

USE OF CLINICAL LABORATORY DATABASES TO ENABLE EARLY IDENTIFICATION OF PATIENTS AT HIGHEST RISK OF DEVELOPING END-STAGE KIDNEY DISEASE

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Introduction

Chronic kidney disease (CKD) is common, particularly amongst older people and those with diabetes or hypertension. A minority of CKD patients develop end-stage kidney disease (ESKD) and require kidney replacement therapy (KRT). KRT has a major impact on survival and quality of life and costs an average £25K per patient per year. Early intervention can delay or halt progression to ESKD but a significant minority of patients remain undetected and thus do not get optimal care until significant loss of kidney function has occurred.

We have recently introduced a system that enables laboratory staff to monitor CKD for all patients tested in hospital clinics or the community. Large numbers of cumulative estimated glomerular filtration rate (eGFR) graphs are reviewed by trained clinical laboratory staff. This enables detection of patients with significantly deteriorating kidney function to be identified and reported directly to clinicians.

Aims

Our aim was to develop a population surveillance system using existing laboratory data to enable patients at high risk of developing ESKD to be identified by reviewing cumulative eGFR graphs.

Database Development

A central Oracle™ database was developed using Microsoft™ Visual Studio 2008. The database combines blood and urine test data and demographic data from 2 separate laboratory information systems (LIMS) covering Heartlands/Solithull hospitals and Good Hope hospital.

Initially, the database was populated with 5 years of historical data. Multiple records for patients are combined. The database is updated daily with data for new patients from the LIMS systems.

The software is capable of creating lists of patients using a variety of search criteria and displaying sequential cumulative eGFR graphs for each patient containing up to 5 years of data.

Reviewing eGFR Graphs

Step 1:

Two searches are made of patients with an eGFR result within the last 7 days, meeting the following criteria;

Search 1 - All patients aged ≤ 65 years with an eGFR ≤ 50 mL/min/1.73 m².

Search 2 - All patients aged > 65 years with an eGFR ≤ 40 mL/min/1.73 m²

Hospital in-patients and patients from known kidney units or kidney clinics are excluded.

Step 2

For each list, a clinical scientist (Band 7+) reviews the cumulative eGFR graphs sequentially.

Depending on the trend, patients are categorised using on-screen buttons as either UI - requiring urgent kidney team investigation, IC - inform the requesting clinician via a paper report including the eGFR graph or NA - no further action required.

On average 420 patients are reviewed each week, which takes 3-3.5 hours staff time, including the reporting.

Figure 1.

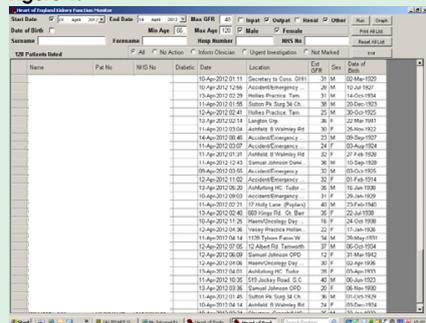


Figure 1 is a screenshot of the main screen showing a list of patients generated from the Oracle™ database. The search includes patients aged 66 and above who had eGFR ≤ 40, excluding results from in-patient or renal unit locations.

Figure 2.

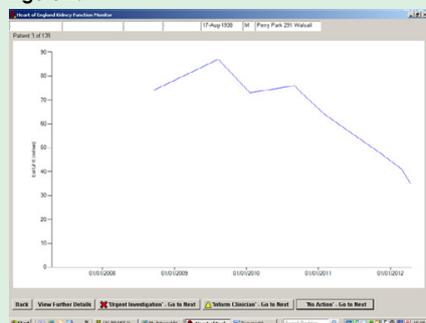


Figure 2 is a screenshot of a cumulative eGFR graph for an individual patient. Large numbers of graphs can be reviewed and patients flagged based on the trend of the graph using buttons at the bottom of the screen into low risk, intermediate risk (inform clinician) or high risk (urgent investigation) of developing ESKD.

The results for this patient (GP patient) show a very steep decline over the last year and would be flagged as high risk. The software allows a report including this graph to be automatically emailed to the kidney team.

Once flagged, a symbol indicates the action on all future eGFR graphs so that clinicians are not contacted multiple times.

Figure 3.



Figure 3, left, shows a sample report that would be sent to the requesting clinician highlighting that the results for this patient had been reviewed and flagged as high risk.

Results

Before introducing the monitoring system into routine practice, the system was tested using retrospective data

Table 1.

Classification	Renal Consultant	Consultant clinical scientist	Junior clinical scientist (Band 7)
No further action (NA)	443	390	381
Inform Clinician (IC)	53	82	68
Urgent Investigation required (UI)	18	41	64
Total high risk (IC + UI)	71 (14%)	123 (24%)	132 (26%)

Table 1 shows the overall number of patients in each classification for test data of 512 patients identified in a single week. As expected, the clinical scientists tend to identify more patients at high risk than the renal consultant. However, as clinical scientists become more experienced we expect these numbers are likely to fall.

Table 2.

	Renal Consultant (reference)	Consultant clinical scientist	Junior clinical scientist (Band 7)
True positives	71	64	65
False positives	0	7	6
True negatives	443	384	375
False negatives	0	59 (11%)	67 (13%)
Diagnostic sensitivity	100%	90%	92%
Diagnostic specificity	100%	87%	86%

Table 2 shows the number of patients classified by each team member as low, intermediate or high risk compared to the renal consultant (gold standard). True positives/negatives were results where the classification matched the renal consultant, whereas false negatives/positives were results where the team member classified a patient differently to the renal consultant. Only 1/19 (5%) of patients considered at highest risk by the renal consultant was missed by a clinical scientist.

Table 3.

Classification	No. patients randomly selected for follow-up	% mortality at 3.5 years of randomly selected patients	% randomly selected patients with significantly decreased eGFR
No further action (NA)	14/43	2/14 (14%)	1/14 (7%)
No further action (NA) Age > 65 years (n=17)	59/177	31/59 (52%)	14/59 (24%)
Inform clinician (IC)	11/20	4/11 (36%)	3/11 (27%)
Inform clinician (IC) Age > 65 years (n=20)	17/62	10/17 (59%)	3/17 (18%)
Require urgent investigation (UI)	5/13	3/5 (60%)	1/5 (20%)
Require urgent investigation (UI) Age > 65 years (n=13)	9/28	6/9 (67%)	3/9 (30%)

Table 3 shows the all causes mortality rate during 3.5 years of follow-up for a random selection of patients from each classification group of patients flagged using retrospective data. This suggests an increased risk of mortality for patients identified and flagged as higher risk compared to those flagged as low risk. Also shown in the final column is % with a significant declining trend in eGFR, defined as a decrease > 5 mL/min/1.73m²/year. This suggests patients flagged as intermediate risk (IC) or highest risk (UI) after review of cumulative eGFR graphs 3.5 years previously are slightly more likely to have a significantly declining eGFR.

Conclusions

We have developed software capable of generating large numbers of cumulative eGFR graphs for a week that can be reviewed in 3-4 hrs by clinical scientists.

We have recently introduced a system that screens all in-patients and primary care patients for significantly deteriorating CKD by reviewing cumulative eGFR graphs for patients with decreased eGFR (420/ 9000) per week.

Patients can be classified by risk - high risk patients are alerted to the requesting clinician or kidney team.

Data from a smaller study for diabetic clinic patients by the HEFT kidney team^{1,2} suggests we may significantly reduce the number of patients requiring to kidney replacement saving an average £25K per patient/year.

Acknowledgements:

- Rayner, HC, Hollingworth L, Higgins R and Dodds S. Systematic kidney disease management in a population with diabetes mellitus turning the tide of kidney failure. *BMJ Qual Saf.* 2011 Oct;20(10):903-10.
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