ENHIDE telehealth primary care support of adults with diabetes and chronic kidney disease: a pilot study – rationale and study design

PETER H WINOCOUR,[1] KAREN MOORE-HAINES,[2] ANDREW SOLOMON,[3] ANNE CURRIE,[4] DAWN HARDY[4]

Abstract

Introduction: **Diabetes is considered the main identified cause of end stage renal disease and this combination is becoming more prevalent as populations age and become more obese. Individuals with diabetes and chronic kidney disease (CKD) have additional multi-morbidity and may represent 25–40% of those on diabetes registers in primary care, where the majority receive medical care. The East and North Herts Clinical Commissioning Group (CCG) commissioned the East and North Herts Institute of Diabetes and Endocrinology (ENHIDE) to pilot an innovative approach to the identification and care of this complex cohort in primary care. This paper reports the project design and objectives.**

Aims: **There were five core objectives of the pilot: (1) to examine the feasibility of extraction of comprehensive datasets from primary care diabetes registers; (2) to examine the feasibility of the individualised data utilisation for patient care; (3) to evaluate the practicality and acceptability of primary care of telehealth virtual case-based reviews; (4) to evaluate the extent of unmet clinical need; and (5) to create new sources of information to improve self-management. In addition, three key performance indicators were set for those with CKD: (1) change in any aspect of management in 20%; (2) reduction of admissions and ambulance call outs for hypoglycaemia in 20%; and (3) reductions in admissions with active foot disease by 20%.**

Study outline: **All patients with estimated glomerular filtration rates (eGFR) <60 mL/min and/or urine albumin creatinine ratio (ACR) >10 mg/mmol were to be identified from practice diabetes registers enabling a holistic review of '15 pillars of care'. In addition to blood glucose management and review of renal function, this included recording of cardiovascular disease (CVD) and CVD risk factor status, risk of hypoglycaemia, assessment of anaemia, metabolic bone disease, foot and retinal health and hospitalisation.**

Progress: **The project was initiated in December 2016 and data are currently being updated for full analysis. 20 of the 55 general practices in the catchment area of the acute trust agreed to participate in the project, enabling case review of 2,874 cases. This initial phase of the pilot has established that the core principles of the project can be delivered in larger numbers, subject to developing new models of data capture and creation of clinically underpinned care algorithms.**

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Key words: diabetes, chronic kidney disease, Telehealth, care planning, clinical information systems, albuminuria, cardiovascular disease, hypertension, lipids, glycaemia, retinopathy, foot heath, metabolic bone health

East and North Herts Institute of Diabetes and Endocrinology (ENHIDE), Howlands Clinic, QEII Hospital, Welwyn Garden City, Herts AL7 4HQ, UK

[1] Consultant Diabetologist and Clinical Director
[2] Project Manager
[3] Consultant Diabetologist
[4] Diabetes Specialist Nurse

Address for correspondence: Dr Peter H Winocour
Consultant Diabetologist and Clinical Director, East and North Herts Institute of Diabetes and Endocrinology (ENHIDE), Howlands Clinic, QEII Hospital, Welwyn Garden City, Herts AL7 4HQ, UK
E-mail: peter.winocour@nhs.net

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Introduction

Diabetes mellitus (DM) remains the main identified cause of end stage renal disease in the UK.[1] Chronic kidney disease (CKD) can be directly attributed to or associated with diabetes mellitus and is currently graded according to both estimated glomerular filtration (eGFR) and albumin excretion rates, with increased albuminuria still considered the hallmark of classical diabetic nephropathy.[2] The incidence of both diabetes and CKD is projected to potentially double through the impact of ageing, obesity and improved case detection. The majority of cases with DM and CKD are likely to be older patients with type 2 diabetes.[3–6]

The current strategy on managing patients with DM with or at risk of CKD is to focus on glycaemic, lipid and blood pressure control, and national guidelines have been developed to support better management,[7–11] recognising nuances of therapy selection in DM CKD, reflecting the impact of obesity and degree of renal disease.

Monitoring of renal function in DM has focused on measuring trends in both estimated GFR (eGFR) and estimates of proteinuria (usually urine albumin:creatinine ratios (ACR)). The current preva-

lence of CKD based on both reduced eGFR and/or raised ACR is at least 40% of people with type 2 DM and up to 15% with type 1 DM.[5] Current models promote delivery of most DM and CKD care in primary care settings. Criteria for specialist referral vary, but mainly reflect advancing proteinuria and/or progressive declining eGFR to the stage of end stage renal disease (stage 4 CKD, eGFR <30 mL/min) or a fall of 5–10 mL/min/1.73 m^2 over a year.[11,12]

However, it is increasingly recognised that the co-existence of DM and CKD needs to be considered more holistically as a complex multi-morbidity disorder.[5] Prevalent cardiovascular disease (CVD) and retinopathy are common, as are earlier manifestations of renal anaemia and metabolic bone disease. There is greater vulnerability to acute illness and hospitalisation with a range of issues including cardiovascular and foot emergencies, infections, hypoglycaemia and acute kidney injury.[13–17]

Failure to provide effective basic care of DM CKD has been reported in the UK and more widely.[18–20] One primary care service has published successful review and improved care processes and quality core measures in DM with renal disease, but did not evaluate anaemia, CVD, bone, eye and foot health.[21] Virtual clinical review of CKD and use of clinical support system decision-making tools have been reported in the management of CKD but have not focused on the wider care implications of the coexistent diabetes and related vascular disease.[22–24]

Outline of the ENHIDE integrated telehealth renal project

The National Health Service in England currently oversees the planning and delivery of healthcare through Clinical Commissioning Groups (CCGs) usually serving populations of 250,000–500,000. The East and North Herts CCG established a revised care pathway for diabetes care in 2010 whereby all referrals from primary care would be managed by a nurse-led single point of access. Those with specialist needs would either be managed in a community specialist nurse and consultant physician service or, if more complex, would be referred onto the hospital-based specialist services. Patients with advanced renal disease (eGFR <30 mL/min and/or nephrotic range proteinuria) would require referral directly to the nephrology services, but those with ACR >30 mg/mmol and/or lesser degrees of CKD (eGFR 30–54 mL/min) were encouraged to be referred to the hospital diabetologist renal clinics. In addition, annual consultant diabetologist visits to all GP surgeries focused on virtual review of high-risk cases, especially those with levels of HbA_{1c} >75 mmol/mol and/or early onset complications or obesity and suboptimal control.

It was recognised that some patients with type 2 DM and CKD presented late from primary care with poor control of glycaemia and CVD risk factors, advanced renal disease, established foot complications, previously unidentified and correctable metabolic bone health issues and complex anaemia, and had an increased risk for emergency ambulance call out with hypoglycaemia. This corroborated findings from the National Diabetes Audit, where there was poor attainment of glycaemic and blood pressure targets.[18]

Based on published literature,[21,25] we anticipated the majority of those with DM and CKD would only be receiving primary care, but there was no information as to the extent of unmet clinical need.

In 2015 the East and North Herts CCG commissioned a 2-year pilot of a novel method of specialist review and support of patients with type 2 DM and CKD diabetic nephropathy (DM CKD-DN) under primary care. The diabetes renal telehealth service set out to provide virtual holistic care of those with DM CKD-DN identified on a practice-by-practice basis through the GP-held practice DM registers. The purpose of the pilot was five-fold:

1. To investigate the feasibility of extraction of comprehensive 'big data' from primary care information systems.
2. To enable clinical data utilisation for individualised virtual diabetes specialist review.
3. To evaluate the practicality and acceptability by primary care of a Skype telehealth virtual case-based discussion for the purposes of patient care and primary health care team upskilling.
4. To record the extent of unmet clinical need, frequency of suggested therapy changes and impact on discharge and referral patterns.
5. To develop strategies to improve self-management of foot health and acute illness with metabolic-renal decompensation.

This methodology paper describes the process for and challenges with establishing the project.

Initially all cases with ACR >10 mg/mmol and/or eGFR <60 mL/min were identified, but subsequently there was a more detailed focus on those aged <75 years and those aged >75 years with an eGFR <45 mL/min and/or ACR >10 mg/mmol. Patients under hospital specialist diabetes and/or renal care were identified and reviewed as well as those solely under primary care. Reports were initially created for both SystmOne and EMIS (Egton Medical Information Systems) primary care systems to enable identification of the numbers of patients from each practice with CKD. A database was created to enable extraction of the core measures and processes required for comprehensive DM CKD pillars of care (Figure 1). Standards of care were established based on the health status measures (Figure 2).

Renal measures

All available estimated GFR measures over a 2-year period from the most recent available result were reviewed in each case using the Integrated Clinical Environment (ICE) system. The biochemistry laboratory reported eGFR using the Modification of Diet in Renal Disease (MDRD) formula until July 2016 with a transitional period until March 2017 when reports were also provided from a different provider laboratory, from which time the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation was used. For the purposes of the DM Renal Telehealth Project, we did not differentiate the two methodologies, given recognition that both estimates underestimate true GFR in diabetes but both perform equally in that regard.[26] True deterioration in eGFR was recorded if there had been a persistent 10% reduction in eGFR from the value 2 years prior to the most updated result and/or a sustained reduction of >10 mL/min/1.73 m^2 over the 2 years. eGFR results were classified as variable when they deteriorated by 10–20% but then improved to the same extent within the 2-year period without a progressive

Figure 1. Care processes and data extraction form

ENHIDE
East and North Herts Institute of Diabetes and Endocrinology

TELEHEALTH RENAL ENHIDE

TeleHealth Renal	Addressograph Name: Date of Birth: Gender: Male ☐ Female ☐ NHS Number: Hospital Number:

Practice Name:	**Date form completed:**
Type of Diabetes: Type 1 ☐	Type 2 ☐ Other.....
Year diabetes diagnosed: YYYY	
Patient Care managed by: Acute DM Care ☐ Acute Renal Care ☐ Primary care ☐ Herts Community Trust ☐	

Reasons for inclusion? eGFR < 60 ☐ ACR > 10 ☐ eGFR < 60 & ACR >10 ☐ Progressive fall in eGFR but > 60 ☐

Patient Tests/Results:

1. **eGFR** a) **Checked in past 15 months?** Yes ☐ No ☐ b) **Result <60** Yes ☐ No ☐
   c) **Result**..... d) **Date:** MM / YY e) Deteriorating ☐ Variable ☐ Stable ☐
2. **ACR** a) **Checked in past 15 months?** Yes ☐ No ☐ b) **Result >10** Yes ☐ No ☐
   c) **Result**..... d) **Date:** MM / YY e) Deteriorating ☐ Variable ☐ Stable ☐
3. **Blood Pressure:** a) **Checked in past 15 months?** Yes ☐ No ☐ b) **Result**..... c) **Date:** MM / YY
   d) **<140/80** Yes ☐ No ☐ N/a ☐ e) **<130/75** Yes ☐ No ☐ N/a ☐
   f) **Treatment**.....
   .....N/a ☐
4. **Lipids** a) **Checked past 15 months?** Yes ☐ No ☐ b) **Date:** MM / YY
   c) **Total Cholesterol** ..... d) **HDL**..... e) **Non HDL**.....
   f) **Treatment**.....
   .....N/a ☐
   g) **Meets Non HDL Cholesterol Target** Yes ☐ No ☐
5. **HbA1c** a) **Checked in past 15 months?** Yes ☐ No ☐ b) **Result**..... c) **Date:** MM / YY
   d) Rising ☐ Variable ☐ Stable ☐ Improving ☐ No previous results to grade ☐
   e) **Treatment**.....
   .....N/a ☐
6. **Hypo Enquiry** a) **Checked in past 15 months?** Yes ☐ No ☐
   b) **Recent Hypos** Yes ☐ No ☐ c) **SAHE in last year** .....**NK** ☐

Continued …

Figure 1. Care processes and data extraction form (continued)

7. Hb	a) Checked in past 15 months? Yes ☐ No ☐ b) Result..... c) Date: MM / YY d) Haematinics checked Y ☐ N ☐ e) Abnormal Y ☐ N ☐ f) Anaemic Y ☐ N ☐ g) Ferritin..... MM / YY h) B12..... MM / YY i) Folate..... MM / YY
8. BMI	a) Checked in past 15 months? Yes ☐ No ☐ b) Result..... c) Date: MM / YY
9. Aspirin Treatment	a) Checked in the last year Yes ☐ No ☐
10.CVA	a) Checked in past 15 months? Yes ☐ No ☐ b) Present Yes ☐ No ☐ c) Date: MM / YY
11.CHD status	a) Checked past 15 months? Yes ☐ No ☐ b) Present Yes ☐ No ☐ c) Date: MM / YY d) Under Cardio? Y ☐ N ☐
12.Feet	a) Checked in past 15 months? Yes ☐ No ☐ b) Date: MM / YY c) Under Podiatry Y ☐ N ☐ NK ☐ d) Neuropathy Yes ☐ No ☐ NK ☐ e) Peripheral Vascular Disease Yes ☐ No ☐ NK ☐ f) Ulceration Yes ☐ No ☐ NK ☐
13. Bone Health	a) Checked in past 15 months? Yes ☐ No ☐ b) Date: MM / YY c) Calcium Y ☐ N ☐ Value.....MM / YY d) Vit D Y ☐ N ☐ Value..... MM / YY e) PTH checked Y ☐ N ☐ Value..... MM / YY
14.Eyes	a) Checked in past 15 months? Yes ☐ No ☐ b) Date: MM / YY c) Retinopathy Yes ☐ No ☐ d) Eye Right ☐ Left ☐ Both ☐ e) Background Retinopathy ☐ Maculopathy ☐ Proliferative retinopathy ☐ f) Under Ophthalmology Yes ☐ No ☐
15.Smoking	a) Checked in the last year Yes ☐ No ☐ b) Status Yes ☐ Previous smoker ☐ Never ☐

Admissions (last 12mths)	Yes/No	Comments
Recent admission to hospital with foot problem?	Yes ☐ No ☐	
Recent hospital admission for diabetes?	Yes ☐ No ☐	
Recent admission to hospital NOT diabetes related?	Yes ☐ No ☐	

Figure 2. Holistic management of diabetes patients with nephropathy–chronic kidney disease

Holistic management of diabetes patients with nephropathy-Chronic Kidney Disease (CKD)

Sick day rule guidance especially important in all patients with CKD

eGFR	eGFR – declines with age and is not validated in elderly > 75. eGFR more reliable when EPI vs MDRD formula. May vary with hydration and protein intake. Acute Kidney Injury trigger further decline with incomplete recovery of eGFR.
	eGFR falling > 5 ml/min/year considered sign of progression but given variability suggest this is confirmed by repeated measurements to reveal clear trend or fall of > 10 ml./min/yr. seen over 2 years when referral to renal dept. is suggested.
	Conservative care of frail elderly with falling eGFR below 30 (esp. below 15) may require discussion with patient and potentially with renal dept. Age itself would not preclude referral when CKD4 develops or deteriorates with potentially reversible cause. All biomedical targets need to be reviewed.

ACR	ACR – marked variability and persistent abnormal category important – i.e. microalbuminuria ACR 2.5(3.5) -10, or 10-30, or > 30, or marked evident proteinuria (> 300) categories. If progressive rise across category consider renal dept. referral especially in absence of retinopathy, in order to exclude vasculitis-GN-myeloma –renal calculus and other causes of proteinuria. If serum albumin falls nephrotic syndrome is suspected – renal dept. referral. Renal vein thrombosis for sudden marked rise in proteinuria. Rare use of dual RAAS (Renin-angiotensin-aldosterone system) blockade under specialist care in marked proteinuria.
	Monitor K (potassium) in all patients with DM – CKD-proteinuria as low renin and/renovascular issues more common. Sub maximal dosing of RAAS blockade with potential future K binders may enable higher doses.
	Modest spironolactone dosage 25 mg may be helpful in proteinuria reduction (as well as CCF) with k monitoring.
	Proteinuria reduction if achieved safely without deterioration in eGFR and/or raised K is beneficial for DM nephropathy. Diltiazem has greater proteinuric reduction effect than amlodipine.

BP	BP targets are 140/90 in DM CKD (150/90 frailer elderly) and 130/80 when evident albuminuria.
	Use of maximal dosage of diltiazem 240-300 LA, Ramipril 10, candesartan 16-32 (esp. if retinopathy) –irbesartan 150- 300- losartan 100 when achievable indicated for albuminuria and retinal protection in established microvascular disease. Diuretic use appropriate add on, where K elevation or deterioration in eGFR attributed to RAAS blockade favour vasodilators – hydralazine, doxazosin, and bisoprolol in preference. Avoid diltiazem with beta blockers in high doses especially where documented bradycardia – heart block Monitor postural hypotension eps if elderly and or neuropathic

Cholesterol	Use high intensity atorvastatin 40-80 mg in majority of cases aiming at non HDL cholesterol target of 2.5 mmmol/l / occ use of ezetimibe as add on. Rosuvastatin up to 20-30 mg if true atorvastatin intolerance. If highest risk and intolerant of statins??? ezetimbe alone . Occ fenofibrate for those with retinopathy-dyslipidaemia (may reduce eGFR modestly) and in exceptional cases refer Dr Winocour-Viljoen Lipid service for PCSK9 inhibitors (e.g. Evolocumab, Alirocumab) if established CVD and statin intolerant and way off target

Continued …

Figure 2. Holistic management of diabetes patients with nephropathy–chronic kidney disease (continued)

HbA1c	HbA1c – consider carefully if anaemia. May be falsely lower if CKD4-5 and occasionally falsely higher if untreated Fe deficiency. Complementary BGM required. Targets vary - 58 for most and 68 in elderly.
Hypos	If on SU-insulin and ? misleading HbA1c ep important to exclude evaluate for hypoglycaemia especially where prior hypos – ambulance call outs or BG levels over tight (4-6 pre-meal) . Assess for hypo awareness. Hypos may be atypical in elderly – if CKD declining err on side of caution re glycaemia targets, Avoid SUs and insulin combo. If cognitive dysfunction extreme caution if CKD.
Hb	Annual check of Hb in DM CKD – if Hb 110 or less assess full haematinic inc Fe balance studies. If potential Fe deficiency may still need referral e.g. gastro, consider B12 deficiency PA-metformin and replace iron. If anaemia review Hba1c in this light. Refer for haematology-renal if Hb 90 g/l? EPO (Erythropoietin)
BMI	If BMI > 30 may adversely impact renal status ., Consider acco renal stats role for weight reducing Rx such as gliflozins and GLP1 analogues according to licensed indications by eGFR at present . Consider insulin sparing options such as gliptins and minimise SU use.
CVD	If established CVD inc PVD and/or raised ACR consider antiplatelet therapy with aspirin or alternatives Highest CVD risk – record and review CVD – CVA – PVD status and take account of lipid – BP – aspirin etc. choices
Feet	Foot care – follow MDT foot care advice re high risk feet. DM CKD has additional independent high risk beyond that attributable to neuropathy - PVD which is more likely in CKD. Patient information card on foot protection and seeking urgent care with Foot Attack-Ulcer- etc. to be encouraged
Bone Health	Metabolic bone health when eGFR < 45 annual PTH, vitamin D and calcium/phosphare. If PTH > 2.5 upper limit of normal (or very low vitamin D < 30 in CKD3b or worse) initiate activated Vit D (1 alpha 250 ng and consider dose increments if PTH does not fall). Review Ca status on the activated vitamin D especially during acute illness
Retinopathy	Retinopathy status – if active retinopathy and typical albuminuria CKD, promote effective safe glycaemic control as stated prior and aim for maximal RAAS blockade if renal status (eGFR-) enables this. If no retinopathy and albuminuric CKD consider non DM causes as stated earlier
Smoking	All patients who smoke should have access to smoking cessation
Hospital Admission	This cohort have greater risk of hospital admissions (all causes including infection) so especially vulnerable to chest infection requiring flu vaccination.

decline. Episodes of transient deterioration in eGFR of >10% were considered to represent potential acute kidney injury with a degree of recovery.

Urine ACRs were measured using a standard polyethylene glycol enhanced immunoturbidimetric assay for albumin and a standard enzymatic assay for urine creatinine, based on a requested early morning urine sample. All available ACR measures over a 2-year period from the most recent available result were reviewed in each case using the ICE laboratory system. Deterioration was documented if the values increased above 3.5 mg/mmol from below that value, and if they increased by more than 20% from the value 2 years prior to the most updated result.

Referral to the nephrology department was generally recommended when eGFR levels were <30 mL/min/1.73 m^2 and/or nephrotic range proteinuria was noted whilst not under specialist renal department care. In addition, atypical proteinuria without retinopathy and without concerns regarding glycaemic control would be considered for referral for renal review of non-diabetes causes of proteinuria.

HbA_{1c}, blood pressure, lipids, use of related therapy and antiplatelet medication and body mass index

The most recent blood pressure was recorded from GP and/or hospital records and lipids and HDL and HbA_{1c} measures using

the ICE laboratory system and evaluated if within 1 year prior to case review. The list of blood pressure, glucose and lipid-lowering medication was recorded from the downloaded GP records and Summary Care Records on the NHS spine where available.

A clinically significant change in HbA_{1c} was documented if the values had changed by more than 10 mmol/mol from values 2 years prior to the most updated result. Those with HbA_{1c} recorded as <50 mmol/mol on insulin and/or insulin secretagogue therapy with hypoglycaemic potential were considered to be at hypoglycaemic risk and coded accordingly.

Blood pressure targets were set at 140/90 mmHg without albuminuria and 130/80 mmHg with albuminuria, with recognition that patients aged >75 might be conservatively managed with a blood pressure target of 150/90 mmHg.[8]

Attainment of the non-HDL cholesterol target of 2.5 mmol/L, in keeping with national guidelines, was determined.[7]

Use of aspirin was recorded from the medication record for each patient. Use of other antiplatelet agents and also warfarin and novel anticoagulants were recorded. Aspirin use or an alternative antiplatelet agent or anticoagulant was considered an appropriate standard for those with established CVD and/or raised albuminuria, in line with JBS3 guidelines.[27]

Body mass index was recorded from GP records and, where >30 kg/m^2, this was taken into account when recommending alternative diabetes therapies where glycaemic control was considered in need of improvement (HbA_{1c} >58, 68, 75 mmol/mol, according to age and presence of co-morbidities).

Referral to specialist diabetes care was recommended where glycaemic control remained poor (HbA_{1c} >75 mmol/mol or there were documented issues with ambulance call outs for hypoglycaemia). Blood pressure >160/100 mmHg was also considered an indication for specialist referral.

Hypoglycaemia enquiry

This was recorded when coded from GP registers using the Read Codes for 'No significant hypoglycaemic attacks '(Y1028) or 'Hypoglycaemia identified' (Xa9Ao/Y1027), or recorded ambulance call out for hypoglycaemia (Y1029)

CHD, CVA, smoking, feet status and podiatry access

Documentation of these measures and activity were recorded from the downloaded GP records using appropriate 'Read Codes'.

Active foot disease or high-risk feet using standardised criteria[28] were considered a basis for recommendation for foot care advice or podiatry referral if not already under such care. Smoking cessation priority was flagged up to the practices among smokers with DM CKD-DN.

Retinopathy status

The retinal status of patients was initially provided from the practice records if screening had been recorded in the last year. A more in-depth investigation was carried out from the East and North Herts Retinal Screening reporting system, an accredited service of the National Diabetes Retinal Screening programme.

Retinal status was recorded as available if within 1 year from the date of patient data review and recorded as to presence in one or both eyes and the level of retinopathy (background, pre-proliferative, proliferative or maculopathy).

Metabolic bone health checks

Documented results for serum calcium, vitamin D and parathyroid hormone measures within 1 year prior to case review were taken from the biochemistry report system with the standard that they should be measured in those with eGFR <45, in keeping with national Renal Association guidance.[29] Vitamin D deficiency was set at total levels (vitamin D2 and D3) <30 mmol/L using the National Osteoporosis Society criteria.[30]

Advice regarding initiation of activated vitamin D from raised parathormone was set in line with guidance from the Renal Association based on progressive increases to values at least twice the upper limit of the reference range.[29]

Anaemia

Haemoglobin (Hb) measurement within the past year from data review was set as a quality standard and values of ≤110 g/L considered as anaemia, in line with the Renal Association NICE guidance.[31] If Hb values were greater than this but with prior documentation of anaemia and on treatment, they were considered anaemic for the purpose of classification within the study.

Haematinics measured with or leading up to diagnosis of anaemia including reduced transferrin and iron, B12, folate and ferritin were recorded as evidence of haematinic checks and, where outwith reference ranges, considered as a record of abnormal haematinic levels.

Hospital admissions

Hospital admissions were recorded on the East and North Herts BIMS reporting system, based on hospital records for the 2 years prior to data review. Hospital admissions were recorded and separated into three categories: diabetes foot admission; other causes of diabetes admission; and non-diabetes admission.

Governance

This pilot was approved by CCG Caldicott Guardian. Ethical approval was not required given this was an extension of clinical care to implement national guidelines.

Process of practice engagement and virtual review

The CCG and project team promoted the new pilot service and set out to recruit 20 practices that were representative of the sociodemographic characteristics of the East and North Herts catchment area. The intention was to identify practices from each of the seven localities. Initially a virtual review of each case took place based on data extraction using a standardised data extraction form (Figure 1), with a recorded management plan fed back to the practice with additional investigations carried out at their next GP visit or annual review, depending on clinical urgency, with the support of the project diabetes specialist nurse if needed. The virtual review reviewed all 15 pillars of care to enable recommendations to be made regarding management change or referral. This included declining patterns

of renal function, inadequate glycaemic, blood pressure and lipid control, consideration of hypoglycaemia risk, assessment for and investigation of anaemia, consideration of obesity in selection of diabetes therapy, assessment of cardiovascular status and record of antiplatelet therapy, assessment of bone health with parathormone measurement, assessment of retinopathy enabling consideration of non-diabetes basis for CKD, identification of foot risk requiring proactive podiatry advice or care, smoking as prompt to enable access to smoking cessation and identification of hospitalisation for diabetes-related and non-diabetes events.

Practices were offered a one-off fee of £200 to enable purchase of a camera for computers and the subsequent Skype 2-hour telehealth meeting. Each participating practice had the option to engage in this, discussing a proportion of the cases with a training session built into the meeting. This session was open to all clinical staff at the practice.

Patients who were under the specialist hospital or community services with DM CKD who were reviewed and considered stable with all pillars of care adequately managed were planned to be discharged back to the practice for ongoing annual virtual review.

In contrast, all patients identified under primary care with poor glycaemic control, progressive renal dysfunction and/or important co-morbidities were to have care escalated for specialist hospital care in either the diabetes or the nephrology services.

All practices were supplied with individualised care plans for all patients in the high-risk criteria and expanded recommendations for 20 cases discussed at the Skype telehealth session.

In addition, all participating practices were supplied with a management summary for the pillars of care (Figure 2).

Outcomes to be measured

The primary outcomes were adherence to recommended targets and process measures in national guidelines and identification of unmet clinical need. There was an expectation of more proactive podiatric support and foot care advice and, in some older cases with CKD, more conservative glycaemic control with potential reduction in the rates of hypoglycaemia. A patient hand-held High-Risk Foot Card was developed for distribution to those with DM CKD with documented at-risk feet (Figure 3), and a patient credit card-sized Sick Day Guidance Card was produced for distribution by practices to all cases included in the renal DM review (Figure 4).

Three key performance indicators of the impact of the project were established by the CCG: (1) changes in any aspect of management in 20% of those with CKD; (2) reduction in admissions and ambulance call outs with hypoglycaemia in those with CKD by 20%; and (3) reduction in admissions with active foot disease in those with CKD by 20%.

Primary care feedback on Skype session

Overall feedback on these sessions was very positive. Responding GPs stated the importance of good communication for optimal management and the educational value and opportunity for discussions when there was uncertainty regarding referral to

Figure 3. High-Risk Foot Card for people with diabetes and chronic kidney disease

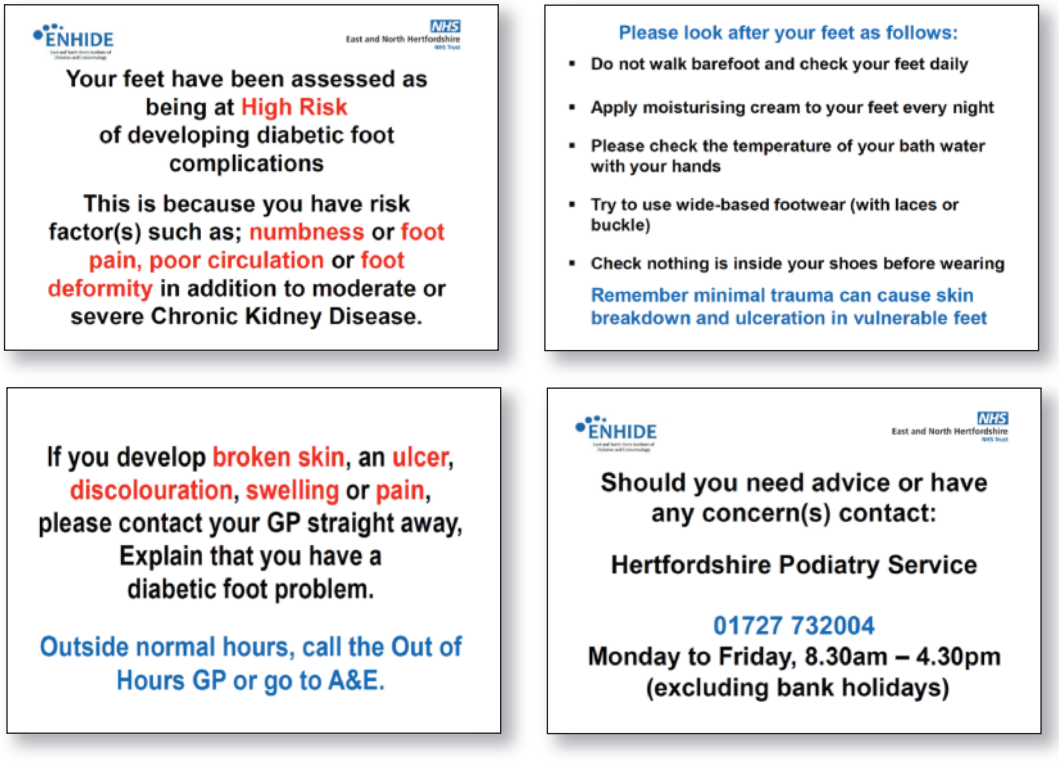
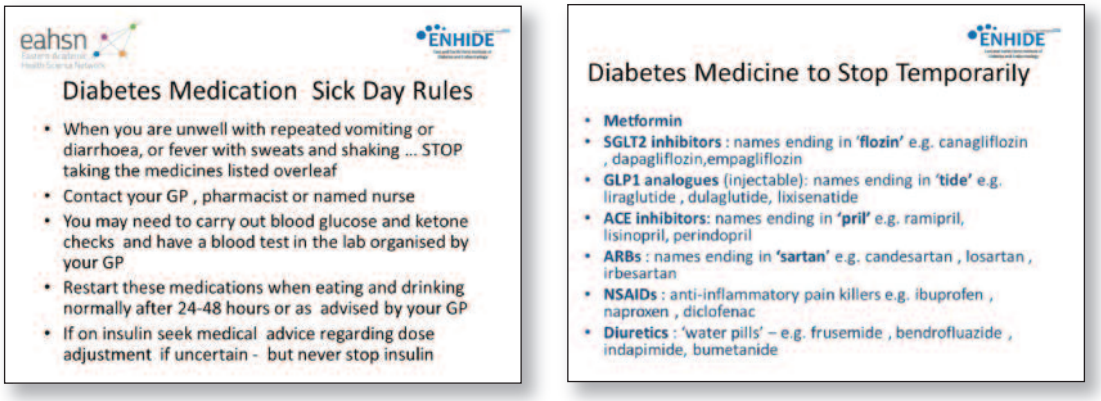


Figure 4. Sick Day Guidance Card



diabetes and/or renal departments. On a small number of occasions the audio and visual quality of the Skype call was poor, although this was intermittent.

Progress and modification to protocol: challenges in project

Of the 55 practices in East and North Herts, 20 agreed to enable data extraction and to take part in the 2-hour telehealth virtual review sessions.

The main challenges in establishment of the project were data extraction, data mergers and review of clinical information in other systems. Manual searches were often required if core information was not apparent after initial data downloads or was out of date. In addition, two different systems were used by primary care for recording patient information (EMIS Web and Systm One), with inconsistent capturing and recording of clinical information. Two of the practices were located at the boundary of the CCG catchment area and frequently used other acute trust clinical services and biochemistry which were closer to them and not readily accessible.

Corroboration of information required separate additional individual case review on digital retinal screening registers and the separate clinical information systems for those under specialist care. In addition, medication records on the main primary care systems only recorded the strength of medication rather than the prescribed dose. Subsequently, access to individual Summary Care Records enabled contemporary prescriptions including withdrawal due to adverse reactions to be recorded. Consequently, each individual case review required up to 30 minutes of individual consultant time.

After piloting this process in three practices, it became evident that the large caseload (approximately 25% of those on DM registers) meant there was inadequate time in the project to individually review every case. Subsequently, all patients under the age of 75 had individualised review and, in addition, those aged over 75 with eGFR <45 mL/min and/or ACR >10 mg/mmol had individual case review.

The pilot service identified substantial unmet clinical need, challenges in data extraction and a requirement for a cohesive approach to address the 15 pillars of care. In addition, high-risk vulnerable and/or disengaged patients were identified who could justify specialist clinic review but for a range of reasons were not able to access this. As of January 2019, the complete dataset is in the process of being refined and analysed.

Key messages

- The majority of people with diabetes and CKD are solely managed in primary care
- This pilot study shows it is feasible to carry out holistic individual virtual case review using current primary care datasets and subsequent telehealth input to general practice

Summary and conclusions

This pilot has successfully addressed the five core objectives established at the outset of the project, albeit with practical challenges in data extraction. Given the substantial numbers identified with complex and unmet clinical need, there is little doubt that a new care model such as this is required. Refinements in data capture and processing along with flexible telehealth contact between primary care and specialist teams can enable more effective integrated care of a large population with diabetes and complex multi-morbidity. Assessment of the key performance indicators will be best judged with ongoing evaluation and continuation of the project. Ongoing review of the medium-term outcomes is currently in process, but longer-term review will be necessary to better establish cost effectiveness and clinical benefits in respect of adverse foot and hypoglycaemia ambulance call outs. The project aims to evaluate both qualitative and quantitative beneficial changes in clinical management and outcomes

and enable a new surveillance and service model that uses digital technology and an alternative to traditional outpatient reviews, given the large numbers with complex co-morbidity and the stated need of the NHS in England to redesign services. Once fully evaluated, we anticipate the future model will be streamlined to extract comprehensive data more readily and use a new clinical algorithm underpinned with specialist oversight to more readily identify those at greatest need of changes in clinical management.

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