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An Electronic Medical Records System for Clinical Research and the EMR–EDC Interface

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The electronic medical record (EMR), sometimes called electronic health record (EHR) or electronic patient record (EPR), has become one of the most important new technologies in healthcare. Electronic storage and exchange of health-care information has been of interest worldwide for years, but recent reports on medical error rates and national mandates for conversion from handwritten documents have heightened its importance. There have been many published EMR implementations in many different subspecialties. Most focus on improvements in efficiency, patient experience, and care. The Medical Records Institute has published the results of their survey of EHR usage,[1] and it demonstrates that usage has been predominately in the ambulatory care sector, with a focus on clinical workflow and quality of care.

Few published articles have focused on systems designed for use in ophthalmology, despite a history of the use of such systems dating back to Alcon's IVY system in the 1990s (Alcon, Ltd., Fort Worth, TX). Published reports from users in the field of ophthalmology have all focused on custom systems, because no commercial product was suitable for their purposes.[2] However, commercial systems are widely used and DeBry[3] has provided a good overview of the systems available as well as the considerations that are important for individual practices. The focus of these reports is on cost savings, time savings, and quality of care.

Concurrent with the increased use of EMR for clinical care, there has been an increase in the use of electronic systems for capture of data in clinical research and clinical trials.[4] Many trials still require researchers to enter data manually on both a paper clinical record and a paper case report form (CRF), from which it is transcribed into an electronic database. With this process data are transcribed twice, once from the encounter note to the CRF, and again into the database, providing multiple potential sources for error. Databases tend to be developed independently for each study making cross-study research difficult and therefore infrequent. Retrospective studies require review of the paper record and recompiling the data of interest. As clinical trials have become more complicated, expensive, regulated, and increasingly monitored, clinical research organizations (CROs) and research coordinating centers have expanded and evolved, especially in terms of data collection and monitoring.[5] With the advent of the internet, CROs and coordinating centers have moved to electronic data capture (EDC),[6,7] which enables data entry for clinical studies to be performed on-site in real time by the researcher. This eliminates one transcription step, but still keeps data in discrete databases and provides no method for retrospective studies.

With the increase in EMR implementation, there has been a subsequent increase in interest in using these systems for clinical research and clinical trials. As researchers have had to enter

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data into two electronic systems, EMR and EDC, speculation on the feasibility of merging these two technologies has begun.[8,9] Bleicher[8] and the document from the eClinical Forum (eCF)[9] discuss some of the different ways that these two systems can be interfaced. In this report, we summarize a system we have built in a research environment at the National Eye Institute (NEI), National Institutes of Health (NIH).

Both the eCF and Bleicher[8,9] discuss the need for using the investigator as the single point of data entry and the need for electronic data transfer to a data-coordinating center to eliminate transcription errors. The data collection system would have to be highly customizable, to allow for the inclusion of elements for specific clinical trials. In addition, with all the data collected in a single system, it would allow for retrospective studies including data from all patients. We chose to build such a system based on the commercially available EMR from Next-Gen, Inc. (Horsham, PA; formerly MicroMed). In use at the NEI since 2002, the system has become the universal method of clinical research data collection in the outpatient clinic and currently contains data from almost 30,000 patient visits. Although the system has provided developmental challenges, we have implemented it as both a record of patient care and a platform for prospective and retrospective studies.

The System

During the planning phases, we evaluated companies that provided software specifically for ophthalmology. After a complete review, the NextGen product was selected for its flexibility in template construction and design as well as its database capabilities. NextGen also provides a variety of hardware and software support specific to their system as well as updates for an annual fee based on the number of users. Because of the size of our project, we purchased a dedicated server and a backup for our clinical data, although in some cases a high-performance computer could be used as a server. It depends on the needs of the practice and the complexity of the system. In addition, PCs were deployed for each examination office, and printers strategically located for highest efficiency.

The NextGen EMR (NG EMR) ships as a blank framework, with some prebuilt modules for the collection of specific elements, like medications, allergies, laboratories, and problems. These modules are built with the goal of facilitating clinical care. For example, the medications module is based on a national formulary that facilitates ordering of prescriptions from a pharmacy. Although sometimes cumbersome to use, these prebuilt modules can be useful in both clinical and research scenarios. It is important to be able to collect this “legacy” data in a way that is easily extractable with the rest of the clinical trial data.[8] The NG EMR is particularly useful for clinical research because of the complete customizability of the data entry screens (or “templates” as they are called). The system includes a template builder that allows on-site development of the data entry screens by research staff. Because of the need for complete custom screen development, we made a decision early in the planning phase to allocate one full-time equivalent (FTE) toward this project. We selected an individual with a solid science and information technology (IT) background to serve both in development and as an advisor to our investigators and coordinating center for forms, regulatory issues, and data management. However, small practices could either contract for this support directly with NextGen or have an existing employee trained to support their systems.

Research is the primary focus of the NEI clinical program, and we designed our data screens first for research purposes and second for clinical care. For research, the system must be searchable, which means large text fields should be eliminated whenever possible, as searches of free text are affected by spelling errors, negative modifiers, and so on. Data elements should be discrete and fairly comprehensive, to facilitate both prospective and retrospective research. Standard language should be used whenever possible, again to facilitate a wide variety of

clinical research.[10] Systems developed for both research and clinical care should retain some of the flexibility of clinical care screens (including text fields for descriptive narrative), while still collecting data with prespecified options for research.

To enable speed of use, information can be compartmentalized, with details hidden and only pertinent information displayed.[2] Although generally each screen corresponds to a database table, NG EMR provides the ability to display elements from one screen (table) on another screen. This allows the details to be hidden and enables the researcher to link to the information pertaining to a particular study, without navigating the entire system.

Our EMR Construction

The practice of ophthalmology requires the collection of data from both clinical history and examination. In addition to the data collected as part of the examination, there is often a considerable amount of specialized testing, such as imaging or psychophysical testing. We have built our screens in four groups for discrete data entry by each of the following caretakers: ophthalmic technicians, photographers, nurses, and physicians.

By nature, testing performed by technicians provides discrete data elements, although some data elements are derived from more extensive data sets. The difference in the derivation and use of data shows some of the advantages of compartmentalizing data and some of the differences between a general clinical practice and a research setting. For instance, the visual acuity examination has different goals in the clinical setting than in the research setting. The clinician wants to have a good estimate of how the patient sees at distance and perhaps whether visual acuity is changing over time. The Snellen Visual Acuity Chart is adequate for this task. However, it does not provide data that are optimal for clinical research. In the research setting, a visual acuity letter score obtained from a logarithmic visual acuity chart, usually after a protocol refraction, is required by the research protocol. By collecting the data using the Early Treatment of Diabetic Retinopathy Study (ETDRS) visual acuity protocol and chart in a subform (or pop-up as the system calls them) and displaying only the total letters and maximum line reached on the main form, both goals can be accomplished (Fig. 1) without complicating the main screen.

The information collected by the nursing staff, such as medical history and chief complaint, is generally in a narrative format, and for clinical care purposes, space for narratives should be provided. However, structured collection of elements such as medications must also be provided to better facilitate clinical research studies. Which elements are provided depends on the practice and the diseases or conditions under study. However, in a multidisciplinary practice those items can be grouped together based on topic (e.g., medical history, family history, and social history) and used in that fashion by the practice as a whole.

The physician's examination requires both discrete data elements and some space for narrative text for complete clinical documentation. As with the nursing data, the elements desired will differ from researcher to researcher, but can still be collected into groups and compartmentalized. In ophthalmology those groups are somewhat intuitive, as the eye is a complex set of systems working together. Data elements are grouped by part of the eye, and those specific elements are hidden in pop-ups, while the top-level screen only displays the systems that were normal and those that had remarkable findings (Fig. 2). In this manner, the physician can quickly and easily enter the part of the eye where there are pertinent findings to record, without having to page through hundreds of elements in parts of the eye that were free of disease. The ability to jump quickly to a subset of elements and to record the pertinent findings enables us to add substantially more data items without increasing the time it would take to collect the data.

The question of research study data collection goes beyond the standard elements collected regularly by a practice. Each study will have specific elements of interest, and some will have additional elements, which are applicable only to that study and not generally captured by the system. We create specialized templates for prospective studies, which allow us to add the study-specific elements as well as display the standard elements, which are outcomes for the study (Fig. 3). The universal system can be used for the full clinical examination, and the special screens are visited to record the study-specific data outcome variables. In addition, special "study management" screens can be created to document additional items needed for clinical trials, such as adverse events, enrollment, termination, and missed visits. Screens, such as those designed to capture adverse events, can be used for every trial, whereas others, such as those collecting enrollment details, will pertain only to an individual study. Such screens are useful for both the individuals collecting the study data and for the protocol coordinators and monitors who manage the study. This method of creating study-specific screens keeps the universal system from becoming bogged down with data elements that are otherwise irrelevant. In essence, this is our version of an eCRF, where necessary data validation checks can be incorporated to correct errors in real time.

Data Extraction

Building the screens for data input is only one half of the problem. The data must also be retrievable to make the system useful. The availability of data extraction techniques in our case database query tools makes the system accessible to address research questions. Multiple database query tools are currently in use at the NEI clinic, each chosen for its specific application. A single tool, Cognos Impromptu (Cognos Corp. Burlington, MA, is used to extract data for research analysis. This tool can be used to extract data in a planned format for prospective studies, and the resulting datasets can be transmitted to our data coordinating center for quality control purposes or data analysis. Using a database query tool allows elements collected in different tables (screens) to be combined into a single table for analysis (Fig. 4). These datasets are subsequently uploaded into the data coordinating center's EDC system.[11] The coordinating center can receive data in the discrete forms necessary for a clinical trial, selecting only those elements required by the study. This direct data transfer eliminates all transcription (and subsequent errors) and also decreases the need for on-site audits, thus decreasing the cost of the clinical protocol.[8] A total of 12 prospective studies in the NEI clinic have been (or are being) managed with the system to date.

The same tools can also be used to extract data directly for retrospective research and have been used at the NEI to facilitate retrospective studies.[12,13] A researcher can, for example, cross-reference treatment groups with visual acuity trends or systemic diagnosis with an ocular finding. Analyses that would previously have taken months of chart review and data entry can now be performed in a matter of days or in some cases, hours. To date, the system has been used at least nine times to provide data for publication. In addition, management related queries can be generated, providing results to administrators on equipment usage, patient census, and more. These management queries can be used to increase productivity and decrease costs.

A second data-extraction tool, Crystal Reports, is used to generate an encounter note that can be filed in the patient's medical record and sent to referring physicians. Because the NEI Clinic is part of a larger hospital, the appropriate documentation must be submitted to the hospital's medical records department, which maintains records in a paper form. Data must be translated, summarized, and presented such that other clinicians, in-house and outside, can see the results of the NEI examination (Fig. 5). The NG EMR provides a link to Crystal Reports so that the paper documentation can be generated directly within the system.

Some Problems and Their Solutions

As with all EMR implementations, users are generally uncomfortable with the change in the medium, the change in the workflow related to computer data entry, and the change in the physician's interaction with the patient as data are being entered. These concerns have been addressed with training, attention to placement of workstations (or use of wireless solutions) to minimize workflow changes, and attention to physical orientation in the examination room to maintain physician–patient interaction. One important workflow change is caused by the difficulty in drawing pictures within the EMR, which can lead to lingering paper documentation or an increase in photographic documentation.

Because of the need for discrete data elements and minimized text fields in a research-based system, there has been some adjustment on the part of all users to the lack of narrative text. As mentioned previously, this concern has been minimized by strategic placement of small "comments" boxes so that users may clarify a finding. Also, the inclusion of very large text fields throughout the system, although not useful for research purposes, will alleviate the problem for users who prefer free text entry in addition to the discrete item entry.

One of the major problems in constructing a system of this magnitude is the "pertinent negative." With hundreds of possible data elements, the time needed to click a specific "yes" or "no" to each question would be prohibitive. The "no" answer must be assumed for all items not specifically marked "yes." This is virtually a necessity for a system that can have universal value for retrospective studies. However, this concern must be addressed for prospective studies, in which a specific data entry for a "no" response is needed. For all study outcomes of interest, one can provide the pertinent negative on the study-specific screen. Elements that are recorded as positive in the universal system can be translated to positive on the study-specific screen. Outcomes that are negative will have to be specifically marked as such, rather than assuming that they are negative from inaction. It is the data from the study-specific screen that is then submitted to the study's data-coordinating center or statistician for analysis, whereas the data on the standard screens remain a part of the universal dataset and are available as part of that collective for retrospective studies.

Implementation of a Research Protocol: An Example

Implementing a prospective study in the system begins just as it would with any electronically managed study, with a thorough examination of the protocol in question. All study outcomes must be identified, as well as whatever supplemental information is necessary to ensure the integrity of the dataset. A study to analyze the effect of an eye drop on progression of geographic atrophy in patients with age-related macular degeneration (AMD) was recently implemented in our system. The main factors being followed are visual acuity, area of geographic atrophy, drusen area, contrast sensitivity, microperimetry, progression of AMD, and drug safety. To collect some of the data, we added the visual acuity, contrast sensitivity, and various other factors to the study-specific screen as described earlier (Fig. 3). As this screen was a more recent implementation, we now realized that a new field was needed to establish the presence of a natural lens, to address the need for the pertinent negative. In the past, we had just added the systemwide field, which has an assumed negative rather than an active one. Links were established between the new field and the system-wide field to synchronize the data sets so that the data would be available as part of the overall database for retrospective studies. Because most other data were being collected by a reading center, no additional fields were required with the exception of a field to record which eye had been selected for treatment.

Special screens were built to collect information on protocol compliance (drug accountability) and to screen for adverse events (telephone), and links to those screens were added to the study-specific screen, along with links to study-management screens such as the visit schedule,

imaging tracking, termination form, and adverse event form. A study-specific medical history form also had to be created for the pertinent negative and for the management needs of the coordinating center. Links between this screen and the general medical history screens were established so that the data would be available as part of the overall system. Design of these study screens is an iterative process, with interim reviews by both physicians and the coordinating center to check for missing data points, management tools, and compatibility with the coordinating center's system. Data transfer forms were built by using Impromptu to present the data in the format needed for transfer to the coordinating center. Because of amendments to the protocol and requirements of the coordinating center's electronic system, small changes had to be made to the screens and data transfer forms along the way, but the ease of customizing the NG EMR makes this a simple process.

Conclusions

The use of the EMR in a clinical setting is increasing throughout all fields of medicine and in clinical practices, private or academic, large or small. As more academic centers begin to implement electronic systems, the question of how to handle clinical research in the electronic environment becomes increasingly important. There has been much discussion of how to integrate the EMR and EDC to facilitate research, and organizations like the Clinical Data Interchange Standards Consortium (CDISC) will be pushing for EMR and EDC technical development in the future. We have presented an example of a functional integration of EMR and EDC that eliminates transcription errors, facilitates retrospective study analysis, and serves as the primary resource for clinical care. Although our scenario may not work for all practices or centers, it is an example of a successful method of implementing an EMR designed for clinical research and of integrating the EMR with an EDC system for research protocols and clinical trials.

Acknowledgements

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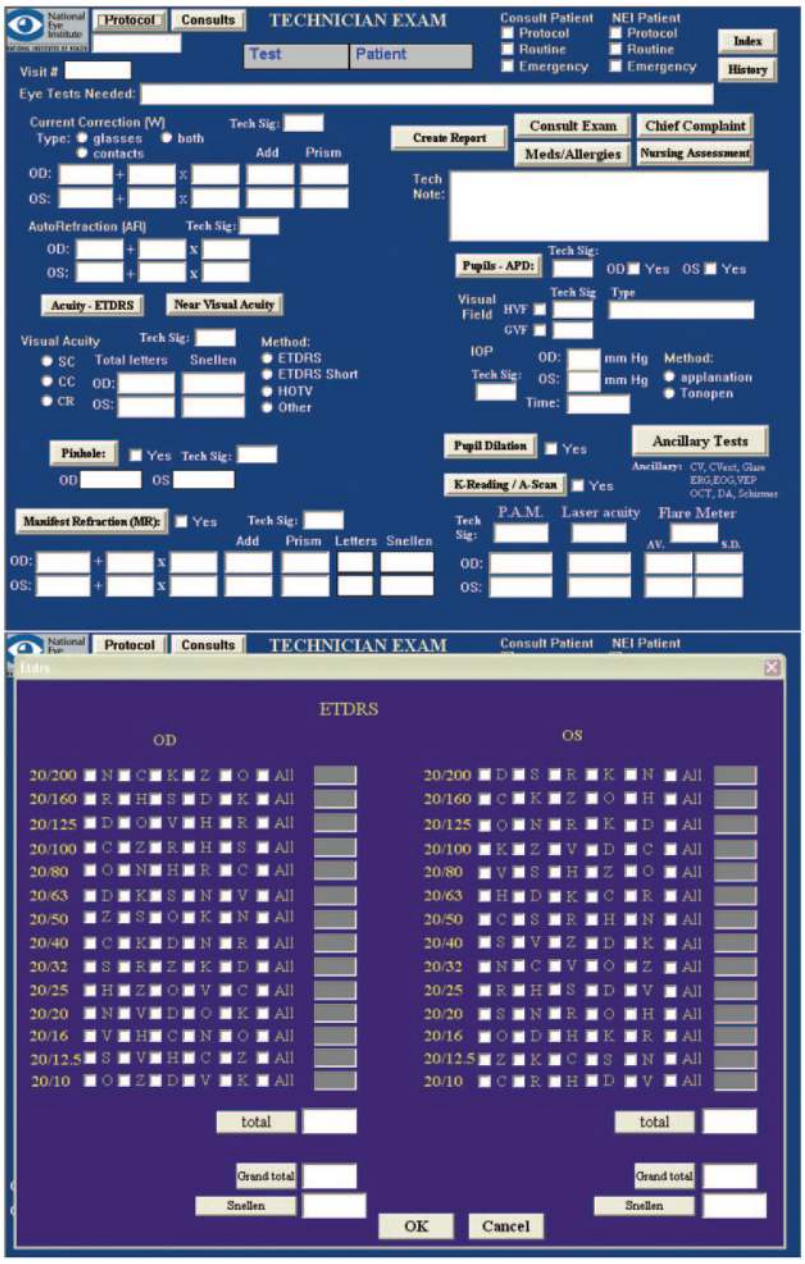


Figure 1.

The ETRDS details screens are hidden within a pop-up accessed from the Acuity-ETDRS button on the main technician screen. Only the total number of letters and Snellen equivalents are displayed on the main technician screen, for easy viewing.

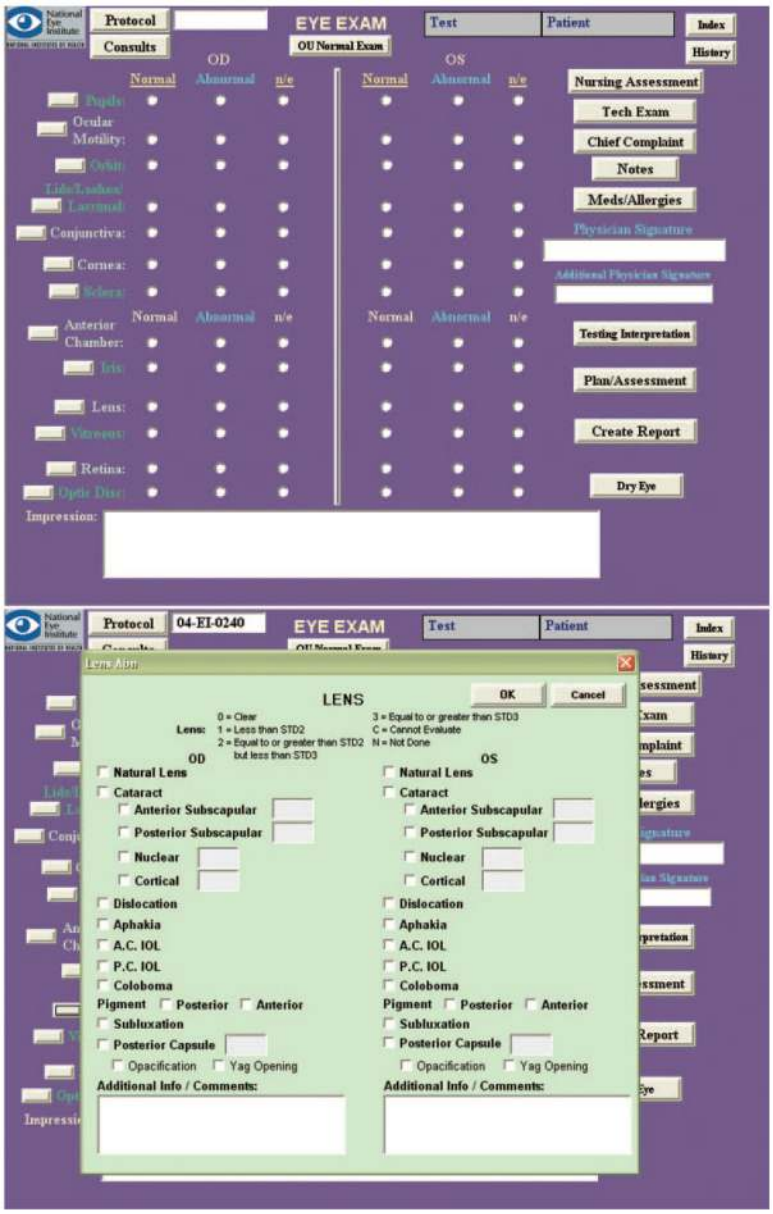


Figure 2.

The physicians screens provide for fast access to record findings and to a comprehensive set of collected data points by compartmentalizing the data into pop-ups (in this case for the lens examination).

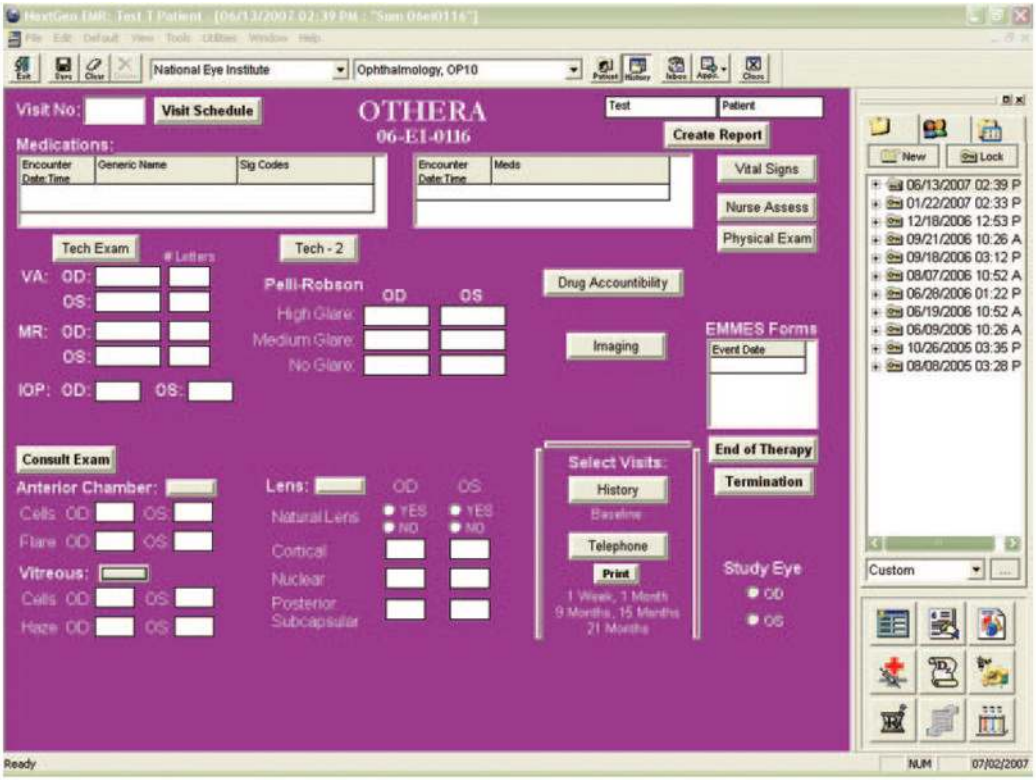
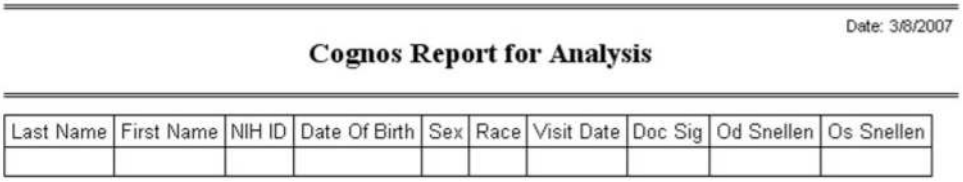


Figure 3.

The protocol screens pull in data from multiple different screens throughout the system, giving researchers a quick view of the protocol-mandated data. This method enables them to avoid missing data and to collect study-specific data points. In this particular screen, most of the data were from elsewhere in the system, but the "Natural Lens" field had to be created anew to satisfy the need to record the pertinent negative.


Date: 3/8/2007

Cognos Report for Analysis

Last Name	First Name	NIH ID	Date Of Birth	Sex	Race	Visit Date	Doc Sig	Od Snellen	Os Snellen

Figure 4.

Not only are the study-specific data collected onto summary screens in the NextGen system, they are also collected into separate data tables for local analysis or submission to the CRO. The collection is accomplished with a commercial tool from Cognos (Burlington, MA). This image shows data taken from demographic, physician, and technician screens as well as the Visit Date, which is system-managed data.

Figure 5.

As the NEI clinic is part of a larger hospital, examination documentation must be provided for inclusion in the patient's overall medical record. The NextGen system provides a link to Crystal Reports which allows generation of a translated, summarized report of the NEI examination in paper form.