AJRR American Joint Replacement Registry
Improving Orthopaedic Care Through Data

9400 West Higgins Road, Suite 210
Rosemont, IL 60018-4975

847-292-0530 | fax 847-292-0531 | www.ajrr.net

October 26, 2015

Division of Dockets Management (HFA – 305)
Food and Drug Administration (FDA)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Subject: Medical Device Epidemiology Network Registry Task Force Report; Availability, Web Site Location and Request for Comments.

The American Joint Replacement Registry (AJRR) appreciates the opportunity to review and comment on the Food and Drug Administration (FDA) *Medical Device Epidemiology Network Registry Task Force Report; Availability, Web Site Location and Request for Comments,* published August 25, 2015 in the Federal Register.

The AJRR is the only national hip and knee arthroplasty registry with data collection from all 50 states, and is the largest with over 335,000 procedures, 580 hospitals, and 4,300 surgeons. AJRR collects Level I (patient, hospital, surgeon, and procedure info) and some Level II (patient risk factors, co-morbidities, post-operative complications, and surgical approaches) data on patients, surgeons, medical devices, and revision complications reported under the procedural codes for primary hip and knee arthroplasty. AJRR also has a mechanism in place for orthopaedic professionals to submit their Physician Quality Reporting System (PQRS) data to CMS through our Qualified Clinical Data Registry (QCDR); this is our second year that we received this designation from CMS and the only national orthopaedic registry as such.

We commend the FDA for establishing The Medical Device Registries Task Force (MDRTF) convened through the Medical Device Epidemiology Network Public Private Partnership (MDEpiNet) to focus on the objectives, operations and architecture of a National Device Evaluation System. We have had the opportunity to review the MDRTF report entitled, "Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research" and have the following comments.

Framing the Dialogue on a National Medical Device Evaluation System:
AJRR agrees that flexible strategies for linking and/or extracting data across interoperable registries and non-registry data source whose data complement one another can correct deficiencies in medical device evaluation. Registries play a unique and prominent role in medical device surveillance because they can provide additional detailed information about patients, procedures, and devices not routinely collected by electronic health records (EHR), administrative, or claims data. For this reason, registries have the potential to serve a critical and complementary role in medical device post-market surveillance moving forward.

AJRR supports the MDRTF recommendations for Coordinated Registry Networks (CRN) architecture, and thus for a National System, focused on leveraging existing, self-sustaining electronic resources, such as device registries, electronic health records, administrative data and even social media and personal mobile device sources. CRN structure can potentially enhance both the quality and efficiency of device evaluation from early feasibility and pivotal approval trials to post-market detection and mitigation of safety signals by new, better device designs, and by improved and more informed use of those devices after widespread release and adoption.

AJRR is encouraged to see that pilot projects, specifically Pilot Project I, geared towards orthopaedic procedures are concomitantly delivering disease-/device-specific advances and predicates generalizable to other devices and will best promote small pragmatic steps advancing toward an optimal National Device Evaluation System that helps to ensure that elements, such as partnering, interoperability solutions, structured data sets, and data dictionaries, are identified and catalogued in the public domain to encourage use and re-use of projects.

Existing Medical Device Registry Models and Leverageable Efforts:
AJRR supports the MDRTF recommendations of ubiquitous adoption of both unique device identification (UDI) and patient identification from point of manufacture through end of patient life, and adoption into the health information systems of healthcare enterprises, from point of entry in the supply chain through billing.

Unique patient identification, whether via direct identifiers or via approaches that preserve privacy and resolve issues of informed consent while allowing for accurate patient matching, are critical in order to associate device follow-up and patient outcomes across most systems. UDI will significantly enhance post-market surveillance activities by providing a standard and unambiguous way to document device use in electronic health records, clinical information systems, claims data sources, and registries, potentially making vast amounts of previously untapped clinical information available for accessing the benefits and risks of medical devices and more meaningfully and efficiently linking data sources.

Ideal Characteristics of a Coordinated Registry Network (CRN):
AJRR agrees with the recommendations of MDRTF that registries, EHRs and other sources participating in CRNs should be well characterized as stand-alone entities, as well as by the presence of open architecture elements that could facilitate their integration into the CRN without excessive re-design. An ideal device registry is designed to function not only as a stand-alone entity but also as one element in a landscape of linked registries and other data sources as a strategically CRN.

AJRR supports the five principles (1) Ability to identify medical devices, (2) use of standardized clinical vocabularies, common data elements and outcome definitions (3) Plans for linking across disparate data sources, (4) Creating robust governance, and (5) Developing incentivized sustainability to guide priorities in creating integrated CRN functionality. CRNs can play a critical role in pre-and post-market studies for regulatory decision-making. Leveraging and linking registry infrastructure through sustainable CRNs promotes ongoing device evaluation with more robust accrual of benefit/risk information while reducing costs.

Priority Medical Device Opportunities:
AJRR agrees that priority device areas should be based on (1) The consequences of device failure that are serious for the public health, leading to serious disability or death, (2) Rapid uptake of the device is expected and adverse events are likely to be rare but very serious, (3) The device utilizes new technology whose long-term safety and effectiveness are not well understood, (4) The device has substantial design variations and outlier performance assessment is critical for decision-making, (5) The performance of the device may vary significantly by surgeons and by important patient subgroups, (6) The costs of the device are substantially higher than current therapy, (7) More information is needed to establish best practices for the use of the device, particularly when off-label use is expected and there are substantial legal implications and (8) Prior regulatory review and reported adverse effects identify unanticipated problems.

In the report, MDEpiNet and MDRTF state "There is also a growing number of state registries established in the past few years, including the American Joint Replacement Registry (AJRR), which was launched in 2009." We would like to clarify that AJRR is not a state registry and should not be referenced as such. The AJRR is nationwide registry collecting data in all 50 states, and as such is the largest hip and knee registry in the US. Our registry provides national benchmark data that already compares patterns of device usage, early complications and reoperations, seen from across the country. By collecting and reporting national data the AJRR provides actionable information that can improve care. These data can empower health care organizations to enhance the patient experience and benchmark performance, orthopaedic surgeons to reduce complications and revision rates, device manufacturers to strengthen quality control through improved post-market surveillance, and health plans to effectively manage costs.

Identification and Optimization of Analytical Methodologies for Device Evaluation:
AJRR agrees that there needs to be a linked infrastructure and implementation of structured data sets and standardized definitions supporting poolability that promote an enriched capacity to capture true heterogeneity of device, operator, patient, hospitals, and outcomes and assign them to appropriate domains. By capitalizing on the variation across the CRN through novel methodology, quantitative metrics of the benefits/risks can be constructed for particular patient subgroups or for particular devices.

Perception, Ethical and Related Considerations: Keys to CRN Sustainability:
AJRR supports the MDRTF's recommendations that propose a path forward that shifts data capture across multiple sources from difficult-to-interpret, idiosyncratic heterogeneity to an enriched substrate and reflecting the dimensionality of device use, procedures, and outcomes to inform both clinical and research interests. Leveraging existing electronic registries clearly provides the most robust path forward both in opportunities for ongoing, informative data capture and through dual purposing and partnering, with a minimum of time to productivity, added work beyond existing workflow, new systems development, and cost.

Potential Barriers to Development of a Coordinated Registry Network
The AJRR has several comments and concerns about the implementation process needed to best support an effective CRN system related to hip and knee arthroplasty implants:
1) HIPPA compliance concerns by any and all participating health care entities and registries when attempting to share any kind of patient specific data, which can be essential to

track selected outcomes such as revisions, reoperations, and late complications. Regulatory relief or safe-harbor provisions for entities participating in federally promoted CRN's would be invaluable in encouraging and speeding CRN development.

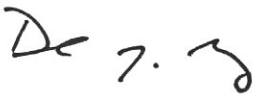
2) Clear designation of these CRN activities as principally quality and safety initiatives, and specifically not formal research activity subject to research related regulations and restrictions such as the ("common rule") This also allows after the fact data sharing and even subsequent research into the data gathered without the need for prior individual patient consent.

3) Likely IT security concerns by potential participants due to the lack of protections against accountability for data breaches even if the breached data is accessed after leaving their control and well after transfer into the hands of a partnering entity involved in the CRN.

A robust discussion of these and other potential barriers would be helpful in allowing a thoughtful approach to solutions via innovative design of the CRN , provision of enabling regulations, and even legislative protections if required for these and similar efforts aimed at improving the public health as it relates to devices.

The AJRR appreciates this opportunity to provide input on the "Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research" report and we look forward to continuing to work with the FDA, MDEpiNet and MDRTF by providing guidance and input on issues applicable to registries, specifically Qualified Clinical Data Registries. If you have any questions regarding our comments, please do not hesitate to contact our Executive Director, Jeffrey P. Knezovich, CAE at (847) 430-5036 or at knezovich@ajrr.net.

Sincerely,



Daniel J. Berry, MD
Chair
American Joint Replacement Registry

cc: Jeffrey P. Knezovich, CAE, Executive Director
David G. Lewallen, MD, Medical Director