

## Research paper

# Understanding risk and safety in home health care: the limits of generic frameworks

Caroline McGraw BSc MSc PhD RGN PGDip  
Professional Development District Nurse, Islington Primary Care Trust, London, UK

Vari Drennan BSc MSc PhD RN RHV  
Professor of Health Policy and Service Delivery, St Georges, University of London, UK

Charlotte Humphrey BA MSc PhD  
Professor of Health Care Evaluation, Florence Nightingale School of Nursing and Midwifery, Kings College, London, UK

## ABSTRACT

**Background** Patient safety and adverse events in primary care are receiving increasing attention from policy makers, professional bodies and researchers. Various taxonomic models have been developed to specify the factors that predispose to adverse events in hospital settings. These are assumed to have general applicability across different healthcare settings. However, they have never been applied to home health care.

**Aims** This study helps define the value of one such model in a domiciliary setting. The principal purpose of the study was to understand the circumstances in which the involvement of local authority-funded home carers as well as NHS-funded district nurses in medication-related activities for older people living at home in the UK might jeopardise patient safety.

**Method** The study was undertaken in two contrasting sites. One was in London and the other in the Midlands. District nurses and home carers were purposively selected to take part in semi-structured

interviews. The data were used to construct a taxonomic model that specified the factors that predispose older people to adverse events when medication-related responsibilities are transferred from district nursing to home care services.

**Results** The new taxonomy was compared to the taxonomic model under investigation. Dissonance existed within a number of categories.

**Conclusions** The model under investigation was found to be too narrow for application in domiciliary settings. The challenges that exist in home health care are often very different from those that exist in hospital settings, from which the model under investigation was derived. The root causes of accidents are most likely to be identified by models empirically derived from, and tailored to fit, the particular circumstances in which they are to be applied.

**Keywords:** frail elderly, home care services, home nursing, medication errors

## How this fits in with quality in primary care

### What do we know?

Learning from adverse events is a central theme in quality assurance and patient safety. Researchers and investigators have conceptualised the occurrence and approached the analysis of adverse events using various taxonomic models. One such model is the Framework of Factors Influencing Clinical Practice (FFICP). This model has proved useful in defining the conditions of safe and unsafe practice in mainly hospital settings.

### What does this paper add?

Taxonomic models have not previously been used to consider the conditions of safe and unsafe practice in the delivery of primary health care to people in their own homes. This paper reports the findings from a study that helps determine the value of the FFICP in home health care settings. Problems are identified when the model is applied in primary care. The study findings raise doubts as to whether any single model can have general applicability across the whole domain of health care. The paper introduces a new taxonomic model named the Framework of Factors Influencing Medication Management in Domiciliary Care (FFIMED), which is empirically derived from and tailored to fit the investigation and analysis of adverse medication events in home health care settings.

## Background

Learning from adverse events is a central theme in quality assurance and patient safety across many health-care systems.<sup>1</sup> The international literature demonstrates that most patient contact is with primary care services.<sup>2,3</sup> In the UK, one million people visit their family doctor, 1.5 million prescriptions are dispensed by community pharmacists, and home nursing services make 10 000 visits every day.<sup>4</sup> There is increasing recognition that, because of the volume of contact that takes place, sometimes things go wrong and patients are harmed.<sup>5</sup>

Adverse patient events often have common characteristics,<sup>6</sup> and many could be avoided if the lessons of experience were learnt.<sup>7</sup> In primary health care in the UK, policy initiatives,<sup>6</sup> professional guidance,<sup>8</sup> and clinical governance mechanisms<sup>9</sup> emphasise the importance of preventing, analysing and learning from patient safety incidents. However, it is only in the last decade that systematic and comprehensive investigation of adverse events has been identified as important in the drive to improve patient safety.<sup>6,10</sup> In contrast, learning from accidents and near misses has long been the cornerstone of safety analysis, and improvement in complex high-risk industries such as aviation and nuclear power generation.<sup>11</sup>

Significant resources have been invested in complex high-risk industries to gather and analyse information on adverse events and to ensure that lessons from failure are implemented. A number of taxonomic models have been developed within these industries to describe the factors that predispose to error, and the sequences of events that lead to an accident or catastrophic outcome. These models include the Zeebrugge–Harrisburg Syndrome,<sup>12</sup> the Generic Organisational Accident Model,<sup>13</sup> and the Model of Threat and Error in Aviation.<sup>14</sup> Their application includes the investigation and analysis of the Chernobyl nuclear disaster in 1986 and the sinking of the cross channel ferry the *Herald of Free Enterprise* in 1987.<sup>15</sup>

This expertise has also been applied to patient safety. The Clinical Safety Research Unit at University College London, in collaboration with the Association

of Litigation and Risk Management, customised the Generic Organisational Accident Model<sup>13</sup> to produce a structured protocol for the investigation and analysis of adverse events in health care.<sup>16</sup> The protocol was underpinned by a Framework of Factors Influencing Clinical Practice (FFICP), which incorporates the major influences on clinicians in their daily work and their systemic contribution to adverse outcomes. The FFICP is summarised in Box 1.

In the FFICP, the major factors influencing safety are listed in the first column (see Box 1). Each major factor is expanded in the second column to provide a detailed specification of the components (known as contributory factors) influencing performance within that category. Further subcomponents are listed elsewhere.<sup>16</sup> As an illustration, the contributory factors and subcomponents within 'patient factors' are shown in Box 2.

The FFICP was derived from a number of sources. These included outputs from single incident analyses in obstetric medicine,<sup>17–19</sup> and publications on error in hospital settings and complex high-risk industries. As such, the FFICP incorporates the generic processes that influence safety in all complex systems whilst at the same time recognising features that are important in health care.<sup>20</sup>

The FFICP is intended to be a single broad taxonomy of factors affecting clinical practice,<sup>21</sup> with the implicit assumption that it has general applicability across the whole domain of health care. A range of applications appear to support this view, since it has been used in obstetric medicine,<sup>16</sup> psychiatry,<sup>22</sup> general practice<sup>23</sup> and community ultrasound.<sup>24</sup> However, there is one increasingly important setting where the FFICP has not yet been applied and where its applicability and appropriateness has yet to be established. That setting is health care within the home. Medical advances mean that more interventions can be provided in domiciliary settings than ever before,<sup>25</sup> and well-established hospital-at-home programmes exist in Australia, France and the UK.<sup>26</sup>

The extent to which the FFICP might be applicable to domiciliary settings is uncertain, because the home is quite different from the hospital settings from which

**Box 1** Framework of factors influencing clinical practice

Major factors	Contributory factors
Institutional context	<ul style="list-style-type: none"> <li>• Economic and regulatory context</li> <li>• NHS executive</li> <li>• Clinical negligence scheme for trusts</li> <li>• Links with external organisations</li> </ul>
Organisational and management factors	<ul style="list-style-type: none"> <li>• Financial resources and constraints</li> <li>• Organisational structure</li> <li>• Policy standards and goals</li> <li>• Safety culture and priorities</li> </ul>
Work environmental factors	<ul style="list-style-type: none"> <li>• Administration</li> <li>• Building and design</li> <li>• Environment</li> <li>• Equipment/supplies</li> <li>• Staffing</li> <li>• Training</li> <li>• Workload/hours of work</li> <li>• Time factors</li> </ul>
Team factors	<ul style="list-style-type: none"> <li>• Verbal and written communication</li> <li>• Supervision and seeking help</li> <li>• Congruence and consistency</li> <li>• Leadership and responsibility</li> <li>• Staff response to incidents</li> </ul>
Individual (staff) factors	<ul style="list-style-type: none"> <li>• Knowledge and skills</li> <li>• Competence</li> <li>• Physical and mental health</li> </ul>
Task factors	<ul style="list-style-type: none"> <li>• Task design</li> <li>• Availability and use of protocols</li> <li>• Availability and accuracy of test results</li> <li>• Decision-making aids</li> </ul>
Patient factors	<ul style="list-style-type: none"> <li>• Condition</li> <li>• Personal</li> <li>• Treatment</li> <li>• History</li> <li>• Staff–patient relationship</li> </ul>

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the FFICP was derived. One example of difference relates to contingencies external to the healthcare system, such as the material and physical dimensions of the home environment (for example, overcrowding and the accessibility of sanitary facilities), which are far less controlled or controllable than is the case in a managed clinical environment. Another example of difference in the UK is that patients in hospital settings receive services delivered by a single organisation, whereas patients living at home, especially those with high levels of dependency, receive services delivered by more than one publicly funded organisation. In particular, there is a division between health care and social care.<sup>27</sup>

Health care is the responsibility of the National Health Service (NHS) and is delivered by a range of providers including family doctors and home nursing services (known as visiting nursing services in some countries and district nursing services in the UK). Social care includes assistance with personal care activities such as washing and dressing, and the management of prescribed medication. These activities are the responsibility of local authorities, which commission personal care services (known as home maker services in some countries and home care services in the UK) from a range of internal (local authority) and external (commercial and not-for-profit) providers.

**Box 2 Patient factors in the FFICP**

Contributory factors	Subcomponents
Condition	<ul style="list-style-type: none"> <li>• Complexity</li> <li>• Seriousness</li> </ul>
Personal	<ul style="list-style-type: none"> <li>• Personality</li> <li>• Language</li> <li>• External support</li> <li>• Social and family circumstances</li> </ul>
Treatment	<ul style="list-style-type: none"> <li>• Known risk factors associated with treatment</li> </ul>
History	<ul style="list-style-type: none"> <li>• Medically</li> <li>• Personally</li> <li>• Emotionally</li> </ul>
Staff–patient relationship	<ul style="list-style-type: none"> <li>• Good working relationship</li> </ul>

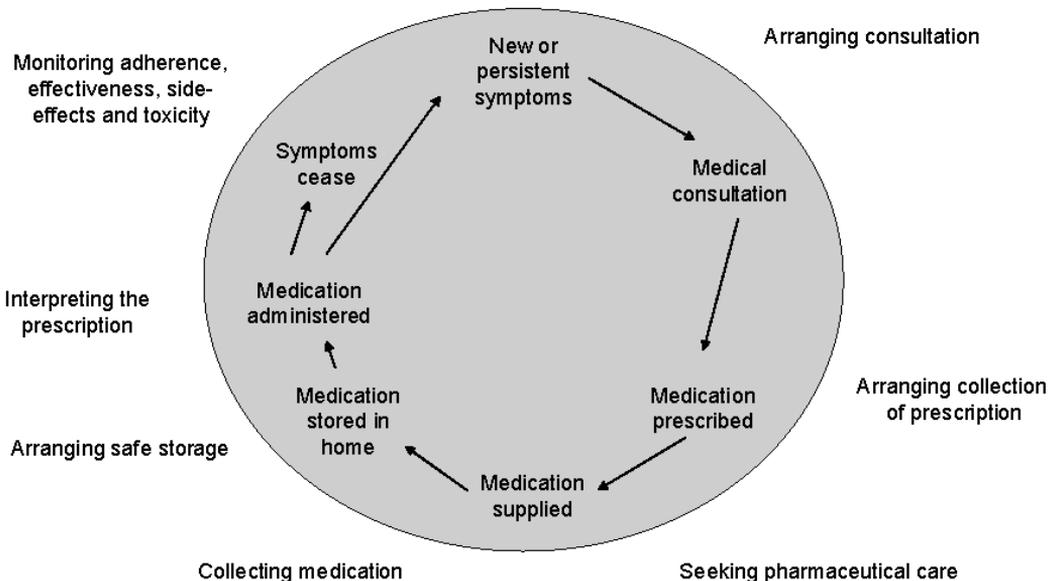
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This paper reports the findings from a study that helps determine the value of the FFICP in domiciliary settings. The principal purpose of the study was to understand the circumstances in which both NHS district nurses and local authority-funded home carer involvement in medication-related activities for older people living at home in the UK might jeopardise patient safety.<sup>28</sup>

Medication contributes to the wellbeing of many older people. However, medication errors can have serious consequences for patients. Adverse drug events and iatrogenic disorders are an important cause of morbidity,<sup>29,30</sup> and as many as one in six admissions of older people to hospital are related to adverse drug

events.<sup>31,32</sup> There are many complex processes and structures involved in medication management for older people living at home. These are shown in Figure 1.

In the UK, publicly funded participants in the medication-management process for older people living at home include general practitioners (GPs), community pharmacists and district nurses. Since home care services have evolved as major providers of personal care, participants also include home carers.<sup>34</sup> District nurses are qualified nurses who have undergone additional post-registration training in order to achieve a recognised district nursing qualification. They hold a caseload of domiciliary patients and manage a team of community staff nurses. All district



**Figure 1** The medication-management process (adapted from Goldstein *et al* 1993; Reproduced with permission of the *International Journal of Pharmacy Practice*)<sup>33</sup>

nurses and community staff nurses working in the UK must be registered with the Nursing and Midwifery Council. In contrast, home carers are not required to have any formal qualifications. Their employers provide on-the-job training. The level of training differs between employers.<sup>35</sup> They are not registered with any regulatory body. Medication-related activities undertaken by home carers include collecting prescriptions, reminding people to take medication, giving medication, and loading medication compliance devices.<sup>34,36</sup> Despite the range of medication-related activities undertaken, evidence suggests that home carers have insufficient pharmaceutical knowledge to meet the demands made upon them.<sup>36</sup>

There has been little empirical patient safety research undertaken in primary care settings in either the UK or the US.<sup>37,38</sup> The limited information that exists concerning adverse medication events relates to errors in prescription,<sup>39</sup> and errors in dispensing.<sup>40</sup> Little is known about errors at other stages in the medication-management process, including the implementation of the prescription once the medication has been supplied.

We set out to classify the factors that predispose older people to adverse events when medication-related activities are transferred from district nursing to home care services, and to develop a taxonomy identifying the domains of risk in domiciliary settings. We subsequently explored the extent of consonance between the domains of risk identified in domiciliary settings and those specified in the FFICP, in order to establish whether the FFICP could be adapted for application in home health care.

## Method

An interview approach was used to explore attitudes and beliefs about the circumstances in which home carer involvement in medication-related activities for older people living at home might jeopardise patient safety. There were multiple categories of people with potentially relevant experience. These included family doctors and community pharmacists, as well as district nurses and home carers. However, encounters between GPs and home carers, and community pharmacists and home carers are limited and it was assumed that few would have sufficient everyday experience or wide-ranging enough experience to provide more than patchy information describing the circumstances in which home carer involvement in medication-related activities might jeopardise patient safety.

It was anticipated that district nurses and home carers would have the most extensive and directly relevant experience of the issues under investigation.

The study was undertaken in two contrasting study sites in order to capture attitudes and events that might be location specific – for example, ways of working that might be affected by patterns of informal care provision and local labour markets. One site was in inner London and the other in central England, in the mixed urban and rural East Midlands region of the UK.

Participants were selected as a purposive sample on the basis of criteria including participation in medication-related activities for at least one older person on a regular basis. The aim was not to achieve a representative sample but to interview staff who would encompass a reasonably comprehensive range of experiences of district nurses and home carers in each study site. There were six categories of respondents in total. These included district nurse team managers, community staff nurses, internal home care managers and home carers, and external home care managers and home carers.

An interview guide was devised that encouraged participants to talk about the difficulties they encountered and the problems that occur when responsibility for medication-related activities is transferred from district nursing to home care services. Questions were framed so that participants did not feel threatened or intimidated. Participants were reminded that the interviewer took a no-blame approach to medication errors and of her belief that errors usually occurred because of faults in the system rather than faults solely in the individual.

Semi-structured interviews were conducted with district nurse managers ( $n = 17$ ), community staff nurses ( $n = 10$ ), internal home care managers ( $n = 10$ ) and home carers ( $n = 6$ ), and external home care managers ( $n = 9$ ) and home carers ( $n = 7$ ). Approval to conduct the study was obtained from the relevant ethical committees.

Data were organised and interpreted using a template approach to qualitative data analysis.<sup>41</sup> An index of themes was compiled from the issues identified by respondents. This was reviewed by a second researcher (together with a selection of interview transcripts) in order to reduce the effects of researcher bias. Themes were ordered to reflect the structure of the FFICP (e.g. major factors, contributory factors and subcomponents). A taxonomy that described the domains of risk in domiciliary settings was constructed accordingly.

## Results

The new taxonomy was compared to the FFICP. All major factors were congruent. Some contributory factors were also interchangeable. However, dissonance existed on a number of contributory factors and

many subcomponents. These included those related to patient factors, reflecting greater patient autonomy in their home surroundings and the key role of family members in care provision outside of hospital settings. For example, respondents cited occasions when patients refused nursing interventions and/or the introduction of clinical equipment (such as medication compliance devices), perceiving them as symbols of dependency. Other respondents described how attentive family members were an important defence against adverse medication events, while others cited occasions when participation in medication-related activities provided malicious family members with a means to harm older relatives.

Dissonance was also found in relation to the work environment and contingencies external to the health-care system. For example, respondents described how high local crime rates and fear of street robbery meant some home carers preferred to leave unused medications in the home rather than carry them to the pharmacist for safe disposal. Other respondents described occasions when they were unable to gain access to patients because the door to their accommodation was securely

locked and patients might not hear the doorbell or would struggle to open the door. Failure to gain entry meant medication doses were sometimes missed and ancillary non-pharmacological support was difficult to sustain. Other important areas of dissonance included poor communication between domiciliary services and secondary care providers, interruptions in staffing continuity (particularly external (commercial) providers), difficulty travelling between assignments, inadequate staff supervision, and inflexible contracting arrangements.

The new taxonomy incorporates the major influences on district nurses and home carers in their daily work and their systemic contribution to adverse outcomes. It is named the Framework of Factors Influencing Medication Management in Domiciliary Care (FFIMED). The framework is summarised in Box 3.

Like the FFICP, each level of analysis expands to provide a detailed specification of the components influencing performance within that category. The subcomponents within each contributory factor are listed in Box 4. Asterisks (\*) identify the areas of dissonance between the FFICP and the FFIMED.

### Box 3 Framework of factors influencing medication management in domiciliary care

Major factors	Contributory factors
Institutional context	<ul style="list-style-type: none"> <li>● Economic context</li> <li>● Links with external organisations</li> </ul>
Organisational and management factors	<ul style="list-style-type: none"> <li>● Financial resources and constraints</li> <li>● Policy standards and goals</li> </ul>
Work environment factors	<ul style="list-style-type: none"> <li>● Building and design</li> <li>● Environment (home)</li> <li>● Environment (local)</li> <li>● Equipment/supplies</li> <li>● Staffing</li> <li>● Training</li> <li>● Workload/hours of work</li> </ul>
Team factors	<ul style="list-style-type: none"> <li>● Verbal and written communication</li> <li>● Seeking help</li> </ul>
Individual (staff) factors	<ul style="list-style-type: none"> <li>● Knowledge and skills</li> <li>● Competence</li> <li>● Physical and mental health</li> </ul>
Task factors	<ul style="list-style-type: none"> <li>● Availability and use of protocols</li> <li>● Decision-making aids</li> <li>● Task definition</li> </ul>
Patient factors	<ul style="list-style-type: none"> <li>● Condition</li> <li>● Personal</li> <li>● Treatment</li> <li>● Staff–patient relationship</li> <li>● Patient choice</li> </ul>

**Box 4** Subcomponents in the FFIMED

Major factors	Contributory factors	Subcomponents
Institutional context	Economic context	<ul style="list-style-type: none"> <li>• Purchasing arrangements (home care)*</li> <li>• Provision of travel and contingency payments (home care)*</li> <li>• Salaries and wages (home care)*</li> <li>• Terms and conditions (shift patterns) (home care)*</li> </ul>
	Links with external organisations	<ul style="list-style-type: none"> <li>• Role confusion (care assessor and home care co-ordinator)*</li> <li>• Proliferation of home care providers*</li> <li>• Use of more than one home care provider per patient*</li> </ul>
Organisational and management factors	Financial resources and constraints	<ul style="list-style-type: none"> <li>• Rationing services*</li> </ul>
	Policy standards and goals	<ul style="list-style-type: none"> <li>• Human resources</li> <li>• Risk management</li> <li>• Quality improvement</li> <li>• Supervision*</li> </ul>
Work environment factors	Building and design Environment (home)*	<ul style="list-style-type: none"> <li>• Ease of access to patient property*</li> <li>• Housekeeping*</li> <li>• Security of medication storage facilities*</li> </ul>
	Environment (local)*	<ul style="list-style-type: none"> <li>• Staff safety*</li> <li>• Travelling between assignments*</li> </ul>
	Equipment/supplies	<ul style="list-style-type: none"> <li>• Functionality</li> <li>• Availability</li> </ul>
	Staffing Training	<ul style="list-style-type: none"> <li>• Staffing continuity*</li> <li>• Induction training</li> <li>• Refresher training</li> </ul>
	Workload/hours of work	<ul style="list-style-type: none"> <li>• Scheduling patient visits (home care)*</li> <li>• Terms and conditions (shift patterns) (home care)*</li> </ul>
Team factors	Verbal and written communication	<ul style="list-style-type: none"> <li>• Communication between district nurses and home carers*</li> <li>• Communication between home carers and patients*</li> <li>• Communication between district nurses and patients*</li> <li>• Communication with secondary care*</li> <li>• Communication with families and informal carers*</li> <li>• Legibility of records</li> <li>• Adequate management plan</li> <li>• Quality of information in the notes</li> </ul>
	Seeking help	<ul style="list-style-type: none"> <li>• Responsiveness of senior staff</li> </ul>
Individual (staff) factors	Knowledge and skills	<ul style="list-style-type: none"> <li>• Verification of skills and knowledge</li> </ul>
	Competence	<ul style="list-style-type: none"> <li>• Verification of competences</li> </ul>
	Physical and mental health	<ul style="list-style-type: none"> <li>• Physical stressors</li> </ul>

**Box 4 Continued**

Major factors	Contributory factors	Subcomponents
Task factors	Availability and use of protocols	<ul style="list-style-type: none"> <li>● Absence of protocols</li> <li>● Quality of information in protocols</li> </ul>
	Decision-making aids Task definition*	<ul style="list-style-type: none"> <li>● Availability of decision-making aids</li> <li>● Inconsistent task definition*</li> </ul>
Patient factors	Condition	<ul style="list-style-type: none"> <li>● Depression*</li> <li>● Dementia*</li> </ul>
	Personal	<ul style="list-style-type: none"> <li>● Personality</li> <li>● Social and family circumstances</li> <li>● Adult protection issues*</li> </ul>
	Treatment	<ul style="list-style-type: none"> <li>● Patient familiarity with treatment regimen*</li> <li>● Treatment effectiveness</li> </ul>
	Staff–patient relationship Patient choice*	<ul style="list-style-type: none"> <li>● Good working relationship</li> <li>● Reluctance to accept nursing intervention and/or equipment*</li> </ul>

\* Areas of dissonance between the FFICP and the FFIMED

## Discussion

A key strength of our new framework for medication management in domiciliary care is that it was derived from the accounts of frontline staff who had been involved in a wide variety of incidents, rather than from secondary sources or single-incident analyses. Several important domains of risk identified within the FFIMED were not specified in the FFICP and would potentially be ignored if the FFICP was applied, without modification, to the analysis of adverse events in domiciliary settings.

In England and Wales, the National Patient Safety Agency (NPSA) has incorporated elements of the FFICP in its root cause analysis e-learning programme. The NPSA was established by the Department of Health to provide a leadership role in improving patient safety. The purpose of the e-learning programme is to prevent, analyse and learn from patient safety incidents. The programme is supported by the Contributory Factors Classification Framework.<sup>42</sup> The framework is intended to be used in the retrospective review of patient safety incidents across NHS institutions and organisations. The content and structure of the framework imitate the major and contributory factors in the FFICP.

The findings from this study raise doubts as to whether any single model can have general applicability across the whole domain of health care. The FFICP was derived from incident analyses in obstetric medicine,<sup>17–19</sup>

and publications on error in hospital settings and complex high-risk industries. While the literature describes the application of the FFICP in psychiatry,<sup>22</sup> general practice,<sup>23</sup> and community ultrasound,<sup>24</sup> without further empirical study there is insufficient evidence to determine whether its application identified the true reasons why the incidents under investigation actually occurred.

Healthcare systems in developed countries have responded to the pressure of litigation for clinical negligence by creating organisations to provide a leadership role in improving patient safety (such as the NPSA in England and Wales, the Australian Commission on Safety and Quality, and the Canadian Patient Safety Institute). These organisations need to recognise that the challenges and hazards that exist in delivering primary health care in the home are very different from those in bounded organisational settings such as hospitals. This paper argues that the root causes of accidents and near misses in primary care settings are more likely to be identified using models empirically derived from, and tailored to fit, the particular circumstances in which they are to be applied.

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#### PEER REVIEW

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#### ETHICAL APPROVAL

Approval to undertake the study was obtained from two NHS local research ethics committees.

#### CONFLICTS OF INTEREST

None.

#### ADDRESS FOR CORRESPONDENCE

Caroline McGraw, Honorary Research Associate, Department of Primary Care and Population Science, Level 2, Holborn Union Building, Archway Campus, Highgate Hill, London N19 5LW, UK. Email: [Caroline.McGraw@islingtonpct.nhs.uk](mailto:Caroline.McGraw@islingtonpct.nhs.uk)

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