



UTILIZING DATA

to improve patient outcomes

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Question #5: Discuss mechanisms that might be supported by CMS that would more quickly generate an improved evidence base that would underpin improved care for the Medicare population affected by lower extremity chronic venous diseases.

Conflict of Interest

- * US Wound Registry is a 501(c)(3) non profit organization
 - * Sponsors the Venous Leg Ulcer Meaningful Use Registry
- * Caroline Fife, MD
 - * Executive Director of USWR (volunteer position)
 - * Major interest: Chief Medical Officer of Intellicure, Inc. (employee, stock)
 - * Mild: Consultant to Cytomedix on CED
- * Neither the USWR nor the VLU Registry have any sponsorship
 - * QCDR Quality measures developed in conjunction with the Alliance of Wound Care Stakeholders
 - * No Venous QCDR measures had funding for development
 - * Programming measures as eQMs provided *gratis* by USWR

EHRs Directly Transmit Data to VLU “Meaningful Use” Registry

- * Uses EHR capabilities:
 - * Any certified EHR can transmit data via a Continuity of Care document (CCD)
 - * Contains all ICD-10 diagnosis codes, CPT codes, demographics, medications, allergies, labs
- * No interfaces needed; No secondary data entry; no charges by the vendor.
 - * 59,116 VLUs currently available
 - * Ulcers are BIG (34cm²), OLD, and patients too sick to have been included in any venous ulcer RCTs
- * **Because CCDs contain no outcome data, this Meaningful Use registry cannot be used by CMS to expand the evidence base**



Outcome Data on VLUs Can come from QCDR Quality Measures

- * USWR has been a Qualified Clinical Data Registry (QCDR) since 2014
 - * Sponsors the Venous Ulcer Registry (and several others)
 - * listed on *Clinical trials.gov*; independent IRB
- * USWR developed 21 wound care related quality measures—important types
 - ✓ * Patient Reported Measures
 - * Wound **Quality of Life** ✓
 - * **Patient Reported Healing (Outcome)**
 - ✓ * **VLU Outcome** (stratified by the venous Wound Healing Index)
 - * **Appropriate use** ✓
 - * Cellular products (a model for venous procedures)
 - * 7 of the QMs are *specific to VLUs*





<https://www.uswoundregistry.com/index.aspx>



CCDs + Outcomes from QCDR Measures = Expanded Evidence Base

- * QCDR quality measures **improve the care** of VLU patients
 - * Vascular screening improved 24% (now 77.5% of patients)
 - * Adequate compression at EVERY visit improved 52% (80% of visits)
- * We know about inequities among Medicare beneficiaries (for example . . .)
 - * Medicare patients without secondary insurance receive only 1% of CTPs
 - * Black males are highly unlikely to receive NPWT
- * We can do Comparative Effectiveness Research on Cellular products
 - * Risk stratified, matched cohorts with real-world outcome data
 - * Actual healing rates with CTPs are ~30%
 - * CER data not published since currently only manufacturers use the registry
 -  * **NIH – “research cannot be done with EHR data”**
 -  * **PCORI- “this is not a national healthcare priority”**
- * QCDR measures could provide a solution but there are HUGE barriers --

Major Barrier: Vendors charge high prices for eCQM installation

Title	Specification	eMeasure - HTML	eMeasure - XML	Downloadable Resource File
Venous Leg Ulcer Outcome Measure: Healing or Closure				



```

<?xml version="1.0" encoding="UTF-8" standalone="true"?>
<!-- ***** QDM Version Used: QDM 4.1.2 ***** -->
- <QualityMeasureDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:qdm="urn:hhs-qdm:hqmf-r2-extensions:v1" xmlns="urn:hl7-org:v3">
  <!-- ***** Measure Details Section ***** -->
  <typeId root="2.16.840.1.113883.1.3" extension="POQM_HD000001UV02"/>
  - <templateId>
    <item root="2.16.840.1.113883.10.20.28.1.1" extension="2014-11-24"/>
  </templateId>
  <id root="40280381-4b88-6976-014b-93491b16008d"/>
  - <code codeSystem="2.16.840.1.113883.6.1" code="57024-2">
    <displayName value="Health Quality Measure Document"/>
  </code>
  <title value="CDR 6: Venous Leg Ulcer Healing or Closure"/>
  <text value="Percentage of patients aged 18 years or older with a diagnosis of venous leg ulcer whose ulcer has achieved H stratified by the Wound Healing Index. Healing or closure is defined as complete epithelialization without drainage or t closed ulceration, although venous compression would still be required."/>
  <statusCode code="COMPLETED"/>
  <setId root="a5f2a331-298f-403b-911b-2854ba79eb8f"/>
  <versionNumber value="0.0.004"/>
  - <author>
    - <responsibleParty classCode="ASSIGNED">
      - <representedResponsibleOrganization classCode="ORG" determinerCode="INSTANCE">
        - <id>
          <item root="2.16.840.1.113883.3.6169"/>
        </id>
        - <name>
          - <item>
            <part value="US Wound Registry"/>
          </item>
        </name>
      </representedResponsibleOrganization>
    </responsibleParty>
  </author>
  - <custodian>
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      - <representedResponsibleOrganization classCode="ORG" determinerCode="INSTANCE">

```



Major Barrier: Vendors charge high prices for eCQM installation

- * This barrier will fall on January 1, 2018
- * When EHR vendors have to meet the 2015 certification standard to have “Open API”
- * This will allow the use of “apps within the EHR
- * Vendors can re-purpose the coding for eCQMs and turn them into apps that can fit into any EHR!
- * If CMS delays MACRA implementation until January 2018, a major technological barrier to the use of QCDRs will be overcome
- * This will obviate the need for interfaces, etc.

Will MIPS Incentivize?

Proposed Quality Reporting in MIPS is easy and irrelevant

1. Participation in a QCDR counts as a **Clinical Practice Improvement Activity** (15%)
 - * Sorry, the category is only 15%
2. Reporting Quality measures through a **QCDR** earns “bonus points” for Quality (50%)
 - * Sorry. No QCDR measures are in the list of accepted measures within MACRA
3. There are “bonus points” for **appropriate use and outcome measures**.
 - * Sorry, but these are difficult measures to PASS, vendors don't want to install them, and EPs easily pass 6 PQRS without them.

Will MIPS Incentivize?

Proposed Quality Reporting in MIPS is easy and irrelevant



Under MIPS, playing at this Quality level
is rewarded the same as . .



Playing at this Quality level. . .

What mechanisms can CMS support to generate an improved evidence base and improve care in VLUs?

- * Participating in the venous QCDR has created a mountain of structured data on VLUs that *could* improve the evidence base and care of venous patients
 - * Clinicians need to see REAL BENEFIT to QCDR participation since barriers are high. MIPS doesn't provide clear benefit.
- 1. CMS could support the reporting of existing venous QCDR measures in MIPS
- 2. CMS could link reimbursement for procedures to quality reporting in CMS recognized registries
- 3. Tell PCORI that these are “national healthcare priorities” and let NIH know that it is possible to do CER from registry data