Developing the foundation for assessment of Devices used for Acute Ischemic Stroke Interventions (DAISI) using a Coordinated Registry Network

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INTRODUCTION

Stroke is the leading cause of disability with treatment costs exceeding $46 billion between 2014 and 2015 in the USA alone.1 2 Every year, approximately 795,000 Americans suffer a new or recurrent stroke resulting in nearly 140,000 deaths, with 87% being ischemic strokes.3 Device-assisted interventions, such as endovascular mechanical thrombectomy, can be used for the emergent treatment of acute ischemic stroke. The comprehensive assessment of safety and effectiveness of device-assisted treatments is complicated by several factors, including complex and unique neurovascular anatomy, the timing of stroke presentations, and variable tissue tolerance to ischemia.

Real-world data (RWD) collected during routine medical care of patients presenting with acute ischemic stroke may be used to develop real-world evidence (RWE) to help evaluate the safety and effectiveness of device-assisted treatments. The generated RWE may support postmarket surveillance requirements, identify potential adverse events, and perhaps guide regulatory decisions. For these reasons, the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA) recognizes the potential value of RWE and its use in the course of clinical and regulatory decision-making when appropriate.3 Coordinated Registry Networks (CRNs) allow for the systematic aggregation of high-quality RWD which can in turn be analyzed, potentially leading to relevant and reliable evidence for the evaluation of medical devices.4 5

Prompted by participation in two public meetings in late 2015, FDA Public Meeting on Acute Ischemic Stroke and the Stroke Treatment Academic Industry Roundtable, the FDA began to consider initiating a registry to advance acute ischemic stroke clinical trials and, where appropriate, to capture data necessary to support regulatory, reimbursement, coverage, and physician decision-making. On February 2, 2017, the FDA held a Public Workshop on a CRN for Devices used for Acute Ischemic Stroke Interventions (DAISI-CRN). The purpose for this workshop was to obtain initial public stakeholders’ input and plan for future collaboration. On November 9, 2017, a multistakeholder group convened to launch the DAISI initiative. The mission of the DAISI initiative is to establish a CRN using RWE generated in the clinical care domain by patients, physicians, providers, and payers, for the purposes of enhancing regulatory and clinical decision-making, improving healthcare, and supporting the development of innovative devices to treat acute ischemic stroke. This CRN will use national and international databases to capture information from patient encounters with medical devices used to treat acute ischemic stroke using common data elements (CDEs) related to patient characteristics, medical history, the procedure, preoperative and postoperative imaging, treatment devices, technical outcomes, and clinical follow-up needed in the CRN for the assessment of successful revascularization using endovascular mechanical thrombectomy devices.

METHODS

Stakeholders from the FDA, physician specialty societies, industry, and academia convened on November 9, 2017 at the FDA White Oak Campus to assess the current
data landscape focused on acute ischemic stroke thrombectomy and identify gaps that the DAISI-CRN would address. The group of stakeholders was then organized into a governance council. The governance council was tasked with overseeing the coordination of data collection and use across data sources. During governance council meetings a quorum for decision-making was defined as having >50% of representatives present. Once a quorum was achieved decisions were made by majority vote. The governance council was led by three clinical co-chairs and a co-chair representing the FDA (online supplemental file 1). These co-chairs were charged with establishing a regular meeting schedule and leading discussions on CDE along with FDA CDRH staff. Stakeholders participated in discussions from their perspectives and provided comments, recommendations, and concerns regarding the CDE. Infrastructure support was provided by the Medical Device Epidemiology Network Science and Infrastructure Center at Cornell University.

Stakeholders identified potential CDE among multiple data sources within the clinical space including: the National Cardiovascular Data Registry - Peripheral Vascular Intervention registry,6 American Heart Association Get with the Guidelines,7 Society for Vascular Surgery-Vascular Quality Initiative,8 NeuroVascular Quality Initiative Quality Outcomes Database,9 Paul Coverdell National Acute Stroke Registry,10 Interventional Stroke Therapy Outcomes Registry,11 and StrokeNet.12 After identifying appropriate data sources, the council verified that specified CRN data elements aligned with the National Institutes of Health (NIH) core data elements and definitions. The co-chairs noted that while a number of data elements are captured in the various data sources it would be crucial to limit the number of identified CDE in order to reduce the burden of data collection and minimize the likelihood of missing or inaccurate data. CDEs were prioritized based on those that could be automatically captured from electronic medical records, imaging reports and other data sources such as the unique device identifier (UDI) of a medical device. Each CDE was accompanied by an agreed-upon definition and format (eg, kg vs lbs.). To achieve consensus on using core minimum data from existing registries, DAISI-CRN used a pragmatic process for data inclusion and harmonization used also in other CRNs.13 14

On May 31, 2018, stakeholders convened for the second annual meeting where the identified CDEs were further discussed. The joint group reviewed a draft proposed CDE and incorporated final agreed-upon revisions. On March 14, 2019 at the third annual meeting, the CDE set was finalized by the governance council and consensus was reached with respect to data elements, definitions, structure, and response fields. In the future, DAISI-CRN will use the CRN maturity framework as a guidance.15

RESULTS

Overview

The DAISI governance council consists of various stakeholders including the FDA, CMS, various physician specialty societies, and industry (online supplemental file 1). During the first annual meeting, the initial list of data elements was narrowed down to 233 CDEs. The finalized CDEs were grouped in the following categories:1 patient characteristics with 13 CDEs;2 medical history with 14 CDEs;3 procedural characteristics with 36 CDEs;4 procedure characteristics with 102 CDEs;5 postprocedural characteristics with 29 CDEs;6 imaging with 3 CDEs;7 and follow-up with 36 CDEs. The CDEs are summarized in online supplemental appendix 2.

Patient characteristics

For patient characteristics there was consensus on capturing patient demographic information such as age, gender, and living status. Further details of the CDE captured in relation to a patient’s medical history are summarized in online supplemental appendix 2.

Medical history

There was consensus on capturing comorbidities associated with acute ischemic stroke such as diabetes, hypertension, and/or coronary artery disease. Additionally, there was consensus on collecting data elements from a patient’s past medical and surgical history related to the neurovascular system such as prior cardiovascular disease or stroke and brain, cardiac, or vascular surgery. The governance council agreed that surgery occurring within the past 30 days should be captured. Both patient-specific characteristics and medical history CDEs can be used to determine if any of the identified elements may predispose to greater risk of acute ischemic stroke and allow risk stratification or adjustment in the outcome analyses of devices for endovascular stroke intervention.

Preprocedural characteristics

There was consensus on capturing visit information such as patient admission date and visit code including emergency department (ER), patient hospital and follow-up clinical visits. Consensus was achieved for collecting preprocedural vital signs, laboratory values and preprocedural medications including blood pressure, coagulation times, hemoglobin, creatinine and glucose levels, and current antiplatelet/anticoagulation utilization. There was consensus on capturing specific clinical stroke-related data prior to the procedure such as the patient’s NIH Stroke Scale/Score (NIHSS), presentation times, and intravenous tissue plasminogen activator utilization.

Procedure characteristics

The governance council achieved consensus on capturing procedure information such as the date of procedure, the primary physician performing the
procedure, as well as Medicare health insurance claim number. It was agreed that specific procedural data should be captured such as initial vascular site of occlusion, types of thrombectomy devices (including UDI if available), number of passes, final expanded Thrombolysis in Cerebral Infarction Reperfusion Scores, adjunctive medical or endovascular interventions (angioplasty/stenting), and procedural complications.

**Postprocedure characteristics**

There was consensus among the governance that general postprocedure hospital stay data such as discharge date and discharge status should be collected. Additionally, medical data gathered during the postprocedure stay should be collected, such as the patients’ NIHSS at discharge and any complications of the procedure. The NIHSS score postprocedure can then be used with the NIHSS collected preprocedure to calculate the NIHSS change to evaluate efficacy postprocedure.

**Imaging**

There was consensus on including CDEs derived from the preoperative and postoperative brain and head/neck imaging including CT, CT angiography, CT perfusion, MRI, MR angiography, MR perfusion, and conventional cerebral angiography images. These data elements would provide imaging-based assessment of core infarct volumes or ischemic penumbra volumes, and enable post-thrombectomy assessment of reperfusion efficacy/stability, intracranial hemorrhage complications, and final infarct burden.

**Follow-up**

There was consensus on including outcome information about the patient such as their living status, date of death, and cause of death (if applicable). Consensus was achieved regarding various clinical outcome metrics at 30 days, 90 days, and 1 year including the patient’s NIHSS, modified Rankin Score, recurrent strokes, and hospital readmissions.

**DISCUSSION**

The advantage of using CRN in regulatory decision-making is of particular interest under circumstances when gold standard, double-blinded RCT are nearly impossible to perform (eg, blinding the patient or providers, randomization of patients presenting with acute ischemic stroke, control population in cerebral vascular anatomy and potential collateral circulation, time of presentation (including time from presentation to thrombectomy as well as patient preferences for interventional vs conservative treatment)).

The DAISI-CRN was developed by multiple stakeholders enabling a robust understanding of the clinical and technological characteristics area and how they can be connected to meet the CRN’s goals. Additionally, the CRN allows for the capture of data elements important for accurate assessment of outcomes and may be useful in future marketing submissions expanding the indication for use for acute ischemic stroke medical devices. Lastly, the CRN makes use of NIH definitions leading to a clear and concise description of the information housed by the CRN.

The governance council selected 234 CDEs, inclusive of a definition and format of each, from the following seven categories: 1 patient characteristics, 2 medical history, 3 preprocedural characteristics, 4 procedure characteristics, 5 postprocedural characteristics, 6 imaging, and 7 follow-up. These CDEs are crucial to the infrastructure of the DAISI-CRN and will enable the registry to use existing data sources, as well as improve RWE generation. Additionally, the inclusion of imaging data enables a unique opportunity for research and technological development as medical imaging data are often the hardest to gather in large quantities. Elements were selected because they already appear in a variety of the identified data pools, which in turn enables a greater level of interoperability within the CRN. Furthermore, the limited number of CDEs decreases the burden on the system and makes interoperability easier to achieve while still providing valuable information.

While the CRN environment offers some advantages, it is important to note its limitations. The number of CDEs are limited in order to enhance efficiency. The governance council prioritized elements that are automatically input into health records. Both aforementioned limits of the CRN mean that potentially valuable data fields acquired by participants may not be incorporated in the CRN’s CDE. There are some limitations to the methodology used in identifying the CDE. Given that the governance council included stakeholders from various backgrounds, trade-offs were required to come to consensus. The identified CDE may also not include the priorities of all included stakeholders due to lack of participation.

The identification of CDE is an important step prior to the linkage of the data sources within a CRN. Once complete the CRN will be able to use the stored RWD to generate RWE which may be used to provide comprehensive assessment of devices over the total product life cycle. The RWE generated by the CRN may be used to inform future clinical and regulatory decision-making.

**Appendix**

**Identified Common Data Elements**

| Patient characteristics (13) | Age at procedure characteristics | Weight (kg) |
|-----------------------------|---------------------------------|-------------|
| Gender                      | Living Status                   |             |
| Race                        | Zip/Postal Code                 |             |
| Primary Insurer             | Ambulatory Status               |             |
| Height (inches)             | Smoking                         |             |
| Identified Common Data Elements | Identified Common Data Elements |
|---------------------------------|--------------------------------|
| **Medical History (14)**        | **Procedure Characteristics (102)** |
| Chronic obstructive pulmonary disease | Procedure Characteristics Date |
| Diabetes                         | Final Pass Stent Ret Dia |
| Dialysis                         | Primary Physician |
| Hypertension                     | Pass 1 Stent Ret Len |
| Atrial Fibrillation              | Assistant |
| Hyperlipidemia                   | Pass 2 Stent Ret Len |
| Prior Congestive Heart Failure   | Medicare Health Insurance Claim Number |
| Pre-Procedural Characteristics (36) | Hypercoagulable State |
| Admit Date                      | Pass 1 Asp Catheter |
| Time at IV tPA Given            | Ipsilateral |
| Time at other IV Thrombolytic   | Contralateral |
| Pre-Stoke Modified Rankin Score (mRS) | Location of Additional Occlusion |
| National Institute of Health Stroke Score | Product Asp Catheter |
| Pre-op Haemoglobin (g/dl)        | Trial Enrollment |
| CT Angiography                   | Final Pass Separator Used |
| Pre-op Haemoglobin (g/L)         | American Society of Anesthesiologists Class |
| MRI                             | Pass 1 Asp Type |
| Creatinine (mg/dl)              | Anaesthesia |
| CT Perfusion                     | Pass 2 Asp Type |
| Creatinine (umol/L)             | Intubated Prior to Angio Suite Arrival |
| Magnetic Resonance Perfusion    | Final Pass Asp Cathet |
| Blood Pressure On Arrival - Systolic | Location of Additional Occlusion |
| CT                              | Side of Additional Occlusion |
| Diastolic                       | Final Pass Asp Cathet |
| Alberta Stroke Programme Early CT Score | Location of Additional Occlusion |
| Glucose                         | Passed Asp Cathet |
| Stroke Onset Witnessed          | Final Pass Asp Cathet |
| Pre-Op American Society of Anesthesiologists Classification | Time at Preceding Asp Cathet |
| Time Last Known Well            | Final Pass Asp Cathet |
| Pre-Op P2Y12 Antagonist         | Time Last Known Well |
| Time at First Emergency Department Arrival | Time Last Known Well |
| Pre-Op Statin                   | Time Last Known Well |
| Time at Second ED Arrival       | Time Last Known Well |
| Pre-Op Chronic Anticoagulant    | Time Last Known Well |
| Time at Most Recent Imaging Done | Time Last Known Well |
| IV Tissue Plasminogen Activator (tPA) Given | Time Last Known Well |
## Identified Common Data Elements

| Category | Data Element | Description |
|----------|--------------|-------------|
| Final Pass | Guide Cath Balloon | ASA Dosage |
| Pass 1 Guide Cath Asp Route | P2Y12 Antagonist Given | P2Y12 Antagonist Dosage |
| Final Pass Guide Cath Asp | Other intraarterial medication (antispasm) | | |
| Pass 1 Inter Cath Asp | Total Fluoro Time | Total Radiation |
| Pass 2 Inter Cath Asp | Contrast Volume | |
| Final Pass Inter Cath Used | Final eTICI Grade | |
| Pass 1 Int Cath Other: Time at Recanalisation | Intra-Procedural Complication | |
| Pass 2 Int Cath Other: | | |
| Final Pass Int Cath Other: | Embolization to Non-target Vessel | |
| Pass 1 Distal Dev Trtmnt App | Location of Vessel Perforation | |
| Pass 2 Distal Dev Trtmnt App | Required Additional Treatment | |
| Final Pass Distal Dev Trtmnt App | Technical Failure | |
| Pass 1 DD Treat App Other | Please Specify: | |
| Pass 2 DD Treat App Other | Procedure Characteristics Time | |
| Final Pass DD Treat App Other | Time to Recanalisation | |
| Pass 1 Stent Retriever | Access artery issues and complications (including but not limited to) | |
| Pass 2 Stent Retriever | Dissection | |
| Final Pass Stent Retriever | Occlusion | |
| Pass 1 Stent Rtrvr Other | Device issues: | |
| Pass 2 Stent Rtrvr Other | Dissection | |
| Final Pass Stent Rtrvr Other | Device failure, breakage, or foreign body embolization | |
| Pass 1 Stent Ret Dia | Device related embol | |
| Pass 2 Stent Ret Dia | Vessel perforation/rupture/extravasation (intracranial) | |

### Post-Procedural Characteristics (29)

| Haemorrhagic Infarction (HI) 1 | Groin Puncture Complication Requiring Intervention | |
| HI2 | Time Point of Occurrence | |

## Identified Common Data Elements

| Category | Data Element | Description |
|----------|--------------|-------------|
| Parenchymal hematoma (PH) 1 | Type Haemorrhagic Transformation | |
| PH2 Type | Haemorrhagic Transformation | Final Infarct Volume defined using imaging type and timepoint |
| Parenchymal hematoma remote from infarcted brain tissue | Final Infarct Volume NA | |
| Intraventricular haemorrhage | Intensive Care Unit Stay | |
| Subarachnoid haemorrhage | Discharge NIHSS | |
| Subdural haemorrhage | Discharge NIHSS NA | |
| Post-Procedural Characteristics (29) | | |
| Haemorrhagic Infarction (HI) 1 | Check All That Apply: | |
| PH2 Type | Haemorrhagic Transformation | |
| Parenchymal hematoma remote from infarcted brain tissue | Final Infarct Volume NA | |
| Intraventricular haemorrhage | Intensive Care Unit Stay | |
| Subarachnoid haemorrhage | Discharge NIHSS | |
| Subdural haemorrhage | Discharge NIHSS NA | |
| Please Specify: | NIHSS Score Change (Timepoint - Pre-Stroke) > 4 | |
| Discharge Date | Suspected Cause of Neurologic Deterioration | |
| Discharge Status | Need for access site arterial repair | |
| Date of Death | Artery Type | |
| Post-Operative Length of Stay | Type of complication | |
| Alive at 24 Hours? | Subsequent complications | |
| 24 Hour National Institute of Health Stroke Score | Retroperitoneal haemorrhage | |
| 24 Hour CT | | |

### Imaging Data (3)

| All Head and Neck CT | All cerebral angiography - Digital Subtraction Angiography | |
| All cerebral angiography - Digital Subtraction Angiography | | |
| All head and Neck Magnetic Resonance-MRI/ Angiography/Perfusion-weighted MRI | | |

### Follow-Up (26)

| Date of Contact | 1 Year NIHSS | |
| Contact By | Re-admission within 1 year | |
| Current Living Status; (Rehab, Nursing Facility, Hospice, Home, Dead) | Antiplatelet or Dual Antiplatelet Therapy type and duration of therapy | |
| Date of Death | Cerebral target (treated) vessel re-occlusion | |
| Cause of Death | Death within 90 days | |
| Current Smoking | Death within 1 year | |
| 30 Day Modified Rankin Score | New cerebral infarct within 30 days | |
| 30 Day National Institute of Health Stroke Score | New cerebral infarct within 90 days | |
Identification of Common Data Elements

| Measure                      | Definition                                                                 |
|------------------------------|-----------------------------------------------------------------------------|
| Re-admission within 30 days  | New cerebral infarct within 1 year                                          |
| 90 Day mRS                  | Discharge Disposition; (Rehab, Nursing Facility, Hospice, Home)             |
| 90 Day NIHSS                 | mRS 2 years                                                                |
| Re-admission within 90 days  | mRS 3 years                                                                |
| 1 Year mRS                   | mRS 5 years                                                                |

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Correction notice

This article has been corrected since it was first published online. Author name has been updated to Sameer A Ansari.

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Contributors

SA, CEB, DSL, DM-D, CP, ASE and ASI contributed to the work described in the manuscript. The initial draft of the manuscript was written by HL. Comments on the draft were then provided by LEG, CEB, MS, ASI, SA, DSL, ASE and DM-D. Direct revisions to the document were provided by LEG, CEB and DSL. HL, with the assistance of DSL, compiled the revisions into the final document.

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Supplemental material

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