GENOMIC DATA WORKGROUP

Issues and Trends
in Electronic Genomic Data Exchange

GENOMICS ISSUE BRIEF | OCTOBER 2015

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INTRODUCTION & PURPOSE

"…the Administration is unveiling details about the Precision Medicine Initiative, a bold new research effort to revolutionize how we improve health and treat disease. Launched with a $215 million investment in the President's 2016 Budget, the Precision Medicine Initiative will pioneer a new model of patient-powered research that promises to accelerate biomedical discoveries and provide clinicians with new tools, knowledge and therapies to select which treatments will work best for which patients."

During the first half of 2015, the Workgroup for Electronic Data Interexchange (WEDI) convened a small group of subject matter experts to discuss challenges and opportunities in genomic information exchange and its impact on existing workflows between key stakeholders. The initial taskforce discussions reviewed the current landscape of clinical genomics and identified some of the key opportunities, challenges, strategies and risks to integrating genomics into care coordination.

Broadly speaking, these issues can be categorized into three domains:

- Data access and integration - how should standardized genomic data be easily retrieved in discrete formats for actionable decision-making, interpretation and reinterpretation.
- Data exchange – how should genomic data be rapidly, safely and securely transmitted between stakeholders (including laboratories, providers, patients and health plans).
- Data governance – how should genomic data be securely stored to protect the privacy and confidentiality of information with robust privacy and consent models.

This paper provides an overview of key issues to enable stakeholder discussion around the standards, protocols, workflow processes and strategies that will be required to access, exchange, store and integrate genomic data, as well as the associated business, clinical, legal, technical and ethical issues that will be encountered within and between healthcare systems, care providers and insurers.

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BACKGROUND

With the recent advancements in genomic sequencing, profiling, testing and phenotyping, the healthcare industry is quickly entering a new era of personalized medicine that will rely upon a more nuanced understanding of the relationship between genetic variants and health, disease, biologic pathways and drug targets. However, the synthesis and interpretation of complex genomic information will require advanced health information technology (health IT) capable of rapidly accessing, exchanging and processing information to fully inform diagnostic, treatment and prevention decisions at the point of care.

Today, a handful of cutting-edge academic medical centers and integrated health systems are deeply involved in genomic research and the application of that research into clinical actions that can be used to improve outcomes and boost drug effectiveness. Similarly, some health plans are beginning to study how to integrate genomic information into advanced risk assessment and care management models.

However, a large gap exists today in building a national infrastructure to support genomic data and to create seamless workflows around care delivery and coordination. This gap is particularly large when evaluated against existing electronic health record (EHR) data collection and functional capabilities and related HIE data exchange capabilities.

The interoperable exchange of electronic clinical data between affiliated and non-affiliated entities has been slow to take hold. While the public and private sectors have moved to adopt and implement EHR systems, health IT solutions vary significantly in their features and capabilities – not to mention their ability to scale beyond basic administrative, documentation, billing, care management and communication features.

Additionally, there is significant variation of data exchange and use within and between organizations. Finally, external regulatory policies such as Health Information Portability and Accountability Act (HIPAA) and state legislation can limit the degree to which data is integrated or communicated – which may become a greater barrier for organizations engaged in multi-state populations. A 2015 survey from WEDI found that the integration of structured and unstructured data from multiple clinical and administrative sources continues to be a significant challenge.

Integration challenges become further magnified with genomic data, which, if captured at all, is generally done so as an unstructured PDF attachment to a medical record and thereby limits the extent to which data can be used in an actionable manner.

Nonetheless, the blending of disparate data is critical to developing advanced clinical decision-support capabilities that can retrieve and synthesize data for clinicians in real-time, and ultimately support population health management.

Recently, the Office of the National Coordinator for Health Information Technology (ONC) has emphasized its renewed commitment to advancing interoperability. However, the industry cannot afford to rely solely upon meeting the short-term goals and requirements of the Meaningful Use EHR Incentive Program, many of which focus heavily on feature functions and document-based exchange of medical records and structured discrete data.

With the recent advancements in genomic sequencing, profiling, testing and phenotyping, the healthcare industry is quickly entering a new era of personalized medicine.

To date, Stage 3 of Meaningful Use has proposed few changes to the family health history requirement of Stage 2 beyond using the information to identify patients that should receive reminders for preventive or follow-up care. However, family health history can and should be used to guide healthcare providers to order appropriate genetic tests and aid with subsequent interpretation of the results.

As currently envisioned, the ONC Roadmap does not sufficiently address the challenges, standards, architecture, or governance associated with the complexity and granularity of genomic data. Given the size and complexity of omic data (e.g. genetic, genomic, exomic, epigenomic, proteomic, microbiomic, etc.), it is likely that document-based storage and exchange is not a feasible long-term approach.

Today, a handful of cutting-edge academic medical centers and integrated health systems are deeply involved in genomic research and the application of that research into clinical actions that can be used to improve outcomes and boost drug effectiveness.

It is therefore paramount to begin engaging stakeholders to discuss the standards, protocols, workflow processes and strategies that will be required to access, exchange, store and integrate genomic data, as well as the associated business, clinical, legal, technical and ethical issues within and between systems as patients move between healthcare systems, care providers and insurers.

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CURRENT STATE OF GENOMIC MEDICINE

Most physicians and genetic specialists currently do not order genomic testing unless a patient presents with a family history, high risk of a condition, existing symptoms of a condition, or a difficult diagnosis – and in most cases, testing only occurs in specialty areas such as oncology and maternal fetal medicine. Test results generally serve to inform a diagnosis or risk assessment, or indicate an appropriate treatment, drug, dosage, or course of action for a complex or rare condition. When the test is ordered for clinical use, a sample is sent to a lab certified by the Clinical Laboratory Improvement Amendments (CLIA) or an entity with equivalent or more stringent standards for analysis.

Administered by the Centers for Medicare & Medicaid Services (CMS), CLIA standards assure accuracy, reliability and timeliness of patient test results for clinical purposes, though it is important to note that CLIA does not currently extend to testing performed under research protocols. Direct-to-consumer services can vary in their adherence to quality standards, though some, such as 23andMe and Color Genomics, have partnered directly with CLIA-certified labs to provide more assurance.

The industry has yet to adopt standardized protocols for applying genomic tests to disease risk assessment, treatment, medication, or epigenetic co-occurrence, creating uncertainty about if and when individuals should be tested – and what course of action to subsequently seek. In light of the current environment, health plans generally restrict coverage of genetic testing to a subset of issues and conditions where there is significant clinical evidence or guidelines.

Because many physicians lack the knowledge, time, or training needed to interpret and apply genomic data to practice, they often rely upon genetic counselors and medical geneticists to 1) help counsel and educate patients about their risk for a genetic variation causing disease in the context of their cultural, personal and familial situation, and 2) walk through test results with the patient and a care team to ensure that appropriate management steps are taken (for example, reviewing screening and surgery options with a patient that has a breast cancer gene mutation, or known pathogenic BRCA variant).

Currently, there are not many genetic specialists; it is estimated that there are approximately 3,000 board-certified genetic counselors in the United States, most of whom work within larger healthcare institutions such as academic medical centers and integrated delivery systems. To date, the use of genetic counselors is not standardized across organizations or settings. Given the limited number of genetic counselors and specialists, it is important to assess practice models and develop additional clinical guidelines to determine best practices to ensure patients and providers can obtain information about the benefits and limitations of genetic testing and receive the support needed to clinically manage patient care.

If clinicians are already having difficulties integrating basic clinical data into the day-to-day workflow, it will be critical to identify how genomic-based care coordination can effectively support care delivery and management without completely overwhelming care teams.

Currently, very few health IT systems are able to effectively exchange, store, or analyze genomic data and/or test results. Most EHR systems have not developed or incorporated modules or interfaces that can fully integrate the sequence data into the workflow.

There is also no consensus on the appropriate storage or repository model to implement. Early adopters of genomic medicine are generally academic medical centers and integrated delivery systems that have built an omic repository to facilitate research and, in some cases,translate findings into clinical practice. However, this approach is not sustainable, much less scalable to the majority of smaller practices, community hospitals and health systems that do not have the resources required for such a model, let alone the ability to collect data.

Given the myriad cultural, operational, administrative, efficiency, safety, security and privacy issues that have arisen over the course of EHR adoption and implementation in the wake of the Meaningful Use program, there is significant cause for concern around the appropriate design and integration of genomic data into practice.

If clinicians are already having difficulties integrating basic clinical data into the day-to-day workflow, it will be critical to identify how genomic-based care coordination can effectively support care delivery and management without completely overwhelming care teams. It is therefore critical to take stock of current activities, initiatives, best practices and challenges across the industry before genomic medicine becomes more widespread.

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GENOMIC DATA ACCESS AND INTEGRATION

A. Data Format

Current EHR systems are generally designed to make documentation and billing more efficient, and to support care management decisions by displaying discrete data and actionable insights across the care continuum. Most of the data stored is structured and discrete (e.g. vital signs/lab test values that can be processed by decision-support rules), unstructured text (e.g. clinician notes, lab reports) or images (e.g. ECG, x-rays, MRIs) that are easy to rapidly retrieve, mine and analyze. The paradigm of genomic data is similar to imaging. Because radiologic images are often too large to compress, only a text report is stored in the EHR database while the images themselves are stored in a picture archiving and communication system (PACS).

The EHR can thus interface with PACS to display the images without having to store them directly or slow down performance. However, the size of genomic data dwarfs the size and granularity of imaging data. A recent study estimated that an EHR averages 375 KB per patient, while a PACS averages 104 MB per patient. In comparison, a genome sequence that identifies 3 to 10 million genetic variants of an individual would require up to 10 GB per person. In other words, a medical image represents around 300 times as much data as its textual report, whereas whole-genome sequencing can be 100 times larger than imaging. The size of omic data can thus make it difficult for information to be rapidly retrieved for analysis and interpretation.

Depending upon which variants of a genome are desired for analysis, high-throughput biotechnology algorithms can generate different types of data for whole-genome sequencing, microarrays for gene expression patterns and sequences and structures of DNA, RNA and protein.

The volume and complexity of the data requires that specialists know which questions and hypotheses should be tested – and how the subsequent results should be analyzed; otherwise, the translated sequence and expression data are unlikely to be actionable.

Until the field matures, it is expected that diverse approaches to accessing, storing, exchanging and formatting genomic data will continue.

B. Data Standards

Unlike traditional lab results that are displayed in direct numeric or binary format, genetic test results are typically presented in a narrative text report that is transmitted via scan, fax or email in a PDF or text format before ultimately being uploaded into an EHR or repository. Generally speaking, this is the only information used by a clinician. On the claims side, a health plan may receive a CPT code indicating that a test has been ordered and/or performed, but the test result(s) will likely not be shared unless they are included in a scanned medical record. The results are often buried in a file rather than presented in a format that is easily searchable and actionable. This also makes

it difficult to analyze data for clinical decision support and future reinterpretation. Until genomic data is provided in standardized, structured and discrete formats that are both human- and machine-readable, value will be limited.

Another challenge in genomic testing is around clinical utility, validity and reliability. Today, tests can often produce results with varying levels of specificity and sensitivity. With an eye to the future, data provenance is important to consider given that clinical laboratories may employ more rigorous methodology and transparent documentation, while the practices of some direct-to-consumer testing companies may not be as clear.

Without more widespread testing and use of standards, it is unclear which terminologies and/or combination of technologies should be implemented. Currently, there are a range of use cases: genetic disorders (ICD codes), clinical genetic and genomic services (CPT codes), genetic test procedures and results (LOINC®), gene ontologies and reference genomes (GO) and disease associations used in genotype-phenotype databases (SNOMED-CT). While the Human Genome Variation Society (HGVS) has advanced this discussion, greater clarity is needed. Similarly, the Clinical Pharmacogenetics Implementation Consortium (CPIC) has helped clarify pharmacogenomics issues by standardizing recommended drug dosage based on genotype and phenotype.

Nonetheless, there is a lack of consensus on how standards should distinguish between a full genome versus a variant and on the extent to which codes and standards should indicate the different layers of data from discrete to summary results. Unlike other clinical laboratory testing, genetic test results must clearly document the methodology of testing employed to facilitate future decisions and reinterpretation. With these issues in mind, the industry needs to accelerate discussions around genomic data standards and identify the subset of elements that should be included as a minimum genomic data set.

HL7 has been working on some of these issues, though interfaces need to be implemented for fully codified and structured data. HL7's newest standard, Fast Healthcare Interoperability Resources (FHIR), includes GeneticObservation, which is a resource under development that will facilitate integration of genetics into clinical application by profiling genetic interpretation results. During taskforce meetings, members discussed current efforts of the IOM Action Collaborative and their DIGITizE initiative to develop a standard for EHR vendors and laboratories to pilot around a pharmacogenomics use case. However, it should be noted that the IOM effort does not extend to how data should be transmitted.

C. Lifespan of Data and Notification

The lifecycle of genomic data is unique to other information typically documented and collected in healthcare for several reasons. Although the human genome remains the same across a patient's lifespan, the sequencing techniques do not. Typical clinical laboratory tests measure parameters with a reference value to produce an interpretation with relevant clinical context. If the understanding of a disease or its causes and indicators change, it can be fairly straightforward to reinterpret longitudinal data and reassess a patient's health.

However, genomic data is different and the science is changing so fast that sequence data may need to be completely reevaluated in the future once methods are further refined for more robust clinical validity and reliability.

This becomes problematic given the nature of genetic testing and is especially true for results that include variants of unknown significance that can be reclassified after a period of time and need to be re-evaluated by a clinician. The size and complexity of the human genome leads many providers to order only an exome sequence (the protein-coding sections of the genome, which are considered to be the most important part of the human genome) or specific variant be tested depending on the clinical scenario. However, in doing so, future reinterpretation is fundamentally limited to the subsection of data that is tested.

On the other hand, if full genome sequencing is ordered, it may raise a host of questions and additional information that a physician and genetic specialist must consider addressing with the patient. Finally, an individual's genomic sequence potentially contains data not just for one person, but rather a large group of people who are biologically related.

Given that relevant information may last several generations and apply to multiple patients, additional consideration must be given to the longitudinal reinterpretation of data and how genomic data from one individual can remain available to subsequent generations of family members. This challenge raises bioethical issues of notification and communication of risk when science has not fully reached consensus on best practices.

D. Interpretation and Clinical Decision Support

It's a common adage that you can't manage what you don't measure. In healthcare, clinicians and care teams monitor a patient's health by collecting data on a host of different indicators. The discrete data can be subsequently measured, tracked and evaluated for information on domains such as health outcomes, medication dosages and physician performance. Clinical decision support (CDS) engines aggregate these data to develop a knowledge or evidence base around which a rules engine is built to support decision-making processes and then suggest appropriate courses of action.

Generally speaking, there are three different paradigms of CDS: active (manual submission of patient data and manual retrieval of knowledge), a semi-active

(automated submission of data and manual retrieval of knowledge) and passive (automated submission of data and automated retrieval of knowledge). Unlike clinical data that can be stored internally, genomic data is generally stored in ancillary systems due to their size. However, given the speed with which the field of genomics is evolving, there is often not enough evidence from functional or comparative studies that can provide sufficiently valid or reliable information.

Until the science matures, genomic decision support will be limited to specific diseases and use cases through a passive model of CDS. Ideally, however, study results and publications would be systematically scanned on a continual basis using the most up-to-date methodsto notify clinical teams of new discoveries.

In today's paradigm of value-based care, population health management, care coordination and risk stratification are key areas of interest for both providers and health plans. Over the past several years, health plans have begun to leverage their experience and expertise in integrating clinical and claims data to build complex models to help stratify patient populations by risk and cost. Using this experience, leading health plans and provider organizations have begun to develop the next generation of analytics based on structured and unstructured clinical data that can be significantly enhanced by the inclusion of robust omic data and interpretation. Genomics has the potential to significantly enhance disease prevention through early risk detection.

Genetic information will offer a significant opportunity to improve impactability models, particularly as advanced techniques integrate other data elements (e.g. patient-generated health data, socioeconomic, behavioral, demographic, or environmental data). As genomic medicine initiatives mature, greater consensus from a legal, clinical and technological perspective is needed on how genetic information is – and should be – collected, utilized and integrated into clinical practice to enhance coordination between health plans and providers and to improve health and care at an individual and population level.

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GENOMIC DATA EXCHANGE

The challenge of making genomic data actionable is two-fold. At one level, most of the information that is exchanged electronically is limited to test results in narrative text files rather than the genome itself coded in structured formats. However, the records are exchanged via fax or email, rather than fully integrated between lab and EHR systems.

Currently, most genetic results are transferred to an EHR by email, fax, or scan – which are the least satisfactory methods in terms of access, computability, interoperability and security. However, depending on the data provenance, the form of exchange may vary slightly. If a genetic test is requested by a clinician, they most likely will only want to view the interpretive report, rather than review the raw data – and oftentimes a genetic counselor may be requested to help explain the findings to a patient and provider. If the test, however, is requested by a consumer to a direct access service, the information delivered may very well be limited to variants indicating risk for specific conditions rather than providing the entire genome.

In the absence of standardization, clinicians may not be able to necessarily use results from direct access services, leading to redundancies if additional testing is requested. Genomic data exchange requires multi-tiered rules of the road to provide modular standards that allow for easily readable documentation, testing and reporting.

Generally speaking, HIE organizations are not set up to support genomic exchange. During taskforce meetings, participants discussed how one large integrated delivery system worked with their state HIE organization to act as a centralized hub for genomic data to stream from their labs and then redirected back out to the health system EHR in a PDF format. Just as it is critical for health information to be accessible in and out of network, so too must genomic data be able to follow a patient across the continuum of care in a safe and secure way.

Although the nature of exchange vastly depends upon the repository model in question, it is unclear how HIE organizations, registries, or other organizations would facilitate the exchange of specific variants or whole genomes through the current pipelines and infrastructure without additional consensus on how genomic information should be documented, accessed, transmitted, displayed, utilized, managed and stored across the continuum.

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GENOMIC DATA GOVERNANCE AND MANAGEMENT

A. Storage

Given the sensitive nature of genomic data, it is critical to store information in a safe and secure way that allows individual data owners to control access.

Unlike other clinical lab/test results in a health record, genomic data storage becomes further complicated by the potential need for reinterpretation of variants of unknown significance and re-sequencing of data using updated technology, making the raw data just as important as its interpretation. However, current compression formats are inadequate for genetic data due to lossless reduction of information and size of the datasets. The practice of comparing variants to a reference genome has become standard, but problems arise when the reference is revised.

There are currently several different models of omic repositories that have varying degrees of storage, governance, interfacing, security and decision support integration. Genomic data stored internally on an EHR system is the most technically advanced and demanding approach. Although changes to genetic variants would be immediately actionable, CDS rules would need to be consistently updated and maintained - not to mention that data would need to be rigorously encrypted. While this approach is straightforward, it could cause all but the most advanced IT infrastructure to significantly slow down performance while processing and analyzing data.

There are models of external warehouses and repositories that require the development of an interface to connect the systems. Genetic data, usually in the form of a variant call file (VCF), could be stored in a repository. As owners and controllers of their own data, healthcare consumers could have the ability to give consent to providers or researchers to access their genetic, genomic and other omic data. Consumer-controlled data-

bases are currently being discussed by the White House Precision Medicine Initiative as a requirement to gain participant trust. There are also models supported by commercial and non-profit organizations that may soon be available.

Genomic data that is clinically relevant should ideally be stored in a single external warehouse or repository that would reduce the burden of storage on EHR performance and enable greater flexibility in accommodating genotype-phenotype analysis and other research queries.

As cloud-computing technology matures, new methodologies such as Hadoop clusters are boosting data storage capacity and analytic processing power by distributing data across a network. In the context of genomics, these advancements are making it easier to store large raw sequence data files (known as FASTQ files) and consolidate structured and unstructured data into a data lake that is more easily accessible.

Compared to internal storage on an EHR, external storage generally allows for more advanced interpretation of the genomic data that can allow for best practice integration into workflow. Currently, many of these external genomic repositories were created and designed for research purposes at a population level. Most of these vendors are now re-focusing their systems to support clinical genetics and genomics.

Given the sensitive nature of genomic data, it is critical to store information in a safe and secure way that allows individual data owners to control access.

The remaining types of repositories are designed for public use. A centralized repository model of large genetic databases and registries (e.g. ClinGen, ClinVar) would allow a more robust CDS engine to develop knowledge and insights over a larger population than one stored on a single proprietary database.

By connecting multiple sites, these centralized repositories could store test results and interpretations that are not yet validated, and upload them into an EHR system once they are determined to be clinically reliable. Another repository could be designed through several modalities, whether through a multi-stakeholder collaborative or a commercial portal. During discussions, the taskforce examined data collection workflows at two large integrated health systems as use case examples.

One organization collects genetic data prior to intake but does not store the information in a centralized location. Similarly, the second organization collects genetic test results and uploads them in PDF format to their EHR, with additional information included as notes.

In looking ahead, the taskforce envisions a modality in which genomic data would be stored in a repository and information would be owned and controlled by patients to allow them the ability to give consent to researchers or providers to access their data.

B. Security

Given the sensitive nature of genomic information, its storage requires fundamentally more robust security, access and privacy controls than other types of clinical data repositories. While healthcare stakeholders employ a variety of security and encryption techniques to protect other types of health data from breaches, hacks and unauthorized access, additional measures are needed for genomic data to be safely and securely transmitted, displayed and stored according to federal HIPAA and Genetic Information Nondiscrimination Act (GINA) statues and/or state confidentiality and protection laws.

C. Privacy

The incorporation of genetic data within an EHR presents a number of health information management and privacy concerns.

The exchange of clinical data is regulated under HIPAA and in some cases further restricted by state law, creating a fragmented environment for exchange. Genetic data might require segregation from other data to prevent disclosure and/or re-identification – however, repositories must also allow data to be re-identified if and when novel genetic discoveries are made and individuals need to be accordingly notified of a new interpretation.

An individual's genomic data contains data not just on one specific patient, but also a large group of people who are biologically related to that individual since many conditions are hereditary. Genetic education and counseling before and after testing is important to ensure that individuals have equitable genomic literacy and access to resources.

There is currently a lack of consensus on a universal legal and policy framework that would standardize repositories' approach to storing and exchanging genetic data among different organizations, stakeholders and states. In addition to privacy, genetic data also introduces complex issues around consent, risk communication and the boundaries of longitudinal responsibility for data reinterpretation for an individual and/or multiple generations.

Given the sensitive nature of genomic information, its storage requires fundamentally more robust security, access and privacy controls than other types of clinical data repositories.

D. Ownership and Consent

Currently, there is no consensus on the appropriate approach to genomic data ownership or a standardized model of consent. However, it is clear that the academic model of opt-in and opt-out will not scale.

In addition to privacy, genetic data also introduces complex issues around consent, risk communication and the boundaries of longitudinal responsibility for data reinterpretation for an individual and/or multiple generations.

Additional layers of complexity must be considered, such as consent for when, how and who can access information at a variant to whole genome level. During discussions, the taskforce highlighted the Platform for Engaging Everybody Responsibly (PEER) as a potential model. Consent management must allow two tiers of control for user permission to 1) view and share information, and 2) specify the genetic datasets to be accessed.

Consent models must also build in capabilities around where, when and why consent stops and delineate between patient autonomy and a clinician's responsibility to provide care. If a genetic test reveals unexpected risk for a condition, there is no clear guideline as to when the patient should be notified or what the obligations of aggressively preventing and treating the condition would be in the absence of additional symptoms or developments.

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LOOKING AHEAD

In the near future, genomic medicine and genetic testing have the potential to fundamentally transform how we understand health and how healthcare is delivered. Nonetheless, greater harmonization and standardization are required before genomics can be successfully integrated into clinical practice at scale.

This brief summarizes some of the nuanced issues that must also be addressed around genomic data - including transmission, privacy controls, security, storage, management, and governance – to support care coordination and collaboration between health plans and providers.

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- ACKNOWLEDGEMENTS -

Adam Scott	-	Aetna
Alanna Kulchak Rahm	-	Geisinger
Alison Martinez	-	Oklahoma Health Care Authority
Devin Jopp	-	WEDI
Grant Wood	-	Intermountain Healthcare
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