YORKSHIRE & HUMBER AHSN

Healthy.io ACR Service for People with Diabetes

Final Report

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Executive Summary

1. INTRODUCTION

Diabetes is a risk factor for the development of chronic kidney disease (CKD), and damage to the kidneys caused by diabetes is a significant risk factor for end stage renal disease (ESRD) [1]. As part of the monitoring of their condition, people with diabetes should be offered annual screening for CKD using an albumin:creatinine ratio (ACR) test [2], usually by bringing a urine sample to their general practitioner (GP). Data from the National Diabetes Audit show that in 2020, only 52.6% of people with diabetes in the West Yorkshire and Harrogate Health & Care Partnership completed the ACR test annually.

Healthy.io has developed a smartphone based urinalysis kit for ACR, using a reagent stick built around existing semi-quantitative urinalysis dipsticks. Users are posted the kit to their home address where they conduct ACR screening. The results are securely shared with their GP practice, automatically via an app, for follow-up by a clinician if needed. Yorkshire and Humber Academic Health Science Network (YHAHSN) and Leeds CCG were successful in obtaining NHSX funding to implement and evaluate the Healthy.io Albumin: Creatinine Ratio (ACR) service in Leeds CCG, with the aim of increasing the number of patients with diabetes that perform an ACR test, thereby identifying undiagnosed diabetic nephropathy. The AHSN asked York Health Economics Consortium (YHEC) to evaluate the project, making use of data emerging from early implementation in Leeds. The evaluation uses an economic model developed by YHEC in 2019, which assesses the costs and outcomes of using the Healthy.io ACR service in diabetes. The evaluation has produced a cost-effectiveness analysis, modelling the costs and outcomes of the service over different time horizons (1 year, 5 years, 10 years and lifetime). The evaluation also includes data on the uptake of the service, feedback on patient experience, and the views of staff in the practices implementing the service.

2. METHODS

The evaluation used a mixed methods approach, including quantitative analysis of data from implementation sites, economic modelling, and qualitative analysis of users' views. A range of data was required for the evaluation. Some measures were obtained through primary data collection. Other values were obtained through use of economic modelling. Aggregated summary data for the whole patient cohort up to 15 March 2021 were provided from Healthy.io to YHEC. Individual case level data were required to undertake sub-analysis by age and sex (known as the 'evaluation sample'). Hence, consent for individual patient data to be used in the evaluation was sought by the Healthy.io call handlers. The up-to-date values for the sensitivity and specificity of Healthy.io ACR testing, plus the unit cost, were provided by Healthy.io. The costs of treating CKD and related cardiovascular events were included in the YHEC economic model, taken from literature, as referenced in Shore et al [5]. Staff feedback on the Healthy.io ACR service was collected in the form of a practice survey. Patient feedback was obtained via a survey built into the Healthy.io app.

The aggregated data for the patient cohort and the patient-level results were synthesised, to provide the number of patients in the cohort at each stage of the implementation. The data on adherence with the Healthy.io ACR home testing service were summarised for the cohort and individual practices. Tests of statistical significance were used to examine the relationship between patient age range, sex and IMD decile and their participation in the service, whether they performed the test, test results, and the responses to the patient survey. The completed practice survey results were tabulated and the themes from the findings summarised.

The YHEC health economic model was used to consider the costs and outcomes of using the Healthy.io ACR test, using the results of the data analysis from this real-world study. Three inputs were derived from the study data:

- Number of patients onboarded to the service (number entering the model)
- Average age of patients (years)
- Adherence with ACR testing (% of those onboarded returning a test result)

There are a number of limitations affecting the analysis, which are described in full in Section 5.4. Largely these are the need to make certain assumptions for the economic analysis, and a number of scenario analyses were performed to observe the impact on the results when compared to the cohort base case values.

3. RESULTS AND DISCUSSION

Uptake of the Healthy.io ACR service

The ACR service began implementation in the autumn of 2020. Pressure on health services due to the ongoing Covid-19 pandemic led to a brief pause of project roll out in early 2021. At the point of the data collection for the analysis (15 March 2021), 9 practices were involved in the project. The practices involved in the analysis, and their adherence to ACR testing prior to the Healthy.io service, are shown in Section 3.1 of the report. The average adherence with urine ACR testing for the 9 practices in the study prior to the Healthy.io service was 39%, which reflects the average across Leeds CCG. The number and proportion of patients at each stage is shown in Table 1. The starting number in the study cohort and patient numbers at each stage, is also illustrated in Figure 3.1 of the report.

The uptake of the service in each practice and across all practices is shown in Table 3.5 of the report. The proportion of those onboarded that went on to successfully perform the test ranged between 37% and 62%, with an average of 50%. The proportion of those who agreed to participate and then performed the test was much higher, ranging from 74% to 90%, with an average of 87%. This is an improvement on the proportion in a study 2 years ago (72%). In the previous study, the administration staff at the participating practices made contact with the onboarded patients, whereas in this study, Healthy.io used an in-house onboarding team to contact patients directly and take them through the whole process.

Table 1: Number and proportion of patients in the cohort at each stage

Description	Numerator	Denominator	%
a) Proportion of eligible patients agreeing to have their details passed from GP practice to Healthy.io (onboarded)	2,020	Not known	91%*
b) Proportion of onboarded patients successfully contacted by Healthy.io	1,622	2,020	80%
c) Proportion of contacted patients who agreed to participate	1,163	1,622	72%
d) Proportion of contacted patients that declined to take part	459	1,622	28%
e) Proportion of onboarded patients that DID perform the test	1,012	2,020	50%
f) Proportion of onboarded patients that DID NOT perform the test	1,008	2,020	50%
g) Proportion of participating patients that DID perform the test	1,012	1,163	87%
h) Proportion of participating patients that DID NOT perform the test	151	1,163	13%
i) Proportion of participating patients who consented to patient-level evaluation	513	1,163	44%

* Based on data from 7 practices

Table 2: Age and sex of patients agreeing and declining to participate

Practice	Age (years)								Sex		TOTALS
	19-29	30-39	40-49	50-59	60-69	70-79	80+	Average age	Male	Female	
Patients agreeing to participate (n=513)[1]											
Number (all practices)	13	40	67	150	135	78	30	58	304	209	**513**
Proportion of total	3%	8%	13%	29%	26%	15%	6%		59%	41%	**100%**
Patients declining to participate (n=459)											
Number (All practices)	3	8	34	73	99	146	96	69	239	220	**459**
Proportion of total	1%	2%	7%	16%	22%	32%	21%		52%	48%	**100%**

[1] Evaluation sample only

459 patients declined to participate in the service when contacted by the Healthy.io call handlers. Table 3.7 in the report shows the reasons given by those who declined. The most common reason was not having access to a smartphone (41%). The second most common reason was a stated preference to take a sample to their GP practice (16%), followed by those who had plans to attend their practice, or who had recently given a sample at the practice (10%). Table 2 show the age and sex of patients at all practices, for those who agreed to participate and those who declined to participate. This shows that the average age of those agreeing to participate in Healthy.io ACR home testing was 58 years, compared to 69 years for those declining to participate. While we were not able to link age and reason for declining at patient level, these data suggest that older patients may be less likely to participate in the service because they do not have the required technology. We understand that not possessing a smartphone was an exclusion criterion for the Leeds CCG implementation, with reliance on using another person's phone not being desirable. While relaxing this criterion in Leeds may have an impact on future uptake, this also highlights that the standard care approach is still appropriate for some patients. Equally, as the population ages, and use of smartphone technology is more prevalent, the service may be increasingly accessible in older age groups.

Statistical tests showed there was a higher proportion of males in the participating group than the declining group and a higher proportion of females in the declining group than the participating group. The younger age ranges were more represented in the participating group compared to the declining group. There was a lower proportion of people from IMD decile 1 and a higher proportion of people from IMD decile 5 in the participating group compared to the declining group. While there was slightly lower uptake in the practice in IMD decile 1, further analysis with a larger number of practices would be beneficial to explore the relationship between deprivation and uptake. Statistical tests showed that, once people have agreed to participate (i.e. be sent a test kit), the likelihood of performing the test does not appear to be significantly associated with age, sex or IMD decile.

ACR test results

Table 3.12 in the report shows the proportion of results in each practice that were normal (77%), abnormal (16%) and high abnormal (8%). The combined proportions with abnormal/high abnormal results ranged from 16% to 43% at practice level, with an average of 23% for all practices in the evaluation sample, and for the whole cohort. At 23%, this is slightly higher than the prevalence of albuminuria in the population as a whole (20%), which is used in the economic model and is taken from the literature. Statistical tests showed there is no significant association between the level of deprivation and the likelihood of an abnormal ACR.

Patient and staff feedback

The patient feedback questions are available only for those patients completing the test, as patients who do not complete the test will not receive the user satisfaction questions via the app. There were 312 responses to the survey questions from the evaluation sample, with the average age for respondents from each practice ranging from 47 to 62 years, with an average of 58 years across all practices (Table 3.14 in the report). For those patients that did perform the ACR home test, and completed the patient survey on the app, 95% found the test either easy or very easy to use, and only 4% of patients who completed the test would prefer to be tested at their GP surgery. Most patients would be highly likely to recommend the service to others.

The response to the practice survey was limited so the responses may not be truly representative of all practices. Nevertheless, some interesting themes arise from the 6 responses received. The respondents were evenly split between clinicians and practice management. Most thought that the service had been quite easy to implement, even though there was more work involved in setting up the service than had been anticipated. In general, the service was viewed as requiring increased time commitment for management/ administration roles within the practice, and reduced time involved for clinicians, although, some of the additional administration/management time is expected to only be required the first time Healthy.io is deployed in the practice. There was a favourable view of the impact of the project on the understanding of practice staff of ACR issues, particularly of treatments for CKD, where to go for advice and when to refer the patient to secondary care. In line with this, 5 of the 6 respondents thought that the ACR guidance would help practices with their management of CKD.

Economic analysis

The Healthy.io ACR service is paid for via a service charge of £14.50 (at the time of writing), for each patient onboarded to the service. The economic analysis aimed to understand the benefits in terms of costs and patient outcomes, and whether these outweighed the cost of the Healthy.io service intervention.

The economic model calculates the incremental costs of digital home ACR testing when compared to the standard care approach of practice based ACR testing, for patients in whom uptake of ACR testing has previously been 0%. The model uses a decision tree to calculate the costs of the ACR testing itself. The decision tree feeds into a 5-state Markov model to capture the long-term outcomes of patients with CKD. The 5 health states are: no CKD; diagnosed CKD; undiagnosed CKD; ESRD; death. The model estimates the overall costs to the healthcare system associated with the 5 health states, based on adherence with ACR testing, epidemiology of albuminuria, literature evidence on the probability of patients transitioning between the health states, and the cost of treating these respective conditions. Costs are calculated over 4 time horizons for the Healthy.io group and an equivalent standard care group: 1 year, 5 years, 10 years and the lifetime of the patient cohort. Clinical outcomes, including total CKD diagnoses, the total number of people with ESRD, and death, are also reported by the model.

The 3 base case values taken from the study cohort data were as follows:

- Number of patients onboarded to the service (number entering the model): 2,020
- Average age of patients: 58 years
- Adherence with ACR testing: 50% of those onboarded, returning a test result

Table 3 shows the results for the whole cohort analysis over the 4 different time horizons, for the base case scenario. This shows that, in the first year, the costs associated with the Healthy.io group (2,020 patients onboarded, 1,012 performing the test) and the standard care group, are £491 per patient and £493 per patient respectively, giving an incremental cost saving for Healthy.io of -£2. The incremental cost per patient onboarded to the service is -£1,262 over a lifetime time horizon. To note, this is a lower figure than the analysis reported in Shore et al [5], partly due to the average age of the patients being higher in the Leeds study, but also due to the fact that the per patient charge at that time was applied only to those patients who successfully completed the ACR test, which was 72% of those who agreed to participate. The equivalent metric in this analysis is 87%. If the same charging model had been in place, the lifetime savings in this analysis would be in excess of £1,700 per patient. The Healthy.io ACR home testing approach is therefore cost saving when compared to standard care, with an incremental cost saving for the whole cohort of -£4,354 in the first year, rising to -£2,548,267 over a lifetime time horizon, for a cohort of 2,020 patients onboarded to the Healthy.io service. The negative value shows it is potentially cost saving rather than cost incurring.

Table 3: Costs over different time horizons (base case, study cohort n=2,020)

	Healthy.io ACR testing	**Standard care**	**Incremental**
1 year time horizon			
Costs per patient	£491	£493	-£2
Total costs per cohort (n=2,020)	**£991,785**	**£996,139**	**-£4,354**
5 year time horizon			
Costs per patient	£5,067	£5,392	-£325
Total costs per cohort (n=2,020)	**£10,235,152**	**£10,892,154**	**-£657,001**
10 year time horizon			
Costs per patient	£14,069	£14,878	-£808
Total costs per cohort (n=2,020)	**£28,420,357**	**£30,052,945**	**-£1,632,589**
Lifetime time horizon			
Costs per patient	£37,994	£39,256	-£1,262
Total costs per cohort (n=2,020)	**£76,748,340**	**£79,296,607**	**-£2,548,267**

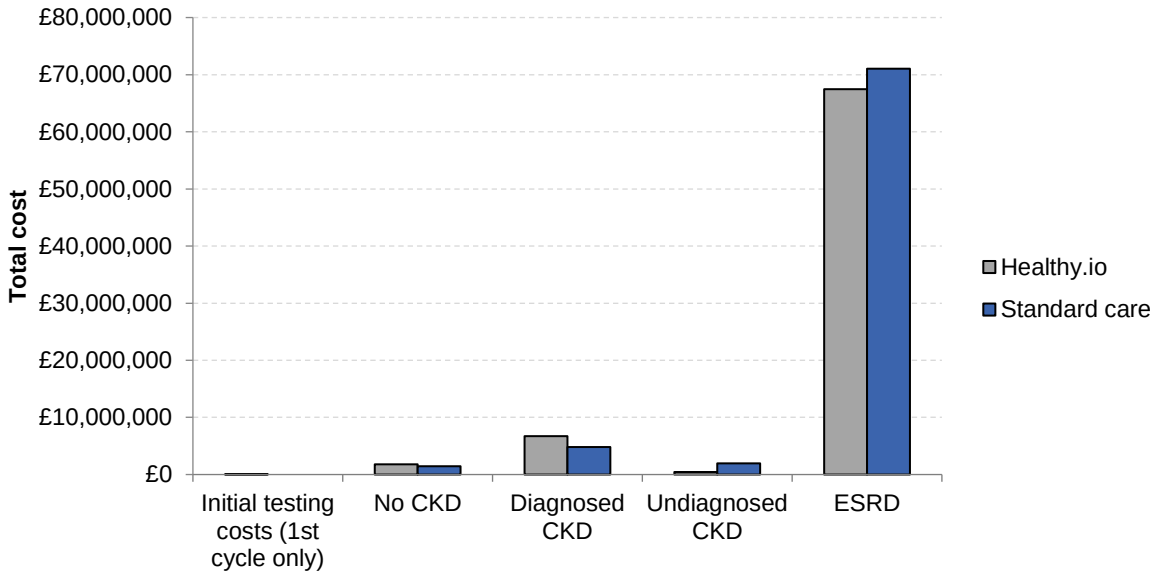
NB. Any slight discrepancies in totals are due to rounding

The cost savings derive from an estimated increase in the total number of CKD diagnoses and a consequent reduction in future cases of ESRD. While there are short term increases in costs due to treating the additional diagnosed cases of CKD, these are outweighed by savings from the associated treatment costs of prevented ESRD and other cardiovascular events, such as hospital admissions, particularly over the longer time horizons. Figure 1 shows the breakdown of the different lifetime costs which make up the totals in Table 3.

The benefits to patients are not merely the convenience of the test, but the potential for detecting previously undiagnosed CKD and being able to intervene earlier. For this cohort analysis, there would be an estimated additional 115 cases of CKD diagnosed in the first year with Healthy.io home testing, with an additional 155 over a lifetime time horizon, compared to standard care. There would be 2 fewer cases of ESRD in the first year, with 15 fewer over a 10 year time horizon. When scaled up across all of the practices in Leeds CCG, this is an estimated additional 1,211 cases of CKD diagnosed in the first year, with an additional 1,633 over a lifetime time horizon, with associated cost savings of -£45,998 in the first year, rising to -£26,920,800 over a lifetime time horizon. Across West Yorkshire, there would be an estimated additional 4,037 cases of CKD diagnosed in the first year, with an additional 5,447 over a lifetime time horizon, with associated cost savings of -£153,400 in the first year, rising to -£89,778,472 over a lifetime time horizon.

Figure 1: Breakdown of costs over lifetime time horizon

Cost breakdown - lifetime time horizon



To give an idea of the costs and health outcomes for an average practice, we have used the average number of patients onboarded per practice across the 9 practices (224 patients), along with the other base case values of average age (58 years) and proportion of those onboarded returning a test result (50%). The results show that there would be an estimated incremental cost saving of -£483 in the first year, rising to -£282,580 over a lifetime time horizon. There would be an additional 13 cases of CKD diagnosed in the first year with Healthy.io home testing, with an additional 17 over a lifetime time horizon, compared to standard care. There would be 2 fewer cases of ESRD over a 10 year time horizon, and 1 fewer death.

Our scenario analysis shows that the results are sensitive to the average age of patients entering the model, with cost savings being greater for younger patients. This is because, on average, younger people have more years of life remaining, and therefore more potential to benefit from the avoidance of ESRD and associated costly treatment. Clearly, the level of adherence also affects the results of the economic modelling, with increased rates of test completion leading to greater savings over time, quite apart from the improved health outcomes for patients.

While we have no evidence to suggest that previously non-adherent patients will be likely to adhere to standard care approaches in the future, we tested the effect on the results of assuming that a proportion of patients (5%, 10% and 15%) do begin to adhere to standard care. As expected, this shows that as the proportion of patients who obtain their ACR test via the standard care approach in future years increases, the potential savings from the Healthy.io approach decreases. In all scenarios, however, the savings remain substantial, with an estimated incremental cost saving of -£849 per patient and approximately -£60million at West Yorkshire level, over a lifetime time horizon, if 15% of patients begin to adhere to standard care ACR testing in future years.

4. CONCLUSIONS

This analysis has sought to assess whether the following anticipated outcomes for the Healthy.io ACR service in Leeds CCG have been achieved:

- Increased number and percentage adherence of ACR tests
- Increased detection of CKD
- Avoidance of ESRD
- Reduced primary care resources
- Reduced acute admission
- Increased satisfaction for people due to not having to travel to clinic for testing

From the data available from the early stage of implementation, we conclude that the project is well on the way to achieving these outcomes. The participation in the service by people with diabetes who were previously not adherent with ACR testing in practice was high, at 50% of those onboarded to the service, and 87% of those who agreed to participate. The findings suggest that uptake may have been higher if patients had been permitted to use another person's smartphone. Patient feedback shows that the majority of patients found the service/technology easy to use and would prefer home testing if given the option.

The analysis did find statistically significant differences in the proportion of people from IMD decile 1 in the participating group compared to the declining group and a higher proportion of people from IMD decile 5. On reflection, the project implementation team would recommend that an analysis of uptake by practice deprivation could have been undertaken prior to roll out, allowing practices in areas of higher deprivation to be onboarded earlier in the study. Having agreed to participate in the service, there was no statistically significant difference in the likelihood of patients performing the test between age, sex and IMD decile.

The testing undertaken found higher than national levels of albuminuria, to be followed up by their GP practices and receive appropriate treatment (23% compared to 20%). Although any changes in the incidence of ESRD will take years to become apparent in this study group, the economic modelling, based on robust literature evidence, suggests that these improved patient outcomes are highly likely to be achieved. The economic modelling estimated the cost savings over the patients' lifetime to be around -£1,262 per patient. Across Leeds CCG, the service has the potential to achieve cost savings of -£26,920,800 over a lifetime time horizon. Across West Yorkshire this rises to -£89,778,472 over a lifetime time horizon.

Additional benefits are that involvement in the project was thought to assist practices' knowledge and awareness of ACR issues, and the support provided for practices in the form of ACR guidance was viewed as helpful. Reflections from the project implementation team are that having a clear follow-up pathway in place is key for an intervention such as this. Greater time to engage on this would have been beneficial, as well as templates (during the pilot phase), to track that ACR tests have been performed and followed up.

The Quality and Outcomes Framework (QOF) for general practices in England previously included a payment incentivising the recording of urine ACR for people with diabetes. The indicator was retired in April 2014, with remuneration being incorporated into the overarching approach to the care of people with diabetes. Since this time, the percentage of people receiving this care process has since dropped considerably [11]. The Healthy.io ACR service presents an alternative approach to provide this service to this group of patients, being more or less cost neutral in year 1 and with potential for cost savings in the longer term, as well as benefits for patients in terms of improved health outcomes. Home urinalysis self-testing of ACR in people with diabetes is estimated to be a cost-effective use of NHS resources in England when used by people who would otherwise not adhere to standard care [5].

Acknowledgements

YHEC would like to thank the members of the Healhty.io ACR project implementation team for their assistance with providing guidance, data and comments on this analysis.

Abbreviations

ACR	Albumin:creatinine ratio
CCG	Clinical commissioning group
CKD	Chronic kidney disease
ESRD	End stage renal disease
IMD	Index of Multiple Deprivation
YHAHSN	Yorkshire and Humber Academic Health Science Network
PCNs	Primary care networks
YHEC	York Health Economics Consortium

1 Introduction

1.1 Healthy.io ACR Testing

Diabetes is a risk factor for the development of chronic kidney disease (CKD), and damage to the kidneys caused by diabetes is a significant risk factor for end stage renal disease (ESRD) [1]. As part of the monitoring of their condition, people with diabetes should be offered annual screening for CKD using an albumin:creatinine ratio (ACR) test [2], usually by bringing a urine sample to their general practitioner (GP). However, a study undertaken in 2015 found that 50% of people with diabetes did not bring a urine sample to their GP appointment [2]. In 2017, adherence to ACR testing in people with diabetes was reported to be 54% [3]. Data show that in 2020, only 52.6% of people with diabetes in the West Yorkshire and Harrogate Health & Care Partnership completed the ACR test annually [4].

Healthy.io has developed a smartphone based urinalysis kit for ACR, using a reagent stick built around existing semi-quantitative urinalysis dipsticks. These strips can detect albuminuria at very low levels and also measure creatinine, resulting in higher sensitivity, specificity and reliability. As a result, NICE recommend them for use in identifying albuminuria in patients at risk of chronic kidney disease [1]. Users are posted the kit to their home address where they conduct ACR screening. The results are securely shared with their GP practice, automatically via an app, for follow-up by a clinician if needed. Yorkshire and Humber Academic Health Science Network (YHAHSN) and Leeds CCG were successful in obtaining NHSX funding to implement and evaluate the Healthy.io Albumin: Creatinine Ratio (ACR) service in Leeds CCG. The hypothesis is that the ACR service will increase the number of patients with diabetes that perform an ACR test, with the aim of identifying undiagnosed diabetic nephropathy. The ACR service began implementation in the autumn of 2020 and aimed to engage with 20,000 service users across the Leeds Primary Care Networks (PCNs). The initial focus was on a smaller number of PCNs, where adherence to the ACR test was shown to be similar to national adherence, at just over 50%, as shown in Table 1.1.

Table 1.1: Proposed PCNs for initial roll out of Healthy.io ACR home testing

PCN	Diabetes population	Average ACR adherence	People with no ACR
Yeadon	1,900	51%	935
Central North Leeds	3,520	51%	1,719
West Leeds	3,845	48%	2,005
Burmantofts, Harehills and Richmond Hill	3,685	52%	1,751
Morley	3,495	59%	1,428
LS25/LS26	4,395	54%	2,036

Source: National Diabetes Audit[2]

[2] NHS Digital. National Diabetes Audit (NDA) 2020-21 quarterly report for England, Clinical Commissioning Groups and GP practices – PROVISIONAL. 14th January 2021.

1.2 Evaluating the Healthy.io ACR Service

The anticipated outcomes for the project in Leeds are:

- Increased number of and percentage adherence to ACR tests
- Increased detection of CKD
- Avoidance of ESRD
- Reduced use of primary care resources (i.e. admin and clinic time) due to remote testing and commissioning of an external service
- Reduced acute admissions
- Increased satisfaction for people due to not having to travel to a clinic for ACR testing

The AHSN asked York Health Economics Consortium (YHEC) to evaluate the project, to provide evidence that these outcomes were being achieved. This evaluation has made use of data emerging from early implementation in Leeds, in an economic model which assesses the costs and outcomes of using the Healthy.io ACR service in diabetes. The model was developed in 2019 by YHEC: 'Economic Evaluation of Healthy.io ACR self-screening test for the detection of Albuminuria in people with diabetes or hypertension'. The evaluation has produced a cost-effectiveness analysis, modelling the costs and outcomes of the service over different time horizons (1 year, 5 years, 10 years and lifetime). The evaluation also includes data on the uptake of the service, feedback on patient experience, and the views of staff in the practices implementing the service.

2 Methods

2.1 Evaluation Overview

The evaluation used a mixed methods approach, including quantitative analysis of data from implementation sites, economic modelling, and qualitative analysis of users' views.

The first step was to develop an economic protocol setting out the main parameters for evaluation, the methods to be used, the data specification and the approach to the analysis. The parameters for the evaluation are described in Table 2.1.

Table 2.1: Evaluation parameters

Parameter	Details
Population	The population eligible for the intervention are those patients with diabetes who have not had an ACR test in the last 12 months.
Intervention	The Healthy.io ACR service, which incorporates the following key steps: ▪ GP practices search their clinical system to identify eligible patients i.e. those without an ACR reading in their patient record in the last 12 months. Patients are excluded at this stage if they are pregnant, have a catheter, are on renal replacement therapy, are at the end of their life, or are in a care home. ▪ Practices contact the patients to inform them of the service and that they will be sent a test kit by Healthy.io. They have one week to let the practice know that they wish to opt out, before their details are passed to Healthy.io. ▪ Healthy.io call handlers contact the patient, confirming they want the service. Patients agreeing to participate will be sent the test kit. At this point they also ask the patient for their consent to use their data for evaluation purposes. ▪ The test kit is sent to the patient, who performs the test at home. The result of the test is sent from their app to their GP via a secure NHS messaging protocol, allowing real-time review of results by their clinical team. ▪ Healthy.io call handlers follow up patients who do not perform the test at home. ▪ When the patient has performed the ACR test, the Healthy.io app asks them to complete 4 questions (on the app), about their experience of performing the test.
Comparator	The comparator group is those patients with diabetes who do not have an ACR test – either at their GP practice or via the Healthy.io service. This group is assumed to be at risk of having undiagnosed CKD and therefore to be at risk of developing ESRD and other cardiovascular events.
Outcomes	▪ Proportion of the population with diabetes having an ACR test in the last 12 months. ▪ Detection of albuminuria amongst patients with diabetes. ▪ Incidence of ESRD amongst patients with diabetes. ▪ Acute admissions due to exacerbation of CKD e.g. acute kidney injury. ▪ Primary care resources for conventional ACR testing. ▪ Primary care resources as an adjunct to the Healthy.io test. ▪ Cost effectiveness of the Healthy.io service. ▪ Patient satisfaction with the ACR testing process.

2.2 Data Acquisition

A range of data was required for the evaluation. Some measures were obtained through primary data collection and were provided to YHEC. Other values were obtained through use of economic modelling. Aggregated summary data for the whole patient cohort up to 15 March 2021 were provided from Healthy.io to YHEC. Individual case level data were required to undertake sub-analysis by age and sex (known as the 'evaluation sample'). Hence, consent for individual patient data to be used in the evaluation was sought by the Healthy.io call handlers at the point at which the patients were sent a test kit. Call handlers asked the following question "Lastly, the service is being evaluated by York Health Economic Consortium, are you happy to take part in the evaluation? All of your details will be anonymised." Healthy.io removed any patient identifiable data before passing to YHEC via secure transfer method. The anonymised data were stored and analysed on the University of York Data Safe Haven. The Index of Multiple Deprivation (IMD) score and decile for each participating practice was obtained from Leeds CCG.

The up-to-date unit cost of Healthy.io ACR testing was provided by Healthy.io. The costs of treating CKD and related cardiovascular events were included in the YHEC economic model, taken from literature, as referenced in Shore *et al* [5]. Costs in the model were updated to 2020/21 values where available, or uprated using the NHSCII inflation tables [6], costs occurring beyond the first year being discounted at 3.5% per year in line with NICE guidelines [7]. Up-to-date sensitivity (93.0%) and specificity (87.0%) data for the Healthy.io ACR test were inserted into the economic model [8].

Staff feedback on the Healthy.io ACR service was collected in the form of a practice survey. This collected quantitative and qualitative data on the following topics:

- Ease of implementing the service
- Views about the effect on uptake of ACR testing
- Views on the service
- Practice time and resources for ACR testing
- ACR guidance
- Clinical templates
- What would help to improve the system of care

A draft survey was produced for comment by members of the project team, the Leeds CCG lead clinicians and the Healthy.io communications lead. The survey questions and responses can be found in Appendix A. The survey was administered via the University of York online survey tool, Qualtrics. Participating practices were invited to take part in the survey via an email from the Leeds CCG clinical lead for diabetes. Patient feedback was obtained via a survey built into the Healthy.io app.

The data specification setting out the measures, the specific data required and the source of the data for the intervention and comparator groups is summarised in Table 2.2. Information governance arrangements were put in place between Leeds CCG/the practices and Healthy.io, for the sharing of data for the purposes of delivering the service. A further data sharing agreement was developed to assure the protection of data shared between Healthy.io and YHEC.

Table 2.2: Data specification for Healthy.io ACR evaluation

Measure	Data/information required	Source of data for intervention group	Source of data for comparator group
Adherence with ACR testing in previous 12 months	Proportion of patients in the population having an ACR test in the last 12 months.	National Diabetes Audit for the number with an ACR test.	National Diabetes Audit for the number with an ACR test.
Uptake of the service	Number of patients onboarded for Healthy.io service after deduction of opt-outs and ineligible patients at GP practice.	Aggregated cohort data from Healthy.io.	Assumption of no testing in the patients who opt-out, decline or are not eligible for the ACR service.
	Number of patients successfully contacted by the Healthy.io service. Practice/age/sex breakdown of patients unable to be contacted.	Aggregated cohort data from Healthy.io.	
	Practice/age/sex breakdown of patients declining the Healthy.io ACR service.	Aggregated cohort data from Healthy.io.	
	Proportion of contacted patients that successfully performed the test.	Aggregated cohort data from Healthy.io. Practice/age/sex breakdown for patients consenting to the evaluation.	
Detection of CKD	Proportion of tests showing an abnormal or high abnormal ACR result.	Aggregated cohort data from Healthy.io. Practice/age/sex breakdown for patients consenting to the evaluation.	Assumption of no detection of abnormal results due to no testing.
Incidence of end stage renal disease	Number of cases of end stage renal disease in intervention and comparator group.	Modelling based on literature estimates in the YHEC model.	Modelling based on literature estimates in the YHEC model.
Acute admissions due to CKD	Number of treatment episodes for acute conditions resulting from untreated CKD.	Modelling based on literature estimates in the YHEC model.	Modelling based on literature estimates in the YHEC model.
Resources for ACR testing	Cost per patient of Healthy.io service.	Healthy.io.	Assumption of no ACR testing in the comparator group.
Costs of treatment	Cost of treating CKD and associated morbidity over specified time horizons.	Based on YHEC model estimates with appropriate updating of costs.	Based on YHEC model estimates with appropriate updating of costs.
Patient feedback	Patient satisfaction with the ACR testing process.	Survey questions in the Healthy.io app following successful completion of the ACR test.	N/A
Staff feedback	Practice staff views on ease of implementation of the Healthy.io service and impact on practices (resources and awareness).	Practice survey administered via an online survey tool, Qualtrics.	N/A

2.3 Data Analysis

2.3.1 ACR service results

The aggregated data for the patient cohort and the patient-level results were synthesised, to provide the number of patients in the cohort at each stage of the implementation. The data on adherence with the Healthy.io ACR home testing service were summarised for the cohort and individual practices. The patient level data were synthesised for each participating practice, to show the age, sex and IMD decile of those agreeing to participate in the service and those who declined to participate. A chi-square test of independence was performed to examine the relationship between participation in the service and age range, sex and IMD decile.

A binary logistic regression model was used to estimate the relationship between uptake (perform test/did not perform test) and age range, sex and IMD decile. The reference categories for the regression were: 18-29 years, female and IMD decile 10.

The proportion of tests showing an abnormal or high abnormal ACR result were summarised for the patient level data and compared to the cohort level results. The association between the proportion of abnormal results and IMD decile was tested using a two-sided Fisher exact test.

Patient survey responses were synthesised, and descriptive statistics produced. Multinomial logistic regression and binary logistic regression models were used to examine any relationship between question response, age range, sex and IMD decile. All statistical analyses were performed in R v 3.6.3 and Microsoft Excel.

The completed practice survey results were tabulated and the themes from the findings, including the additional comments, were summarised.

2.3.2 Economic analysis

The YHEC health economic model was used to consider the costs and outcomes of using the Healthy.io ACR test in populations of people with diabetes. The results of the data analysis were used in the model, to examine the impact on costs and outcomes from this real-world study. Three inputs were derived from the study data:

- Number of patients onboarded to the service (number entering the model)
- Average age of patients (years)
- Adherence with ACR testing (% of those onboarded returning a test result)

The model combines two structures. First, a decision tree captures adherence with testing and the diagnostic outcomes of the tests. Secondly, the decision tree feeds into a Markov model that is used to estimate the long term outcomes for patients with CKD. The details of the model development and structure are reported in Shore et al [5].

3 Healthy.io ACR Results

3.1 Practices Included in the Analysis

The staged roll out of the Healthy.io ACR service in Leeds commenced in the autumn of 2020. Pressure on health services due to the ongoing Covid-19 pandemic led to a brief pause of project roll out in early 2021. At the point of the data collection for the analysis (15 March 2021), 9 practices were involved in the project. The project is continuing to engage with further practices/PCNs throughout 2021. The data shown in these results therefore represent a sample of the practices that will ultimately participate in the project. 7 of the practices are in the Morley PCN area, with 1 practice each from 2 other PCNs. The participating practices, their PCN, the IMD score and ethnicity estimate are shown in Table 3.1.

Table 3.1: Practice included in the analysis

Practice	PCN	IMD 2019 score[3]	IMD Decile	Ethnicity estimate[4]
Roundhay Road Surgery	BHR*	49.5	1	6.1% mixed, 46.7% Asian, 15.0% black, 2.5% other non-white ethnic groups
South Queen St Medical Practice	Morley	24.3	5	1.4% mixed, 2.9% Asian, 1.0% other non-white ethnic groups
Morley Health Centre	Morley	23.8	5	1.6% mixed, 3.5% Asian, 1.2% other non-white ethnic groups
Dekeyser Group Practice	Morley	22.9	5	1.5% mixed, 3.0% Asian, 1.0% other non-white ethnic groups
Gildersome Health Centre	Morley	20.8	6	1.9% Asian, 1.7% other non-white ethnic groups
Windsor House Group Practice	Morley	19.8	6	1.4% mixed, 3.0% Asian
Leigh View Medical Practice	Morley	17.6	7	1.2% mixed, 2.1% Asian
Drighlington Medical Centre	Morley	14.5	7	1.0% mixed, 2.7% Asian
Menston and Guiseley Practice	Yeadon	6.2	10	1.3% Asian, 1.6% other non-white ethnic groups

* Burmantofts, Harehills & Richmond Hill

The National Diabetes Audit uses practice data to monitor the care of people with diabetes. It includes the percentage of people registered with diabetes who received the 9 key processes of diabetes care, including the urine ACR. Table 3.2 shows the number of patients with diabetes in the cohort at these practices (types 1 and 2, all ages), plus the adherence with urine ACR (ACR adherence). The average adherence with urine ACR testing for the 9 practices in the study prior to the Healthy.io service was 39%, which reflects the average across Leeds CCG.

[3] Source: Leeds IMD 2019 LSOA level and practice deprivation Oct 2020 sharing 22.4.21

[4] National general Practice profiles, accessed 21.4.2021 at: https://fingertips.phe.org.uk/profile/general-practice/data#page/12/gid/2000005/pat/166/ati/7/are/B86678/iid/639/age/28/sex/4/cid/4/tbm/1

Table 3.2: Adherence with ACR testing prior to Healthy.io service

Practice	Diabetes population	People with no urine ACR	ACR adherence September 2020
Roundhay Road Surgery	395	295	25%
South Queen St Medical Practice	245	145	41%
Morley Health Centre	170	145	15%
Dekeyser Group Practice	810	440	46%
Gildersome Health Centre	210	150	29%
Windsor House Group Practice	925	630	32%
Leigh View Medical Practice	870	435	50%
Drighlington Medical Centre	155	70	55%
Menston and Guiseley Practice	460	285	38%
All practices	4,240	2,595	39%
Leeds CCG	44,725	27,415	39%

Source: National Diabetes Audit[5]

Patients have the option to opt-out of the Healthy.io service when contacted by the practice by text. Healthy.io monitored opt-out rates at 7 of the 9 practices, keeping the material used for patient information under review. Most recently, the text to patients provided a link to a patient leaflet and a hosted website/privacy notice. The patient leaflet is included in Appendix B. The number and proportion of patients actively opting out of the service at the practice stage is shown in Table 3.3. There was a considerable variation in the level of opt out across the practices, ranging from 0% to 25%, with an average of 9% across all practices.

Table 3.3: Number and proportion of patients opting out of the Healthy.io ACR service

Practice name	No. of eligible patients	No. who opted out	% who opted out	Material used for patient info
Roundhay Road Surgery	No data	No data	No data	Leeds CCG page & patient leaflet
South Queen St Medical Practice	116	29	25%	Patient leaflet
Morley Health Centre	120	7	6%	Patient leaflet
Dekeyser Group Practice	599	78	13%	Leeds CCG page
Gildersome Health Centre	116	2	2%	NHS apps library
Windsor House Group Practice	No data	No data	No data	Leeds CCG page & patient leaflet
Leigh View Medical Practice	295	1	0%	Patient leaflet
Drighlington Medical Centre	43	0	0%	Leeds CCG page
Menston and Guiseley Practice	224	22	10%	Patient leaflet
Totals	**1,513**	**139**	**9%**	

[5] Source: NHS Digital. National Diabetes Audit (NDA) 2020-21 quarterly report for England, Clinical Commissioning Groups and GP practices – PROVISIONAL. 14th January 2021

There are several stages in the Healthy.io process where patient numbers reduce, for a variety of reasons. The number and proportion of patients at each stage is shown in Table 3.4. To note, 575 patients were either not eligible for the service or opted out at the practice level. It is not possible to distinguish between these 2 reasons for not proceeding to onboarding with Healthy.io. Hence the proportion of eligible patients agreeing to be onboarded is taken from the data in Table 3.3, which shows that 91% of the eligible patients did not opt out when contacted by their practice. These patients were subsequently 'onboarded' to Healthy.io. The call handlers at Healthy.io were able to successfully contact 80% of the onboarded patients, 72% of whom agreed to participate in the service (i.e. be sent a test kit). 87% of those agreeing to be sent a test kit went on to perform the test. This equates to 50% of the number onboarded to the service.

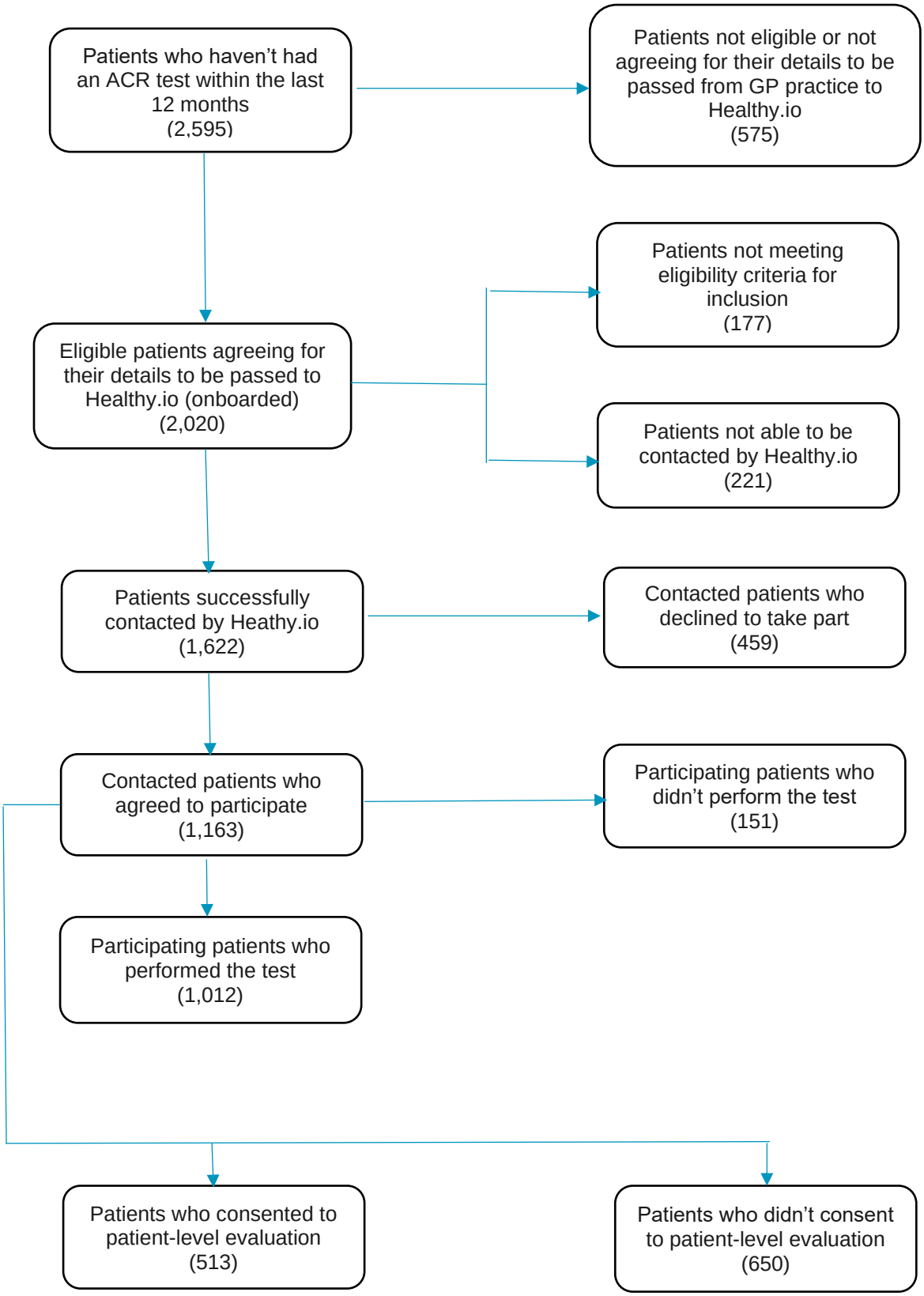
Table 3.4: Number and proportion of patients in the cohort at each stage

Description	Numerator	Denominator	%
a) Proportion of eligible patients agreeing to have their details passed from GP practice to Healthy.io (onboarded)	2,020	Not known	91%*
b) Proportion of onboarded patients successfully contacted by Healthy.io	1,622	2,020	80%
c) Proportion of contacted patients who agreed to participate	1,163	1,622	72%
d) Proportion of contacted patients that declined to take part	459	1,622	28%
e) Proportion of onboarded patients that DID perform the test	1,012	2,020	50%
f) Proportion of onboarded patients that DID NOT perform the test	1,008	2,020	50%
g) Proportion of participating patients that DID perform the test	1,012	1,163	87%
h) Proportion of participating patients that DID NOT perform the test	151	1,163	13%
i) Proportion of participating patients who consented to patient-level evaluation	513	1,163	44%

* Based on data from 7 practices (Table 3.3)

The starting number in the study cohort and patient numbers at each stage, is illustrated in Figure 3.1.

Figure 3.1: Numbers of patients involved at each stage of the Healthy.io process



3.2 Uptake of ACR Testing

The uptake of the service in each practice and across all practices is shown in Table 3.5. The proportion of those onboarded that went on to successfully perform the test ranged between 37% and 62%, with an average of 50%. The proportion of those who agreed to participate and then performed the test was much higher, ranging from 74% to 90%, with an average of 87%. This is an improvement on the proportion in the study 2 years ago (72%), which was used to populate the economic model [5].

Table 3.5: Number and proportion of those onboarded that performed the test

Practice name	No. onboarded*	No. agreeing to participate	Onboarded and successfully performed test		
			No.	% of those onboarded**	% of those agreeing to participate
Roundhay Road Surgery	227	109	83	37%	76%
South Queen St Medical Practice	87	60	54	62%	90%
Morley Health Centre	113	49	43	38%	88%
Dekeyser Group Practice	521	336	297	57%	88%
Gildersome Health Centre	114	50	45	39%	90%
Windsor House Group Practice	424	258	228	54%	88%
Leigh View Medical Practice	292	146	127	43%	87%
Drighlington Medical Centre	42	27	20	48%	74%
Menston and Guiseley Practice	200	128	115	58%	90%
TOTAL (All practices)	**2,020**	**1,163**	**1,012**	**50%**	**87%**

* Model input: number entering model

** Model input: adherence with Healthy.io test

The number and proportion of patients at each practice consenting for their data to be included in the evaluation is shown in Table 3.6. The average proportion of those who agreed to participate and then performed the test is 89%, ranging from 74% to 100%.

Table 3.6: Uptake among patients AGREEING to participate in Healthy.io ACR service and consenting to evaluation (n=513)

Practice name	Number consenting to evaluation	Successfully performed test? YES		IMD decile
		Number	% of those agreeing to take part	
Roundhay Road Surgery	7	7	100%	1
South Queen St Medical Practice	48	42	88%	5
Morley Health Centre	22	21	95%	5
Leigh View Medical Practice	56	52	93%	5
Dekeyser Group Practice	179	158	88%	6
Gildersome Health Centre	29	28	97%	6
Windsor House Group Practice	101	89	88%	7
Drighlington Medical Centre	19	14	74%	7
Menston and Guiseley Practice	52	46	88%	10
TOTAL (All practices)	**513**	**457**	**89%**	

Table 3.7 shows the reasons given by those who declined to participate in the service when contacted by the Healthy.io call handlers. The most common reason was not having access to a smartphone (41%). The second most common reason was a stated preference to take a sample to their GP practice (16%), followed by those who had plans to attend their practice, or who had recently given a sample at the practice (10%).

Table 3.7: Reasons for DECLINING to participate in Healthy.io ACR testing (n=459)

Practice	Number	Percentage
Don't own a smartphone and no access to one	190	41%
Rather bring a sample to surgery	75	16%
Going regularly to the clinic / just gave a sample / already have an appointment	46	10%
Not interested	31	7%
No reason given	30	7%
Other	23	5%
Lack of confidence with apps and self-administered tests	16	3%
No answer	14	3%
Not comfortable with technology	9	2%
Doesn't trust the service	6	1%
Smartphone is broken	3	1%
Does not want to share their information	4	1%
Patient does not speak English	5	1%
Had a test error and didn't want to do another one	5	1%
On dialysis	1	0%
In a care home	1	0%
TOTAL	**459**	**100%**

3.2.1 Patient characteristics

Tables 3.8 and 3.9 show the age and sex of patients at each practice, for those who agreed to participate and those who declined to participate. This shows that the average age of those agreeing to participate in Healthy.io ACR home testing was 58 years, compared to 69 years for those declining to participate.

A chi-square test of independence was performed to examine the relationship between participation and age range, sex and IMD decile. Table 3.10 shows the summary statistics for this analysis and shows there was a significant difference in the distribution of age, sex and IMD decile between the participating group when compared to the declining group. There was a higher proportion of males in the participating group than the declining group and a higher proportion of females in the declining group than the participating group. The younger age ranges were more represented in the participating group compared to the declining group. There was a lower proportion of people from IMD decile 1 and a higher proportion of people from IMD decile 5 in the participating group compared to the declining group.

Table 3.8: Age, sex and practice of patients AGREEING to participate (n=513 consenting to evaluation)

Practice	Age (years)								Sex		TOTALS	IMD Decile
	19-29	30-39	40-49	50-59	60-69	70-79	80+	Average age*	Male	Female		
Roundhay Road Surgery			3	4				49	4	3	**7**	1
South Queen St Medical Practice	1	6	3	15	11	8	4	58	34	14	**48**	5
Morley Health Centre		3	5	8	4	2		53	15	7	**22**	5
Dekeyser Group Practice		11	21	47	55	37	8	61	98	81	**179**	5
Gildersome Health Centre	2	3	4	4	10	4	2	57	18	11	**29**	6
Windsor House Group Practice	4	8	15	31	22	14	7	57	59	42	**101**	6
Leigh View Medical Practice	4	3	8	20	18	3		57	34	22	**56**	7
Drighlington Medical Centre	1	2	2	6	4	3	1	56	10	9	**19**	7
Menston and Guiseley Practice	1	4	6	15	11	7	8	61	32	20	**52**	10
TOTAL (All practices)	**13**	**40**	**67**	**150**	**135**	**78**	**30**	**58**	**304**	**209**	**513**	
Proportion of total	**3%**	**8%**	**13%**	**29%**	**26%**	**15%**	**6%**		**59%**	**41%**	**100%**	

* Model input: average age

Table 3.9: Age, sex and practice of patients DECLINING to participate (n=459)

Practice	Age (years)								Sex		TOTALS	IMD Decile
	17-29	30-39	40-49	50-59	60-69	79-79	80+	Average age	Male	Female		
Roundhay Road Surgery	0	1	13	8	8	6	5	59	22	19	**41**	1
South Queen St Medical Practice	1	1	0	2	2	3	2	64	5	6	**11**	5
Morley Health Centre	0	0	4	6	10	10	6	67	19	17	**36**	5
Dekeyser Group Practice	0	1	7	21	36	56	19	68	77	63	**140**	5
Gildersome Health Centre	0	1	2	2	7	14	14	73	19	21	**40**	6
Windsor House Group Practice	0	2	3	12	11	15	18	70	29	32	**61**	6
Leigh View Medical Practice	1	2	4	17	19	26	18	68	46	41	**87**	7
Drighlington Medical Centre	0	0	0	0	0	0	1	82	1	0	**1**	7
Menston and Guiseley Practice	1	0	1	5	6	16	13	72	21	21	**42**	10
TOTAL (All practices)	**3**	**8**	**34**	**73**	**99**	**146**	**96**	**69**	**239**	**220**	**459**	
Proportion of total	**1%**	**2%**	**7%**	**16%**	**22%**	**32%**	**21%**		**52%**	**48%**	**100%**	

Table 3.10: Age, sex and IMD decile of those agreeing to participate and those who declined to participate

Variable	Agreed to participate	Declined to participate	Chi squared (p value)
Male	304 (59%)	239 (52%)	$\chi^2 = 4.79$, $p = 0.03$
Female	209 (41%)	220 (48%)	
19-29 years	13 (3%)	3 (1%)	$\chi^2 = 123.09$, $p < 0.001$
30-39 years	40 (8%)	8 (2%)	
40-49 years	67 (13%)	34 (7%)	
50-59 years	150 (29%)	73 (16%)	
60-69 years	135 (26%)	99 (22%)	
70-79 years	78 (15%)	146 (32%)	
80+ years	30 (6%)	96 (21%)	
IMD 1	7 (1%)	41 (9%)	$\chi^2 = 35.75$, $p < 0.001$
IMD 5	249 (49%)	187 (41%)	
IMD 6	130 (25%)	101 (22%)	
IMD 7	75 (15%)	88 (19%)	
IMD10	52 (10%)	42 (9%)	

Using the individual patient data, a binary logistic regression model was used to estimate the relationship between the likelihood of performing test/not performing test) and age range, sex and IMD decile. The variables 'IMD decile' and 'clinic name' were found to be dependant ($\chi^2 = 2052$, df = 32, $p < 0.001$). Therefore, only IMD decile was included in the regression model since it is more informative. The model fit also improved using IMD decile vs. clinic name (AIC = 368.96 vs. AIC = 369.21).[6] Each category was compared to reference categories: 18-29 years, female and IMD decile 10.

The results of the regression modelling are shown in Table 3.11. The odds ratio represents the odds of performing the ACR test assuming all other variables remains fixed. There is no statistically significant association between performing the test and age range, sex or IMD decile (i.e. the likelihood of performing the test does not appear to be significantly associated with age, sex or IMD decile). The fitted model showed no improvement over the NULL model.

Table 3.11: Odds ratio of performing the ACR test for different variables[7]

Variable	Odds Ratio of performing ACR test	P value
Intercept	0.20	0.07
30-39 years	1.15	0.88
40-49 years	0.36	0.28
50-59 years	0.91	0.90
60-69 years	0.48	0.38
70-79 years	0.70	0.69
80+ years	0.39	0.38
Sex (male)	0.99	0.97
IMD 1	0.00	0.99
IMD 5	0.95	0.92
IMD 6	0.83	0.72
IMD 7	0.98	0.97

[6] AIC: Akaike Information Criterion

[7] Odds ratio: Value=1 means no difference in adherence; OR > 1 more likely to adhere; OR < 1 less likely to adhere (compared to the reference case).

3.3 ACR Test Results

Table 3.12 shows the proportion of results that were normal, abnormal and high abnormal, for the cohort and the evaluation sample analysis. This shows that the proportions of abnormal results (16%) and high abnormal results (8%) for the whole cohort (n=1,012) were much the same as for the smaller group in the evaluation sample analysis (n=457). This suggests that the evaluation sample is representative of the whole cohort in the service roll out so far.

Table 3.12: ACR test results for cohort (n=1,012) and evaluation sample analysis (n=457)

Practice	Normal result (<3.4 mg/mmol)		Abnormal result (3.4 - 33.9 mg/mmol)		High abnormal result (>33.9 mg/mmol)		Total
	Number	Percentage	Number	Percentage	Number	Percentage	
Roundhay Road Surgery	4	57%	3	43%	0	0%	**7**
South Queen St Medical Practice	33	79%	7	17%	2	5%	**42**
Morley Health Centre	12	57%	5	24%	4	19%	**21**
Dekeyser Group Practice	133	84%	13	8%	12	8%	**158**
Gildersome Health Centre	18	64%	7	25%	3	11%	**28**
Windsor House Group Practice	66	74%	17	19%	6	7%	**89**
Leigh View Medical Practice	40	77%	10	19%	2	4%	**52**
Drighlington Medical Centre	11	79%	1	7%	2	14%	**14**
Menston and Guiseley Practice	34	74%	6	13%	6	13%	**46**
TOTAL (All practices)	**351**	**77%**	**69**	**15%**	**37**	**8%**	**457**
COHORT DATA	**777**	**77%**	**158**	**16%**	**77**	**8%**	**1,012**

The combined proportions with abnormal/high abnormal results are shown in Table 3.13 for both the evaluation sample and the whole cohort. The proportion of patients with abnormal ACR results ranged from 16% to 43% at practice level, with an average of 23% for all practices in the evaluation sample, and for the whole cohort. At 23%, this is slightly higher than the prevalence of albuminuria in the population as a whole (20%), which is used in the economic model and is taken from the literature. As this is the prevalence in the whole population and not just the tested population, it is not directly comparable with the results here. However, the value of 23% has been used in the model in sensitivity analysis to see what affect this would have on the results of the economic model.

The association between the proportion of abnormal results and IMD decile was tested using a two-sided Fisher exact test (a chi-square was inappropriate in this case, due to small counts in the data). This showed that there is no significant association between the level of deprivation and the likelihood of an abnormal test result (p=0.2328).

Table 3.13: Abnormal or high abnormal ACR test results and practice IMD score (n=457 evaluation sample, n=1,012 cohort))

Practice	Abnormal or high abnormal result (>3.4 mg/mmol)		IMD decile
	Number	Percentage	
Roundhay Road Surgery	3	43%	1
South Queen St Medical Practice	9	21%	5
Morley Health Centre	9	43%	5
Dekeyser Group Practice	25	16%	5
Gildersome Health Centre	10	36%	6
Windsor House Group Practice	23	26%	6
Leigh View Medical Practice	12	23%	7
Drighlington Medical Centre	3	21%	7
Menston and Guiseley Practice	12	26%	10
TOTAL (All practices)	**106**	**23%**	**N/A**
COHORT DATA	**235**	**23%**	**N/A**

3.4 Patient Feedback

The Healthy.io app asked patients for feedback on their experience of using the test at home, using the following 4 questions:

1. Please rate the ease of using the ACR home based urine test (very easy to very difficult)
2. Did you encounter any problems with the device?
3. Given the choice of doing testing at the doctor's office or receiving a test at home, which do you prefer?
4. How likely is it that you would recommend ACR home based urine testing to a friend or colleague? Range 0-10 (not at all likely - extremely likely).

These data are available only for those patients completing the test, as patients who do not complete the test will not receive the user satisfaction questions via the app. There were 312 responses to the survey questions from the evaluation sample and 742 from the whole cohort.

The average age for respondents from each practice ranged from 47 to 62 years, with an average of 58 years across all practices, as shown in Table 3.14.

Table 3.14: Average age of patients responding to survey questions (n=312)

Practice	Average age of respondents (years)
Roundhay Road Surgery	47
South Queen St Medical Practice	57
Morley Health Centre	53
Dekeyser Group Practice	61
Gildersome Health Centre	58
Windsor House Group Practice	57
Leigh View Medical Practice	55
Drighlington Medical Centre	57
Menston and Guiseley Practice	62
TOTAL (All practices)	**58**

The responses to the questions are summarised in Tables 3.15 to 3.18, for the evaluation sample and for the whole cohort. The proportions of responses for the evaluation sample and the cohort are very similar, suggesting that the patients who agreed for their data to be used in the evaluation are representative of the whole cohort overall.

Using data from the evaluation sample, the results show that 95% of patients found the ACR home based urine test either easy or very easy to use, with only 2 patients (0.5%) finding it to be difficult. 95% of respondents reported having no problems using the device. When asked about preference of testing location, only 4% would prefer to be tested at the GP surgery, with 78% saying they would prefer home testing if given the option. When asked if they would recommend the service to others, on a scale of 0 (not at all likely) to 10 (extremely likely), 88% of respondents scored 8, 9 or 10, suggesting that they viewed the service favourably.

Multinomial logistic regression models were used to estimate the relationship between question response and age range, sex and IMD decile for Q1, Q3 and Q4 of the patient questionnaire. However, the low/zero responses in various categories meant that the analysis was not robust or informative. A binary logistic regression model was used to estimate the relationship between question response and age range, sex and IMD decile for Q2, which resulted in no significant associations.

Table 3.15: Ease of using the ACR home based urine test

Q1. Please rate the ease of using the ACR home based urine test	Cohort responses (n=742)		Evaluation sample (n=312)	
	Number	Percentage	Number	Percentage
a) Very easy	546	73%	231	74%
b) Easy	161	22%	64	20.5%
c) Not difficult / Not easy	26	3.5%	15	5%
d) Difficult	7	1%	2	0.5%
e) Very difficult	2	0.5%	0	0%
TOTALS	**742**	**100%**	**312**	**100%**

Table 3.16: Problems using the device

Q2. Did you encounter any problems with the device?	Cohort responses (n=742)		Evaluation sample (n=312)	
	Number	Percentage	Number	Percentage
a) No problems	702	95%	297	95%
b) Yes, I had problems	40	5%	15	5%
TOTALS	**742**	**100%**	**312**	**100%**

Table 3.17: Preference of testing at home or at GP practice

Q3. Given the choice of completing your ACR test by providing a sample to your GP practice or receiving a test at home, which do you prefer?	Cohort responses (n=742)		Evaluation sample (n=312)	
	Number	Percentage	Number	Percentage
A) Prefer testing AT HOME	565	76%	245	78%
B) No preference	135	18%	55	18%
C) Prefer testing at the DOCTOR'S	42	6%	12	4%
TOTALS	**742**	**100%**	**312**	**100%**

Table 3.18: Likelihood of recommending to others

Q4. How likely is it that you would recommend ACR home based urine testing to a friend or colleague? Range 0-10 (not at all likely - extremely likely)	Cohort responses (n=742)		Evaluation sample (n=312)	
	Number	Percentage	Number	Percentage
0	7	1%	1	0%
1	2	0%	0	0%
2	2	0%	0	0%
3	4	1%	1	0%
4	5	1%	3	1%
5	30	4%	12	4%
6	19	3%	10	3%
7	37	5%	11	4%
8	93	12%	42	13%
9	89	12%	39	13%
10	454	61%	193	62%
TOTALS	**742**	**100%**	**312**	**100%**

3.5 Practice Feedback

There were 6 responses to the practice survey, from 5 of the practices. The responses came from 3 GPs, 2 practice managers and 1 assistant manager. The detailed responses to each question can be found in Appendix A. The following is a summary of the key points.

5 of the 6 respondents thought that it had been quite easy to implement the digital home ACR testing in their practice, with 1 (practice manager) reporting that it had been quite difficult. A general theme from the comments was that there had been a bit more work involved in setting up the service than anticipated, but that the process had been straightforward. 2 respondents commented that the additional time spent implementing the project could have been used for following up patients with missing ACR results, although they did not comment on whether this would be likely to happen in the absence of the Healthy.io service. The weekly newsletters were found to be a mixed blessing by 1 respondent, in that they felt that the content was useful but also they felt obliged to read them in case they were missing something important.

When considering the time involved for different members of the practice team when compared to the standard process of ACR testing, there was a range of responses. In general, the service involved similar or greater amounts of time for the practice manager, administrator/ receptionist and the system/IT lead. Similar numbers of respondents thought the ACR home testing approach would take more or less time for GPs and practice nurses and marginally less time for healthcare assistants. One respondent (practice manager) felt that it would probably save time in the practice in the long run.

All respondents thought that the ability for patients to do the ACR test at home was likely to increase the uptake of ACR testing a bit (5 respondents) or a lot (1 respondent). They thought it would highlight the importance of the test, but would suit some patients more than others.

When asked if staff had a better understanding of ACR issues as a result of being involved in the project, two thirds of the responses were favourable, showing a little better understanding, or much better understanding, particularly of treatments for CKD, where to go for advice and when to refer the patient to secondary care. In line with this, 5 of the 6 respondents thought that the ACR guidance would help practices with their management of CKD. 4 respondents reported that their practice has a template for the management of CKD on the clinical system, with 3 of the opinion that this was used. Other suggestions for improving care for people with diabetes with respect to their kidney function were allowing more nurse time in reviews, and educational opportunities for practice staff.

4 Economic Analysis

4.1 Cost of Healthy.io ACR Testing

The Healthy.io ACR service is paid for by a per patient service charge. At the time of writing this is £14.50 per patient. This charge is applied to the number of patients 'onboarded' to the service by Healthy.io i.e. the number of patients passed from GP practice lists to Healthy.io. Whilst it is acknowledged that not all of these patients will agree to participate in the service and go on to perform the test, once the patient details are passed to Healthy.io, resources are expended by the company to contact and screen the patient.

The economic model estimates the cost of ACR testing using the standard cost approach to be approximately £5.42 per test (Appendix C). This charge is applied in the economic model only to those patients who are assumed to be adherent with standard care ACR testing in year 2 onwards (see scenario analysis in Section 4.2.3).

4.2 Results of the Economic Modelling

The economic model calculates the incremental costs of digital home ACR testing when compared to the standard care approach of practice based ACR testing, for patients in whom uptake of ACR testing has previously been 0%. The model uses a decision tree to calculate the costs of the ACR testing itself. The decision tree feeds into a 5-state Markov model to capture the long-term outcomes of patients with CKD. The 5 health states are: no CKD; diagnosed CKD; undiagnosed CKD; ESRD; death. All patients in the model are at risk of dying due to general all-cause mortality. Patients with CKD or ESRD are at an increased risk of dying and are also at risk of cardiovascular complications, particularly stroke or myocardial infarction [5]. The model estimates the overall costs to the healthcare system associated with the 5 health states, based on adherence with ACR testing, epidemiology of albuminuria, literature evidence on the probability of patients transitioning between the health states, and the cost of treating these respective conditions.

Costs are calculated over 4 time horizons for the Healthy.io group and an equivalent standard care group: 1 year, 5 years, 10 years and the lifetime of the patient cohort. For the standard care group, the model makes the assumption that the patients would have continued to be non-adherent with standard care ACR testing in future years (an assumption which is varied in scenario analysis - see Section 4.2.3). While patients who continue to be non-adherent with the standard care approach to ACR testing would not incur the cost of the test itself, costs will be incurred to the healthcare system for any patients who have undetected albuminuria and go on to develop ESRD and related conditions in later years. For the Healthy.io group, the model assumes that Healthy.io testing continues year on year, also assuming that the same proportion is adherent with the Healthy.io testing approach each year. The model does not apply the cost of Healthy.io testing to patients who are diagnosed with CKD each year, as they are no longer in the 'No CKD' health state and will be under a different care process in the practice.

The model calculates the incremental costs of Healthy.io for the whole patient cohort, by deducting the costs associated with the standard care group, from the costs associated with the Healthy.io group. The incremental costs per patient onboarded to the service are calculated by dividing the cohort costs by the number of patients onboarded.

Clinical outcomes, including total CKD diagnoses, the total number of people with ESRD, and death, are also reported by the model.

4.2.1 Cohort level results

3 values were taken from the study data to run the base case scenario through the model. The base case values for the cohort analysis are as follows:

- Number of patients onboarded to the service (number entering the model): 2,020
- Average age of patients: 58 years
- Adherence with ACR testing: 50% of those onboarded, returning a test result

Table 4.1 shows the results for the whole cohort analysis over the 4 different time horizons. This shows that, in the first year, the costs associated with the Healthy.io group and the standard care group are £491 per patient and £493 per patient respectively, giving an incremental cost saving for Healthy.io of -£2. The incremental cost per patient onboarded to the service is -£1,262 over a lifetime time horizon. The Healthy.io ACR home testing approach is therefore cost saving when compared to standard care, with an incremental cost saving for the whole cohort of -£4,354 in the first year, rising to -£2,548,267 over a lifetime time horizon, for a cohort of 2,020 patients onboarded to the Healthy.io service. The negative value shows it is potentially cost saving rather than cost incurring.

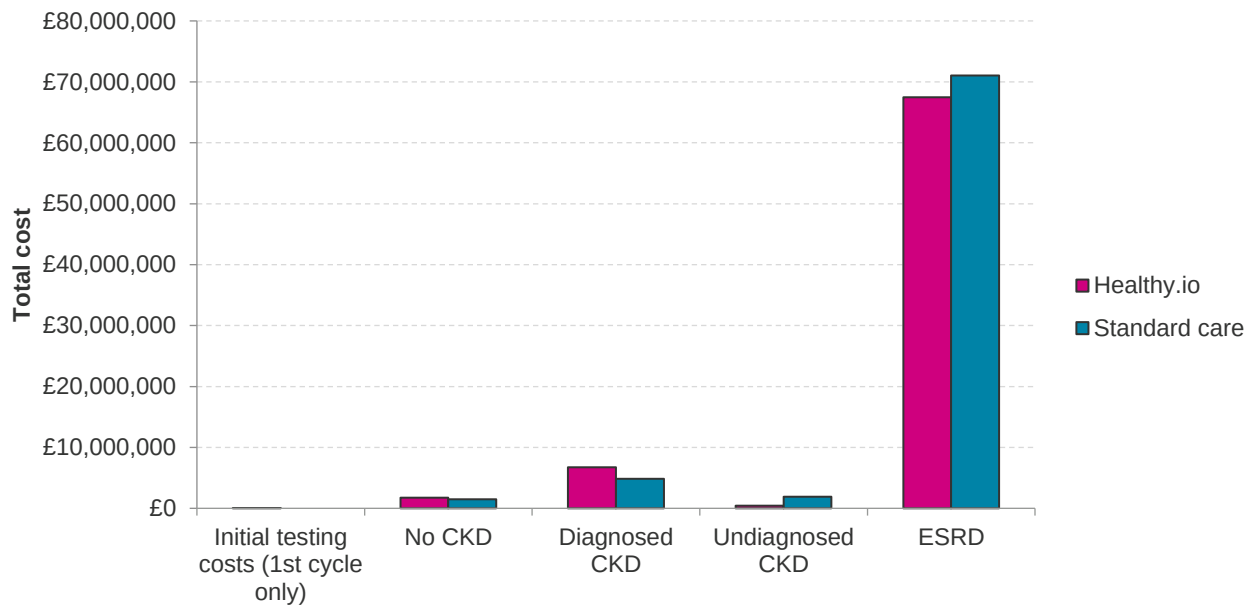
Table 4.1: Costs over different time horizons (study cohort, base case)

	Healthy.io ACR testing	Standard care	Incremental
1 year time horizon			
Costs per patient	£491	£493	-£2
Total costs per cohort (n=2,020)	£991,785	£996,139	-£4,354
5 year time horizon			
Costs per patient	£5,067	£5,392	-£325
Total costs per cohort (n=2,020)	£10,235,152	£10,892,154	-£657,001
10 year time horizon			
Costs per patient	£14,069	£14,878	-£808
Total costs per cohort (n=2,020)	£28,420,357	£30,052,945	-£1,632,589
Lifetime time horizon			
Costs per patient	£37,994	£39,256	-£1,262
Total costs per cohort (n=2,020)	£76,748,340	£79,296,607	-£2,548,267

NB. Any slight discrepancies in totals are due to rounding

The cost savings derive from an estimated increase in the total number of CKD diagnoses and a consequent reduction in future cases of ESRD. While there are short term increases in costs due to treating the additional diagnosed cases of CKD, these are outweighed by savings from the associated treatment costs of prevented ESRD and other cardiovascular events, particularly over the longer time horizons. Figure 4.1 shows the breakdown of the different lifetime costs which make up the totals in Table 4.1.

Figure 4.1: Breakdown of costs over lifetime time horizon



The model also reports clinical outcomes, comparing the total CKD diagnoses, total people with ESRD and total deaths, for Healthy.io compared to standard care. Table 4.2 shows the results of this modelling over the 4 time horizons in this cohort of 2,020 patients from the 9 practices in the study. This shows that there would be an additional 115 cases of CKD diagnosed in the first year with Healthy.io home testing, with an additional 155 over a lifetime time horizon, compared to standard care. There would be 2 fewer cases of ESRD in the first year, with 155 fewer over a 10 year time horizon.

Table 4.2: Number of health outcomes (study cohort, base case)

	Healthy.io ACR testing	Standard care	Incremental
1 year time horizon			
Total number of CKD diagnoses	170	55	115
Total number of patients with ESRD	13	15	-2
Total number of deaths	6	6	0
5 year time horizon			
Total number of CKD diagnoses	444	341	103
Total number of patients with ESRD	114	126	-12
Total number of deaths	70	73	-3
10 year time horizon			
Total number of CKD diagnoses	626	527	99
Total number of patients with ESRD	237	253	-15
Total number of deaths	202	208	-7
Lifetime time horizon			
Total number of CKD diagnoses	1,033	879	155
Total number of patients with ESRD	558	569	-12
Total number of deaths	2,020	2,020	0

We have scaled up these results to present an estimate of the potential costs and health outcomes across all of the practices in Leeds CCG and the West Yorkshire CCGs, to understand the potential impact as the Healthy.io service rolls out more widely. This required the following assumptions to be made:

- The proportion of previously non-adherent patients onboarded to the Healthy.io service is the same as for this study cohort: 78% [8]
- The average age of patients is the same as the study cohort: 58 years
- The uptake of the Healthy.io service across all of the Leeds CCG and West Yorkshire CCG practices is the same as the study cohort: 50% of those onboarded

Table 4.3 shows the results of this modelling over the 4 time horizons for Leeds CCG. This shows that for Leeds CCG, there is a potential incremental cost saving with the Healthy.io approach of -£45,998 in the first year, rising to -£26,920,800 over a lifetime time horizon, for a cohort of 21,340 patients onboarded to the Healthy.io service.[9]

For the Leeds CCG practices there would be an estimated additional 1,211 cases of CKD diagnosed in the first year, with an additional 1,633 over a lifetime time horizon. There would be 17 fewer cases of ESRD in the first year, with 162 fewer over a 10 year time horizon.

Table 4.3: Incremental costs and health outcomes (Leeds CCG, base case)

	Healthy.io ACR testing	Standard care	Incremental
1 year time horizon			
Costs per patient	£491	£493	-£2
Total costs per cohort (n=21,340)	£10,477,569	£10,523,567	-£45,998
Total number of CKD diagnoses	1,792	582	1,211
Total number of patients with ESRD	143	159	-17
Total number of deaths	65	68	-3
5 year time horizon			
Costs per patient	£5,067	£5,392	-£325
Total costs per cohort (n=21,340)	£108,127,798	£115,068,594	-£6,940,796
Total number of CKD diagnoses	4,694	3,602	1,092
Total number of patients with ESRD	1,203	1,326	-123
Total number of deaths	736	768	-32
10 year time horizon			
Costs per patient	£14,069	£14,878	-£808
Total costs per cohort (n=21,340)	£300,242,778	£317,490,028	-£17,247,250
Total number of CKD diagnoses	6,614	5,565	1,048
Total number of patients with ESRD	2,508	2,670	-162
Total number of deaths	2,130	2,202	-72
Lifetime time horizon			
Costs per patient	£37,994	£39,256	-£1,262
Total costs per cohort (n=21,340)	£810,796,815	£837,717,616	-£26,920,800
Total number of CKD diagnoses	10,914	9,281	1,633
Total number of patients with ESRD	5,893	6,015	-123
Total number of deaths	21,340	21,340	0

[8] 2,595 patients without a urine ACR, of which 2,020 onboarded i.e. 78%. To note, this is not the same metric as item (a) in Table 3.4.

[9] Number of patients without an ACR in Leeds CCG 27,415; number onboarded at 78% is 21,340.

Table 4.4 shows the results of the modelling over the 4 time horizons for the West Yorkshire CCGs. This shows that there is a potential incremental cost saving with Healthy.io approach of -£153,400 in the first year, rising to -£89,778,472 over a lifetime time horizon, for a cohort of 71,167 patients onboarded to the Healthy.io service.[10]

For the West Yorkshire CCGs there would be an estimated additional 4,037 cases of CKD diagnosed in the first year, with an additional 5,447 over a lifetime time horizon. There would be 56 fewer cases of ESRD in the first year, with 3,496 fewer over a 10 year time horizon.

Table 4.4: Incremental costs and health outcomes (West Yorkshire CCGs, base case)

	Healthy.io ACR testing	Standard care	Incremental
1 year time horizon			
Costs per patient	£491	£493	-£2
Total costs per cohort (n=71,167)	£34,941,760	£35,095,160	-£153,400
Total number of CKD diagnoses	5,978	1,940	4,037
Total number of patients with ESRD	475	532	-56
Total number of deaths	217	226	-9
5 year time horizon			
Costs per patient	£5,067	£5,392	-£325
Total costs per cohort (n=71,167)	£360,596,579	£383,743,517	-£23,146,938
Total number of CKD diagnoses	15,654	12,013	3,642
Total number of patients with ESRD	4,012	4,423	-411
Total number of deaths	2,455	2,561	-106
10 year time horizon			
Costs per patient	£14,069	£14,878	-£808
Total costs per cohort (n=71,167)	£1,001,282,932	£1,058,800,974	-£57,518,042
Total number of CKD diagnoses	7,102	7,343	-241
Total number of patients with ESRD	22,056	18,560	3,496
Total number of deaths	8,365	8,904	-539
Lifetime time horizon			
Costs per patient	£37,994	£39,256	-£1,262
Total costs per cohort (n=71,167)	£2,703,935,190	£2,793,713,662	-£89,778,472
Total number of CKD diagnoses	36,398	30,951	5,447
Total number of patients with ESRD	19,652	20,061	-409
Total number of deaths	71,167	71,167	0

4.2.2 Practice level results

The economic analysis at practice level has been performed by using the practice specific values for number onboarded, average age, and percentage of onboarded patients who performed the test. As the size of the cohort is different for each practice, Table 4.5 shows only the cost per patient across the different time horizons for each practice. This can be multiplied by the number of patients onboarded to estimate the costs for a cohort size appropriate for the practice. All practices show incremental savings at patient level over all time horizons. Similar to the evaluation cohort results, the incremental financial gain is under £10 per patient in the first year. At 5 years, the gains increase to between £266 (Gildersome Health Centre) and £390 (South Queen Street) per patient.

[10] Number of patients without an ACR in West Yorkshire CCGs 91,425; number onboarded at 78% is 71,167.

The incremental savings over a lifetime range between £1,087 (Dekeyser Group Practice) to £1,717 per patient (Roundhay Road Surgery). We can see that although the uptake of the service was lower at Roundhay Road Surgery, the lower average age of the patients means there is greater potential to benefit from the avoidance of ESRD and associated costly treatment over the remaining years of life. This is similar at 10 years. However, when looking at the 1 and 5 year time horizons, this picture reverses. Roundhay Road Surgery has lower savings per patient than Dekeyser Group Practice, as the lower uptake of the service has more of an effect on the short term economic results.

Table 4.5: Practice results over different time horizons (base case) – costs per patient

	Time horizon	Healthy.io ACR testing	Standard care	Incremental
Roundhay Road Surgery (IMD 1) Number onboarded: 227 Average age: 49 years Adherence: 37%	1 year	£542	£544	-£1
	5 years	£5,859	£6,163	-£304
	10 years	£16,948	£17,769	-£821
	Lifetime	£64,695	£66,412	-£1,717
South Queen St Medical Practice (IMD 5) Number onboarded: 87 Average age: 58 years Adherence: 62%	1 year	£486	£493	-£7
	5 years	£5,002	£5,392	-£390
	10 years	£13,940	£14,878	-£938
	Lifetime	£37,807	£39,256	-£1,448
Morley Health Centre (IMD 5) Number onboarded: 113 Average age: 53 years Adherence: 38%	1 year	£518	£518	£0
	5 years	£5,553	£5,841	-£288
	10 years	£15,805	£16,571	-£766
	Lifetime	£52,088	£53,520	-£1,432
Dekeyser Group Practice (IMD 5) Number onboarded: 521 Average age: 61 years Adherence: 57%	1 year	£468	£470	-£2
	5 years	£4,765	£5,094	-£329
	10 years	£12,991	£13,776	-£785
	Lifetime	£30,723	£31,809	-£1,087
Gildersome Health Centre (IMD 6) Number onboarded: 114 Average age: 57 years Adherence: 39%	1 year	£496	£493	£2
	5 years	£5,219	£5,484	-£266
	10 years	£14,534	£15,227	-£693
	Lifetime	£40,783	£41,917	-£1,135
Windsor House Group Practice (IMD 6) Number onboarded: 424 Average age: 57 years Adherence: 54%	1 year	£490	£493	-£4
	5 years	£5,127	£5,484	-£358
	10 years	£14,343	£15,227	-£884
	Lifetime	£40,494	£41,917	-£1,424
Leigh View Medical Practice (IMD 7) Number onboarded: 292 Average age: 57 years Adherence: 43%	1 year	£494	£493	£1
	5 years	£5,193	£5,484	-£292
	10 years	£14,479	£15,227	-£748
	Lifetime	£40,698	£41,917	-£1,219
Drighlington Medical Centre (IMD 7) Number onboarded: 42 Average age: 56 years Adherence: 48%	1 year	£492	£494	-£1
	5 years	£5,224	£5,553	-£329
	10 years	£14,700	£15,535	-£835
	Lifetime	£43,225	£44,628	-£1,403
Menston and Guiseley Practice (IMD 10) Number onboarded: 200 Average age: 61 years Adherence: 58%	1 year	£468	£470	-£2
	5 years	£4,761	£5,094	-£333
	10 years	£12,982	£13,776	-£794
	Lifetime	£30,710	£31,809	-£1,099

To give an idea of the costs and health outcomes for an average practice, we have used the average number of patients onboarded per practice across the 9 practices (224 patients), along with the other base case values of average age (58 years) and proportion of those onboarded returning a test result (50%). The results are shown in Table 4.6, which shows there would be an estimated incremental cost saving of -£483 in the first year, rising to -£282,580 over a lifetime time horizon. There would be an additional 13 cases of CKD diagnosed in the first year with Healthy.io home testing, with an additional 17 over a lifetime time horizon, compared to standard care. There would be 2 fewer cases of ESRD over a 10 year time horizon, and 1 fewer death.

Table 4.6: Results for an average practice over different time horizons (base case)

	Healthy.io ACR testing	Standard care	Incremental
1 year time horizon			
Costs per patient	£491	£493	-£2
Total costs per cohort (n=224)	£109,980	£110,463	-£483
Total number of CKD diagnoses	19	6	13
Total number of patients with ESRD	1	2	0
Total number of deaths	1	1	0
5 year time horizon			
Costs per patient	£5,067	£5,392	-£325
Total costs per cohort (n=224)	£1,134,987	£1,207,843	-£72,856
Total number of CKD diagnoses	49	38	11
Total number of patients with ESRD	13	14	-1
Total number of deaths	8	8	0
10 year time horizon			
Costs per patient	£14,069	£14,878	-£808
Total costs per cohort (n=224)	£3,151,564	£3,332,604	-£181,040
Total number of CKD diagnoses	69	58	11
Total number of patients with ESRD	26	28	-2
Total number of deaths	22	23	-1
Lifetime time horizon			
Costs per patient	£37,994	£39,256	-£1,262
Total costs per cohort (n=224)	£8,510,707	£8,793,287	-£282,580
Total number of CKD diagnoses	115	97	17
Total number of patients with ESRD	62	63	-1
Total number of deaths	224	224	0

4.2.3 Scenario analysis

The practice level results indicate that the average patient age and uptake of the service can affect the average costs per patient over time. Shore *et al* [5] conducted univariate sensitivity analysis on the economic model, testing the impact of varying the model inputs on the results. The average starting age of patients entering the model was found to be one of the key drivers of the results. Other important variables were the relative risk reduction in progression to ESRD with treatment, the proportion of patients presenting with symptoms each year, relative risk of mortality from undiagnosed CKD, and the transition from CKD to ESRD multiplier. In all their analyses, Shore *et al* found that independent changes in model parameters within plausible ranges did not change the direction of the results, and the Healthy.io service remained cost saving.

For our analysis, we have varied 3 parameters in the model, to observe the impact on the results when compared to the cohort base case values. Tables 4.7 and 4.8 show the results of varying the following:

- Average age of patients: increasing the average age of patients being onboarded to the service from 58 to 61 years. The average age of diabetic patients who are unscreened for ACR nationally is 61 years [9].
- Adherence with the service: increasing the adherence with the service (percentage of those onboarded who perform the test) from 50% to 60%.
- Prevalence of albuminuria: increasing the prevalence from 20% (the national average) to 23% (the prevalence in the study population who performed a test).

The scenario which has the greatest impact in terms of increased savings and reduced number of patients with ESRD, is when adherence with ACR testing is increased from 50% to 60% of those onboarded to the service. Percentage adherence is the main variable which the CCG, practices and Healthy.io have scope to influence while implementing the service. While 60% uptake may seem ambitious, the fact that 1 of the practices achieved 62% adherence and 2 others achieved 57% and 58%, suggests that this may be achievable.

Table 4.7: Results of scenario analyses: total cohort costs over lifetime time horizon

Scenario	Healthy.io ACR testing	Standard care	Incremental
Base case (n=2,020)	£76,748,340	£79,296,607	-£2,548,267
Increasing average age from 58 to 61 years	£62,244,642	£64,254,834	-£2,010,192
Increasing adherence from 50% to 60%	£76,429,085	£79,296,607	-£2,867,521
Increasing prevalence of albuminuria from 20% to 23%	£81,061,979	£83,792,569	-£2,730,590
All of the above	£65,588,724	£68,031,056	-£2,442,332

Table 4.8: Results of scenario analyses: number of CKD diagnoses, patients with ESRD and deaths in the cohort over lifetime time horizon

	Healthy.io ACR testing	Standard care	Incremental
Base case (n=2,020)			
Total number of CKD diagnoses	1,033	879	155
Total number of patients with ESRD	558	569	-12
Total number of deaths	2,020	2,020	0
Increasing average age from 58 to 61 years			
Total number of CKD diagnoses	975	825	149
Total number of patients with ESRD	482	493	-11
Total number of deaths	2,020	2,020	0
Increasing adherence from 50% to 60%			
Total number of CKD diagnoses	1,040	879	161
Total number of patients with ESRD	557	569	-13
Total number of deaths	2,020	2,020	0
Increasing prevalence of albuminuria from 20% to 23%			
Total number of CKD diagnoses	1,045	900	145
Total number of patients with ESRD	580	591	-12
Total number of deaths	2,020	2,020	0
All of the above			
Total number of CKD diagnoses	993	849	144
Total number of patients with ESRD	501	514	-12
Total number of deaths	2,020	2,020	0

Future Adherence with the Standard Care Approach to ACR Testing

A further scenario analysis was performed to test a key assumption in the model, relating to the future adherence with the standard care approach to ACR testing. The model assumes that patients who have previously been non-complaint with this approach will continue be so in future years. We tested the impact on the results if a proportion of these patients began to adhere to ACR testing via the standard care approach, and continued to be so over a lifetime time horizon. The results of the analysis, per patient, for the study cohort, and for the Leeds and West Yorkshire cohorts, are shown in Tables 4.9 and 4.10.

The results show that, as the proportion of patients who obtain their ACR test via the standard care approach in future years increases, the potential savings from the Healthy.io approach decreases. This is to be expected, as there is an additional cost associated with the Healthy.io testing approach, and some of the savings achieved from diagnosing and treating CKD earlier are attributed to the standard care approach, for which there is no additional cost. In all scenarios however, the cost savings of Healthy.io remain substantial, with an estimated incremental cost saving of £849 per patient and approximately £60 million at West Yorkshire level, over a lifetime time horizon, if 15% of previously non-adherent patients were to adhere to standard care ACR testing in the future.

The effect on incremental clinical outcomes is similarly affected when patients begin to adhere to standard care. The additional number of CKD diagnoses achieved via the Healthy.io approach also reduces, and the number of cases of ESRD prevented by the Healthy.io approach is reduced, as standard care is responsible for some of the positive health outcomes. Nevertheless, there are incremental gains in terms of clinical outcomes from the Healthy.io approach in all scenarios tested.

Table 4.9: Increased future adherence with standard care: incremental costs over lifetime time horizon

Future adherence with standard care	Incremental costs			
	Patient	Study cohort (n=2,020)*	Leeds CCG (n=21,340)	West Yorkshire CCGs (n=71,167)
0% (base case)	-£1,262	-£2,548,267	-£26,920,800	-£89,778,472
5%	-£1,108	-£2,237,964	-£23,642,652	-£78,846,140
10%	-£971	-£1,961,594	-£20,722,981	-£69,109,295
15%	-£849	-£1,714,080	-£18,108,156	-£60,389,089

* n=number onboarded to Healthy.io.

Table 4.10: Increased future adherence with standard care: number of CKD diagnoses and patients with ESRD over lifetime time horizon*

Future adherence with standard care	Incremental costs		
	Study cohort (n=2,020)	Leeds CCG (n=21,340)	West Yorkshire CCGs (n=71,167)
0% (Base case)			
Total number of CKD diagnoses	155	1,633	5,447
Total number of patients with ESRD	-12	-123	-409
5%			
Total number of CKD diagnoses	119	1,259	4,199
Total number of patients with ESRD	-10	-106	-354
10%			
Total number of CKD diagnoses	88	934	3,115
Total number of patients with ESRD	-9	-92	-306
15%			
Total number of CKD diagnoses	61	649	2,165
Total number of patients with ESRD	-7	-79	-264

* Deaths are not included here, because over a lifetime time horizon, there will be no incremental difference in deaths between the Healthy.io group and standard care group.

5 Discussion

This analysis sought to estimate the impact of the Healthy.io ACR home testing service in Leeds CCG, in terms of cost-effectiveness and health outcomes, as well as summarising patient and practice feedback on the service. Due to the impact of Covid-19, the implementation of the service could be said to be still in its early stages. Nevertheless, a cohort of over 2,000 patients was available for analysis, from 9 practices.

5.1 Uptake of the ACR Service

The average adherence with urine ACR testing across the participating practices prior to the roll out of the project was 39%. Of those previously non-adherent patients who were eligible to use the Healthy.io service, 91% agreed to be onboarded to the service, of whom 80% were successfully contacted by Healthy.io and 72% of these agreed to participate (be sent a test kit). The proportion of those who agreed to participate and then performed the test is high, at 87%. This is an improvement when compared to a previous study in 2019 (72%), which was used to populate the economic model in 2019 [5]. In the previous study, the administration staff at the participating practices made contact with the onboarded patients, whereas in this study, Healthy.io used an in-house onboarding team to contact patients directly and take them through the whole process. This additional level of control over the process may explain the improved uptake and indicate a more effective approach.

The average proportion of patients in the evaluation sample who performed the test was 89%, ranging from 74% to 100%. The slightly higher values in this sub-group compared to the whole cohort may reflect a relationship between their willingness to be included in the evaluation, and their likelihood of going on to complete the test. The proportion of onboarded patients who went on to complete the test was 50% overall, ranging from 37% to 62% at practice level.

The most common reason for declining to participate in the service when contacted by Healthy.io was not having access to a smartphone (41% of those declining). The second most common reason was a stated preference to take a sample to their GP practice (16%). It is interesting to note that the average age of those agreeing to participate in Healthy.io ACR home testing was 58 years, compared to 69 years for those declining to participate. We were not able to link age and reason for declining at patient level, although these data suggest that older patients may be less likely to participate in the service because they do not have the required technology. We understand that not possessing a smartphone was an exclusion criterion for the Leeds CCG implementation, with reliance on using another person's phone not being desirable. In 2 previous implementations of Healthy.io, 11% and 18% of the respective populations who took part in the service had done so via someone else's smartphone [10]. While relaxing this criterion in Leeds may have an impact on future uptake, this also highlights that the standard care approach is still appropriate for some patients. Equally, as the population ages, and use of smartphone technology is more prevalent, the service may be increasingly accessible in older age groups.

As well as age differences, the analysis revealed that there are statistically significant differences in the distribution of sex and IMD decile between patients who agreed to participate in the service compared to those who declined to take up the offer. The participating group has a higher proportion of males, a higher proportion of people from IMD decile 5, and younger patients, whereas the declining group has a higher proportion of females, people from IMD decile 1 and older patients. Given the findings noted above about the age of those declining the service, the higher proportion of older patients in the opting out group is not surprising. The difference between males and females is interesting, although we do not currently have any insight as to a possible explanation for this. While there was slightly lower uptake in the practice in IMD decile 1, further analysis with a larger number of practices would be beneficial to explore the relationship between deprivation and uptake. The analysis did not, however, find any statistically significant association between age, sex or IMD decile, and the likelihood of those who agreed to participate in the service going on to actually perform the test. There was also no significant different in the age range, sex and IMD decile for the responses to the patient feedback questions.

For those patients that did perform the ACR home test, and completed the patient survey on the app, 95% found the test either easy or very easy to use, and only 4% of patients who completed the test would prefer to be tested at their GP surgery. From previous feedback, Healthy.io reported that for the small proportion (5%) who had problems using the device, these were due to technical problems. Most patients would be highly likely to recommend the service to others.

The combined proportions with abnormal/high abnormal ACR results was 23%, for both the evaluation sample and the whole cohort. This is slightly higher than the prevalence of albuminuria in the population as a whole (20%). The proportion of patients with abnormal ACR results ranged from 16% to 43% at practice level.

5.2 Economic Analysis

The Healthy.io ACR service is paid for via a service charge of £14.50 (at the time of writing), for each patient onboarded to the service. The economic analysis aimed to understand the benefits in terms of costs and patient outcomes, and whether these outweighed the cost of the Healthy.io service intervention.

The economic modelling estimated the cost savings of home testing compared to standard care over the patients' lifetime, to be around -£1,262 per patient, for the base case scenario. For the cohort in the study (2,020 patients onboarded, 1,012 performing the test), home testing shows cost savings of -£4,354 in the first year, rising to -£2,548,267 over a lifetime time horizon. To note, this is a lower figure than the analysis reported in Shore *et al* [5], partly due to the average age of the patients being higher in the Leeds study, but also due to the fact that the per patient charge at that time was applied only to those patients who successfully completed the ACR test, which was 72% of those who agreed to participate. The equivalent metric in this analysis is 87%. If the same charging model had been in place, the lifetime savings in this analysis would be in excess of £1,700 per patient.

The economic model assumes that there will be saved time for administration staff in following up patients for testing, but additional time to administer the results from home ACR testing within the clinical system. However, the Healthy.io process now includes automatic uploading of results into the GP system, so the savings quoted here may slightly be on the conservative side, as this additional time (4.5 minutes of administration staff) is no longer needed. Time required for GPs is assumed to be the same, and there is an assumed saving for practice nurses, in not having to spend time taking the test with patients, plus a small saving on consumables. The small number of responses to the practice survey support the assumptions in the economic model that there are time savings in practices for clinical staff, but increased time for administration staff. Nevertheless, time and resource expended by Healthy.io contacting patients does replace some of the time spent by the practice repeatedly following up those without an ACR test. Some administration time is required when practices are setting up to use Healthy.io for the first time, and would not be required in the future. Furthermore, Healthy.io has drawn on lessons from this, and other deployments at scale, and has implemented process improvements which support practice implementation. These include automating calendar invites, signing documents online instead of requiring them to be printed and returned, utilising remote software to set up the technical aspects of the service, as well as building out and providing the relevant searches and reports for each site's electronic medical record.

The cost savings of Healthy.io, albeit small in year 1, derive from an estimated increase in the total number of CKD diagnoses and a consequent reduction in future cases of ESRD. While there are short term increases in costs due to treating the additional diagnosed cases of CKD, these are far outweighed in the longer term by savings from the associated treatment costs of prevented ESRD and other cardiovascular events, such as hospital admissions. The benefits to patients are not merely the convenience of the test, but the potential for detecting previously undiagnosed CKD and being able to intervene earlier. For this cohort analysis, there would be an estimated additional 115 cases of CKD diagnosed in the first year with Healthy.io home testing, with an additional 155 over a lifetime time horizon, compared to standard care. There would be 2 fewer cases of ESRD in the first year, with 15 fewer over a 10 year time horizon.

When scaled up across all of the practices in Leeds CCG, this is an estimated additional 1,211 cases of CKD diagnosed in the first year, with an additional 1,633 over a lifetime time horizon, with associated cost savings of -£45,998 the first year, rising to -£26,920,800 over a lifetime time horizon. Across West Yorkshire, there would be an estimated additional 4,037 cases of CKD diagnosed in the first year, with an additional 5,447 over a lifetime time horizon, with associated cost savings of -£153,400 the first year, rising to -£89,778,472 over a lifetime time horizon.

Our scenario analysis shows that the results are sensitive to the average age of patients entering the model, with cost savings being greater for younger patients. This is because, on average, younger people have more years of life remaining, and therefore more potential to benefit from the avoidance of ESRD and associated costly treatment. Clearly, the level of adherence also affects the results of the economic modelling, with increased rates of test completion leading to greater savings over time, quite apart from the improved health outcomes for patients.

While we have no evidence to suggest that previously non-adherent patients will be likely to adhere to standard care approaches in the future, we tested the effect on the results of assuming that a proportion of patients (5%, 10% and 15%) do begin to adhere to standard care. As expected, this shows that as the proportion of patients who obtain their ACR test via the standard care approach in future years increases, the potential savings from the Healthy.io approach decreases. In all scenarios, however, the savings remain substantial, with an estimated incremental cost saving of -£849 per patient and approximately -£60million at West Yorkshire level, over a lifetime time horizon, if 15% of patients begin to adhere to standard care ACR testing in future years.

5.3 Practice Views

The response to the practice survey was limited so the responses may not be truly representative of all practices. Nevertheless, some interesting themes arise from the 6 responses received. The respondents were evenly split between clinicians and practice management. Most thought that the service had been quite easy to implement, even though there was more work involved in setting up the service than had been anticipated. In general, the service was viewed as requiring increased time commitment for management/ administration roles within the practice, and reduced time involved for clinicians. As mentioned above, some of the additional administration/management time is expected to only be required the first time Healthy.io is deployed in the practice.

All respondents thought it was likely to increase the uptake of ACR testing a bit. Although this survey was done after the Healthy.io service was completed in the participating practices, this suggests that there may be a gap in understanding of how much adherence rates had improved, compared to rates before the service was rolled out.

There was a favourable view of the impact of the project on the understanding of practice staff of ACR issues, particularly of treatments for CKD, where to go for advice and when to refer the patient to secondary care. In line with this, 5 of the 6 respondents thought that the ACR guidance would help practices with their management of CKD.

5.4 Limitations

There are a number of limitations affecting this analysis as follows:

The analysis was based on a single arm observational evaluation with no counterfactual data. The economic model therefore assumes that people in the standard care arm had 0% adherence with ACR testing, given that they were previously non-adherent with standard care testing. As described above, we tested the effect of increasing adherence with ACR testing in the standard care arm in subsequent years, and found the intervention remained cost saving, although the level of benefit was reduced.

The economic model contains transition probabilities and rates of progression to ESRD and incidence of CKD related conditions. There is an assumption that these are similar in the patient population in Leeds CCG. There is also an assumption that patients with an abnormal ACR are followed up clinically and have appropriate interventions.

The estimate of health outcomes for the Leeds and West Yorkshire CCGs assumes that the proportion of previously non-adherent patients onboarded to the Healthy.io service, the average age of patients, and the uptake of the Healthy.io service, are the same as for the 9 study practices. As the average adherence in the study practices is the same as for Leeds CCG, this seems to be a reasonable assumption.

It was not possible to test any relationship with ethnicity for this analysis, mainly since the data on ethnicity in primary care patient records are not currently considered to be of sufficient quality.

As there were only 6 replies to the practice survey, it is not possible to tell how representative these are of all practices.

The model compares the time taken for conducting the Healthy.io home testing approach compared to the standard approach for those patients that complete the test. This does not take account of time and effort expended by practice staff (in standard care) that does not result in a successfully completed test. It was not possible to collect granular data on the amount of time taken in practices that does not result in a completed test. It was considered that detailed questions on this in the practice survey were too onerous for practices to complete with any accuracy. Therefore, there may be more effort expended by practices to reach patients that is not included in this analysis, and the staff time savings at practice level may therefore be slightly underestimated.

5.5 Conclusions

This analysis has sought to assess whether the following anticipated outcomes for the Healthy.io ACR service in Leeds CCG have been achieved:

- Increased number and percentage adherence of ACR tests
- Increased detection of CKD
- Avoidance of ESRD
- Reduced primary care resources
- Reduced acute admission
- Increased satisfaction for people due to not having to travel to clinic for testing

From the data available from the early stage of implementation, we conclude that the project is well on the way to achieving these outcomes. The participation in the service by people with diabetes who were previously not adherent with ACR testing in practice was high, at 50% of those onboarded to the service, and 87% of those who agreed to participate. The findings suggest that uptake may have been higher if patients had been permitted to use another person's smartphone. Patient feedback shows that the majority of patients found the service/technology easy to use and would prefer home testing if given the option.

The analysis did find statistically significant differences in the proportion of people from IMD decile 1 in the participating group compared to the declining group and a higher proportion of people from IMD decile 5. On reflection, the project implementation team would recommend that an analysis of uptake by practice deprivation could have been undertaken prior to roll out, allowing practices in areas of higher deprivation to be onboarded earlier in the study. Having agreed to participate in the service, there was no statistically significant difference in the likelihood of patients performing the test between age, sex and IMD decile.

The testing undertaken found higher than national levels of albuminuria, to be followed up by their GP practices and receive appropriate treatment (23% compared to 20%). Although any changes in the incidence of ESRD will take years to become apparent in this study group, the economic modelling, based on robust literature evidence, suggests that these improved patient outcomes are highly likely to be achieved. The economic modelling estimated the cost savings over the patients' lifetime to be around -£1,262 per patient. Across Leeds CCG, the service has the potential to achieve cost savings of -£26,920,800 over a lifetime time horizon. Across West Yorkshire this rises to -£89,778,472 over a lifetime time horizon.

Additional benefits are that involvement in the project was thought to assist practices' knowledge and awareness of ACR issues, and the support provided for practices in the form of ACR guidance was viewed as helpful. Reflections from the project implementation team are that having a clear follow-up pathway in place is key for an intervention such as this. Greater time to engage on this would have been beneficial, as well as templates (during the pilot phase), to track that ACR tests have been performed and followed up.

The Quality and Outcomes Framework (QOF) for general practices in England previously included a payment incentivising the recording of urine ACR for people with diabetes. The indicator was retired in April 2014, with remuneration being incorporated into the overarching approach to the care of people with diabetes. Since this time, the percentage of people receiving this care process has since dropped considerably [11]. The Healthy.io ACR service presents an alternative approach to provide this service to this group of patients, being more or less cost neutral in year 1 and with potential for cost savings in the longer term, as well as benefits for patients in terms of improved health outcomes. Home urinalysis self-testing of ACR in people with diabetes is estimated to be a cost-effective use of NHS resources in England when used by people who would otherwise not adhere to standard care [5].

6 References

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10. Source: Healthy.io Clinical and Partnerships Lead, based on patient survey results.
11. Diabetes UK. Position statement: The Future of the Quality and Outcomes Framework in England. February 2018.

Appendix A: Practice Survey and Responses

Q1. How easy has it been implementing the digital home ACR testing project in your practice?

Response	Role of survey respondent			Total
	GP	Practice Manager	Assistant Manager	
Quite easy	3	1	1	**5**
Quite difficult	0	1	0	**1**

Any comments on the ease of implementing digital home ACR testing:

- The implications of the subsequent workload were underestimated but the process was good to implement.
- There were searches to run, they emailed us with patients to check, they wanted to have several Zoom meetings. They send us at least one email per week. The results came into the practice and if the results were not acceptable the GP would then have to arrange the patient to be invited in for the traditional test.
- Took some time to enable the integration and get started but otherwise straightforward

Q2. What effect do you think digital home ACR testing is likely to have on the uptake of the ACR test by patients with diabetes?

Response	Role of survey respondent			Total
	GP	Practice Manager	Assistant Manager	
Increase a bit	2	2	1	**5**
Increase a lot	1	0	0	**1**

Any comments on the effect of home testing on uptake of the ACR test:

- Fits well with engendering more self-management and arm's length care. Only improves uptake in a certain cohort so is not a complete solution.
- Raises the profile and importance of ensuring this is done.

Q3. In your opinion, do you think that offering digital home testing is a better way for practices to obtain an ACR test from a patient?

Response	Role of survey respondent			Total
	GP	Practice Manager	Assistant Manager	
For some patients	3	2	0	**5**
Yes	0	0	1	**1**

Please explain your answer:

- Although uptake has been good, the time that the practice has spent on engaging with the project, we could have spent inviting patients in for the traditional test, and the result may have been the same.
- It's a useful exercise and an alternative way of capturing the information as patients seemed to respond, but this could be done via practices following up missing ACR results in a different format or with increased emphasis.
- Not all patients are non-adherent.
- Requires a smartphone. Prefer not to use on known microalbuminuria patients as need quantitative result to assess trend rather than just 'abnormal'.

Q4. We would like to know whether using digital home ACR testing has saved time in the practice or increased time spent, compared to the standard approach used for annual ACR testing.

When thinking about all of the tasks that are involved in the standard process of ACR testing (e.g. calling patients in to pick up a pot, labelling the pot, sending it to the lab, reviewing results etc), in your opinion does digital home ACR testing take more or less time for the following staff, compared to the time taken for the standard approach?

Response	Practice staff role					
	Practice nurse	GP	Healthcare assistant	Practice manager	Administrator / receptionist	System / IT lead
A lot less time	1	2	1			1
A bit less time	1		1		1	
No difference	1	2	1	1		2
A bit more time	2	1	1	2	4	1
A lot more time		1		1		1
Staff not involved in ACR testing				1		1

Any comments on how you feel the pilot of digital home ACR testing has saved time in the practice or increased time spent:

- Although we understand the desire to keep us informed, the weekly newsletters have added to the workload, as we don't know whether we would miss some useful information if we didn't read them.
- I think in the long run it would save time.

When thinking about setting up the digital home ACR testing project in your practice, how much time and effort did this take, compared to organising the standard approach for annual ACR testing?

- Initial set up took up a lot of time especially for lead admin and practice manager.
- It took more time than expected, particularly on the follow up of these patients setting it up was facilitated by the team so wasn't difficult
- Lots of extra time, reading all the information, doing the searches, amending the searches, checking individual patients, looking up missing phone numbers, writing to those with no phone numbers.
- Main issue was setting up the integration so GPs see the result in their inbox. Some training as to the format of the result as different to usual hospital method. Reveals lack of understanding of the significance of abnormal results.

Q5. Overall, do you think that staff at your practice have a better understanding of the following as a result of being involved in the project

Response	Importance of ACR testing in patients with diabetes	Implications of positive ACR result	Causes of albuminuria/ proteinuria	How to manage someone with an ACR test	Recommended treatments for CKD	Where to go for advice	When to refer
Much better understanding	1				2	1	1
A little better understanding	3	2	4	4	2	3	3
No change	2	2	2	2	2	2	2

Q6. Does the ACR guidance developed for this pilot help practices with their management of chronic kidney disease (CKD) and raised ACR?

Response	Role of survey respondent			Total
	GP	Practice Manager	Assistant Manager	
Yes	3	1	1	**5**
Unsure	0	1	0	**1**

Any comments on the ACR guidance: None

Q7. Does your practice have a template on the clinical system for the management of CKD?

If yes, is it used?

Question	Response	Total
Template in the practice?	No	**1**
	Unsure	**1**
	Yes	**4**
If yes, is it used?	No	**2**
	Yes	**3**

One practice had 2 respondents - one (assistant manager) was aware of the template and thought it was used; the other (GP) was not aware of the template.

Q8. What would help to improve the system of care for people with diabetes regarding preserving their kidney function? E.g. educational opportunities, templates.

- Allowing enough time to discuss when having their reviews (Nurse time and resource), provide easy to read leaflets, identifying missing results.
- Educational opportunities to the wider team as diabetes is so ubiquitous. Template design to bring advice and guidance to the workflow as in part a checklist.

Appendix B: Patient Leaflet

UK_ACR_Patient-leaflet_Leeds.pdf

Appendix C: Cost of Standard Care ACR Testing

Item	Cost
Cost of diagnostic test	£0.24
Admin time to chase patient sample (0.5 minutes @ £26 per hour)	£0.22
Admin time to inform patient of result per test (2 minutes @ £26 per hour)	£0.86
Nurse time for testing & recording of results per test (5 minutes at £39 per hour)	£3.25
Container	£0.73
Gloves	£0.03
Apron	£0.09
Total per test	**£5.42**