Working with VISION Data

Kayla Moore and Jialin Mao

Accessing VISION Data: How to get your project on "The List"

Kayla Moore, MPH

MDEpiNet

SVS | VQI
VASCULAR QUALITY INITIATIVE

Overview: Understanding how to work with VISION Data

- What makes VISION special?

- What are the Medicare-derived late outcomes?

- What are the rules governing use of VISION data? (scope, access, data transfers)

- How do I get my project on the *"on-deck list"*?

- How to avoid common pitfalls

- Where do I find more information?

Context: What makes VISION special?

- VQI + Medicare Claims = VISION
  - 140+ clinical covariates in VQI
  - Longitudinal follow-up in Medicare (can follow individuals if they move to different centers)
  - Cost data
- Existing CMS Data Use Agreement
  - Bypasses need to obtain a new DUA for every research question (*restrictions apply*)
  - Significant savings in cost and time – a new CMS DUA takes a minimum of 3-5 months. Data is costly and requires additional resources for security, cleaning, linking, and developing analytic datasets
- Analytic team with specialized knowledge

Restrictions Apply:
Rules governing use of CMS Data

- Data must remain on secure HIPAA/FISMA compliant server

- Access is restricted to individuals named on the DUA

- No individual level data can be removed from the server

- Only aggregate/de-identified data (tables, figures be removed from the server.

- Output is reviewed by IT security team prior to transfer to ensure suppression requirements are applied (no cell sizes less than 10)

- In addition, CMS requires that each DUA be project-specific and tied to a single funding source

Security Architecture
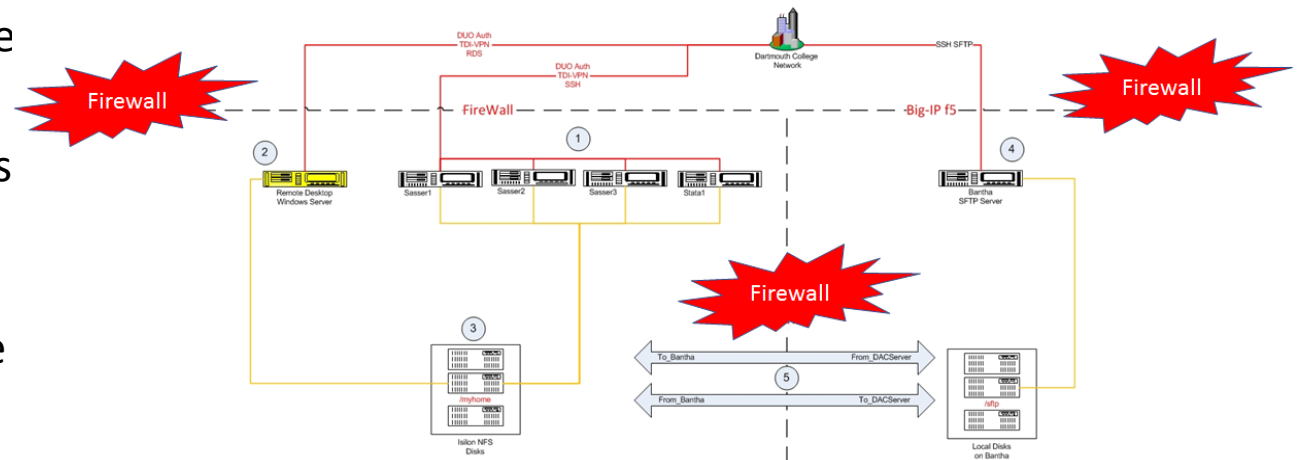
Scope of research allowed under WCM's existing DUA

Research must focus on <u>evaluation of device outcomes</u>, including the following:

- safety and efficacy of devices
- the impact of provider characteristics on device outcomes
- health disparity related to device use and outcomes
- the impact of medical practice guidelines and healthcare policies

What if I want to use VISION data for a project that is not within the scope of the existing DUA?

- Obtain separate funding and apply for a "re-use" of the VISION DUA

What are the Medicare-derived variables in VISION?

- Death
- Procedure-specific adverse outcome (stroke, aortic rupture, amputation)
- Reintervention (repeated vascular procedures)
- Readmission
- Post-procedure imaging (CT, MRI)
- Cost

Contact us to request a copy of the late outcomes variable dictionary

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   - ❑ Clarity/feasibility of research question

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   - ❑ Addresses a gap in knowledge

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3. VISION Analytic Team requests research memorandum

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   - ❑Addresses a gap in knowledge
3. VISION Analytic Team requests research memorandum
4. VISION Analytic Team works with you to refine analytic plan and conduct analyses

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Externally funded projects

Example: NIH, AHA, PCORI, FDA

1. Engage VISION team during proposal development to:
   - ❑ Ensure feasibility
   - ❑ Obtain preliminary data for use in proposal
   - ❑ Define scope and budget for VISION Team (can vary from basic DUA support to in-depth analytic support)

2. Obtain VQI/RAC Approval

3. Apply for a "re-use" DUA to use VISION data at WCM (CMS requires a separate DUA for each funding source)

Recap: Steps for success & How to avoid Common Pitfalls

- Before RAC proposal
  - ✓ Become familiar with rules governing use of VISION Data
  - ✓ Identify which late-outcomes variables you wish to use
  - ✓ Ensure project is feasible (aligns with available data years, not overly complex)
  - ✓ Ensure projects includes a device-specific component
  - ✓ Contact VISION Team with any questions
- After RAC Approval
  - ✓ Follow-up with VISION Team to discuss timeline/priority
  - ✓ Be open to potential collaboration with other investigators with overlapping projects

Additional Information

https://www.vqi.org/data-analysis/blinded-datasets/

Kayla.O.Moore@Dartmouth.edu

Now that you are on "the list"

Working with the VISION analytical team

Jialin Mao, MD, MS

A full research protocol

I. Brief background and research question

a. Brief background
(Please specify the specific goals and objectives of research, and hypothesis if any)

b. Device being studied
(The DUA with CMS is device based. Examples: stents, carotid patches, angioplasty balloons)

c. Prior research related to the topic that you think would be helpful to refer to, if any

II. Methods

a. Datasets and population

Please specify the VQI-Medicare linked dataset you intend to use

☐EVAR   ☐Open AAA   ☐CEA   ☐CAS
☐PVI   ☐Infra   ☐Supra   ☐TEVAR

Years of inclusion: _____
(currently there are linked data up to 2016 available)

b. Study population

b1. Inclusion criteria (i.e. age group, sex, indication or diagnosis, specific procedure)

(If you know the exact variable for procedures/indications in VQI that will be used here, specifying here would be helpful.)

Example:
  - *Medicare beneficiaries above age 65 linked to VQI*
  - *Undergoing balloon angioplasty or stent placement*
  - *Femoral popliteal disease*

b2. Exclusion criteria, if any (i.e. certain patient characteristics, previous or concurrent procedure)

c. Key variables

c.1. Exposure (i.e. time trend, comparison groups):

c.2. Outcomes:

c.3. Covariates:

If not otherwise specified, we will include age, sex, race/ethnicity, and procedure year by default. Please specify other important covariates you'd like to include:
(i.e. comorbidities, procedure characteristics, center volume)

d. Statistical methods

Please include any preliminary thoughts you have. This can be further refined later.

III. Additional information

Include any additional information you'd like to provide.

Dataset and years

- Dataset
  - AAA, Carotid, PAD
  - Vein will be added this year

- Data years: currently up to 2016, expecting update to 2018
  - Are there restrictions to the years of data due to procedures or the availability of variables?
  - Is the current sample size going to be big enough?

  ➡ ***Wait or change some criteria?***

Note: CMS data release + DUA amendment -> 2 year data lag

Study design

- Inclusion/exclusion criteria

- Exposure and outcome

- Important covariates

- Statistical methods: preliminary thoughts are ok!

Have questions? Contact us!

What's helpful for the analytical team to know?

- A little bit background would be helpful

- Former studies with similar topics or designs

- Definition of variables based on VQI data

- Things that you are looking for from claims data

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What if the variables are not in the current dataset?

What happens next

✓On deck

✓Full protocol

✓Your turn
- We will review your protocol and mark our questions and thoughts
- We will reach out to you to kick start:
  - We are all very good at using Zoom now
  - We bring our questions, you bring yours
- Likely staged process
  - Clarify questions
  - Query rough numbers
  - Analysis <-> Changes

Questions?

Thank you