Generating stronger evidence in limb loss and preservation – the establishment of a US registry

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BACKGROUND: There is a significant global burden of disease associated with limb loss and limb preservation. In the European Union (EU15+), an increasing amputation incidence has been observed in six countries, decreasing incidence in nine countries, and four countries show varying trends between sexes. Despite the significant burden there is a paucity of evidence on effective practices and technologies in this population. Published research studies typically rely on administrative data sources, hospital discharge statistics, or small single-center studies with limited longitudinal follow-up. Although limb loss is a common outcome measure in studies that evaluate effectiveness of diabetes and peripheral arterial disease care, little is known about the effectiveness of practices and technologies following limb loss. A similar medical situation exists in the United States. To advance scientific developments, the Limb Loss and Preservation Registry (LLPR) has been developed.

METHOD: The LLPR is a centralized multi-stakeholder trusted independent data warehouse designed to collect relevant data and perform analysis to improve the quality of care for patients with limb loss and limb preservation. It stores data in the Google Cloud Platform. Data security meets stringent security requirements for holding protected health information. Access to the LLPR is controlled and managed to ensure that only authorized devices or persons have appropriate access in accordance with business needs. All computers that are permanently or intermittently connected to the LLPR have an approved credentials-based access control system. The LLPR is designed to obtain and link data from hospitals, clinicians, and patients to assess the effectiveness of different care approaches and timing of specific care procedures to enhance patient-centered clinical decision-making (Figure 1). Data elements reflect characteristics of the individuals, interventions, and outcomes. The LLPR uses a web-based user-interface which allows a diverse stakeholder community role-based access to standard reports, to develop ad hoc queries and to use embedded analytical business intelligence tools to analyze the data and respond to research questions efficiently and effectively.
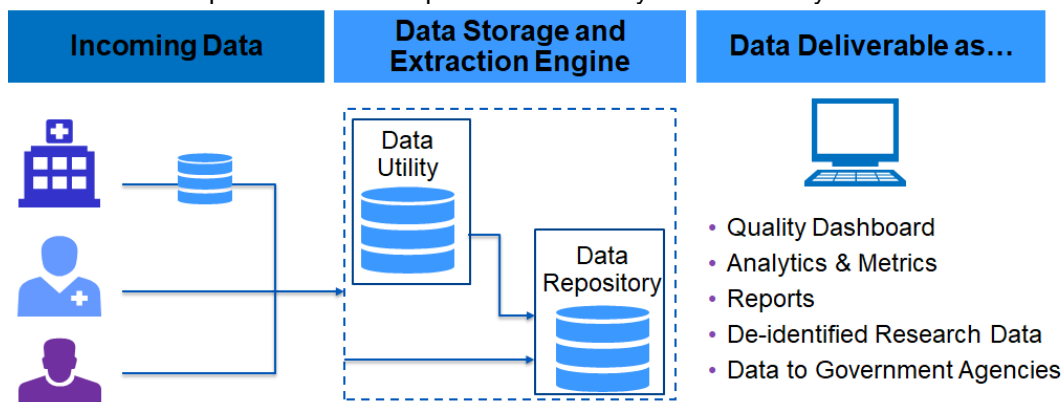

Figure 1. Notional Data Flow Diagram

RESULTS: The LLPR is an organized system designed to make critical data on Limb Loss and Preservation available to scientists, clinical researchers, hospitals, clinics and individual providers, academia, patients, health-related industries, and the federal government. Data collection from hospitals and prosthetic providers has begun. The knowledge gained will inform clinical care decisions. The comprehensive national registry will allow the capture of critical information related to the causes, processes of care, and outcomes of more than 500 amputations per day occurring in the United States. It provides the capability to evaluate disparities in access to care, care processes, and care delivery across geographic, demographic, etiological, and economic sectors.

DISCUSSION AND CONCLUSION: The LLPR is designed to standardize, measure, and report patient outcomes data, support evidence-based decision making, enhance health care delivery, and establish and disseminate best practices. Data collection from individuals with limb loss and preservation of all ages, ranging from pediatrics to geriatrics, treated throughout the nation provides an opportunity to fill data gaps for patient subgroups. Registry data enriches research and education opportunities, has a positive impact on patient outcomes, and potentially reduces long-term care costs across all geographic, demographic, and economic sectors. With appropriate research questions and data acquired through the continuum of care, marked improvement in outcomes can be achieved.