implemented Codes for devices for cost reporting and cost tracking purposes. Therefore, hospitals have a third option to report charges for drug eluting stents. That is, hospitals may report HCPCS code C1874, “Stent, coated/covered, with delivery system,” with an appropriate Revenue Code to report their charge for drug eluting coronary stents. When using HCPCS code C1874 to bill separately for the drug eluting stent, hospitals should ensure that the charge for C1874 does not include the charge for the G0290 and G0291. Payment for placement of the stents, and the stents themselves, are made under APC 0656.

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Recommendations

Check the literature.
- Some algorithms have been developed to identify specific types of treatments

Check with MAC (formerly Carrier) for whether new or emerging technologies are covered

Cast a wide net…
- To account for the wide variety of coding options search for all the relevant codes in each SAF
  …then make sensible restrictions. E.g.,
  - Consider requiring an in-hospital surgical procedure (MedPAR or Inpatient) also has a physician (Carrier) claim from a surgeon on the same date.
  - Eliminate claims conducted in unreasonable places of service, unreasonable lengths of stay, or other unreasonable data

Conclusion

- A number of important challenges in defining the treatment in observational CER studies
- Medications, procedures, devices, and delivery system strategies can be identified and used as treatments in CER using administrative claims data

References & Resources

References & Resources


