Request for Information and Preliminary Proposal for The Infectious Diseases Society of America (IDSA) Clinical Data Registry

December 2016

DISCLAIMER: THIS DOCUMENT IS INTENDED TO GATHER INFORMATION ON POTENTIAL STRATEGIC PARTNERS FOR THE INFECTIOUS DISEASES SOCIETY OF AMERICA CLINICAL DATA REGISTRY (CDR) AS PART OF THE DUE DILIGENCE PROCESS. A POTENTIAL PARTNER SHOULD ONLY SUBMIT A RESPONSE IF THEY ARE COMMITTED TO ENGAGE THE INFECTIOUS DISEASES SOCIETY OF AMERICA IN THE CREATION OF A CDR. THIS DOCUMENT AND RESPONSE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE INFECTIOUS DISEASES SOCIETY OF AMERICA AND THE RESPONDER. THE INFECTIOUS DISEASES SOCIETY OF AMERICA RESERVES THE RIGHT TO ENGAGE ONE, NONE, OR MULTIPLE RESPONDERS IN A FORMAL CONTRACTING PROCESS. THE INFECTIOUS DISEASES SOCIETY OF AMERICA WILL USE THE SUBMITTED RESPONSE TO THIS REQUEST AS THE BASIS FOR SUCH CONTRACT.

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1. Introduction

1.1 Explanation of document

This document provides a list of specific information requests to be completed and returned to the Infectious Diseases Society of America (IDSA) to inform its Clinical Data Registry initiative. At any time, the responder is invited to contact IDSA for further clarification or to answer any questions.

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The information submitted by the applicant will be considered confidential and not shared outside of IDSA.

1.2 Scope & Purpose

The scope of the IDSA Clinical Data Registry is to accept patient data from practicing infectious diseases physicians on the care provided to patients with various infectious diseases (see Appendix A). These data will inform the main goals of IDSA Clinical Data Registry, which are to:

1. Provide a unified method for IDSA members to collect and submit Merit-based Incentive Payment System (MIPS) data and Maintenance of Certification (MOC) data to meet quality improvement and regulatory requirements.
2. Demonstrate the value of the infectious disease specialty.
3. Facilitate appropriate secondary uses of the aggregated data (e.g., research, benchmarking).

1.3 Process & Timeline

Responses to this request for preliminary proposal are due by January 13, 2017 by 5 PM EST.

2. Use Cases

The following use cases present the core, high-level functionalities that must be supported by the IDSA Clinical Data Registry in Phase One—collecting and submitting MIPS and MOC data on behalf of users. IDSA recognizes that implementing a registry is a multi-phased project. Phase Two would include these functions as well as the capacity to benchmark performance, facilitate research on the efficacy and value of infectious diseases care, and collect public health surveillance data (e.g. regional antimicrobial resistance data, National Healthcare Safety Network facility-level data).

2.1 Use case: Patient-level quality reporting to meet MIPS and MOC requirements

This use case requires the vendor to a) register participants; b) accept clinical data from physicians on measures used by the CMS MIPS and submit these data to CMS; c) accept clinical data from physicians on measures used by the IDSA for Maintenance of Certification (MOC) and submit these data to oversight organizations; and d) provide reports back to participants rating the quality of their care and actionable data to improve performance on these measures.

Use Case key functions: Population quality reporting to meet MIPS and MOC requirements

Core technical function: Patient-level Quality Reporting for MIPS and MOC	**Request for Information**
Performance Measures are Added to the Clinical Registry as identified	
Measures to include in registry are identified.	• Describe plan to work with IDSA to refine performance measures that could be implemented in the registry. • Discuss vendor capability to expand the number of measures and modules in the future.
Performance measure is converted to a formalized language. Performance measure is encoded into the registry	• Vendor would be responsible for encoding it into the registry for processing.
Physician Signs up and Interacts with the Registry	
Practice/provider creates an account	• Describe process for individual registration and the vendor's capacity to manage several hundred to several thousand users.
Practice adds providers to the account	• Discuss capabilities to report on an entire practice as well as on individual physicians. • Describe the process to group providers and add providers to an existing account.
Patient data are standardized across data systems. Security and privacy standards are in place.	• Describe how vendor will standardize and integrate disparate data sources (e.g. multiple EHRs, practice management systems, lab, and pharmacy systems). • Discuss vendor capability to integrate additional data elements (i.e., patient demographics, severity ratings, patient reported outcomes) from other data sources. • Describe ability to accept data from the top 10 EHR vendors and standardized data submitted to the Clinical Data Registry. • Discuss HIPAA and security measures to protect patient and provider privacy, limiting access to the data to authorized individuals only, etc. o Discuss management of IRB approval
Data are submitted to the registry	• Discuss the process physicians use to submit data manually and by transferring data from their electronic health record and other electronic data sources. To include, process of "data dump" by larger practices • Describe the vendor's process for receiving data and any data quality and integrity processing conducted during and after data submission (validation testing and auditing). Include a discussion as to how increasing data storage requirements (which will incorporate cost data) will be managed over time.

Analysis is run to identify performance rates	• Discuss data analytics used to determine quality score.
Data are submitted to CMS for MIPS participation and to MOC vendor for Maintenance of Certification	• Describe process used transmit data to CMS • Describe operations required at the practice and provider level.
Performance rate is reported to physician and/or practice.	• Describe how the vendor would report to physician, practices (small and large), and health systems o Are providers able to view performance at physician, practice, system levels?
Physician uses the report to improve their performance metric	• Describe how their reports will enable physician to identify groups of patients to target and links to quality improvement resources.

2.2 Use Case: Ad hoc query by the Infectious Diseases Society of America

The use case allows IDSA to query the data for trends and care gaps. IDSA would use these data to direct resources to assist infectious diseases physicians to improve quality and to promote public policy that facilitates the acceleration of this quality improvement. It also allows for secondary uses of the data by researchers and others. IDSA should be able to generate queries that result in both reports and exportable data sets.

Core technical function Ad-hoc query by IDSA	**Request for Information**
Ad hoc Query by IDSA	
IDSA has centralized user interface to construct queries of the aggregate clinical data set	• Describe level of user technical skills required.
A native query is created or a new query is created as a modification of an existing query	• Describe level of user technical skills to create new queries. • Describe the ability to have a library of saved queries.
Query is analyzed for performance issues, trends	• Describe how the system is able to analyze the query for performance characteristics and trends
Ad hoc Query by Participating Physicians	
Physician access to data and ability to generate ad hoc queries	• Describe the accessibility of data for physicians at the point of care and ability to generate reports prior to vendor analysis for MIPS and MOC reporting o Ability to access data in near real time o Physician ability for data analysis
IDSA Access to Reports	

IDSA reviews the performance metrics in aggregate for all participants in the registry and a report is generated on the statistics of the clinical data registry	• Discuss the process IDSA would use for querying and reporting data in aggregate.

3. Additional Information Requests

As part of your submission, please address each of the following points.

1. Provide your key contact's information for all communications about this proposal and the IDSA registry initiative.

2. Provide a brief background of your company and experience in clinical data registries, working with professional associations, and experiencing with obtaining Qualified Clinical Data Registry (QCRD) designation from the Center for Medicare and Medicaid Services (CMS).

3. Discuss how you can support Phase One Use Cases
   a) 2.1: Patient-level quality reporting to meet MIPS and MOC requirements
   b) 2.2: Ad Hoc Query by IDSA

4. Discuss how you can support Phase Two Use Cases
   a) Benchmarking (relative to national average and peers)
   b) Collecting Patient Reported Outcomes (on and off site data collection from patients or their care givers).

5. Describe your unique technologies, methodologies, and resources not mentioned elsewhere, to support the clinical data registry.

6. Discuss current business and financial models.

7. As part of the deployment of the clinical data registry, successively larger pilots are planned. Please discuss anticipated costs to support the following pilots, including vendor ability to host the clinical data registry and be responsible for scaling the hardware, software and technical assistance to support the registry. (Cost data submitted with this RFI will not be used to rank applicants, but rather provide IDSA with an approximate cost range. A formal contracting process would be used to formalize any cost data.)
   a) 50 physicians
   b) 500 physicians
   c) 1,000 physicians
   d) 5,000 physicians

8. Please provide any additional information you believe is relevant to this application and this clinical data registry initiative.

Appendix A:

Merit-based Incentive Payment System (MIPS) Quality Measures

Quality ID	MIPS Quality Measure Title
110	Preventive Care and Screening: Influenza Immunization
111	Pneumonia Vaccination Status for Older Adults
128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up Plan
130	Documentation of Current Medications
160	HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis
205	HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis
226	Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention
338	HIV Viral Load Suppression
340	HIV Medical Visit Frequency
390	Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options
400	One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk
401	Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis
407	Appropriate Treatment of MSSA Bacteremia

IDSA Antimicrobial Stewardship Measure Concepts

Appropriate Use of Anti-MRSA Antibiotics	
Measure Description	
Percentage of patients with empiric anti-MRSA antibiotics discontinued when no resistant *Staphylococcus aureus* isolates are present in sterile site cultures	
Measure Components	
Numerator Statement	Number of denominator eligible patients who have sterile site cultures negative for resistant *Staphylococcus aureus* isolates **AND** discontinuation of intravenous anti-MRSA antibiotic at or before 72-hours of therapy **Definitions:** *Anti-MRSA antibiotic* – For the purposes of this measure, anti-MRSA therapy includes Ceftaroline, Dalbavancin, Daptomycin, Linezolid, Oritavancin, Tedizolid, Telavancin, Tigecycline, Vancomycin *Sterile site* – For the purposes of this measure, sterile sites include blood, cerebrospinal fluid, pleural fluid, pericardial fluid, peritoneal fluid, joint/synovial fluid, bone, internal body sites (lymph node, brain, heart, liver, spleen, vitreous fluid, kidney, pancreas, or ovary). **Numerator Quality-Data Coding Options for Reporting Satisfactorily:** **IV anti-MRSA antibiotic discontinued at or before 72-hours of therapy when**

	sterile site cultures are negative for resistant *Staphylococcus aureus* isolates **Performance Met: GXXXX**: Documentation of discontinuation of IV anti-MRSA antibiotic at or before 72-hours of therapy after sterile site cultures are negative for resistant *Staphylococcus aureus* isolates **<u>OR</u>** **IV anti-MRSA antibiotic <u>NOT</u> discontinued at or before 72-hours of therapy when sterile site cultures are negative for resistant *Staphylococcus aureus* isolates** **Medical Performance Exclusion: GXXXX:** Documentation of medical reasons for not discontinuing IV anti-MRSA antibiotic at or before 72-hours of therapy after sterile site cultures are negative for resistant *Staphylococcus aureus* isolates
Denominator Statement	Inpatients age 18 years or older with the RxNorm Code for Vancomycin, Linezolid, Daptomycin, Tigecycline, Oritavancin, Dalbavancin, Telavancin, Tedizolid, Ceftaroline Injectable Solution
Denominator Exclusion	- Patients with beta-lactam antibiotic allergies - Patients who expire prior to clinical isolate results - Patients who transfer to a different hospital prior to obtaining clinical isolate results - Pediatric specific units and free standing pediatric hospitals

72-hour Review of Antibiotic Therapy for Sepsis	
Measure Description	
Percentage of patients with sepsis who have their empiric antibiotic therapy reviewed at or before 72-hours after empiric antibiotic therapy was initiated	
Measure Components	
Numerator Statement	Number of denominator eligible patients who have evidence that a healthcare provider has reassessed the empiric antibiotic therapy according to available culture data for potential de-escalation at or before 72-hours after empiric antibiotic therapy was initiated **<u>Definitions:</u>** *De-escalation* – For the purposes of this measure, de-escalation is the switch to a new antimicrobial with a narrower spectrum **<u>AND/OR</u>** the withdrawal of one or more antimicrobials empirically prescribed *Medical Decision Making (MDM)* – For the purposes of this measure, MDM is the review and analysis of available blood culture, susceptibility profile, and diagnostic data for potential de-escalation

	<u>Numerator Quality-Data Coding Options for Reporting Satisfactorily:</u> **Empiric antibiotic therapy reassessed at or before 72-hours after empiric antibiotic therapy was initiated** **Performance Met: GXXXX**: Documentation of medical decision making (MDM) for potential de-escalation of empiric antibiotic therapy **<u>OR</u>** **Empiric antibiotic therapy not reassessed at or before 72-hours after empiric antibiotic therapy was initiated** **Medical Performance Exclusion: GXXXX:** Documentation of medical reasons for not reassessing empiric antibiotic therapy at or before 72-hours after initiation of empiric antibiotic therapy for potential de-escalation
Denominator Statement	Inpatients age 18 and over with an ICD-10-CM Principal or Other Diagnosis Code of Sepsis, Severe Sepsis, or Septic Shock
Denominator Exclusion	- Patients who expire before antibiotic therapy can be reviewed (before 24 hours after initiating antibiotic therapy) - Patients who receive palliative care within 48 hours after initiation of antibiotic therapy - Patients who are transferred to another hospital prior to review of antibiotic therapy

<u>Antimicrobial Stewardship Outcomes of Interests</u>

- Survival from Staph aureus bacteremia
- Readmission after treatment of Staph aureus bacteremia
- Survival from neutropenic fever
- Time to initiation of effective antimicrobial therapy
- Duration of antimicrobial therapy
- Infection source identification and control

<u>Wound Care Outcomes of Interests</u>

- Avoidance of hospital admission
- Avoidance of antimicrobial use
- Wound care/closure

Prosthetic Joint Infection Measure Concepts

Measure Title	Numerator	Denominator
Debridement of Prosthetic Joint Infection	Patients who receive debridement	Patients diagnosed with prosthetic joint infection within 30 days of prosthesis implantation OR within 21 days of onset of infectious symptoms
Prosthetic Joint Infection Outcome	Patients who retained prosthetic implant	Patients diagnosed with prosthetic joint infection that received debridement
Appropriate Treatment of Staphylococcal Prosthetic Joint Infection	Patient is administered IV beta-lactam antibiotic with rifampin for at least 14 days but less than 43 days	Patients diagnosed with Staphylococcal prosthetic joint infection that received debridement

Prosthetic Joint Infection Outcomes of Interest

- Outpatient versus Inpatient management (or days of hospitalization) with ID consultation
- Prosthetic joint infection patient's need for chronic suppressive therapy and duration

Clostridium difficile Infection (CDI) Measure Concepts

Measure Title	Numerator	Denominator
Diagnosis of C. diff Infection	Patients who have one unformed stool sample tested for CDI	Patients who have an diarrheal episode during an hospital inpatient stay
Appropriate Treatment of C. diff Infection	Patients who administered oral vancomycin	Patients diagnosed with severe CDI – defined as leukocytosis with white blood cell count greater than 15,000 cells/microL OR an increase in the serum creatinine level to 1.5 times the premorbid level

CDI Outcomes of Interest

- Relapse rate for C. difficile over 6 months
- Avoidance of empiric antibiotic for patients with history of C. diff

Outpatient Parenteral Antimicrobial Therapy (OPAT) Measure Concepts

Measure Title	Measure Description, Specifications
Plan of care documentation at initial visit	**Numerator**: Patient visit in which there is a documented plan of care which includes, at a minimum: • Route of administration including location and type of vascular access • Antimicrobial name, dose, and anticipated duration of therapy • Plans for initial laboratory testing • Plans for next follow-up visit to physician • Documentation of patient education about infection, antimicrobial, and possible adverse effects **Denominator**: All initial patient visits for patients receiving an in-office antimicrobial infusion **Denominator Exclusion**: None **Measure**: Percentage of initial patient visits for patients receiving an in-office antimicrobial infusion in which a plan of care is in place which includes, at a minimum: • Route of administration including location and type of vascular access; • Antimicrobial name, dose, and anticipated duration of therapy • Plans for initial laboratory testing • Plans for next follow-up visit to physician Documentation of patient education about infection, antimicrobial, and possible adverse effects
Maintenance Visit – History	**Numerator**: Patient visits during which the following symptoms (fever, rash, and diarrhea) were assessed and a history was taken which included asking about the following: pain at site, leakage, swelling (site or extremity), and erythema **Denominator**: All patient visits with a physician during which patient received an in-office antimicrobial infusion **Denominator Exclusions**: Documentation of medical reason(s) for not assessing the following symptoms: fever, rash, and diarrhea **Measure**: Percentage of patient visits for patients receiving an in-office antimicrobial infusion during which the following symptoms (fever, rash, and diarrhea) were assessed and a history was taken which included asking about the following: pain at site, leakage, swelling (site or extremity), and erythema
Maintenance Visit – Physical Examination	**Numerator**: Patient visits during which the patient's entrance site for OPAT was inspected for the following: leakage, swelling at site, extremity swelling, erythema, and tenderness *and* the patient's vital signs (temperature, pulse, respirations and blood pressure) were recorded **Denominator**: All patient visits during which patient received an in-office antimicrobial infusion **Denominator Exclusion:** None

	Measure: Percentage of patient visits for patients receiving an in-office antimicrobial infusion the patient's entrance site for OPAT was inspected for the following: leakage, swelling at site, extremity swelling, erythema, and tenderness *and* the patient's vital signs (temperature, pulse, respirations and blood pressure) were recorded
Laboratory Testing – CBC	**Numerator:** Number of calendar weeks during which a CBC panel is reviewed **Denominator:** Calendar weeks for all patients receiving an in-office antimicrobial infusion **Denominator exclusions:** Documentation of medical reason(s) for not reviewing a CBC panel Documentation of patient reason(s) for not reviewing a CBC panel **Measure:** Percentage of calendar weeks for all patients receiving an in-office antimicrobial infusion during which a CBC panel is reviewed
Laboratory Testing – Creatinine or GFR	**Numerator:** Number of calendar weeks during which creatinine or GFR results are reviewed **Denominator:** Calendar weeks for all patients receiving an in-office antimicrobial infusion **Denominator exclusions:** Documentation of medical reason(s) for not reviewing creatinine or GFR results Documentation of patient reason(s) for not reviewing creatinine or GFR results **Measure:** Percentage of calendar weeks for all patients receiving an in-office antimicrobial infusion during which creatinine or GFR results are reviewed

OPAT Outcomes of Interests

- Readmission rate during the course of antimicrobial therapy
- PICC lines saved during the course of antimicrobial therapy (CLABSI or DVT saved)
- Frequency of antimicrobial change during the course of antimicrobial therapy