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Resource Center for Health Policy

Genetic Services Policy Project Final Report

Appendix C: Case Study of Intermountain Healthcare's Clinical Genetics Institute

Why the Case Study Approach?

The field of genetic services is a relatively new one; some organizations are embracing rapid growth in this area while others are moving more slowly. In such a new and varied field where there is as yet no standard response, it is helpful to use a case study approach to examine clinical integration of genetic services. The primary advantage of this approach is that the smaller unit of analysis allows for an exploration that is more detailed, more specific, and therefore more meaningful. It is also useful in facilitating examination and analysis at the level of the organization. Our purpose is to study the integration of genetic services into clinical settings.

In selecting a site for a case study, we sought organizations that are intentionally integrating genetic services into their clinical pathways. Intermountain Healthcare, located in Salt Lake City, Utah, provides many useful characteristics for a case study. The city itself, and Utah generally, is particularly conducive for such research because of several factors: the strong cultural interest in family history, the availability of an extensive body of medical records linked to family pedigrees, public willingness to participate in biomedical and public health research, investment in biotechnology as an economic base, and the presence of the University of Utah and various commercial enterprises. "Because Utahns tend to have large families and keep extensive genealogy records, they are ideal partners for investigating human genetics" (Eccles Institute of Human Genetics website). In addition, the traditionally low rates of tobacco and alcohol use and relatively homogenous demographics of the population minimize variation of many of environmental and socioeconomic contributors to disease and provide "a much cleaner data set," according to University of Utah instructor Deborah Neklason. "It means [researchers] can more easily separate genetic influences from other, lifestyle-related causes of illness" (Sussingham).

Intermountain Healthcare was selected as the site of the case study largely because it is a leading integrated health care system that is interested in genetics. Intermountain began exploring means of integrating genetic services in 2004, culminating in the creation of the Clinical Genetics Institute (CGI). We chose to use CGI as the basis for a case study in part because of its surrounding conditions and a commitment by top administrators to integrate genetic services in an explicit program. In addition, Intermountain's structure as a payer and provider allows for the study of multiple facets: as the payer and provider, as the payer for other providers, and as the provider for other payers. The fact that Intermountain offers both clinical care and insurance products provides an opportunity to study the integration of genetic services from the perspectives of health care providers, hospital administrators, and payers.

Narrative about Utah and Intermountain

The state of Utah is an interesting outlier in statistical measures, a state in which the population tends to be younger, more educated, and healthier in many regards than the national averages. The population has a higher percentage of Caucasians—in fact, Utahns of northern and western

European ancestry were the population chosen to represent Caucasians in the International HapMap Project (National Human Genome Research Institute, 2006)—a strong cultural interest in genealogy and willingness to participate in research, and widespread economic investment in the life sciences and biotechnology industries. Salt Lake City is home to the state government, a public university, many for-profit businesses and nonprofit organizations, the Church of Jesus Christ of Latter-Day Saints (often referred to as the LDS or Mormon Church), and Intermountain Healthcare. The teachings of the LDS Church—the importance of genealogy and family history, healthy living, education, and volunteering—are reflected in many of these anomalous trends.

While traditionally home to a relatively homogenous citizenry of Caucasian residents, conservative values, and lower than average cost of living and wages, things are starting to change. Immigration, cost-of-living, and salaries are increasing (Key Informant A, 2006), and liberal views are becoming more common in the urban area (Key Informant B, 2006). Salt Lake City, the capital, seems to be changing more quickly than the rest of the state. Divides in political views, coupled with the competing priorities of life sciences, infrastructure development, and education, may lead to tensions in the future over the proper role of genetic services.

The state government is conscious of Utah's relatively high birthrate and how that affects both the recently expanded newborn screening panel and Medicaid budgets. Medicaid finances nearly one-third of the state's births, which is lower than the national average of more than 40 percent (Statehealthfacts.org website). Disproportionate shares of Medicaid enrollees in Utah live in a few outlying communities comprised mainly of members of the Fundamentalist LDS Church. FLDS members often practice plural marriages (polygamy) and family intermarriage. The twin towns of Hildale, Utah, and Colorado City, Arizona, have higher rates of poverty than their state averages: 33 percent of city residents receive food stamps, compared to less than 5 percent in Utah and 7 percent in Arizona (Zoellner, 1998). The cities also have the world's highest incidence of fumarase deficiency, a rare genetic disorder that causes severe mental retardation, which genetics experts attribute to the practice of cousin marriage (Szep, 2007).

There is growing interest in research into birth defects and the genomic contribution to chronic disease; the University of Utah is conducting bench science in this area. In 2006, the U.S. Centers for Disease Control and Prevention awarded a $2 million, five-year grant to a new Intermountain Center of Excellence for Infection Prevention Strategies (INTERCEPT), a partnership between Intermountain Healthcare, University Health Care and the Veterans Affairs Salt Lake City Health Care System, for a joint study on health information technology and infection prevention (University of Utah, 2006).

Intermountain Healthcare, with its companion insurer SelectHealth, is one of the largest health systems in Utah, and one of the top-rated integrated health care systems in the country. Despite occasional concerns about market share and antitrust regulations, the state generally perceives Intermountain in a positive light. Given a growing national interest in genetics in the last decade, Utah's rich and unique genetics-related resources, and an integrated data system, Intermountain Healthcare saw an opportunity to develop genetic services capacities with an emphasis on prevention, clinical utility, and cost-effectiveness.

The Clinical Genetics Institute

Intermountain Healthcare has been working to integrate genetic services into the broader health care delivery system through its Clinical Genetics Institute (CGI). In spring of 2004, several Intermountain executives began discussing the idea of such an institute. The Clinical Genetics Institute was the brainchild of three Intermountain Healthcare physicians and was supported by the administration. Some touted genetics as the "next big thing," while others described it as "the ultimate preventive medicine" (Key Informant C, 2006). Despite an enthusiastic task force at the beginning of the process, within a year one of the three promoters passed away and one retired from active practice. Although the institutional support for CGI remained, the clear vision and focused energy were lost. The administration hired a director with prior experience in genetics clinics, who brought his own vision of how best to integrate genetic services.

CGI's past: During key informant interviews in the summer of 2006, we discovered that there is little consensus on CGI's original purpose and that its role within Intermountain was not clearly articulated in the beginning. One member of the senior leadership team recalled that the purpose of CGI was to do genetic research and discovery to strengthen clinical care programs, and to serve as the broader base of genetics information. Another leader believed CGI was created both to serve as a central genetics resource for Intermountain and to evaluate genetic tests.

CGI in the present: We first interviewed key informants during the summer of 2005. Little was known about the Clinical Genetics Institute, which had only begun a few months earlier. During our expanded follow-up interviews in the summer of 2006, we noted no new large-scale activities. There was, however, the addition of the Adult Genetics Clinic, a monthly clinical diagnosis activity within CGI. We found that, within and outside of Intermountain Healthcare, knowledge of CGI's activities and purpose was limited and often conflicting.

In an attempt to evaluate whether the CGI had a significant impact on clinical services, claims data were also reviewed. Specifically, data were compiled based on CPT codes (service codes) for genetic testing, genetic counseling and consultation for conditions consistent with the clinical case studies used in this project (e.g., breast/ovarian cancer, cystic fibrosis, sickle cell disease and multiple congenital anomalies) over a three year period (calendar years 2004-2007). Analysis of these data revealed no significant changes in service utilization or claims over this time frame. It may be that more time would be necessary to see any service trends and/or these data accurately reflect the changing focus of the expectation of the CGI.

Although most people within Intermountain Healthcare spoke highly of CGI's leadership, few were able to articulate its specific activities, and many outside stakeholders had not heard of CGI. One Intermountain senior manager thought CGI's primary purpose was to evaluate the counseling and payment issues surrounding new genetic tests and to develop protocols for clinical use. The respondent, who did not know any details, thought of CGI as a "system interface" for genetic activities and speculated that it might be working with the oncology program. The respondent believed that CGI's impact lies in helping to surface the future of genetics across the Intermountain system, facilitating genetic counseling in the oncology program, helping people understand the need for guidance regarding new genetic tests, and serving as the impetus for enacting that structure. The staff of CGI saw its role as promoters of genetic services, though the original plan for CGI was to provide critical technology assessment.

When asked whether CGI is meeting expectations, a senior manager responded with uncertainty as to what to expect, noting that things are moving "at a snail's pace" (Key Informant C, 2006). However, the manager also recognized that it can be difficult to get people involved and was pleased with the progress CGI has made so far. Another manager, responding to the same question, answered that CGI seems to be consistent with company expectations but was not personally sure what to expect. Representatives of the affiliated insurer, SelectHealth, seemed to have a more specific idea of CGI's activities, a view that was not echoed by other groups and individuals. They saw a distinction between the types of genetic test analyses performed by CGI and SelectHealth. There is a difference between the payer perspective of cost-effectiveness and the clinical perspective of clinical utility; SelectHealth worked with CGI to align benefit design with clinical needs. SelectHealth representatives described their relationship as "cordial and collaborative" (Key Informant D, 2006). Others with whom we spoke did not seem to know what CGI does. Health plan physicians saw CGI's role as educating physicians once technology assessment decisions were made.

CGI's future: One senior leader envisioned CGI playing a larger clinical and basic research role, performing crosscutting education, and conducting technology assessments in the future. Another manager predicted that CGI's role would be as a collaborator, potentially with the University of Utah or Sorensen Molecular Genealogy Foundation, and would offer education "in a big way" (Key Informant C, 2006).

The three original promoters of CGI envisioned that it would conduct research to guide the policy of Intermountain and SelectHealth in using new genetic tests. The director, however, developed a broader set of activities for CGI that was more in line with his interests and experience; the shift in focus coincided with the center's change in leadership. Without the involvement of two of CGI's original promoters, the driving impetus became less immediate and the focus less clear, leaving CGI staff to figure out their place within the broader organization. As of the 2006 interviews, CGI had not reported to the Board formally and had only talked informally with an immediate supervisor on a somewhat regular basis. The supervisor had a generally positive view of CGI, but did not keep track its actual activities. As in most organizations, this case illustrates a few basic principles: communication is key; commitment of leadership is necessary; and the mission and vision must be clear and consistent.

CGI faces an organizational/structural difficulty because of the fact that most clinical programs at Intermountain are organized vertically, yet CGI is conceptually horizontal, cutting across many programs. Its current strategy is largely to be present, to attend meetings and present ideas. In particular, CGI has recognized the inadequate supply of genetic counseling and has been a champion of additional genetic counselor capacity.

The intent of the case study was to analyze how one organization worked to integrate genetic services into the health care delivery system. By examining both the Clinical Genetics Institute's challenges and opportunities, other organizations will be better able to anticipate potential obstacles, capitalize on opportunities, and differentiate which factors are specific to CGI and which are more universally applicable.

Challenges for the Clinical Genetics Institute

If the Clinical Genetics Institute may be viewed as a fledgling organization (though the Intermountain system itself has been in existence for decades), its staff has faced challenges similar to those of many new initiatives. Such issues include the commitment of leadership, the clarity and consistency of the mission and purpose, organizational structure and funding, communication with key stakeholders, and external factors such as the economy, legislation, and community demographics.

Internal Challenges: Among the primary challenges in a new initiative are to retain leadership support and involvement; to balance limited resources with other initiatives within the organization; to possess the full range of necessary expertise; and to negotiate disagreements with internal and external stakeholders. CGI had a strong start because of the enthusiasm of its proponents and an executive-level decision to support the start-up of CGI. Once the original backers of CGI left Intermountain, however, much of the drive dissipated. The administration did not curtail CGI, but it did not actively support it either, causing (allowing) CGI's staff to fly under the radar and work to create a niche for themselves.

The diminished institutional support for CGI did not necessarily reflect an actual reduction in interest; rather, competing initiatives garnered more attention and fiscal resources. For example, Intermountain invested in a new data system and began construction of a new flagship hospital, both of which diverted significant available funding and administrative resources. The creation of Intermountain's new data system limits the addition of family history information in the current medical record system; this has hindered CGI's plans in delivering genetic services. Additionally, CGI's resources are limited by having a small staff. Though staff members display evident enthusiasm and have relevant experience, their expertise covers only a part of the broad scope of operating a clinical genetics institute within an integrated health care system. If, in accordance with the original vision, CGI were to develop new models of education and outcomes research, it is questionable whether they would have sufficient resources and background to fully develop the research and implement its findings.

Some disagreement exists, both external and internal to Intermountain, regarding the purpose of CGI. Some perceive an overlap between CGI's mission and activities that other groups are already performing. There is also disagreement about whether Intermountain needs increased genetic counseling capacity, and where the additional genetic counselors would be located administratively and physically. The delicate balance of collaboration and competition between Intermountain Healthcare and the University of Utah's medical facilities further complicates this disagreement. The lack of clear purpose and uniform stakeholder understanding hampers efforts.

The Clinical Genetics Institute does not currently have an established, measurable set of outcomes to justify expenditures and make a case for expanded capacity. The units of assessment—number of clinical services, percent increase in patient volume, reports of technology assessments, etc.—are yet to be determined, but will soon be needed to be able to assess its impact and strategically plan for the future.

External Challenges: Other challenges arise outside of the organization's direct control, such as legislative actions, regulatory changes, and the culture of the broader community. CGI and

Intermountain Healthcare have not been immune to these challenges. Intermountain, as the largest provider of health care services and health insurance in the state of Utah, has faced periodic charges of antitrust violations. Although a 2006 legislative task force reported that Intermountain did not use unfair business practices, sensitivity about its market share remains (Argue et al., 2006). Partially in response to those concerns, Intermountain's health care and insurance plans changed their names in 2005: Intermountain Health Care and IHC Health Plans became Intermountain Healthcare and SelectHealth. One of Intermountain's challenges will be to remain cognizant of the external pressures that precipitated the renaming.

Like all health care organizations, Intermountain must operate in a changing regulatory environment. Utah is one of only a few states in the country to require genetic counselor licensure, which creates new opportunities and issues for reimbursement for licensed counselors. The original version of the law required genetic counselors to have graduated from a currently accredited program. This proved problematic, however, for those who attended a program that was accredited at the time of their graduation but has since lost accreditation or ceased operations. The law was later revised to allow for a temporary license provision.

The state legislature voted down a so-called "any willing provider" bill in 2005. Approximately half of all states have "any willing provider" laws. The law typically means that health insurers must accept contracts with any willing health care provider in the geographical service area, as long as the provider is "qualified under state law" and "willing to meet the terms and conditions set forth by the insurer" (National Conference of State Legislatures).

Intermountain's insurance side, SelectHealth, offers three network HMO plans and a fourth preferred provider organization (PPO) plan. The enactment of an "any willing provider" law would have altered the structure and dynamics of SelectHealth's plans by mandating that it open its provider networks to any willing provider.

Finally, CGI is conscious of the opportunities and limitations posed by operating within the bounds of what is culturally acceptable in Utah. Staff personnel remain mindful of the connection between genetic services and reproductive decision-making, as well as the predominantly pro-life culture in the state.

Opportunities for the Clinical Genetics Institute

Internal: The Clinical Genetics Institute has several opportunities, particularly the continued support of an administration that sees CGI as a long-term investment. CGI recently reconstituted its advisory board, creating an opportunity to clarify its mission and define its message. In addition, although the new flagship hospital, heart and lung center, and trauma and critical care facilities compete with CGI for Intermountain's internal resources, they also draw external attention to Intermountain and provide more opportunities for clinical research and integration. There are also opportunities for collaboration with the genetic counselor program at the University of Utah and the state Genetics Advisory Committee.

Another advantage is Intermountain's structure. With clinics across the state and the rise of telemedicine, CGI is well positioned to deliver clinical genetic services and counseling over a broad geographic area. Because Intermountain is an integrated system, there is a seamless

transition from primary care to specialty follow-up care. This may facilitate better integration of genetic services. Intermountain also has mechanisms for integration and provider education that surpass many other organizations. With this system already in place, CGI can widely disseminate its content more easily than if it had to create new educational opportunities.

CGI could serve as an intermediary player, encouraging Intermountain and UU to move from competition to collaboration. One interviewee suggested that CGI could provide guidance regarding insurance coverage decisions for genetic services; currently, if the UU sees an Intermountain patient, SelectHealth generally will not pay for it.

External: Utah state government activities may provide opportunities for the Clinical Genetics Institute. The reconstitution of CGI's governing body coincided with that of the state Genetics Advisory Committee. The activities of the two may provide fodder for discussions and recommendations. Additionally, the requirement for genetic counselor licensure provides opportunities to advance the field of genetic counseling, which is a key component of CGI's work. Licensure allows for the possibility that genetic counselors could bill directly for their services, which may increase reimbursement and attract more genetic counselors to the state. An influx of genetic counselors would increase opportunities for collaborative training and delivery, particularly if genetics becomes an important component in all medical specialty training programs. The resulting billing information may provide data for research into how genetic counseling is used, whether it is cost-effective, and what other effects it may have.

CGI may be in a unique position to create a business case for providing genetic services in general and genetic counseling in particular. Because of the research and clinical practice possibilities, CGI and Intermountain could provide national models for effective genetic services integration.

References

Argue DA, Harris BC, Kneuper RA, Mirrow SM, Gale JM, Berlin WE, Miles JJ. "Competition in Utah Health Care Markets: Report to the Privately Owned Health Care Organization Task Force of the Utah Legislature." Economists Incorporated with Ober | Kaler. Washington D.C. May 5, 2006. http://le.utah.gov/interim/2006/HealthCareReport/Utah_Report.pdf.

Eccles Institute of Human Genetics website. Department of Human Genetics. University of Utah. http://www.genetics.utah.edu/. Retrieved April 5, 2007.

Key Informant A. Private correspondence interview. July 2006.

Key Informant B. Private correspondence interview. July 2006.

Key Informant C. Private correspondence interview. July 2006.

Key Informant D. Private correspondence interview. July 2006.

National Conference of State Legislatures. "Any Willing Provider." Health Policy—Federal Issues. http://www.ncsl.org/statefed/health/AWP.htm. Retrieved April 29, 2008.

National Human Genome Research Institute. "About the International HapMap Project." U.S. National Institutes of Health. Last reviewed: October 2006. Accessed April 16, 2007. http://genome.gov/11511175

Statehealthfacts.org website. "Utah | Health Coverage & Uninsured." http://www.statehealthfacts.org /cgi-bin/healthfacts.cgi?action=profile&area=Utah&category=Health+Coverage+%26+Uninsured. Retrieved March 14, 2007.

Sussingham, Robin. "Utah: A Gold Mine for Genetic Research." Genetic Science Learning Center, University of Utah. Undated. http://learn.genetics.utah.edu/features/utah/. Retrieved April 2, 2007.

Szep, Jason. "Polygamist community faces rare genetic disorder." *Reuters.* June 14, 2007. http://www.reuters.com/article/domesticNews/idUSN0727298120070614?pageNumber=1&virtualBrandChannel=0

University of Utah. "Research to Stem Hospital Infections Bring Together Three Major Utah Health-Care Systems." *University of Utah News Center*. May 8, 2006. http://unews.utah.edu/p/?r=050806-1

Zoellner, Tom. "Polygamy on the Dole; Welfare aids the illegal lifestyle of many families in Utah-Arizona border community; Polygamy Thrives With Taxpayer Funds." *Salt Lake Tribune*. Jun 28, 1998. pg. A.1.

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