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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.[1] 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 tolerability 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 >30% 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] preprocedural 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.[16] Many 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		
	Height (cm)	Quit Smoking Date
	Weight (lbs)	
Medical History (14)	Chronic obstructive pulmonary disease	Prior Coronary Artery Bypass Graft
	Diabetes	Prior Percutaneous Coronary Intervention
	Dialysis	Prior Carotid Endarterectomy/ Carotid Artery Stenting
	Hypertension	Major surgery
	Atrial Fibrillation	Major Brain surgery
	Hyperlipidemia	Major cardiac Procedure Characteristics
	Prior Congestive Heart Failure	Major vascular Procedure Characteristics
Pre-Procedural Characteristics (36)	Admit Date	Time at IV tPA Given
	Visit Code	Other IV Thrombolytic Given
	Transferred From?	Time at other IV Thrombolytic
	CAD Symptoms	Pre-Stroke Modified Rankin Score (mRS)
	Prior Stroke Event	National Institute of Health Stroke Score
	Pre-op Haemoglobin (g/dl)	CT Angiography
	Pre-op Haemoglobin (g/L)	MRI
	Creatinine (mg/dl)	CT Perfusion
	Creatinine (umol/L)	Magnetic Resonance Perfusion
	Blood Pressure On Arrival - Systolic	CT
	Diastolic	Alberta Stroke Programme Early CT Score
	International Normalised Ratio	Core Infarct Volume (DWI Volume)
	Glucose	Stroke Onset Witnessed
	Pre-Op American Society of Anesthesiologists Physical Status Classification	Time Last Known Well
	Pre-Op P2Y12 Antagonist	Time at First Emergency Department Arrival
	Pre-Op Statin	Time at Second ED Arrival
	Pre-Op Chronic Anticoagulant	Time at Most Recent Imaging Done
	IV Tissue Plasminogen Activator (tPA) Given	Time at Image Interpretation

Identified Common Data Elements		
Procedure Characteristics (102)	Procedure Characteristics Date	Final Pass Stent Ret Dia
	Primary Physician	Pass 1 Stent Ret Len
	Assistant	Pass 2 Stent Ret Len
	Medicare Health Insurance Claim Number	Final Pass Stent Ret Len
	Hypercoagulable State	Pass 1 Asp Catheter
	Ipsilateral	Pass 2 Asp Catheter
	Contralateral	Final Pass Asp Catheter
	Initial Location of Occlusion	Pass 1 Asp Cath Other
	Side of Occlusion	Pass 2 Asp Cath Other
	Location of Additional Occlusion	Final Pass Asp Cath Other
	Side of Additional Occlusion	Pass 1 Separator Used
	Expanded Thrombolysis In Cerebral Infarction Grade	Pass 2 Separator Used
	Trial Enrollment	Final Pass Separator Used
	American Society of Anesthesiologists Class	Pass 1 Asp Type
	Anaesthesia	Pass 2 Asp Type
	Intubated Prior to Angio Suite Arrival	Final Pass Asp Type
	Time at Arrival to Angio Suite	Additional Treatment
	Time at Groin Puncture	Extra Cranial Angioplasty
	Stroke Onset to Groin Puncture	Side of Extra Cranial Angioplasty
	ED Arrival to Groin Puncture	Extra Cranial Stent
	Number of Passes	Side of Extra Cranial Stent
	Pass 1 Intervention Type	Intra-arterial Thrombolytic Given
	Pass 2 Intervention Type	Thrombolytic Dosage
	Final Pass Intervention Type	IIb/IIIa Inhibitor Given
	Pass 1 Clot Location	Heparin Given
	Pass 2 Clot Location	Total Heparin Units
	Final Pass Clot Location	Activated Clotting Time
	Pass 1 Guide Cath Balloon	Angiomax Given
	Pass 2 Guide Cath Balloon	ASA Given Intra-procedurally

Identified Common Data Elements		
	Final Pass Guide Cath Balloon	ASA Dosage
	Pass 1 Guide Cath Asp	Route
	Pass 2 Guide Cath Asp	P2Y12 Antagonist Given
	Final Pass Guide Cath Asp	P2Y12 Antagonist Dosage
	Pass 1 Inter Cath Asp	Other intraarterial medication (antispasm)
	Pass 2 Inter Cath Asp	Route
	Final Pass Inter Cath Asp	Total Fluoro Time
	Pass 1 Inter Cath Used	Total Radiation
	Pass 2 Inter Cath Used	Contrast Volume
	Final Pass Inter Cath Used	Final eTICI Grade
	Pass 1 Int Cath Other:	Time at Recanalisation
	Pass 2 Int Cath Other:	Intra-Procedural Complication
	Final Pass Int Cath Other:	Embolization to Non-target Vessel
	Pass 1 Distal Dev Trtmt App	Location of Vessel Perforation
	Pass 2 Distal Dev Trtmt App	Required Additional Treatment
	Final Pass Distal Dev Trtmt 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 emboli
	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		
	Parenchymal hematoma (PH) 1 Type Haemorrhagic Transformation	Check All That Apply:
	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
	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 /CT Angiography/CT Perfusion	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

Identified Common Data Elements		
	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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