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What drives quality improvement in chronic kidney disease (CKD) in primary care: process evaluation of the Quality Improvement in Chronic Kidney Disease (QICKD) trial

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3 **What drives quality improvement in chronic kidney disease (CKD) in primary care: process evaluation of the**
4 **Quality Improvement in Chronic Kidney Disease (QICKD) trial**
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For peer review only

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3 **What drives quality improvement in chronic kidney disease (CKD) in primary care: process evaluation of the**
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5 **Quality Improvement in Chronic Kidney Disease (QICKD) study**
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9 **Abstract:**

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11 **Objectives:**

12 This study is a process evaluation of the Quality Improvement in Chronic Kidney Disease (QICKD) study,
13 comparing audit-based education (ABE), and sending clinical guidelines and prompts (G&P) with usual practice
14 (UP). This evaluation's objectives were to explore how far clinical staff in participating practices were aware of
15 the intervention, and why any change in practice might have taken place.
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17
18 **Setting:**

19 Four primary care practices in England: two received ABE, and two G&P. We purposively selected one
20 northern/southern/city and non-urban practice from each study arm, to limit geographical bias. They were
21 selected from a larger pool of 132 practices, as part of QICKD trial.
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23
24 **Participants:**

25 The four study practices were purposively sampled, and focus groups carried out with staff from each. All staff
26 members were invited to attend, with no selection for role or sex.
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29 **Interventions:**

30 Focus groups in each of the four practices, both at the mid-study point and at the end: eight focus groups in
31 total across four practices. These were recorded, transcribed and analysed using the Framework approach.
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34 **Results:**

35 Five themes emerged: (1) Involvement in the study made participants more positive about the CKD Register;
36 (2) Clinicians did not always explain to patients they had CKD (3) Whilst practitioners improved their
37 monitoring of CKD, many were sceptical that it improved care, (4) The impact on practice of the study
38 interventions were generally positive; particularly the interaction with specialists, included in ABE. (5) The
39 study stimulated ideas for future clinical practice.
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41
42 **Conclusion:**

43 Improving quality in CKD is complex. Lack of awareness of clinical guidelines and scepticism about their validity
44 are barriers to change. Whilst pay-for-performance incentives are the main driver for change, quality
45 improvement interventions can have a complementary influence.
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50 Data sharing statement:

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52 Extra information and focus group transcripts can be obtained by emailing s.lusignan@surrey.ac.uk.
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Key words:

Quality improvement;

Kidney diseases;

General practice;

Medical record systems, computerized;

Controlled clinical trial;

Focus groups;

Blood pressure;

Motivation;

Health care economics and organisation;

Healthcare quality, access and evaluation

Article Summary – Strengths and Limitations of this Study:

- Strength: This study provides important analysis of qualitative factors that affect chronic kidney disease management in primary care, beyond pay for performance strategies
- Limitation: The study assessed a small number of practices (two in each arm, four in total), and results may have been unduly influenced by opinion leaders within practices

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3 **What drives quality improvement in chronic kidney disease (CKD) in primary care: process**
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5 **evaluation of the Quality Improvement in Chronic Kidney Disease (QICKD) trial**
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11 **Background:**
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16 Chronic kidney disease (CKD) is a common condition and an increasingly important public health
17 issue¹. It is estimated that CKD amounts for approximately 1.3% of annual health service spending in
18 England². CKD is an established, independent risk factor for cardiovascular disease³; significantly
19 more patients with CKD die from cardiovascular complications than progress to end-stage kidney
20 disease (ESKD)^{4,5}. Most patients with mild-to-moderate CKD are treated in primary care.⁶ General
21 practice is therefore an important service sector to target for initiatives to improve CKD care,
22 principally by lowering blood pressure, to slow progression of renal disease⁷ and reduce
23 cardiovascular risk^{8,9}.
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34 There is limited evidence about how best to improve the quality of CKD management in primary
35 care¹⁰. The Quality Improvement in Chronic Kidney Disease (QICKD) study was designed to address
36 this question. QICKD was a three-arm cluster randomised control study comparing the effect of two
37 recognised quality improvement interventions with usual practice (UP) in improving systolic blood
38 pressure control in CKD, in primary care settings across England¹¹. The two quality improvement
39 interventions were audit-based education (ABE) and guidelines and prompts (G&P). ABE is a quality
40 improvement (QI) intervention developed over the last 15 years, which provides education, peer
41 support, and uses audit to document the gap between achievement and guidelines. This is a
42 complex, non-judgemental, educational intervention underpinned by the use of IT to extract and
43 make comparisons between practices and against evidence-based guidelines (Box 1,¹²). In
44 observational studies, ABE improved the quality of cardiovascular disease (including CKD)
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3 management,¹³ as well as in the QUICKD trial¹⁴. G&P is a much less elaborate intervention and the
4
5 most commonly used quality improvement intervention in primary care¹⁵. This usually involves
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7 distribution of clinical guidelines, generally on paper, sometimes with postal reminders as well as
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9 internet resources.
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12 The QUICKD trial reported a modest but statistically significant improvement in systolic BP in people
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14 with CKD exposed to ABE compared with UP (odds ratio of 1.24 of achieving at least a 5mmHg
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16 reduction in systolic blood pressure); whereas G&P showed no significant difference¹⁴.
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20 Given the complex nature of quality improvement interventions such as G&P and ABE, we carried
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22 out a process evaluation to explore practitioners' perceptions of the extent to which they were
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24 exposed to the intervention, the nature of that exposure, and the degree to which the trial
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26 interventions might have influenced practice. A secondary aim of the study was to identify what
27
28 factors might have influenced the management of CKD in community settings over the course of the
29
30 trial.
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33 During the course of the trial there were a number of changes in primary care that affected CKD
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35 management. Pay-for-Performance (P4P) was introduced in April 2004, mainly targeted on vascular
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37 disease, with a CKD domain added in 2006. This scheme uses routine data to determine the level of
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39 case ascertainment, on a disease register, and sets financially incentivised quality indicators;
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41 practitioners are asked to maintain a list of patients reaching the criteria for a diagnosis of CKD, and
42
43 ensure they meet certain treatment targets. The CKD indicator includes a treatment target of
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45 keeping BP below 140/85 mmHg preferentially using angiotensin-modulating drugs in the presence
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47 of proteinuria. However, national evidence-based guidance proposes different thresholds and
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49 targets for treatment. P4P guidance set less challenging BP levels than national evidence-based
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51 guidelines (Table 1).
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3 **Table 1: Guidance introduction before and during the QICKD trial, including variation in BP**
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5 **target and proteinuria**
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11 **Method:**

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14 *Overview:* We purposively sampled four practices, two from the ABE and two from the G&P arms of
15 the QICKD trial and held focus groups to explore any impact of the QICKD trial interventions. The
16 focus groups were recorded, transcribed and analysed using the Framework approach.¹⁶
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22 *The QICKD trial practices:*

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24 We recruited 132 practices, with 16 dropping out before randomisation. There were 30, 32 and 31
25 practices allocated to the ABE, G&P and UP arms respectively. In addition we recruited a further 10
26 per arm who also received a questionnaire about their confidence and competence in managing CKD
27 (but due to an allocation error there were actually 29). This was carried out to test whether quality
28 improvement might be secondary to improving confidence, knowledge and competence in
29 managing CKD.¹⁷ We identified four practices, two from each active study arm for in-depth process
30 evaluation using focus groups.
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42 *Purposive sampling of the in-depth process evaluation (PE) practices:*

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44 Four general practices were selected to participate in the process evaluation, in parallel to the
45 randomised control study. Two practices from this group received ABE, and the other two G&P. We
46 purposively selected one from the north, one from the south, and one city and one non-urban
47 practice from each active study arm, in order to limit geographical bias that may arise with practices
48 operating in different populations.
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3 Focus groups were carried out in each of the PE practices, both at the mid-study point and at the
4
5 end, to give eight focus groups in total across four practices. Focus groups are advantageous in their
6
7 ability to extract the attitudes and beliefs of participants, and are more likely to do so when
8
9 compared with individual interviews or observation.^{18,19} A set of non-prescriptive themes was
10
11 produced amongst the research team in order to guide the interaction and prompt reflection, but no
12
13 attempt was made to suggest responses or limit discussion; thus allowing maximal interaction
14
15 between participants and opportunity for related concepts to emerge. The four areas explored
16
17 were:
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21 1. Understanding the effects of the two quality improvement interventions
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23 2. Explore the extent to which practices were aware of the interventions and their impact
- 24
25 3. Understanding how CKD management had changed since P4P was introduced
- 26
27 4. Identify any other factors which may have impacted on the quality of CKD management during
28
29 the study
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34 Interviews were transcribed and analysed using a multistep iterative process known as a framework
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36 analysis. The framework approach consists of an initial period of familiarisation with the data;
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38 verbatim transcripts were created by a specialist clerical officer at the University of Surrey; noting
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40 recurrent or intensely expressed issues and themes.²⁰ We subsequently developed a thematic
41
42 framework using the issues and themes noted in the first stage and their relevance to the four areas
43
44 intended to be explored in the focus groups. These themes were then indexed and charted
45
46 according to themes and sub themes. The final step was a review of these charted themes in order
47
48 to identify associations, detect anomalies and refine the thematic framework. Thus, a set of major
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50 themes are outlined in the results section, with associated subthemes.
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56 *Ethical considerations:*
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3 The study, including its process evaluation was approved by a research ethics committee prior to the
4 commencement of the trial.
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10 **Findings:**

11 ***Overview of the findings:***

12 Overall the practitioners found that participating in the trial improves their understanding of CKD.
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14 However, the concept of CKD itself, how risk is stratified in CKD and changes in management made it
15 a challenging condition to explain to patients. Practitioners perceived that P4P targets may have
16 had a greater impact on CKD management than the study intervention. They enjoyed and found the
17 face-to-face education useful; but some found the paper feedback they received confusing.
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27 ***Improving the validity of the CKD Disease Register***

28 Practitioners were positive about the concept of a CKD disease register. Several participants
29 acknowledged that initially they were not aware that having two eGFR readings, at least three
30 months apart, were needed to meet the diagnostic criteria for CKD; creation of a CKD register was
31 considered useful in limiting over-diagnosis of CKD.
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37 *"We used to put our patients on [the CKD disease register] straight away if they only came*
38 *once in for eGFR measurement which was below 60, or it might be 58 and they ended up*
39 *going on the register...the register has maybe got a bit smaller after that and the reason for*
40 *that was actually cleaning it up and making sure patients are there appropriately."*
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46 (FG2)

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48 Nevertheless, there was variation between practices in how the register was maintained and new
49 patients added. Some practices were systematic and used audit tools to identify cases; whilst others
50 opportunistically identified patients with CKD in routine primary care consultations, or looked for
51 cases proactively, in chronic disease management clinics (e.g. practice hypertension clinics).
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Explanation of CKD diagnosis

Many practitioners commented on the difficult balance between avoiding unnecessary anxiety and social stigma by giving patients what they considered a potentially confusing diagnosis. They were concerned about labelling patients with a chronic disease label, especially older people in whom CKD is extremely common. At the same time they did not want to conceal information from them. It was noted that patients often required a great deal of reassurance and explanation of the condition, even with early-stage disease – particularly given the often-silent nature of the condition:

“But sometimes it's difficult, especially with CKD 3 for example you just kind of, you don't want to label them as chronic kidney disease and it's difficult for them to kind of come to terms with it.”

(FG1)

“People automatically think dialysis, don't they? So ‘You've got kidney disease’ and they're like, ‘Oh, my god.’”

(FG4)

Although some participants did acknowledge that providing the diagnosis of CKD is necessary for patient concordance with treatment, most chose to use terms such as “kidney strain” as opposed to the words “chronic kidney disease”, and discuss it as a function of age rather than active disease. As a CKD diagnosis was based on laboratory results, often the diagnosis was added to a patient's records when results were reviewed rather than in a face-to-face contact. It was often not practical with the business of the day and the number of results, to inform all patients and to cross-check if there had been a proteinuria test and if it were positive. Both of these factors probably contribute to the observation that not all patients with CKD were informed of their diagnosis.

Meeting CKD targets

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3 A key issue raised was the contradictory blood pressure targets advised for CKD patients in national
4 guidance and the P4P scheme. The BP guidance set out by the Royal College of Physicians & Renal
5 Association was different from that set within the PFP indicators for primary care, which were again
6 different from that set by National Institute for Health and Care Excellence (NICE) – the National
7 body that develops evidence guidelines (Table 1).^{21,22} Whilst many practitioners chose to follow the
8 P4P blood pressure target, others alter the aggressiveness of their management dependent on
9 patient group:
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18 *"I tend to go for younger patients particularly. If they are 38 and they have got hypertension*
19 *and we are treating them, the QOF [P4P] target is 150/90 and if we are getting 148/88, it's*
20 *okay but they have got another thirty years of that."*
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24 (FG1)

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26 Guidance from NICE was felt to be too lengthy and confusion was frequently reported with the
27 interpretation of the newly introduced proteinuria measure, albumin:creatinine ratio (ACR), both in
28 its measurement and its effect on patient management:
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33 *"I think the confusion is what level of ACR you act on. I think it's slightly clearer with the NICE*
34 *guidelines, basically if you're talking about ACRs of more than 30, 70 or 30 if they've got*
35 *blood, and I think the little bit of uncertainty is in diabetics an ACR of more than 3.5 is classed*
36 *as microalbuminuria but in non-diabetics what do you do with ACRs between 3 and 30? I*
37 *think that's the slight area of uncertainty that I feel."*
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44 (FG6)

45 46 47 48 **The impact of the study interventions**

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50 The question of what impact study interventions (audit-based education and guidelines with
51 prompts) had on clinical practice drew mixed responses. Two of the four practices felt guidelines
52 were useful both to base their local policy on, and more commonly as a reference for clarification:
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3 *“...it was shown very clear when to refer, when you've got proteinuria when to refer, when,*
4 *so that not everyone with proteinuria had to be referred and so the guidelines I thought were*
5 *very clear and good.” (FG1)*
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11 Practices responding in this fashion had generally been proactive in seeking out and using local
12 guidelines, and implementing new policy such as ACR measurement. They also commented on the
13 usefulness of the educational meetings, particularly where their representative could discuss
14 concerns with a consultant nephrologist and subsequently drive change within their group.
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21 However, the other two practices felt that the written information provided, both in the form of
22 audit data and prompts, were not especially useful:
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26 *“And there was a whole load of audit stuff that went in that I just looked through, but again*
27 *it was quite complicated, involved I should say, involved, so I'm afraid we didn't take any*
28 *notice of that either.”*
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32 (FG8)
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35 A theme throughout all focus groups was the difficulty in interpreting the effect of study
36 interventions given the P4P introduction in tandem, and the expected familiarity that develops with
37 new policy implementation over time. Whilst some noted that interventions provided more
38 background and understanding of the evidence behind national guidelines (particularly soon after
39 their initial introduction), P4P targets remain the driving force behind local practice:
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45 *“So I think that's universally accepted, that if you keep the QOF [P4P] up-to-date you'll get*
46 *money, you'll get points, so I think you can't beat on that one.” (FG5)*
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50 51 52 **Ideas for future clinical practice** 53 54 55 56 57 58 59 60

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3 Ideas for future practice were largely clustered around tools to make the process of updating the
4
5 CKD register or accessing guidelines more efficient, and improving access to specialist advice. A
6
7 number of practices identified the scope for guidelines with prompts to be incorporated into their
8
9 current electronic patient management systems:
10

11 *“I think one of the [ideas], is to develop some sort of software which then integrates the*
12 *clinical system so when you see patients [with] CKD it actually pops up a window saying you*
13 *haven't done x, y, z.”*

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18 (FG1)
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20 Others noted that workshops or “virtual clinics”, where practice members had direct access to
21
22 specialists, proved very useful:
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24 *“we had quite a useful exercise where we had, it wasn't actually for CKD but it could apply to*
25 *CKD, we had a diabetic endocrinologist come and a diabetic specialist nurse and they sat*
26 *down and they did a virtual clinic involving diabetics who had HbA1c under ten and they said*
27 *what to do about them.”*

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32 (FG2)
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38 **Summary**

39 Five main themes emerged from this study (Table 2). Firstly, the need to improve the accuracy and
40
41 understanding of the CKD disease register; most importantly, many people were included who may
42
43 not have had two qualifying eGFR measurements at least three months apart. Secondly, a diagnosis
44
45 of CKD was hard for some professionals to share with patients, who they felt needed a lot of
46
47 reassurance. Some clinicians avoided using the term. Thirdly, practitioners were more driven to
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49 change practice by pay-for-performance indicators than they were by evidence-based guidance; they
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51 tended to use the former to drive their practice. Fourthly, the study provided an opportunity to
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53 develop practice guidance and the presence of a specialist nephrology doctor or nurse was useful,
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3 whereas much of the study information was less so. Finally, participants could see how prompts,
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5 role play through virtual clinics, workshops and updates might be useful tools for keeping up to date.
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10 **Table 2: Main themes and subthemes derived from the process evaluation**

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14 **Discussion:**

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16 **Principal findings**

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18 The process evaluation practices in the QICKD trial were exposed to the intervention as planned;
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20 those exposed to ABE has the chance to test some of their uncertainties about CKD and its
21
22 management. Reaction towards the study interventions and P4P varied both between and within
23
24 individual practices. However, five major themes consistently emerged in analysis of focus group
25
26 discussions. The introduction of a nationally defined CKD register was generally viewed as a positive
27
28 step in formalising diagnostic criteria, reducing “false additions” and facilitating audit. Practices
29
30 were encouraging about the effects of study interventions, particularly ABE, in improving awareness
31
32 and understanding of CKD, and would largely support similar interventions in future. The ABE
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34 practices found the interaction with a specialist advising about how to implement guidance
35
36 particularly useful. However, P4P measures were regarded as the main driving force behind changes
37
38 in practice.
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44 Concerns persist about the difficulty in explaining the diagnosis of CKD to patients, the stratification
45
46 of risk, and the inconsistency in updating the CKD register. Additionally, many participants
47
48 questioned the usefulness of conflicting blood pressure guidelines from NICE and P4P, which added
49
50 what was perceived to be unnecessary complexity (Table 1).
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55 ***Practice Implications***

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3 Quality improvement (QI) interventions such as ABE and G&P appear to have some positive
4 influence on the primary care management of CKD. Practitioners reported that they found the
5 interactive sessions where their data were presented and they could interact with a specialist
6 nephrologist most useful. Receiving information on paper was remembered but perceived to be
7 confusing. The costs of providing such sessions are obviously high but could be used where
8 achieving change was a high priority and such sessions could be integrated into other locality-based
9 educational interventions. By way of contrast, providing written information did not appear to have
10 impact, and maybe those looking to improve quality by mailing out to practices should think
11 carefully about whether this is likely to be effective; especially where there is complexity.
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24 However, over the period of this study the major impetus for improving quality appeared to be
25 exposure to P4P. Where QI interventions appear particularly useful is in providing further guidance
26 in conjunction with newly-introduced P4P targets, and clarifying any inconsistencies or confusion. QI
27 interventions can support introduction of new guidelines by familiarising practices with new
28 evidence and offering support and constructive feedback for implementation, which would not
29 otherwise be available. Interaction with a specialist, consulting about the level of care in the
30 practice, as part of the ABE process, rather than about individual patients was a different but useful
31 experience.
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44 Greater appreciation of the benefits of identifying people with CKD and a fuller understanding of
45 appropriate CKD management beyond the mechanistic application of P4P indicators is needed. This
46 evaluation revealed inconsistency in application and gaps in clinicians' understanding. These
47 findings are also replicated in other studies²³. Concurrent introduction of QI interventions with
48 future P4P targets and national guidance plus continuing education, would avoid confusion over
49 their use and could increase speed of uptake and achievement of targets. This study has shown that
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3 primary care practitioners are generally supportive of such measures and found them useful in
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5 guiding their own practice's adoption of guidelines. However, despite this practitioners reported
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7 difficulty in explaining a diagnosis of CKD to their patients. There appears to be a gap in current
8
9 guidance; namely a lack of explanation about how health care professionals best to communicate
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11 the nuances of a condition such as a CKD diagnosis to patients, adapted for level of risk; a problem
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13 reported by other studies.^{24,25}
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16 17 18 ***Comparison with the literature*** 19

20 Much research has focused on the extent to which P4P affects clinical practice in primary care, much
21
22 less about what constitutes effective quality improvement, or that promotes effective management
23
24 of CKD in primary care. There is evidence that P4P does indeed result in acceleration of target
25
26 achievement, such as a progressive reduction in blood pressure²⁶, or improved diabetic control²⁷.
27
28 However, this improvement appears to slow once targets are reached, and quality of care can
29
30 decline for non-incentivised criteria²⁸. New P4P guidelines are not always immediately accepted and
31
32 embraced by practices, and low practitioner confidence in management of CKD (particularly high-risk
33
34 patients, such as those with proteinuria) provide a plausible explanation as to why they might have a
35
36 negative effect on target attainment, even where P4P is in place¹⁷. There may be an underlying
37
38 diffusion of knowledge and management of CKD.²⁹ There appeared a greater acceptance amongst
39
40 healthcare professionals of CKD as a relevant diagnosis, compared with previous studies²³, but this
41
42 may simply be due to the length of time that has now elapsed since the introduction of P4P (2006)
43
44 and NICE guidance (2008, Table 1).
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50 It has been shown that quality improvement strategies can be useful in improving specific targets in
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52 CKD, such as blood pressure¹⁴ and requirement for renal replacement therapy^{30,31}.
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Limitations

This study examined a small number of practices; we purposively sampled two each from the two study intervention arms; and from different parts of the country. The practices contained a larger number of individuals and it is possible that opinion leaders within those practices, or practices and localities within which they were based may have adopted procedures and processes that were not representative of the study practices as a whole. These limitations are all possible, but the study team who conducted these interviews were also exposed to the other practices involved in the trial.

Additionally, quality improvement interventions such as ABE or G&P can vary in design between studies, with no common detailed approach for their implementation. In systems such as the NHS, data is readily accessible, and creating personalised feedback for practices should be relatively straightforward and is already done in a number of areas such as prescribing. However, meeting time for practitioners is expensive especially where in ABE, a facilitator (to explain the data) and a specialist physician or nurse is brought along too. Whilst these roles might be combined, ABE is an expensive interaction, an issue raised in a commentary on the QICKD trial.³²

Further research

Whilst there has undoubtedly been engagement with CKD through the P4P process, the case has for P4P in CKD remains unproven.^{33,34} Future research should seek to determine whether improvements identified following QI interventions can be generalised. We need to have a greater understanding about why clinicians found this a difficult diagnosis to explain to patients. We also need to test whether computerised medical record systems could improve the way they display information; in the case of CKD a combination of finding two renal function tests at least three months apart, whether there is a significant level of proteinuria, a relevant co-morbidity, and if BP is correctly controlled for this level of risk are all recorded in different places (Table 1). We also need

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3 to know whether ABE is cost-effective. It is only likely to be so if embedded into existing educational
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5 processes carried out on a locality basis.
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8 9 **Conclusions**

10 P4P incentives were the major driver of improved management of CKD in primary care; however, QI
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12 interventions can have a complementary role. This process evaluation demonstrates the place for a
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14 QI intervention alongside the introduction of P4P guidelines. The focus groups reported positive
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16 interactions from ABE, particularly with a kidney doctor or nurse. It is plausible that the interaction
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18 involved in ABE contributed towards the modest but significantly greater reduction in systolic BP in
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20 this arm compared with sending out G&Ps.
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31 **Box 2: Summary conclusions**
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Competing Interests

AN: None

SdeL: Principal investigator QICKD Trial. SdeL led the group that provided the clinical input into the development of the CKD pay-for-performance indicator.

NT: Deputy on NICE guideline development group for CKD (2008)

AT: QICKD investigator and led the feedback to some practices.

HG: Co-design of QICKD study, senior investigator.

Authors' contributions

AN: Took the transcripts and an initial analysis of the findings and wrote the paper, under SdeL's supervision

SdeL: Conceived and designed the QICKD trial in collaboration with the other protocol authors. Supported and iterated the development of the paper with AN

NT: Project co-ordinator. Organised the ABE intervention in the southern localities. Undertook the focus groups, reviewed and edited the paper.

AT: Review and editing of paper

HG: Review and editing of paper

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Table 1: Guidance introduction before and during the QICKD trial, including variation in BP target and proteinuria measures

Year	Guidance	Body	Role	BP
2005	National Service Framework for renal disease: Part 2 Chronic Kidney Disease	Department of Health	National guidance on managing CKD	Strict application of National guidance for Hypertension and/or Diabetes
2006	Royal College of Physicians & Renal Association	Included other Royal Colleges	Guidelines from joint learned societies to fill a gap in guidance	>140/90 mmHg to an optimal BP of <130/80 mmHg >130/80 mmHg to an optimal BP of <125/75 mmHg where the PCR ratio is >100 mg/mmol
2006	Quality and Outcomes Framework (QOF) CKD guidance	NHS Employers, then NICE	Pay-for-performance P4P for chronic disease management	<140/85 – though people with comorbidities also subject to appropriate guidance (e.g. Diabetes)
2007	Recruitment into QICKD trial			
2008	Early identification and management of chronic kidney disease in adults in primary and secondary care	National Institute for Health and Care Excellence (NICE)	Clinical Guideline No 73 (CG73), National evidence-based guidance	Systolic BP >140 mmHg (target range 120–139 mmHg) and the diastolic blood pressure below 90 mmHg. 120-129/<80 in DM with CKD where ACR > 2.5 (men) > 3.5 (women) or where ACR>70
2010	Final data collection QICKD trial			

PCR=Protein:Creatinine Ratio ACR=Albumin:Creatinine Ratio

Table 2: Conceptual framework listing main themes and subthemes derived from the process evaluation

Main Themes	Subthemes derived from focus group analysis
A. Improving the validity of the CKD Register	<p>A1. Stop diagnosing CKD on basis of one low eGFR reading, instead use two three months apart</p> <p>A2. Auditing is carried out opportunistically, etc.</p> <p>A3. Introduction of a CKD disease Register curbed diagnostic over-enthusiasm</p> <p>A4. Clinical judgement exercised over whether patients with variable scores around threshold should be included on the Register</p> <p>A5. If patient won't benefit from treatment put on Register but "Exception report" (A process that makes them no longer part of pay-for-performance indicator group)</p> <p>A6. Nurses pick-up patients with low eGFR through clinics run for the primary prevention of heart disease, or through yearly audit/checks of computerised records</p>
B. Explaining to patients they have CKD	<p>B1. Tension between not hiding CKD diagnosis from patients and wishing to avoid causing excessive anxiety and social consequences of labelling</p> <p>B2. Avoiding the phrase "chronic kidney disease", using "kidney strain" instead</p> <p>B3. Giving CKD diagnosis is necessary for patient participation in management</p> <p>B4. Patients require a lot of reassurance post-diagnosis</p>
C. Meeting CKD Targets (BP, ACR)	<p>C1. Few problems in adopting albumin creatinine ratio (ACR) as routine practice</p> <p>C2. Unsure about necessity of early morning urine sample for ACR</p> <p>C3. Uncertainty about significance of ACR in patient management</p> <p>C4. Use pay-for-performance rather than evidence-based (NICE) BP maintenance targets</p> <p>C5. Use evidence-based (NICE) rather pay-for-performance targets, as the lower the BP level the better</p> <p>C6. Setting and maintaining BP targets are dependent on patient group</p> <p>C7. National evidence-based (NICE) guidelines too detailed to be practical</p> <p>C8. Increase in workload following CKD pay-for-performance indicator was unpopular</p>
D. Impact on practice of the study	D1. Base local practice on study guidelines

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3	interventions	D2. Presence of a nephrologist at workshops very useful
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5		D3. Difficult to determine whether study interventions catalyst for change or
6		introduction of pay-for-performance targets
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8		D4. Study's information resources not useful
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10		D5. Developed own template for tests following participation
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12	E. Ideas for future	E1. Electronic management guideline prompt i.e. desk-top icon, flagged-up through
13	practice	pay-for-performance reminders (built into primary care computerised medical
14		record systems) - more practical than paper-based
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16		E2. Run 'virtual clinical' as training exercise
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18		E3. Electronic practice up-dates
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20		E4. Workshops to compare experience with other practices
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Box 2: Summary conclusions

- CKD is a difficult condition to explain to patients, risk stratification is complex, and the relevant data are dispersed through computerised medical record systems
- Pay-for-performance incentives are the major driver for change in the management of CKD in primary care
- Quality improvement interventions may have a complementary role with future P4P initiatives
- Audit-based education was positively received by practices but further research is needed to demonstrate whether it is cost-effective

Box 1: Components of Audit-Based Education (ABE)

ABE is an intervention developed over 10 years ago; its aim is to provide feedback about performance against guidance. ABE includes feedback about quality compared with peers in a workshop setting usually led by a local general practitioner with a specialist (nephrology consultant or nurse) available as an expert resource, and also supported by academic detailing. ABE usually also identified lists of patients within the practices needing intervention. It consists of:

1. Anonymised extraction of the dataset required to report whether there was any quality improvement. The usual components are:
 - a. Denominator to allow standardisation of prevalence
 - b. Subset of people with the target condition – to create a virtual disease register
 - c. Clinically relevant co-morbidities, risk factors and treatment
2. Processing that data to make it informative and providing comparative feedback combined with academic detailing. A key feature is presenting comparative feedback comparing practices at twice yearly meetings held within a locality / primary care organisation. These meetings are called Data Quality Workshops (DQW), generally locally led with a consultant of the relevant discipline attending as a specialist resource
3. In addition to the presentation at the DQW practices are provided two additional printed aids:
 - a. “Laminate” – a single laminated A4 page summary of the practice demographics and case ascertainment compared with others who attended the DQW. This is for the practice notice board or other prominent location (we recommend wherever they take their breaks).
 - b. Workbook – a slide by slide explanation of the DQW presentation – and what the data means for their practice, compared with their peers and any evidence-based guidance.
4. Running local searches in the practices to provide lists of patients that need to be targeted for intervention. These lists are usually generated by individual GP. Experiential learning is that audit lists of up to 150 per 10,000 registered patients result in change.
5. Supporting education about the evidence-base and providing coding or other computerised medical record system training is provided as required.
6. Participants have been encouraged to contribute to the future development of the ABE programme.

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BMJ Open

What drives quality improvement in chronic kidney disease (CKD) in primary care: process evaluation of the Quality Improvement in Chronic Kidney Disease (QICKD) trial

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3 **What drives quality improvement in chronic kidney disease (CKD) in primary care: process evaluation of the**
4 **Quality Improvement in Chronic Kidney Disease (QICKD) trial**
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3 **What drives quality improvement in chronic kidney disease (CKD) in primary care: process evaluation of the**
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5 **Quality Improvement in Chronic Kidney Disease (QICKD) study**
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9 **Abstract:**

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11 **Objectives:**

12 This study is a process evaluation of the Quality Improvement in Chronic Kidney Disease (QICKD) study,
13 comparing audit-based education (ABE), and sending clinical guidelines and prompts (G&P) with usual practice
14 (UP), in improving systolic blood pressure control in primary care. This evaluation aimed to explore how far
15 clinical staff in participating practices were aware of the intervention, and why change in practice might have
16 taken place.
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19 **Setting:**

20 Four primary care practices in England: two received ABE, and two G&P. We purposively selected one
21 northern/southern/city and rural practice from each study arm (from a larger pool of 132 practices, as part of
22 QICKD trial).
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25 **Participants:**

26 The four study practices were purposively sampled, and focus groups conducted with staff from each. All staff
27 members were invited to attend.
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30 **Interventions:**

31 Focus groups in each of four practices, at the mid-study point and the end. Four additional trial practices not
32 originally selected for in-depth process evaluation took part in end of trial focus groups: to a total of twelve
33 focus groups. These were recorded, transcribed and analysed using the Framework approach.
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36 **Results:**

37 Five themes emerged: (1) Involvement in the study made participants more positive about the CKD Register;
38 (2) Clinicians did not always explain to patients they had CKD; (3) Whilst practitioners improved their
39 monitoring of CKD, many were sceptical that it improved care, and were more motivated by pay-for-
40 performance measures; (4) The impact of study interventions on practice was generally positive; particularly
41 the interaction with specialists, included in ABE; (5) The study stimulated ideas for future clinical practice.
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43
44 **Conclusion:**

45 Improving quality in CKD is complex. Lack of awareness of clinical guidelines and scepticism about their validity
46 are barriers to change. Whilst pay-for-performance incentives are the main driver for change, quality
47 improvement interventions can have a complementary influence.
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Key words:

Quality improvement;

Kidney diseases;

General practice;

Medical record systems, computerized;

Controlled clinical trial;

Focus groups;

Blood pressure;

Motivation;

Health care economics and organisation;

Healthcare quality, access and evaluation

Article Summary – Strengths and Limitations of this Study:

- Strength: This study provides important analysis of qualitative factors that affect chronic kidney disease management in primary care, beyond pay for performance strategies
- Limitation: The study assessed a small number of practices (four in each arm, eight in total in total), and results may have been unduly influenced by opinion leaders within practices

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3 **What drives quality improvement in chronic kidney disease (CKD) in primary care: process**
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5 **evaluation of the Quality Improvement in Chronic Kidney Disease (QICKD) trial**
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11 **Background:**
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16 Chronic kidney disease (CKD) is a common condition and an increasingly important public health
17 issue¹. It is estimated that CKD amounts for approximately 1.3% of annual health service spending in
18 England². CKD is an established, independent risk factor for cardiovascular disease³; significantly
19 more patients with CKD die from cardiovascular complications than progress to end-stage kidney
20 disease (ESKD)^{4,5}. Most patients with mild-to-moderate CKD are treated in primary care.⁶ General
21 practice is therefore an important service sector to target for initiatives to improve CKD care,
22 principally by lowering blood pressure, to slow progression of renal disease⁷ and reduce
23 cardiovascular risk^{8,9}.
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34 There is limited evidence about how best to improve the quality of CKD management in primary
35 care¹⁰. The Quality Improvement in Chronic Kidney Disease (QICKD) study was designed to address
36 this question. QICKD was a three-arm cluster randomised control study comparing the effect of two
37 recognised quality improvement interventions with usual practice (UP) in improving systolic blood
38 pressure control in CKD, in primary care settings across England¹¹. The two quality improvement
39 interventions were audit-based education (ABE) and guidelines and prompts (G&P). ABE is a quality
40 improvement (QI) intervention developed over the last 15 years, which provides education, peer
41 support, and uses audit to document the gap between achievement and guidelines. This is a
42 complex, non-judgemental, educational intervention underpinned by the use of IT to extract and
43 make comparisons between practices and against evidence-based guidelines (Box 1,¹²). In
44 observational studies, ABE improved the quality of cardiovascular disease (including CKD)
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3 management,¹³ as well as in the QUICKD trial¹⁴. G&P is a much less elaborate intervention and the
4
5 most commonly used quality improvement intervention in primary care¹⁵. This usually involves
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7 distribution of clinical guidelines, generally on paper, sometimes with postal reminders as well as
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9 internet resources.
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12 The QUICKD trial reported a modest but statistically significant improvement in systolic BP in people
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14 with CKD exposed to ABE compared with UP (odds ratio of 1.24 of achieving at least a 5mmHg
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16 reduction in systolic blood pressure); whereas G&P showed no significant difference¹⁴.
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20 Given the complex nature of quality improvement interventions such as G&P and ABE, we carried
21
22 out a process evaluation to explore practitioners' perceptions of the extent to which they were
23
24 exposed to the intervention, the nature of that exposure, and the degree to which the trial
25
26 interventions might have influenced practice. A secondary aim of the study was to identify what
27
28 factors might have influenced the management of CKD in community settings over the course of the
29
30 trial.
31

32
33 During the course of the trial there were a number of changes in primary care that affected CKD
34
35 management. Pay-for-Performance (P4P) was introduced in April 2004, mainly targeted on vascular
36
37 disease, with a CKD domain added in 2006. This scheme uses routine data to determine the level of
38
39 case ascertainment, on a disease register, and sets financially incentivised quality indicators;
40
41 practitioners are asked to maintain a list of patients reaching the criteria for a diagnosis of CKD, and
42
43 ensure they meet certain treatment targets. The CKD indicator includes a treatment target of
44
45 keeping BP below 140/85 mmHg preferentially using angiotensin-modulating drugs in the presence
46
47 of proteinuria. However, national evidence-based guidance proposes different thresholds and
48
49 targets for treatment. P4P guidance set less challenging BP levels than national evidence-based
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51 guidelines (Table 1).
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Table 1: Guidance introduction before and during the QICKD trial, including variation in BP target and proteinuria

Method:

Overview: We identified four practices, two from each active study arm for in-depth process evaluation. These practices undertook two focus groups: one at mid-point during the study and another at the end of the study. In addition, another four practices undertook a focus group at the end of the study. The focus groups were recorded, transcribed and analysed using the Framework approach.¹⁶

Description of the QICKD trial practices:

We recruited 132 practices, with 16 dropping out before randomisation. There were 30, 32 and 31 practices allocated to the ABE, G&P and UP arms respectively. In addition we recruited a further 10 per arm who also received a questionnaire about their confidence and competence in managing CKD (but due to an allocation error there were actually 29). This was carried out to test whether quality improvement might be secondary to improving confidence, knowledge and competence in managing CKD.¹⁷ We identified four practices, two from each active study arm for in-depth process evaluation using focus groups.

Participants and recruitment:

At the start, four general practices were selected to participate in the process evaluation, in parallel to the randomised control study. Two practices from this group received ABE, and the other two G&P. These practices participated in focus groups at the mid-point and end of the trial period. We purposively selected one from the north, one from the south, and one city and one non-urban practice from each active study arm. Another four practices were involved in a focus group at the

1
2
3 end of the project (again, two received ABE and the other two G&P). The additional focus groups
4
5 were undertaken in order to increase the representativeness of the findings (twelve groups in total).
6
7 All focus groups were attended by the 6-9 members of the multi-professional team (GP, practice
8
9 nurses, health care assistants and practice manager). The focus groups were undertaken by a
10
11 member of the research team, and experienced qualitative researcher.
12
13

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19 *Data collection:*

20
21 Focus groups are advantageous in their ability to extract the attitudes and beliefs of participants,
22
23 and are more likely to do so when compared with individual interviews or observation.^{18,19} The
24
25 focus groups comprised 6 to 9 health professionals, GPs were a majority in all, other professions
26
27 were practice manager and practice nurse . A non-prescriptive interview guide was developed by the
28
29 research team in order to guide the interaction and prompt reflection, but no attempt was made to
30
31 suggest responses or limit discussion; thus allowing maximal interaction between participants and
32
33 opportunity for related concepts to emerge. The four areas explored were:
34
35

- 36
37
38 1. Understanding the effects of the two quality improvement interventions
39
40 2. Explore the extent to which practices were aware of the interventions and their impact
41
42 3. Understanding how CKD management had changed since P4P was introduced
43
44 4. Identify any other factors which may have impacted on the quality of CKD management during
45
46 the study
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51 *Data analysis:*

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53 Focus groups data were transcribed and analysed using a multistep iterative process known as
54
55 Framework analysis. The Framework method was selected because it is a method that is considered
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1
2
3 suitable for use in teams where not all members have experience of qualitative research²⁰. The
4
5 framework approach consists of an initial period of familiarisation with the data; verbatim
6
7 transcripts were created by a specialist clerical officer at the University of Surrey; noting recurrent or
8
9 intensely expressed issues and themes.²¹ We subsequently developed a thematic framework using
10
11 the issues and themes noted in the first stage and their relevance to the four areas intended to be
12
13 explored in the focus groups . These themes were then indexed and charted according to themes
14
15 and sub themes. The final step was a review of these charted themes in order to identify
16
17 associations, detect anomalies and refine the thematic framework. Thus, a set of major themes are
18
19 outlined in the results section, with associated subthemes.
20
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24 *Ethical considerations:*

25
26 The study, including its process evaluation was approved by a research ethics committee prior to the
27
28 commencement of the trial.
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32

33 **Findings:**

34 ***Overview of the findings:***

35
36 Overall the practitioners found that participating in the trial improves their understanding of CKD.
37
38 However, the concept of CKD itself, how risk is stratified in CKD and changes in management made it
39
40 a challenging condition to explain to patients. Practitioners perceived that P4P targets may have
41
42 had a greater impact on CKD management than the study intervention. They enjoyed and found the
43
44 face-to-face education useful; but some found the paper feedback they received confusing.
45
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50 ***Improving the validity of the CKD Disease Register***

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52 Practitioners were positive about the concept of a CKD disease register. Several participants
53
54 acknowledged that initially they were not aware that having two eGFR readings, at least three
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1
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3 months apart, were needed to meet the diagnostic criteria for CKD; creation of a CKD register was
4
5 considered useful in limiting over-diagnosis of CKD.
6

7 *“We used to put our patients on [the CKD disease register] straight away if they only came*
8 *once in for eGFR measurement which was below 60, or it might be 58 and they ended up*
9 *going on the register...the register has maybe got a bit smaller after that and the reason for*
10 *that was actually cleaning it up and making sure patients are there appropriately.”*
11
12
13
14

15 (FG2)
16

17
18 Nevertheless, there was variation between practices in how the register was maintained and new
19 patients added. Some practices were systematic and used audit tools to identify cases; whilst others
20 opportunistically identified patients with CKD in routine primary care consultations, or looked for
21 cases proactively, in chronic disease management clinics (e.g. practice hypertension clinics).
22
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27

28 **Explanation of CKD diagnosis**

29
30 Many practitioners commented on the difficult balance between avoiding unnecessary anxiety and
31 social stigma by giving patients what they considered a potentially confusing diagnosis. They were
32 concerned about labelling patients with a chronic disease label, especially older people in whom CKD
33 is extremely common. At the same time they did not want to conceal information from them. It was
34 noted that patients often required a great deal of reassurance and explanation of the condition,
35 even with early-stage disease – particularly given the often-silent nature of the condition:
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43

44 *“But sometimes it's difficult, especially with CKD 3 for example you just kind of, you don't*
45 *want to label them as chronic kidney disease and it's difficult for them to kind of come to*
46 *terms with it.”*
47
48

49 (FG1)
50

51
52 *“People automatically think dialysis, don't they? So ‘You've got kidney disease’ and they're*
53 *like, ‘Oh, my god.”*
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(FG4)

Although some participants did acknowledge that providing the diagnosis of CKD is necessary for patient concordance with treatment, most chose to use terms such as “kidney strain” as opposed to the words “chronic kidney disease”, and discuss it as a function of age rather than active disease. As a CKD diagnosis was based on laboratory results, often the diagnosis was added to a patient’s records when results were reviewed rather than in a face-to-face contact. It was often not practical with the business of the day and the number of results, to inform all patients and to cross-check if there had been a proteinuria test and if it were positive. Both of these factors probably contribute to the observation that not all patients with CKD were informed of their diagnosis.

Meeting CKD targets

A key issue raised was the contradictory blood pressure targets advised for CKD patients in national guidance and the P4P scheme. The BP guidance set out by the Royal College of Physicians & Renal Association was different from that set within the PFP indicators for primary care, which were again different from that set by National Institute for Health and Care Excellence (NICE) – the National body that develops evidence guidelines (Table 1).^{22,23} Whilst many practitioners chose to follow the P4P blood pressure target, others alter the aggressiveness of their management dependent on patient group:

“I tend to go for younger patients particularly. If they are 38 and they have got hypertension and we are treating them, the QOF [P4P] target is 150/90 and if we are getting 148/88, it’s okay but they have got another thirty years of that.”

(FG1)

Guidance from NICE was felt to be too lengthy and confusion was frequently reported with the interpretation of the newly introduced proteinuria measure, albumin:creatinine ratio (ACR), both in its measurement and its effect on patient management:

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2
3 *"I think the confusion is what level of ACR you act on. I think it's slightly clearer with the NICE*
4 *guidelines, basically if you're talking about ACRs of more than 30, 70 or 30 if they've got*
5 *blood, and I think the little bit of uncertainty is in diabetics an ACR of more than 3.5 is classed*
6 *as microalbuminuria but in non-diabetics what do you do with ACRs between 3 and 30? I*
7 *think that's the slight area of uncertainty that I feel."*
8
9

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14 (FG6)

15 16 17 18 **The impact of the study interventions**

19
20 The question of what impact study interventions (audit-based education and guidelines with
21 prompts) had on clinical practice drew mixed responses. Two of the four practices felt guidelines
22 were useful both to base their local policy on, and more commonly as a reference for clarification:
23
24

25
26 *"...it was shown very clear when to refer, when you've got proteinuria when to refer, when,*
27 *so that not everyone with proteinuria had to be referred and so the guidelines I thought were*
28 *very clear and good."* (FG1)
29
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35 Practices responding in this fashion had generally been proactive in seeking out and using local
36 guidelines, and implementing new policy such as ACR measurement. They also commented on the
37 usefulness of the educational meetings, particularly where their representative could discuss
38 concerns with a consultant nephrologist and subsequently drive change within their group.
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45 However, the other two practices felt that the written information provided, both in the form of
46 audit data and prompts, were not especially useful:
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50 *"And there was a whole load of audit stuff that went in that I just looked through, but again*
51 *it was quite complicated, involved I should say, involved, so I'm afraid we didn't take any*
52 *notice of that either."*
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54

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56
57 (FG8)
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3 A theme throughout all focus groups was the difficulty in interpreting the effect of study
4 interventions given the P4P introduction in tandem, and the expected familiarity that develops with
5 new policy implementation over time. Whilst some noted that interventions provided more
6 background and understanding of the evidence behind national guidelines (particularly soon after
7 their initial introduction), P4P targets remain the driving force behind local practice:
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12

13
14 *“So I think that’s universally accepted, that if you keep the QOF [P4P] up-to-date you’ll get*
15 *money, you’ll get points, so I think you can’t beat on that one.” (FG5)*
16
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18
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20 **Ideas for future clinical practice**

21
22 Ideas for future practice were largely clustered around tools to make the process of updating the
23 CKD register or accessing guidelines more efficient, and improving access to specialist advice. A
24 number of practices identified the scope for guidelines with prompts to be incorporated into their
25 current electronic patient management systems:
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30
31 *“I think one of the [ideas], is to develop some sort of software which then integrates the*
32 *clinical system so when you see patients [with] CKD it actually pops up a window saying you*
33 *haven’t done x, y, z.”*
34
35
36

37 (FG1)
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40 Others noted that workshops or “virtual clinics”, where practice members had direct access to
41 specialists, proved very useful:
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44 *“we had quite a useful exercise where we had, it wasn’t actually for CKD but it could apply to*
45 *CKD, we had a diabetic endocrinologist come and a diabetic specialist nurse and they sat*
46 *down and they did a virtual clinic involving diabetics who had HbA1c under ten and they said*
47 *what to do about them.”*
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51 (FG2)
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57 **Summary**

Five main themes emerged from this study (Table 2). Firstly, the need to improve the accuracy and understanding of the CKD disease register; most importantly, many people were included who may not have had two qualifying eGFR measurements at least three months apart. Secondly, a diagnosis of CKD was hard for some professionals to share with patients, who they felt needed a lot of reassurance. Some clinicians avoided using the term. Thirdly, practitioners were more driven to change practice by pay-for-performance indicators than they were by evidence-based guidance; they tended to use the former to drive their practice. Fourthly, the study provided an opportunity to develop practice guidance and the presence of a specialist nephrology doctor or nurse was useful, whereas much of the study information was less so. Finally, participants could see how prompts, role play through virtual clinics, workshops and updates might be useful tools for keeping up to date.

Table 2: Main themes and subthemes derived from the process evaluation

Discussion:

Principal findings

The process evaluation practices in the QICKD trial were exposed to the intervention as planned; those exposed to ABE has the chance to test some of their uncertainties about CKD and its management. Reaction towards the study interventions and P4P varied both between and within individual practices. However, five major themes consistently emerged in analysis of focus group discussions. The introduction of a nationally defined CKD register was generally viewed as a positive step in formalising diagnostic criteria, reducing “false additions” and facilitating audit. Practices were encouraging about the effects of study interventions, particularly ABE, in improving awareness and understanding of CKD, and would largely support similar interventions in future. The ABE practices found the interaction with a specialist advising about how to implement guidance particularly useful. However, P4P measures were regarded as the main driving force behind changes in practice.

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5 Concerns persist about the difficulty in explaining the diagnosis of CKD to patients, the stratification
6
7 of risk, and the inconsistency in updating the CKD register. Additionally, many participants
8
9 questioned the usefulness of conflicting blood pressure guidelines from NICE and P4P, which added
10
11 what was perceived to be unnecessary complexity (Table 1).
12
13

14 15 16 ***Practice Implications***

17
18 Quality improvement (QI) interventions such as ABE and G&P appear to have some positive
19
20 influence on the primary care management of CKD. Practitioners reported that they found the
21
22 interactive sessions where their data were presented and they could interact with a specialist
23
24 nephrologist most useful. Receiving information on paper was remembered but perceived to be
25
26 confusing. The costs of providing such sessions are obviously high but could be used where
27
28 achieving change was a high priority and such sessions could be integrated into other locality-based
29
30 educational interventions. By way of contrast, providing written information did not appear to have
31
32 impact, and maybe those looking to improve quality by mailing out to practices should think
33
34 carefully about whether this is likely to be effective; especially where there is complexity.
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39 However, over the period of this study the major impetus for improving quality appeared to be
40
41 exposure to P4P. Where QI interventions appear particularly useful is in providing further guidance
42
43 in conjunction with newly-introduced P4P targets, and clarifying any inconsistencies or confusion. QI
44
45 interventions can support introduction of new guidelines by familiarising practices with new
46
47 evidence and offering support and constructive feedback for implementation, which would not
48
49 otherwise be available. Interaction with a specialist, consulting about the level of care in the
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51 practice, as part of the ABE process, rather than about individual patients was a different but useful
52
53 experience.
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3 Greater appreciation of the benefits of identifying people with CKD and a fuller understanding of
4 appropriate CKD management beyond the mechanistic application of P4P indicators is needed. This
5 evaluation revealed inconsistency in application and gaps in clinicians' understanding. These
6 findings are also replicated in other studies²⁴. Concurrent introduction of QI interventions with
7 future P4P targets and national guidance plus continuing education, would avoid confusion over
8 their use and could increase speed of uptake and achievement of targets. This study has shown that
9 primary care practitioners are generally supportive of such measures and found them useful in
10 guiding their own practice's adoption of guidelines. However, despite this practitioners reported
11 difficulty in explaining a diagnosis of CKD to their patients. There appears to be a gap in current
12 guidance; namely a lack of explanation about how health care professionals could best communicate
13 the nuances of a condition such as a CKD diagnosis to patients; a problem reported by other
14 studies.^{25,26}

31 ***Comparison with the literature***

32
33 Much research has focused on the extent to which P4P affects clinical practice in primary care, much
34 less about what constitutes effective quality improvement, or what promotes effective management
35 of CKD in primary care. There is evidence that P4P does indeed result in acceleration of target
36 achievement, such as a progressive reduction in blood pressure²⁷, or improved diabetic control²⁸.
37 However, this improvement appears to slow once targets are reached, and quality of care can
38 decline for non-incentivised criteria²⁹. New P4P guidelines are not always immediately accepted and
39 embraced by practices, and low practitioner confidence in management of CKD (particularly high-risk
40 patients, such as those with proteinuria) provide a plausible explanation as to why they might have a
41 negative effect on target attainment, even where P4P is in place¹⁷. There may be a gradual,
42 underlying diffusion of knowledge and management of CKD.³⁰ There appeared a greater acceptance
43 amongst healthcare professionals of CKD as a relevant diagnosis, compared with previous studies²³,
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3 but this may simply be due to the length of time that has now elapsed since the introduction of P4P
4
5 (2006) and NICE guidance (2008, Table 1).
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9 It has been shown that quality improvement strategies can be useful in improving specific targets in
10
11 CKD, such as blood pressure¹⁴ and requirement for renal replacement therapy^{31,32}.
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13

14 15 16 **Limitations**

17
18 This study examined a small number of practices; we purposively sampled two each from the two
19
20 study intervention arms; and from different parts of the country. The practices contained a larger
21
22 number of individuals and it is possible that opinion leaders within those practices, or practices and
23
24 localities within which they were based may have adopted procedures and processes that were not
25
26 representative of the study practices as a whole. Additionally, these individuals may have unduly
27
28 dominated the focus group discussion, compared with more junior practice members. These
29
30 limitations are all possible, but the study team who conducted these focus groups were also exposed
31
32 to the other practices involved in the trial.
33
34

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36
37 Additionally, quality improvement interventions such as ABE or G&P can vary in design between
38
39 studies, with no common detailed approach for their implementation. In systems such as the NHS,
40
41 data is readily accessible, and creating personalised feedback for practices should be relatively
42
43 straightforward and is already done in a number of areas such as prescribing. However, meeting
44
45 time for practitioners is expensive especially where in ABE, a facilitator (to explain the data) and a
46
47 specialist physician or nurse is brought along too. Whilst these roles might be combined, ABE is an
48
49 expensive interaction, an issue raised in a commentary on the QICKD trial.³³
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52

53 54 55 **Further research**

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3 Whilst there has undoubtedly been engagement with CKD through the P4P process, the case has for
4 P4P in CKD remains unproven.^{34,35} Future research should seek to determine whether
5
6 improvements identified following QI interventions can be generalised. We need to have a greater
7
8 understanding about why clinicians found this a difficult diagnosis to explain to patients. We also
9
10 need to test whether computerised medical record systems could improve the way they display
11
12 information; in the case of CKD a combination of finding two renal function tests at least three
13
14 months apart, whether there is a significant level of proteinuria, a relevant co-morbidity, and if BP is
15
16 correctly controlled for this level of risk are all recorded in different places (Table 1). We also need
17
18 to know whether ABE is cost-effective. It is only likely to be so if embedded into existing educational
19
20 processes carried out on a locality basis.
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27 Conclusions

28 P4P incentives were the major driver of improved management of CKD in primary care; however, QI
29
30 interventions can have a complementary role. This process evaluation demonstrates the place for a
31
32 QI intervention alongside the introduction of P4P guidelines. The focus groups reported positive
33
34 interactions from ABE, particularly with a kidney doctor or nurse. It is plausible that the interaction
35
36 involved in ABE contributed towards the modest but significantly greater reduction in systolic BP in
37
38 this arm compared with sending out G&Ps.
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Box 2: Summary conclusions

Competing Interests

AN: None

SdeL: Principal investigator QICKD Trial. SdeL led the group that provided the clinical input into the development of the CKD pay-for-performance indicator.

NT: Deputy on NICE guideline development group for CKD (2008)

AT: QICKD investigator and led the feedback to some practices.

HG: Co-design of QICKD study, senior investigator.

Authors' contributions

AN: Took the transcripts and an initial analysis of the findings and wrote the paper, under SdeL's supervision

SdeL: Conceived and designed the QICKD trial in collaboration with the other protocol authors. Supported and iterated the development of the paper with AN

NT: Project co-ordinator. Organised the ABE intervention in the southern localities. Undertook the focus groups, reviewed and edited the paper.

AT: Review and editing of paper

HG: Review and editing of paper

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Data sharing statement:

No additional data available.

Table 1: Guidance introduction before and during the QICKD trial, including variation in BP target and proteinuria measures

Year	Guidance	Body	Role	BP
2005	National Service Framework for renal disease: Part 2 Chronic Kidney Disease	Department of Health	National guidance on managing CKD	Strict application of National guidance for Hypertension and/or Diabetes
2006	Royal College of Physicians & Renal Association	Included other Royal Colleges	Guidelines from joint learned societies to fill a gap in guidance	>140/90 mmHg to an optimal BP of <130/80 mmHg >130/80 mmHg to an optimal BP of <125/75 mmHg where the PCR ratio is >100 mg/mmol
2006	Quality and Outcomes Framework (QOF) CKD guidance	NHS Employers, then NICE	Pay-for-performance P4P for chronic disease management	<140/85 – though people with comorbidities also subject to appropriate guidance (e.g. Diabetes)
2007 Recruitment into QICKD trial				
2008	Early identification and management of chronic kidney disease in adults in primary and secondary care	National Institute for Health and Care Excellence (NICE)	Clinical Guideline No 73 (CG73), National evidence-based guidance	Systolic BP >140 mmHg (target range 120–139 mmHg) and the diastolic blood pressure below 90 mmHg. 120-129/<80 in DM with CKD where ACR > 2.5 (men) > 3.5 (women) or where ACR>70
2010 Final data collection QICKD trial				

PCR=Protein:Creatinine Ratio ACR=Albumin:Creatinine Ratio

Table 2: Conceptual framework listing main themes and subthemes derived from the process evaluation

Main Themes	Subthemes derived from focus group analysis
A. Improving the validity of the CKD Register	<p>A1. Stop diagnosing CKD on basis of one low eGFR reading, instead use two three months apart</p> <p>A2. Auditing is carried out opportunistically, etc.</p> <p>A3. Introduction of a CKD disease Register curbed diagnostic over-enthusiasm</p> <p>A4. Clinical judgement exercised over whether patients with variable scores around threshold should be included on the Register</p> <p>A5. If patient won't benefit from treatment put on Register but "Exception report" (A process that makes them no longer part of pay-for-performance indicator group)</p> <p>A6. Nurses pick-up patients with low eGFR through clinics run for the primary prevention of heart disease, or through yearly audit/checks of computerised records</p>
B. Explaining to patients they have CKD	<p>B1. Tension between not hiding CKD diagnosis from patients and wishing to avoid causing excessive anxiety and social consequences of labelling</p> <p>B2. Avoiding the phrase "chronic kidney disease", using "kidney strain" instead</p> <p>B3. Giving CKD diagnosis is necessary for patient participation in management</p> <p>B4. Patients require a lot of reassurance post-diagnosis</p>
C. Meeting CKD Targets (BP, ACR)	<p>C1. Few problems in adopting albumin creatinine ratio (ACR) as routine practice</p> <p>C2. Unsure about necessity of early morning urine sample for ACR</p> <p>C3. Uncertainty about significance of ACR in patient management</p> <p>C4. Use pay-for-performance rather than evidence-based (NICE) BP maintenance targets</p> <p>C5. Use evidence-based (NICE) rather pay-for-performance targets, as the lower the BP level the better</p> <p>C6. Setting and maintaining BP targets are dependent on patient group</p> <p>C7. National evidence-based (NICE) guidelines too detailed to be practical</p> <p>C8. Increase in workload following CKD pay-for-performance indicator was unpopular</p>
D. Impact on practice of the study	D1. Base local practice on study guidelines

<p>interventions</p>	<p>D2. Presence of a nephrologist at workshops very useful</p> <p>D3. Difficult to determine whether study interventions catalyst for change or introduction of pay-for-performance targets</p> <p>D4. Study's information resources not useful</p> <p>D5. Developed own template for tests following participation</p>
<p>E. Ideas for future practice</p>	<p>E1. Electronic management guideline prompt i.e. desk-top icon, flagged-up through pay-for-performance reminders (built into primary care computerised medical record systems) - more practical than paper-based</p> <p>E2. Run 'virtual clinical' as training exercise</p> <p>E3. Electronic practice up-dates</p> <p>E4. Workshops to compare experience with other practices</p>

For peer review only

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Box 2: Summary conclusions

- CKD is a difficult condition to explain to patients, risk stratification is complex, and the relevant data are dispersed through computerised medical record systems
- Pay-for-performance incentives are the major driver for change in the management of CKD in primary care
- Quality improvement interventions may have a complementary role with future P4P initiatives
- Audit-based education was positively received by practices but further research is needed to demonstrate whether it is cost-effective

Box 1: Components of Audit-Based Education (ABE)

ABE is an intervention developed over 10 years ago; its aim is to provide feedback about performance against guidance. ABE includes feedback about quality compared with peers in a workshop setting usually led by a local general practitioner with a specialist (nephrology consultant or nurse) available as an expert resource, and also supported by academic detailing. ABE usually also identified lists of patients within the practices needing intervention. It consists of:

1. Anonymised extraction of the dataset required to report whether there was any quality improvement. The usual components are:
 - a. Denominator to allow standardisation of prevalence
 - b. Subset of people with the target condition – to create a virtual disease register
 - c. Clinically relevant co-morbidities, risk factors and treatment
2. Processing that data to make it informative and providing comparative feedback combined with academic detailing. A key feature is presenting comparative feedback comparing practices at twice yearly meetings held within a locality / primary care organisation. These meetings are called Data Quality Workshops (DQW), generally locally led with a consultant of the relevant discipline attending as a specialist resource
3. In addition to the presentation at the DQW practices are provided two additional printed aids:
 - a. “Laminate” – a single laminated A4 page summary of the practice demographics and case ascertainment compared with others who attended the DQW. This is for the practice notice board or other prominent location (we recommend wherever they take their breaks).
 - b. Workbook – a slide by slide explanation of the DQW presentation – and what the data means for their practice, compared with their peers and any evidence-based guidance.
4. Running local searches in the practices to provide lists of patients that need to be targeted for intervention. These lists are usually generated by individual GP. Experiential learning is that audit lists of up to 150 per 10,000 registered patients result in change.
5. Supporting education about the evidence-base and providing coding or other computerised medical record system training is provided as required.
6. Participants have been encouraged to contribute to the future development of the ABE programme.

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