

Elab Project Overview

The Elab Project began in 1998 and was initiated by Network 11 and through their leadership the Elab project was expanded to six ESRD Networks by 2002. Through this large-scale demonstration project, Network 11 developed and tested the methods for obtaining, matching, and reporting the laboratory data from national ESRD laboratories. Due to the success of the project, and the Statement of Work requirements that emphasize streamlining processes by utilizing existing data with an emphasis on electronic data submission, it was recommended that the established Elab project be expanded to all ESRD Networks. eSOURCE is working with Network 11 to transfer and build on their knowledge to expand and transition the data collection process as part of the Core Data Set.

The purpose of this data collection process is to provide ESRD Networks with the necessary data to fulfill their contractual quality improvement oversight responsibilities using a data collection method that does not unnecessarily burden the staff at the dialysis facility. The goals and objectives are:

1. Collect the quality indicators that are needed to measure quality improvement for anemia management and dialysis adequacy through electronic transfer of data.
2. Generate facility-specific reports with state, ESRD Network, and national comparisons that can be used by the ESRD Networks and the dialysis facilities for quality improvement purposes.
3. Include additional quality measures for renal Osteodystrophy, diabetes, and lipid measures to enable additional quality improvement activities to be conducted without additional burden at the facility level.

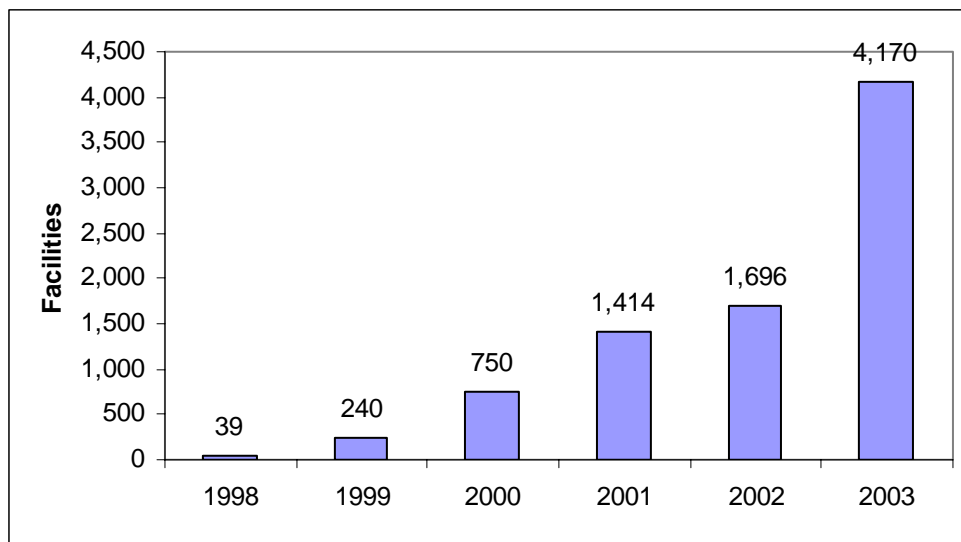
By expanding the Elab system, the data collection process is streamlined and the duplication of efforts was dramatically reduced. Elab benefits include the following:

- Reduces hand transcription and entry of lab data, which is labor intensive for dialysis facility and Network personnel.
- Minimizes errors that occur with manual data abstraction.
- Improves accuracy in data collection because data is being transferred from the primary source.
- Permits automated compilation and analysis of large data sets, rather than conducting studies based on small sample sizes. Now quality improvement studies can include 100% of the patients in 100% of the dialysis units.
- Provides facility-specific profiles that can be quickly generated with comparative data by affiliation, state, and Network.
 - Please Note facility-specific profiles have facility, state, and Network comparison data at this time. National comparison data will be prepared next.

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This electronic transfer of national ESRD lab data for all Networks contained approximately 90% of all facilities. The national data was collected from the following labs: Davita, DCI, ESRD Laboratories, FMCNA, Gambro, Gambro Outreach, RCG, Satellite Laboratories, Scantibodies, Spectra East and Spectra West and Non-National Laboratories. The first monthly lab value for October, November, and December 2003 was collected and averaged together for reporting purposes. After the files that contained all patients serviced by the national and non-national labs were received, they were matched to their appropriate facility in SIMS using matching algorithms based on the patient demographics provided. An extract was then created and sent to Biostatistics Consulting Laboratory where facility specific reports and a database were created for each Network.

Number Dialysis units participating in Elab 1998-2003



All laboratory testing and the release of the testing results from labs are regulated in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). The Clinical Laboratory Improvement Amendments of 1988 (CLIA) established quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The release of the Elab data to Networks was delayed this year to ensure the project was compliant with CLIA regulations. eSOURCE received approval from CMS to release the data and was instructed to suspend future collections until all of the regulations regarding the release of lab data are reviewed. Federal CLIA regulations state that "Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test." State laws define who is authorized. CMS will make their decision on future lab collections after an analysis of these state CLIA laws.

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This has been a huge project. As with any new, national initiative, we will find opportunities to enhance and improve the processes. We have already seen some minor need for enhancements, but nothing that would warrant further delays in getting this to you as soon as possible. We hope that you will find the user guide helpful, and we hope that this data and standard reports will be useful to you in your quality improvement activities.

If you have any questions regarding the Elab Project please contact:

Shannon Wright
ESRD Core Data Set Coordinator
eSOURCE - Southeastern Kidney Council, Inc.
Suite 270 - 1000 St. Albans Drive
Raleigh, NC 27609
swright@esrdsources.net
Phone: 919-855-0882
Fax: 919-855-0753