



## ***Complex Case Management and New Technology Series*** ***– Pilot on Genomics in Context***

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### **Study Aim**

To understand how patients, providers, employers and affiliates incorporate new technology for complex case management, using genomic information as a real world example among self-funded employer clients and their employees (beneficiaries who receive genomic testing).

### **Our Approach to the Study Design**

As part of CWHP's series on *Complex Case Management and New Technology*, we have proposed an *Exploratory Design* for this study because we are investigating the introduction of new technology in the form of genomic data for which there is little known about its use in complex case management and there are few studies to refer to or rely upon to predict an outcome. The focus is on gaining insights and familiarity with basic details, settings and concerns and generating new ideas and assumptions. This approach can help establish whether a more rigorous study is feasible in the future and under what conditions. Exploratory designs are also used to establish preferred methodologies for gathering information about inputs and outcomes in recently established areas of study.

When new technology is introduced in a field, there are often shifts in strategy and varying approaches to the integration of the technology itself, including how it is communicated, introduced and evaluated. An *Exploratory Design* is flexible and able to address a variety of research questions in real time, changing with the nature of the observed phenomena. Indeed, it is the preferred approach to establish research and evaluation priorities for emerging fields.

There have been some studies to date of how genomic information is utilized or could be utilized more effectively in clinical settings. For example, one study outlined a general diagnostic process for a patient-centric genomic workflow and concluded that the field could benefit from lessons learned in developing technical and infrastructural best practices.<sup>1</sup> At least four stages were outlined for that study including *clinical workup, sequencing and technical processing, analysis and interpretation of results, and follow-up research study*. The study also found that well-informed decision-making was hampered by key difficulties in connecting genomic information with validated clinical markers and other measures. Another case study found similar results in terms of the importance of turning data into useful information while incentivizing data sharing and standards.<sup>2</sup> What many researchers and practitioners in this

genomic space appear to agree upon is the need to improve the communication between patients, caregivers, scientists, clinicians and genomic practitioners.<sup>3</sup>

### **Genomics in the Context of Multimorbidity and Complex Case Management**

Little is known about how employers and other payers approach the potential use of genomic information in improving health outcomes. This study will help outline self-insured company's concerns and interests around the use of genomic information, including its benefits for improved employee health-related outcomes, for employees with complex care needs. Below we outline what is known about patient and provider concerns based on existing research. This proposed study will identify additional concerns from an employer perspective. A glossary of terms will be developed as part of this project to help communicate the various perspectives throughout the project and in the final reports.

#### ***Provider Concerns***

Multimorbidity has been defined elsewhere as the “co-existence of two or more chronic conditions, where one is not necessarily more central than the others”.<sup>4</sup> Health care providers can sometimes focus on one diagnosis as more central than others with implications for care quality. Sometimes patients will have a primary diagnosis associated with a single health care visit and secondary or tertiary diagnoses for conditions that are distinct from the primary diagnosis. For example, an individual may have chronic heart disease and also have kidney disease as well as depression as co-morbid conditions. Patients with multimorbidity often need to see multiple specialists to receive care appropriate to their condition.<sup>5</sup> Patients with multimorbidity present a variety of challenges to the current health care delivery system. Obtaining high quality care at a reasonable cost and in a timely and easily accessible fashion can be difficult for patients with multimorbidity.<sup>6</sup> Because healthcare is divided along specialist lines that represent different body systems, each separate specialty group focuses their primary attention on diagnosing and treating the range of conditions on which they have been trained.<sup>7</sup> Primary care and general internal medicine providers often play the gate-keeping role in both the outpatient and inpatient care settings. If a patient hasn't already received a diagnosis of a particular condition, they will generally see their primary care provider for routine exams or for non-emergent symptoms. The primary care provider will often run a series of lab and other diagnostic tests targeted to particular symptom complaints and determine to which specialist, if any, the patient should be referred.

For this study we are focusing on patients who have already been diagnosed with at least one of the following chronic conditions: diabetes, depression, cancer and a pain-related condition (for which pain medication is prominent). We have a particular interest in understanding multimorbidity and how the patients and providers are able to manage these types of complex cases.

For those with multimorbidity, obtaining care for more than one condition can be difficult for both the patient and the gate-keeping provider. Primary care providers are most often not equipped to care for individuals with multimorbidity over the long term and must rely on referrals to specialists and other providers to obtain needed care. This continues to be a major

challenge in the current health care system. Various structures, roles and systems have been created to try to address some of the difficulties of caring adequately for persons with multimorbidities. One such strategy is the assignment of a case manager or multi-specialty case management team to be responsible for complex cases.

### ***Patient Concerns***

Some patients are concerned about the cost of their healthcare, the quality of the care received and access to ongoing treatment. For patients with multimorbidity these concerns loom even larger and suggest a range of barriers that can be difficult for the patient to overcome.<sup>8</sup> Costs of health care services continue to rise for a variety of reasons and for the patient with multiple conditions, their care costs will often be exponentially higher than the costs of a patient with a single condition. Some of the cost of care is associated with treatment from multiple providers, multiple tests and receipt of multiple therapies or prescriptions depending on the diagnosed conditions.<sup>9</sup> With each additional condition, we can expect the costs of care to the patient to increase. On top of the costs associated with needed care are costs associated with inefficient or needless care. Duplication of services, contradictory lab tests and conflicting medications can all increase the cost of medicine in ways that could be avoided with a more integrated approach to care. Newer technologies, including the genomic information referenced for this study, are being introduced to help navigate complex care needs for patients with chronic conditions, comorbidities and polypharmacy. For the most part, providers are not trained in caring for individuals with multimorbidity and therefore, quality of care measures tend to trend with medical guidelines developed along specialty lines.<sup>10</sup> There is some effort on the part of the DHHS, NCQA, AHRQ, other organizations and researchers to establish guidelines for care of individuals with multimorbidity, but currently the health care delivery system is not organized in a way that will improve overall quality of care for the whole patient, as opposed to quality of care improvements for the specialty care lines influenced by the various diagnoses associated with the patient with multimorbidity.<sup>11,12,13,14</sup>

### ***Quality of Life and Functional Outcomes***

This study will focus on patient-centered outcomes in a commercial population of employees with health care benefits provided partially or fully through their employers (companies self-insured for health benefits). At various levels – society, employers, employees (as patients)– there is an interest in making sure that advances in medical technology result in measurable improvements in quality of life and functional outcomes of relevance to both payors and beneficiaries. Patients are of course concerned about their immediate health care needs and any condition that might be associated with a high risk of death, such as uncontrolled hypertension, will receive attention from both the provider and the patient. Beyond the risk of death are an array of concerns that patients have around overall function and quality of life.<sup>15,16</sup> Patients want to be able to continue functioning at a level they have been used to, whether that is returning to work after a surgery or engaging in normal activity of daily living despite a regimen of treatments for an array of chronic conditions.<sup>17</sup> Indeed, some studies have shown that having comorbidities, as opposed to the underlying disease progression itself, was associated with important quality of life outcomes such as maintaining employment.<sup>18</sup> With a focus on quality of life and functional outcomes comes a different way to approach medicine.

One such way is integrative medicine that seeks to treat the whole person, bringing together teams of specialists, social workers and other providers to diagnosis and treat patients in a more holistic fashion. Certainly complex case management, which we have already mentioned, is aimed at improving results for patients while avoiding duplication and unnecessary services. With an aging population and increasing prevalence of chronic diseases, it becomes even more critical that we focus on longer and healthier working lives. Functional outcomes related to work, therefore, will be part of the patient data collection in light of the commercial population studied.

### ***Implications for Targets of Survey, Interviews and Administrative Data Review***

As noted above, the current health care system is not structured optimally to benefit the patient with multimorbidity. Instead, there is the tendency for care to be duplicative, conflicting or unavailable to the person with multiple chronic conditions. As the population ages and chronic conditions become more prevalent the system will need to change if it is to offer patients better access, cost and quality options.<sup>19,20,21</sup> Key to these systems change will be renewed financing mechanisms to encourage funding of integrative practices and technologies. Additional providers will focus on coordination of care and social support services that acknowledge the importance of quality of life and patient functional measures as important patient-centered outcomes of health care. Patients and their caregivers will also take on greater responsibility for their care, demanding such integrative care practices and technologies. With the right set of people, technology and policy solutions, we might expect to improve treatment, but also to prevent and reduce multi-morbidities and their impact in the future.<sup>22</sup>

Though in its infancy in terms of clinical implementation, there remains enthusiasm for the potential of genomic information to greatly improve our understanding of individual needs and develop personalized health practices.<sup>23</sup> The difficulty at present is this type of genomic information is so new that providers, patients and others are unsure how to utilize the information, what it tells them and how to make treatment decisions based on this new evidence. Companies providing this type of information, whether genetic counselors or other affiliated providers, are often asked by patients and families about caregiver and social support advice, not only about genetic and medical information.<sup>24</sup>

### **Summary of Study Design**

The primary innovation we will be studying is the use of genomic information as part of complex case management.

Many patients for whom additional genomic information might be made available tend to have multiple chronic conditions and exposure to polypharmacy as noted. We will be studying the process of identifying patients, providing genomic information to the patient and/or provider, how that information is used, how the case management is assigned (to one or more parties), clinicians and other affiliate providers such as genomic counselors that are included in the intervention and barriers and opportunities for improved outcomes for both clinicians and patients with a focus on quality of life and work function outcomes in addition to clinical

outcomes. As such, we will be obtaining data through survey, telephone calls and administrative record review to better understand the perspectives, practices and policies currently in play and/or being developed. We will also interview a selection of individuals associated with employers who affiliate with this research effort. The intent of the study is to understand where the process appears to be working well from the perspective of multiple stakeholders and where there are areas for improvement. The results are expected to be useful to the field of practice as well as inform future needed research including novel methodologies that are required for patient-centered research involving complex case management and new technology.

While we will not be testing the accuracy of the genomic information provided, nor will we as researchers participate as part of an intervention, the research project will be gathering data directly from patients and providers and the study complies with Institutional Review Board rules. The [Advarra Institutional Review Board \(IRB\)](#) determined that this research project is exempt from IRB oversight using the Department of Health and Human Services regulations found at 45 CFR 46.104(d)(2 and 4). The IRB also completed the necessary additional limited review considerations as set forth under the Revised Common Rule, 45 CFR 46.104(d). Advarra IRB exempt determination finalized on April 3, 2019, Protocol ID# Pro00033042.

Here we summarize the study design in brief; for additional information please contact the PI, Dr. Kimberly Jinnett, at [kjinnett@tcwhp.org](mailto:kjinnett@tcwhp.org).

**Protocol Design** - We will design protocols for data collection as outlined below. After identifying patients who consent to the survey, we will select a subset of providers treating those patients. We will also gather data from affiliate providers and employer representatives affiliated with this study.

This study will include a series of email surveys and phone interviews with providers, patients, affiliate providers (e.g., lab partners, genetic/genomic counselors, case managers) and employer representatives (e.g., medical director, human resource benefits professionals). A review of administrative records will also be included in this study (e.g., claims and cost data, clinical and management reports).

### **Exploratory Topics**

In addition to the data provided through administrative and clinical records, we will focus survey and interview questions and our analyses on functional health outcomes, work disruption and care coordination including the following topics:

1. Complex case management and new technology, Can the current provider-based system accommodate and effectively use the new genomic technology? If so how? How does case complexity fit it? Are there effective ways to manage complex cases? How does genomic data inform complex case management? Answers will reflect the perspectives of the various stakeholders, not to be confused with rigorous evaluations of “effectiveness”.

2. Telemedicine and geographic location. Is telemedicine utilized more for self-referral or direct-to-consumer testing? How do providers utilize telemedicine if at all? Does the use of telemedicine vary by geography? Are there care deserts represented by the selected sample in terms of high quality specialty care needs and transportation or access issues?
3. Quality of life and work outcomes. What is the patient's work status (employer, leave, disability, not employed). How have their needs affected their work (attendance, performance, work disability)? What are they most concerned about (clinical outcomes, quality of life, etc)? If not currently working, would they want to get back to work? What do they see as barriers?
4. Conditions. This study will focus on individuals with diabetes, depression, cancer, pain or multimorbidity, but not select on these conditions. As an exploratory study we are not able to generalize to a population of individuals with any given condition, but we can compare the different perspectives and experiences of patients and providers with or treating the various conditions and multi-morbidities.
5. Provider & Affiliate Perspectives. *Providers* –We will not ask about specific clinical decisions, but instead ask a set of questions around the provider's general use of genomic information and their experience with utilizing this new information in their practice. *Affiliate Providers*- We want to ensure that the perspectives of genomic counselors, case managers, genomic testing companies, telemedicine providers and any other key providers involved in generating or delivering information are incorporated in the study. In addition to understanding the data and information they use to make decisions, we will ask about their perspectives around complex case management, what is working well and where gaps remain. *Employer Representatives* – For employers who choose to affiliate with this research effort, we will interview a selection of employer representatives around their decision to participate, how they measure success of their employee health investments and their perspectives around their company's employee health needs, particularly as it relates to chronic conditions, multimorbidity and complex case management.

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