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## Informationist Role: Clinical Data Management in Auditory Research

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### Abstract

Informationists at NYU Health Sciences Libraries (NYUHSL) successfully applied for a NLM supplement to a translational research grant obtained by PIs in the NYU School of Medicine Department of Otolaryngology titled, "Clinical Management of Cochlear Implant Patients with Contralateral Hearing Aids". The grant involves development of evidence-based guidelines for post-implant management of patients with bimodal cochlear implants. The PIs are also seeking to acquire new data sets to merge with grant-generated data. In light of the shifting data requirements, and the potential introduction

of additional datasets, informationists will evaluate and restructure the data model and data entry tool. Report queries will be refined for the new data model and options for a query tool appropriate for users unfamiliar with query languages will be assessed and implemented. The services offered through this supplement represent the deepest and most detailed data management support offered by NYUHSL to date. The components of the supplement are being analyzed as a pilot of a broader offering of these data management services.

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### Introduction

In recent years, NYU Health Sciences Libraries (NYUHSL) has been building a suite of data management services. Through gradual and strategic development, NYUHSL is beginning to pilot data management services across the clinical, research, and education missions of the NYU Langone Medical Center. These services include: teaching research data management to researchers; acting in an advisory capacity on master data management; some aspects of clinical and basic science research data management; and enterprise data governance and data process management. The informationist supplement provided a timely opportunity to focus on several key areas of

these services. Specifically, it supports informationists in performing a deep exploration of the lifecycle management of small clinical research datasets.

NYUHSL applied for and received two *NLM Administrative Supplements for Informationist Services in NIH-funded Research Projects*, both with data management aspects. The other supplement is described by Surkis et. al (2013). The supplement described in this paper is primarily data focused with informationists playing a role throughout the lifecycle of clinical research data management; from data modeling and data collection tools to data query tools and long-term usability of data. The services offered through this supplement represent the most

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in-depth data management support offered by NYUHSL to a single research project to date. The components of the supplement are being analyzed as a pilot of a broader offering of these data management services. There are two differentiating characteristics of the work in this supplement as compared to typical data management service offerings by NYUHSL. First, a deep understanding of the core grant subject matter is critical to success, and second, although a handful of library staff have the skills to offer fairly sophisticated data support including data modeling and query building, this is not typically offered by the library. This paper will review the parent grant's specific aims as they pertain to the supplement, the specific aims of the supplement, and how the NYUHSL hopes to leverage this work to generate interest in its expanding data management services.

### **Parent Grant**

The NLM informationist supplement described here is for the *National Institute on Deafness and Other Communication Disorders* grant titled, "Clinical Management of Cochlear Implant Patients with Contralateral Hearing Aids." The principal investigators are Dr. Mario Svirsky and Dr. Arlene Neuman. Cochlear implants (CIs) are devices that replace the sense of hearing with electronic means. There is a new phenomenon of a rapidly growing number of "bimodal" patients – people who hear using a cochlear implant in one ear and a conventional hearing aid in the other ear. These patients' sense of hearing is derived from two different forms of sound input: The CI delivers an electrical signal to implanted electrodes that directly stimulate the auditory nerve of a deaf ear, and the hearing aid delivers an acoustic signal to an ear that has residual hearing. Even though "bimodal" patients are quickly becoming a majority among CI users, very little is known about how these patients should be managed clinically. Current clinical practice usually entails the separate fitting of each device by a different audiologist,

using methods that are normally employed for standalone devices. This paradigm is based more on historical circumstances than on evidence of its effectiveness. The goal of the parent grant is to develop data-based tools that will allow clinicians to optimize speech perception by better coordinating the fitting of the hearing aid and the cochlear implant, and improving post-implantation follow-up (Svirsky et. al. 2012). The specific aims of the parent grant are:

- 1) To develop guidelines that will help clinicians select an appropriate hearing aid bandwidth for bimodal patients as a function of their residual hearing.
- 2) To develop a flowchart with recommendations concerning which frequency allocation table should be used in the cochlear implant of bimodal patients as a function of their residual hearing.
- 3) To develop guidelines for the post implant follow up of bimodal patients including recommendations for the frequency of evaluation and conditions, tasks, and tests to be used.

Underlying each specific aim is the need for extensive collection and analysis of the data that will support decisions about best practices for audiological management of bimodal patients. The integration of a team of informationists will introduce improvements in the data structure and analysis tools, thus significantly advancing investigators' ability to make data-driven decisions and fulfill the grant's specific aims.

### **Need for Informationists**

A relatively simple data management plan was sufficient to support the initial scope of the grant. The research data was kept in a Microsoft Access database with spreadsheets for more transient data such as contact details of potential subjects. When the database was created, a library of core queries was built and others were created

manually as needed.

Over the course of the grant, two factors impacted the scope of the data management needs of the researchers. First, the PIs discovered an available dataset at the University of São Paulo that may be of unique interest because the hearing aids and cochlear implants were fit and adjusted by the same group of audiologists. The PIs are also seeking additional existing datasets that may contain relevant information, from several cochlear implant clinics overseas. By combining the datasets, the investigators hope to identify strong patterns, as well as to determine whether the patterns already identified are supported and reinforced by the independently generated data set. Second, the data elements being collected by the researchers had to expand to include the changing parameters of CI and hearing aid use in patients over time.

The Microsoft Access database that was developed early in the research process was unable to support either additional datasets or the expanded data elements. These changes necessitated expanding the scope of the data management plan. Furthermore, given the problems that had already been encountered, researchers saw the need to build a data model that could support expansion of future data needs.

### **Supplement Proposal**

The first specific aim of the supplement is *to evaluate and restructure the data model, database, and data entry tool used for data collection to allow for more comprehensive collection of data from disparate sources*. A number of the parameters of the original data model need to be changed to meet the current data requirements, including the incorporation of additional datasets as described above. Additionally, there is a significant need to create tools that can run queries across the entire dataset and better support analysis of bimodal patient data. These needs require a unified data model, and so

necessitate a significant redesign of the database.

In addition to the data modeling requirements, the software currently being used is outdated and insufficient to meet the needs of the PIs. Included in the supplement scope is a platform migration to a more sustainable database tool that offers the access controls necessary for clinical research, flexibility with the data model, and a clear user interface for data entry.

Finally, the model should attempt to be scalable to meet future needs. Although it is impossible to allow for every eventuality, a strong data model should be easily extensible to meet additional needs that may arise. The ultimate goal is for the researchers to be empowered to move forward without repeatedly needing extensive data work.

The second specific aim of the supplement is *to refine existing reporting queries to address changes to the data structure and to create new queries to address new parameters*. Due to the changes in the data needs, the original queries no longer fulfill the analysis requirements for the study and do not query the entire dataset. With the redesign of the data model, the original queries will be rewritten to cover the entire dataset and additional queries developed to support new study requirements.

The third specific aim is *to develop a tool that allows users unfamiliar with query languages or the specific database to search and report on data*. As long-term studies progress, there is often a need to perform new kinds of analyses on the data. Ideally, the researchers are able to create and execute most queries without soliciting expert help. In anticipation of these needs, the tool (s) chosen or created for the redesign must allow for simple query creation so the PIs can independently query the data.

In addition to the data modeling, queries, and tool migration, the informationists will

create extensive documentation of the work to support continued use and adaptation of the tools. Clear documentation of the data and query logic are critical in this type of data management service to create a more self-sufficient research team.

## Evaluation

Formative assessment techniques are integrated into the work plan for each of the specific aims to evaluate the progress, success, and impact of the informationists' work. Success is defined as the meeting of requirements gathered at the outset of the project to the satisfaction of the PIs. Usability testing of the input mechanisms before and after the work will assess the improvements in the new interface. Evaluation of the revised data model will be through its ability to support the two datasets and all required reports. The informationists will work with the principal investigators to validate the accuracy of the new reports. Throughout the process there will be ongoing discussion and feedback to inform any changes that need to be made. As the process unfolds, potential data management services that can be standardized and added to the current suite of researcher services will be evaluated.

## Progress to Date

After three months, the informationists have met with the investigators and their research team on a number of occasions. Much of the time spent with PIs has been used to understand datasets, workflows, current tools, and analysis needs of the team. The original database has been de-identified and imported into MySQL as an intermediate platform in which to analyze the current queries. The informationists have mapped the existing data structure and are converting the original queries from MS Access to MySQL views.

Next steps include proceeding with the design of a new data model incorporating the original data elements with new elements and documenting the model to allow for fu-

ture expansion. The informationists will simultaneously evaluate other platforms for data entry, management and analysis. One possibility is the institutionally supported instance of *REDCap*, a system recommended for active clinical research data management in small- to medium-sized projects. Important features of the tool include interfaces to set up surveys for data entry and data export tools, which are vital to the future portability of the data. The informationists will evaluate whether the system fits the needs of the researchers.

## Conclusions

The NLM supplement allows informationists to perform a qualitative exploration of various facets of data management as experienced by clinical researchers, and provides the library with a valuable case study for future data management support. It also tests a potential funding model for librarians to perform this type of work.

The data management needs of the grant require sophisticated skills in data modeling and query writing, as well as database development. NYUHSL can provide the necessary skills for the project, but it is unclear whether the library can or should play such a deep role in every project of this nature. If the needs of this research team are representative of the types of data management issues faced by researchers in small teams, then scaling the service at this depth to multiple research projects would require a level of support that NYUHSL is not currently staffed to provide. By going through this process, however, the library can benchmark the needs of the research team and determine what might be an appropriate level of research data management support to offer. It is also an opportunity to demonstrate the types of support the library is capable of providing and will supply an argument for being written into future research grants.

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