HIMSS Analytics

HIMSS Analytics Stage 7 Case Study

National Institutes of Health Clinical Center

Profile

The Clinical Center is the research hospital at the National Institutes of Health (NIH) campus in Bethesda, MD and is the nation's largest hospital devoted entirely to clinical research. Since the hospital's opening in 1953, NIH scientists have worked with volunteer patients to create medical innovations. Clinical Center successes include pioneering the cure of cancerous solid tumors with chemotherapy; the use of nitroglycerin to treat heart attacks; identifying a genetic component in schizophrenia; conducting the first successful replacement of a mitral valve to treat heart disease; and the creation of blood tests to identify both Acquired Immune Deficiency Syndrome (AIDS) and hepatitis.
These and other research concepts pioneered at the Clinical Center have been adopted as standard practice in medical treatment throughout the world.

The Clinical Center has been a leader in the "bench-to-bedside" concept. Its specialized hospital design places patient care units in close proximity to research laboratories. This model supports interaction and collaboration among clinical researchers. The Clinical Center also offers world-class training in clinical research for physicians, dentists, nurses, medical students and other members of the medical research team. This environment, offering access to the most advanced techniques, equipment and ideas, attracts a global network of scientists.
The original Warren G. Magnuson Clinical Center, built in 1953, adjoins the Mark O. Hatfield Clinical Research Center, which opened in 2005. The hospital has 240 inpatient beds, 11 operating rooms, 82 day hospital stations, critical care services and research labs, an ambulatory care research facility and a complex array of imaging services. The Clinical Center is also one of the few facilities in the world with state-of-the-art infrastructure that allows for isolation capabilities and infection control while patients participate in clinical research studies.

Patients at the Clinical Center consent to participate in research studies, also called protocols, and are treated without charge. Admission is selective: only those patients who have a medical condition being studied by NIH Institutes or Centers and who meet the specific inclusion criteria can enroll in the studies. There are currently approximately 1,500 clinical research studies underway at the Clinical Center, including those focused on cancer, infectious diseases, blood disorders, heart disease, lung disease, alcoholism and drug abuse. More than 500,000 patients from all 50 states, and from countries around the world, have participated in clinical research at the Clinical Center.

The Clinical Center began using an electronic medical record in 1976 which was configured to meet the unique needs of the research environment. In 2004, the electronic medical record was upgraded to the current system. Since then, the functionality has continued to expand and extensive integration has been achieved with other clinical and research systems at the NIH. In June 2015, the NIH Clinical Center was certified as HIMSS Analytics Stage 7.

The Challenge

Pharmacogenomics, also referred to as pharmacogenetics (PG), is the science that examines the inherited variations in genes that dictate drug response and toxicity. Knowledge about PG can optimize the use of medications.

Our goal was to implement clinical decision support (CDS) to provide PG information and recommendations to the prescriber at the time of medication ordering. We felt that sufficient information existed about recommendations for drug-gene variation pairs so that obtaining "genetic" information could be considered part of routine clinical care. We first implemented CDS for medications where HLA gene variations predict for severe dermatologic toxicity. In the second phase, CDS was implemented for drugs where Drug Metabolizing Enzymes and Transporters (DMET) gene variations can predict drug dosage, response, or toxicity.

Implementation Overview

We felt that institutional support was critical to the implementation. The Medical Executive Committee and the Director of the Clinical Center enthusiastically supported our program. We formed a Pharmacogenetics Implementation Task Force composed of informaticists, physicians, pharmacists, nurses, pharmacologists, and geneticists to review the clinical information and to make clinical recommendations. These medication-related recommendations need approval from the Pharmacy & Therapeutics (P&T) Committee prior to implementation. The implementation task force has now become a formal subcommittee of the P&T Committee and is co-chaired by a physician and pharmacist.
Medications included in our PG program are configured on order set forms, which allows combining medication and lab tests in one view and also allows clinical decision support (CDS) algorithm to be configured behind the order set form. The CDS first looks for the results of the pharmacogenetic test. If the result is present, the CDS then provides a recommendation specific to the test result and clinical information known about the drug-gene variation pair. If a result is not found, the prescriber can order the pharmacogenetic test directly from the order set form.

We decided on a two-phased approach based on two primary factors. The first phase was to implement CDS for medications where HLA-associated gene variations (i.e. abacavir, allopurinol, carbamazepine) are associated with severe hypersensitivity reactions (i.e. toxic epidermal necrolysis, Stevens-Johnson syndrome). Although these reactions are not common, our institution felt that this was an important medication safety effort and that preventing even one severe reaction was cost-beneficial. Our Department of Transfusion Medicine performs high-resolution DNA-sequencing for HLA gene variants. This allows us to control the name of the test, which is important for data retrieval.
The second phase of the program was to implement CDS for drug-gene variation pairs that are associated with DMET. One example would be mercaptopurine and thiopurine metyltransferase (TPMT) where better initial dose estimates which prevent severe hematologic toxicity can be made by knowing TPMT metabolizer status. Implementation of this phase required identifying a lab that can perform this test according to CLIA regulations and in a cost-efficient manner. The DMET test we use is a chip that can determine over 220 genes and over 1,000 single nucleotide polymorphisms. We needed to devise a method where the results can be transmitted from this outside lab into our EHR in an actionable format to work with our CDS. This effort required a large multidisciplinary team.

The clinical approach for the second phase is consistent with our overall philosophy about making genetic information available to the patient. PG genes are inherited and therefore do not change over a person's lifetime. We decided that all of the information is part of clinical care so, rather than obtaining informed consent, we decided to create a standardized education document. Although we implement CDS only for P&T Committee approved drug-gene variation pairs, we make all of the information available to the prescribers and to the patient either through a .pdf file (phenotype data) or electronically (raw data). This allows future use of the information and also allows clinicians to make individual decisions about using the data, although we did not build specific CDS for that drug. We consider this to be the preliminary steps towards pre-emptive PG testing.

**"The power of an EHR comes from implementing clinical decision support.
As part of Clinical Decision support pharmacogenomics is a key first step to precision medicine."
J. McKeeby, CIO, NIH Clinical Center**

Resulting Value / ROI

- Optimized medication use and promoted medication safety by reducing the possibility for adverse medication reactions, predicting drug response, and predicting drug dosage.
- Clinicians adopted to the program and ordered pharmacogenetic tests.
- Patients, as gleaned from a presentation about our program, were very enthusiastic about access to pharmacogenetic information.
- The very broad multidisciplinary approach brought several departments together into a much stronger bond than existed before this project.
- Set the foundation for pre-emptive pharmacogenetic testing and for other clinical genetic tests.

Lessons Learned

- Creation of an institutional approval structure in advance is critical to the success of implementing a program that might be considered controversial (i.e. providing “genetic” information).
- A multidisciplinary team is essential to implement complex decision support. Our effort would not be successful if we didn’t include the local experts from several disciplines.
- Be open to changes after initial implementation. Although we tested the initial phase of the program with several medical groups, we made several changes soon after implementation because several users thought the program could be improved. Continued evaluation led to further changes after one year of use.

“Positively affecting the treatment of our patients is the power of precision medicine. The implementation of Pharmacogenomics at the NIH Clinical Center has been a success.”
J. McKeeby, CIO, NIH Clinical Center