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Developing minimum core data structure for the obesity devices Coordinated Registry Network (CRN)

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ABSTRACT

Obesity continues to be a major public health issue, with more than two-thirds of adults in the USA categorized as overweight or obese. Bariatric surgery is effective and yields durable weight loss; however, few qualified candidates choose to undergo surgical treatment. Less-invasive alternatives to bariatric surgery are being developed to bridge the treatment gap. Recognizing the burden of conducting pivotal clinical trials and traditional post-approval studies for medical devices, the Food and Drug Administration (FDA) Center for Devices and Radiological Health has encouraged the development of real-world data content and quality that is sufficient to provide evidence for Total Product Life Cycle medical device evaluation. A key first step is to establish a minimum core data structure that provides a common lexicon for endoscopic obesity devices and its corresponding interoperable data elements. Such a structure would facilitate data capture across existing workflow with a 'coordinated registry network' capability. On July 29, 2016, a workshop entitled, 'GI Coordinated Registry Network: A Case for Obesity Devices' was held at the FDA White Oak Campus by the Medical Device Epidemiology Network public–private partnership and FDA to initiate the work of developing a common lexicon and core data elements in the metabolic device space, which marked the inauguration of the Gastrointestinal Coordinated Registry Network project. Several work groups were subsequently formed to address clinical issues, data quality issues, registry participation, and data sharing.

Summary box

⇒ As obesity is a widespread public health epidemic with increasing prevalence and complex comorbidities, there is a need for innovation in the metabolic device space to expand available treatment options. However, this is challenged by the diversity of patient phenotypes and surgical procedures across medical practitioners, by the heterogeneity of assessments, long-term outcomes and by safety definitions needed to compare devices.

⇒ An infrastructure that harnesses existing data elements emerging from national and international electronic data sources which supports collection of structured, high-quality, real-world data would allow for comparative assessment of device performance across technologies and trials by answering questions of long-term safety, performance, and effectiveness.

⇒ The Gastrointestinal Coordinated Registry Network was established via a public-private partnership between Food and Drug Administration and Medical Device Epidemiology Network to define, develop, and implement a common lexicon and the corresponding interoperable data elements for the surveillance and evaluation of endoscopic obesity and metabolic devices.

INTRODUCTION

Obesity is a public health epidemic affecting 42.4% (2017–2018) of US adults.[1] Due to the chronic nature and wide spectrum of manifestations and comorbidities, obesity may not be amenable to just one treatment. Although the safety of these surgeries has markedly improved over the recent years, there continues to be a certain rate of comorbidities associated with bariatric operations.[2] Meta-analysis studies have shown that the mortality rate 30 days post-surgery is 0.31%, while 17% of patients suffer from complications within 5 years of surgery.[3 4] It is partly due to these reasons that only a small percentage of qualified candidates seek surgical treatment. The need for innovation and expansion of available treatment options is challenged by the heterogeneity of assessments and safety definitions needed to compare devices, rendering some procedures safer and more efficacious. An infrastructure supporting collection of structured, high-quality, real-world data could develop evidence for regulatory decisions more efficiently, thus promoting innovation and decreasing the burden of data collection on clinical practitioners.

As the market for obesity and bariatric surgery devices expands, the need to harness existing data elements emerging from national and international data sources

becomes increasingly paramount. Understanding the importance of creating an interoperable infrastructure for gaining real-world evidence (RWE) while monitoring device evaluation and surveillance across the device life cycle, the U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH), together in a cooperative agreement with the Medical Device Epidemiology Network (MDEpiNet), have put forth the effort of establishing Coordinated Registry Networks (CRNs).[5 6] CRNs are interoperable, comprehensive, and organized data systems that aid in improving patient healthcare via continuous collection of the most relevant data and meaningful outcomes. They are a structured, common lexicon of data elements that adds quality and efficiency across study designs and develops device benefit/risk evidence.

In some device areas, quality registries capturing more than 95% of procedures performed in USA provide a basis for such CRN lexicon.[7 8] In other areas where no such infrastructure yet exists, the precompetitive, collaborative development of a minimum core data structure has been the successful focus of National Evaluation System for health Technology (NEST) Demonstration Programs (which provide proof of concept for scalable approaches to evidence generation across device types and across the total life cycle of a product) such as MDEpiNet's RAPID (Registry Assessment of Peripheral Interventional Devices),[9] and CRNs such as WHT-CRN (Women's Health Technology)[6 10] and SPARED-CRN (The Study of Prostate Ablation Related Energy Devices).[11 12]

Comparably to these predicates, obesity device development is challenged by a diversity of patient phenotypes and of surgical procedures across medical practitioners. To reconcile the prodigious amounts of available data, a forum was held by the FDA and MDEpiNet to define, standardize and implement a set of minimum core data elements, which would allow for the development of a bariatric device evaluation system across different electronic data sources. Stakeholders from a wide range of affiliations were present to participate in discussions regarding the objectives of the meeting. The overall project envisioned a registry which would allow for comparative assessment of performance across technologies and trials. The longitudinal capture of registry data would provide valuable and actionable public health information by answering questions of long-term safety and effectiveness. An obesity CRN would provide relevant information regarding comorbidity occurrence, impact on patient quality of life and incidence outcome, while also addressing key MDEpiNet concepts such as infrastructure integration of real-world data, cost efficiency, and novel analytic methodologies.

Insights through the stages of developing a precompetitive collaboration of academic, regulatory, and industry stakeholders to produce a minimum core data structure report describes the formation of the GI-CRN as a model for leveraging real-world obesity device data.[13]

Table 1 List of stakeholders present at the inaugural obesity-Coordinated Registry Network meeting

Category	Stakeholder
US federal agencies	► United States Food and Drug Administration (FDA) ► National Institutes of Health ► Centers for Medicare & Medicaid Services (CMS) ► Office of the National Coordinator for Health Information Technology (ONC) ► National Library of Medicine (NLM)
Academic institutions	► Harvard ► Duke Clinical Research Institute (DCRI)
Professional societies	► American Society for Metabolic and Bariatric Surgery (ASMBS) ► Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) ► American Gastroenterological Association (AGA)
Clinical research companies	► EPIC Electronic Health Record Software Company
Medical device manufacturers	► Apollo ► Aspire Bariatrics ► Ethicon EndoSurgery ► Boston Scientific ► Reshape Medical ► Endochoice
Independent non-profit, non-governmental organizations	► Patient-Centered Outcomes Research Institute (PCORI)
Patient organizations	► Obesity Action Coalition (OAC) ► 501(c)(3) National Non-profit Organization Dedicated to Advocacy for Persons with obesity

METHODS

On July 29, 2016, the inaugural Gastrointestinal CRN (GI-CRN) think tank meeting was held jointly by the FDA and MDEpiNet public–private partnership at the FDA White Oak Campus to discuss the feasibility, collective interest, and approach to define, develop, and implement a common lexicon and the corresponding interoperable data elements for the surveillance and evaluation of endoscopic obesity and metabolic devices. Table 1 outlines the participating stakeholders in the inaugural meeting; further outreach, however, will continue to expand the list of affiliates and add value to the CRN. Chosen delegates representing stakeholders and patients convened at the summit to discuss the major objectives and potential challenges of the initiative, creating three workgroups to accomplish the necessary technical tasks. Individuals self-identified for participation in the workgroups. None of the working groups had a predetermined number of individuals, and decisions were made following open forum discussions leading to consensus.

RESULTS

Working groups

Clinical registries workgroup

A clinical registries workgroup discussed the needs relevant to obesity device registries. It was agreed that the lack of uniformity in case report forms leads to insufficient data to meet regulatory, reimbursement, quality improvement and accreditation needs. There was discussion of whether all obesity device implantation should be performed within bariatric centers of excellence (COE), as ongoing COE registry participation could facilitate data collection. However, it was recognized that many implantations are and will be performed in centers without COE designations. The group further discussed the challenges of broadening registry and the value of comprehensive data acquisition versus a more minimal core data set approach to combat registry fatigue. Additionally, patient retention and engagement were identified as barriers to collection of longer-term outcomes data. Relevant approaches to address these challenges included widescale use of unique device identifiers (UDIs), along with the use of patient portals for longitudinal patient-based reporting.

Patient-reported outcomes workgroup

A second group, focused on patient-reported outcomes (PROs), discussed several available PRO instruments before recommending the usage of the Impact of Weight on Quality of Life-Lite for its demonstrated efficacy and acceptance among the clinical research community.[14–16] In addition, the group suggested collection of patient preference information, since successful treatment of obesity may positively affect patients' psychology and physiology. Systematic collection of longitudinal PROs and patient preference data via a registry or electronic health records (EHR) could impact our understanding of obesity trajectories and the interactions between patient psychological and behavioral domains. The group envisioned that these approaches could be leveraged to better customize individual treatment and enhance sustained weight loss.

Informatics workgroup

The informatics workgroup reviewed the CRN framework for the acquisition and aggregation of high-quality clinical, administrative, and patient-reported interoperable data from the point of use through longitudinal assessment. Based on lessons learnt from antecedent CRNs, the workgroup discussed the role of the FDA Global Unique Device Identification Database, case report forms and data dictionaries in defining the clinical core data set lexicon. Generic steps include the identification of registry(s) already operational in a specific domain, development of harmonized clinical definitions of the relevant core clinical concepts, technical specification of the core clinical lexicon as computable data elements, and use of master patient and device indices. A relative lack of systematic capture and use of the UDI by healthcare systems was identified as an opportunity to be addressed. Despite the certification requirement for EHR systems for inclusion of a device implant table (https://www.healthit.gov/sites/default/files/2015Ed_CCG_a14-Implantable-device-list.pdf), it was noted that the majority of healthcare enterprises have not implemented the systematic capture and use of the UDI into the processes of care.

DISCUSSION

Why obesity devices?

Obesity is a widespread chronic disease, with increasing prevalence and treatment costs. The extensive array of technologies available within the obesity device space speaks to the complexities of treating obesity. As it is a chronic and often unremitting disease, obesity may not be responsive to just one treatment, but rather to multiple modalities along a spectrum. Other considerations when reviewing an obesity device are comorbidity resolution, alteration of GI anatomy, impact on sequential therapies and patient quality of life, and the risks associated with placement and removal of the devices. Compounding the device complexity perspective, obesity is also managed across many medical specialties.

Benefits of a core clinical lexicon and data set

Historically, a condition of bariatric and metabolic device premarket approval has been the conduct of a post-approval study (PAS) consisting of hundreds of patients followed over 5–10 years. When source data is consistent, the efficiency of device evaluations across the device total product lifecycle can be augmented. However, replacing the PAS model with RWE derived from clinical, transactional, and patient-reported sources requires the ability to access accurate and semantically consistent information.[17] A key goal of this initiative is to specify the core data set for obesity device evaluation. This could address industry concerns regarding the use of RWE versus PAS. RWE could detect unanticipated or rare serious adverse events across broad patient populations or practices, while the data flow could support iterative improvements or novel indications for device use without additional randomized controlled trials. RWE could also identify evidence gaps for healthcare industries and support demonstration of 'reasonable and necessary' utility of obesity devices in support of reimbursement decisions.

Recently, two reports for standardizing procedural outcomes in the UK have been published, namely the Core Outcome Measures in Effectiveness Trials (COMET)[18 19] and the core outcome set (COS) for BARIAtric and metabolic surgery Clinical Trials (BARIACT).[20] The commencing COMET initiative developed as researchers became aware of excluded, selective or inconsistent reporting of critical data in otherwise valid studies. A COS was rationalized to standardize trial reporting and thus minimize reporting errors, while facilitating clear and succinct data presentation. The ensuing BARIACT project employed the usage of a COS specifically for bariatric surgeries. If such surgical COS elements

could be collated with the RWE mobilized through the GI-CRN, the ensuing emergent data could have the potential to exponentially improve patient outcomes and quality of life, while minimizing procedural costs and associated risks.

Evolution of the CRN and the next steps

Phase I: This phase was initiated shortly after the occurrence of the inaugural GI-CRN meeting. The first step consisted of identifying and defining the core concepts necessary to evaluate bariatric and metabolic devices across different electronic data sources. Multiple stakeholders and patient representatives were engaged in Phase I work, which encompassed a thorough systematic review of the peer-reviewed literature, case report forms, and the data collection instruments of the American College of Surgeons Metabolic and Bariatric Surgery Accreditation and Quality Improvement registry. After collating the concepts, stakeholders held several meetings to review comparison reports and develop a consensus recommendation for a final list of core concepts. This list is not fully finalized, but it includes elements such as relevant clinical information, device characteristics and parameters, and endpoints critical to safety and effectiveness evaluations.

Phase II: The second phase will formalize the technical specification of the core concepts as common data elements, and thus create the minimum core data set for device evaluation in this space. The technical specification will include the review and finalization of definitions for each core concept, identification of allowed (permissible) values and associated definitions, meta-data specification to describe format, structure, and other data constraints, and identification of code set bindings to facilitate interoperability. The main objective in this phase is to promote the availability of semantically interoperable data, while also testing for end-to-end data mobility, across health information technology platforms.

Phase III: The final phase will leverage the core data elements as the data infrastructure of the GI-CRN to conduct 'better, faster, cheaper' studies to answer critical questions with the potential to augment clinical science, regulatory knowledge, and patient value. It will benefit from lessons accumulated from the MDEpiNet CRN Learning Community, comprising of national CRNs in 12 clinical areas and four international registry consortia (www.MDEpiNet.net).

CONCLUSION

Obesity is an unrelenting global epidemic, with heterogeneities in surgical devices, professional disciplines, and patient phenotypes hampering the pace of innovation. Development of a set of standardized core data elements characterized for instantiation across electronic health systems will facilitate evidence development for bariatric and metabolic device benefit/risk evaluation. Advancement of the GI-CRN, a collaborative CRN for medical device evidence, promises to support the development of sustained infrastructure to capture the critical data serving multiple patient, governmental, academic, clinical, and industry landscapes, while simultaneously meeting the needs of the FDA and reducing clinician burden related to data capture and management.

Plans are currently under way to reconvene the workgroups and resume efforts towards the development and maturity of the GI-CRN.

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