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Title Page

Descriptive Title: Evaluation of the suitability of root cause analysis frameworks for the investigation of community-acquired pressure ulcers: a systematic review and documentary analysis

Concise Title: Evaluation of root cause analysis frameworks for the investigation of community-acquired pressure ulcers

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Structure Abstract

Aims and objectives: The aim of this study was to evaluate the suitability of root cause analysis frameworks for the investigation of community-acquired pressure ulcers. The objectives were to identify to what extent these frameworks take cognisance of the setting where the ulcer was acquired as a person's home and different to a hospital setting.

Background: Pressure ulcers involving full thickness skin loss are increasing being regarded as indicators of nursing patient safety failure requiring investigation using root cause analysis frameworks. Evidence suggests that root cause analysis frameworks developed in hospital settings ignore the unique dimensions of risk in home healthcare settings.

Design and methods: A systematic literature review and documentary analysis of frameworks used to investigate community-acquired grade three and four pressure ulcers by home nursing services in England.

Results: No published papers were identified for inclusion in the review. Fifteen patient safety investigative frameworks were collected and analysed. Twelve of the retrieved frameworks were intended for the investigation of community-acquired pressure ulcers; seven of which took cognisance of the setting where the ulcer originated as the patient's home and different to a hospital setting.

Conclusion: This study provides evidence to suggest that many of the root cause analysis frameworks used to investigate community-acquired pressure ulcers in England are unsuitable for this purpose.

Relevance to clinical practice: This study provides researchers and practitioners with evidence of the need to develop appropriate home nursing root cause analysis frameworks to investigate community-acquired pressure ulcers.

What does this paper contribute to the wider global clinical community?

- Pressure ulcer reduction is a global nursing priority. Despite an increase in the provision of nursing care in home and ambulatory settings in most countries, the published literature on pressure ulcer preventative has predominantly focused on hospital settings.
- This paper explores the application of root cause analysis approaches to community-acquired pressure ulcer investigation. The findings from England provide evidence to suggest that many frameworks used to investigate community-acquired pressure ulcers do not take cognisance of the setting where the ulcer was acquired as a person's home and different to a hospital setting; the absence of any international literature suggests this is true of other countries.
- The study provides researchers and practitioners with the impetus to develop and use home nursing root cause analysis frameworks to investigate community-acquired pressure ulcers.

Key words

- Pressure ulcers
- Ambulatory
- Adverse events
- Community nursing
- Quality and safety

INTRODUCTION

Pressure ulcers involving full thickness skin loss are increasing being regarded as indicators of nursing patient safety failure requiring investigation, identification of key learning points and implementation of actions to prevent future occurrences (National Quality Forum (NVQ) 2011; National Patient Safety Agency (NPSA) 2010). There is evidence that these types of patient safety investigations, with their frameworks for root cause analysis (RCA) originating in hospital settings, have deficiencies when used in home nursing settings (McGraw et al 2008). This paper reports on a study which evaluated the suitability of investigative patient safety frameworks for pressure ulcers developed while in the care of home nursing services in England.

BACKGROUND

The increased provision of care in home or ambulatory settings rather than in hospital settings is a policy priority in many healthcare systems; for example see the Australian Commonwealth Government (2011) and Health Canada (2007). At the same time, policy makers and service providers are also adopting community based models of chronic disease management, supporting ageing in place, and responding to patient preferences to die at home rather than hospital. In addressing this agenda, many countries are looking to home nursing services to deliver good patient outcomes as well as assist in the containment of healthcare costs. However, community-acquired pressure ulcers present a threat to both patient outcomes and healthcare costs, particularly in home healthcare settings where the nursing contribution to health and wellbeing forms a small part of the patient's overall daily experience (Drennan et al 2005).

Pressure Ulcers

Pressure ulcers are a significant source of physical, social and psychological burden to patients (Gorecki et al 2009). They also have significant financial implications for the providers of healthcare services in relation to expenditure on treatment interventions (Bennett et al 2004), the cost of litigation (Voss et al 2005) and, in some countries, financial penalties for health care providers, such as reduced reimbursement charges by the National Medical Insurance system in Japan (Baharestain et al 2009), the withdrawal of Medicare reimbursement charges in the United States (USA) (Welton 2008), and ineligibility for additional payments through the Commissioning for Quality and Innovation Payment (QUIP) framework in the National Health Service (NHS) in England (Department of Health (DH) 2012).

The patients most at risk of pressure ulcer development in home healthcare settings are the very old and those with reduced mobility, increased dependency and one or more long term condition involving neurological deficits and/or tissue malnutrition (Waterlow 2005). Pressure ulcers are classified according to four levels of injury from stage 1 (non-blanchable

redness of intact skin) to stage 4 (full thickness tissue loss with exposed bone, tendon or muscle) (European Pressure Ulcer Advisory Panel (EPUAP)/National Pressure Ulcer Advisory Panel (NPUAP) 2009). As well as being a serious consequence of illness and disability, pressure ulcers are increasingly considered to be an indicator of nursing quality; for example, all stage 3 and 4 pressure ulcers have been added to the NQF list of Patient Safety Never Events in the USA (NQF 2011) whilst a zero tolerance approach to pressure ulcers has been adopted by the NHS in the England (NPSA 2010). In the USA and England, patient safety and healthcare quality policies require that all stage 3 and 4 pressure ulcers need to be investigated using a retrospective RCA approach (Joint Commission 1997; NPSA 2010).

Policy frameworks aim to reduce the incidence of '*never events*' by understanding why they happened and seeking to learn the lessons of failure. Responsibility for completing the investigation lies with the front-line nurses and their managers working in the ward, care home or community setting where the pressure damage originated. The purpose of the investigation is to identify the direct cause of the event and develop an action plan to prevent reoccurrence.

Root Cause Analysis Investigation

The theoretical foundations of the RCA approach to incident investigation lie in the systems approach to human error and human factors research in complex high technology industries such as aviation, off shore oil production and nuclear power generation (Social Care Institute for Excellence (SCIE) 2008). Human factors experts in these industries developed frameworks to identify causal or contributory factors underlying adverse events and help trace errors back to their root causes; for example, see Pheasant (1988), Reason (1993) and Helmreich et al (1999). These frameworks have subsequently been adapted for use in healthcare settings; for example, see the World Health Organisation (WHO) (2009), Bagian et al (2002), Taylor-Adams and Vincent (2004) and Lawton et al (2012). Published examples of their application suggest these frameworks are typically applied to incident investigation at the acute end of inpatient service provision such as obstetric units (Stanhope et al 1997; Cottee and Harding 2008; Harding 2012) and emergency departments (van Vuuren 1999; Mills et al 2012; Guzzo et al 2012).

More recently, RCA frameworks have been adapted and extended for application in hospital-acquired pressure ulcer investigations; for example, see the Facility-Acquired Pressure Ulcer Investigation Tool in the USA (TMF, the Medicare Quality Improvement Organisation for Texas 2011) and the University Hospitals Coventry and Warwickshire Trust Pressure Ulcer Pro-forma in the UK (McDonagh 2013). These frameworks classify the generic factors contributing to adverse events, whilst at the same time incorporating standardised prompt questions that recognise features of particular importance to pressure ulcer prevention and management (**see figure 1**).

Root Cause Analysis Investigation and Home Nursing

The application of RCA frameworks in community settings is limited by the lack of an empirical base and their reliance on classifications generated from complex high technology industries and domains at the acute end of inpatient service provision. Evidence from the UK suggests that RCA frameworks derived from complex high technology industries and inpatient settings are too narrow for application in the community. McGraw et al (2008) considered the applicability of a generic accident framework in home healthcare settings in a study that sought to understand the circumstances in which the involvement of social care services as well as home nursing services in medication-related activities for older people might jeopardise patient safety. In the UK, healthcare is the responsibility of the NHS and community based healthcare services are delivered by a range of providers including home nursing services (known in the UK as district nursing services). Social care includes assistance with personal care activities such as eating and drinking, going to the toilet, washing and dressing, and the management of prescribed medication. In the absence of assistance from family or friends, these activities are the responsibility of local authorities, which commission personal care services (known in the UK as home care services) from a range of internal/governmental (local authority) and external/non-governmental (commercial and not-for-profit) providers.

Using data collected from interviews with district nurses and home carers, McGraw et al constructed a taxonomic model that specified the factors that predispose older people to adverse events when medication-related responsibilities were transferred from one of these services to the other. This framework was called the Framework of Factors Influencing Medication Management in Domiciliary Care Settings (FFIMED). The authors compared the FFIMED with an existing healthcare framework, the London Protocol (Taylor-Adams and Vincent 2004), and identified a number of areas of dissonance.

The FFIMED recognised two unique features that effected safety in home healthcare settings. The first was that patients are in control of all decisions affecting the implementation of their prescribed treatment. The second was that patients do not experience around the clock nursing care or supervision, and personal care needs will usually be met by family members or agencies operating at a distance from home nursing services. The authors concluded that the root causes of accidents are most likely to be identified by frameworks empirically derived from, and tailored to fit, the particular circumstances in which they are to be applied.

The study reported in this paper is underpinned by two premises. The first is that the specific features of the home as healthcare settings that effected medication related patient outcomes also effect pressure ulcer prevention and management. Selected examples of the influence of patient autonomy and choice on patient safety outcomes are provided in **figure 2**. The second premise is that the causal or contributory factors underlying community-acquired pressure ulcers will only be detected if the frameworks underpinning pressure

ulcer investigations recognise and include the unique dimensions of risk in home healthcare settings. From our previous research we argue that these include the potential influence of the autonomous patient who can choose to accept or decline healthcare recommendations, interventions and/or technologies in their own home; the limited role and influence of home nursing services in the delivery of personal care activities to patients in their own home; and limited opportunities for face to face contact between home care services (formal carers) and home nursing services, and family members and friends (informal carers) not living with the patient.

METHODS

The aim of this study was to evaluate the existence and suitability of root cause analysis frameworks for the investigation of community-acquired pressure ulcers. The objectives were to identify whether frameworks existed that took cognisance of the setting where the ulcer was acquired as a person's home and different to a hospital setting. The study was undertaken in two phases. The first was a systematic review of the international literature. The second part was a documentary analysis of a sample of frameworks used by home nursing services to investigate community-acquired pressure ulcers.

Systematic Review

Search Methods

The method for the systematic review followed that of the Cochrane Collaboration (Higgins and Green 2011). Synonyms were identified to describe the type of intervention (RCA), the type of patient condition (pressure ulcer) and the type of care setting (home healthcare) (see **figure 3**). Medline with Full Text, CINAHL Plus with Full Text, Internurse, and Google Scholar were searched. Only articles published in the English language were selected, covering the period January 1994 to November 2013.

Selection Criteria

To be included in the review, papers had to comprehensively describe the content and components (including prompt questions) of one or more root cause analysis frameworks used to investigate community-acquired pressure ulcers. It was anticipated that only structured case studies would be available; however, no eligibility criteria were set in relation to study design.

Results

Searches identified 48 potentially relevant articles. The titles and abstracts generated were reviewed by one researcher with a second involved to make decisions where there was uncertainty. Forty-seven articles were excluded at the screening stage and one full text article was obtained. The full text article (Keevil and Kimpton 2012) was reviewed and subsequently excluded at the eligibility stage as it did not describe the content and

components of any root cause analysis framework. The process for the literature search is summarised in **figure 4**.

No articles were identified that met the inclusion criteria for the systematic review.

Documentary Analysis

In the absence of any papers meeting the study objectives, a documentary analysis of current frameworks used by home nursing services was undertaken.

Sample Protocol

The aim was to obtain a purposive sample of patient safety investigation frameworks used in each geographical area of England. The sampling framework was the four geographical clusters of the NHS England Commissioning Board (London, the North, the Midlands and the East, and the South). Each commissioning organisation has responsibility for purchasing home nursing services to meet the needs of their local population. Home nursing services can be purchased from a range of qualified providers, including community interest companies, NHS Foundation Trusts, NHS Trusts, and commercial organisations. There are over 100 organisations providing home nursing services in England (Spilsbury et al 2013). The aim was to obtain a sample of 20 frameworks from a diversity of organisations within a range of geographical areas.

Data Collection

Data collection took place in July 2013. Initially the search was contained to the internet, where a number of provider services make their policies and procedures publically available. This was followed by requests under the 2000 Freedom of Information Act to additional organisations purposively selected in the four regions providing home nursing services. The use of Freedom of Information requests for research purposes is an emerging approach in the social sciences (Murray 2012). Eligible organisations were randomly selected from the Directory of Community Health, Mental Health and Learning Disabilities (Fermor 2013). In the UK, the Freedom of Information Act only creates a public right of access to information held by public sector organisations; therefore only NHS Foundation Trusts and NHS Trusts were approached. NHS Foundations Trusts differ from NHS Trusts in that they are independent legal entities and have unique governance arrangements; they are free from central government control and are self-standing, self-governing organisations.

Data Analysis

Documentary analysis involves the scrutiny of the manifest dimensions of documents, where explicit words, terms and phrases are identified which can be taken as an indicator of values (Masterson 1998). Criterion was set to determine the extent to which frameworks recognised the unique dimensions of risk in home healthcare settings; namely whether the frameworks explored the potential contribution of the autonomous patient, the limited role

and influence of home nursing services in the delivery of personal care and the involvement of formal and informal carers in pressure ulcer prevention and management, and limited opportunities for face to face contact between home nursing services and formal and informal carers. One researcher examined all retrieved frameworks and extracted relevant data into tables, these tables were subsequently analysed by a second researcher and any discrepancy in views resolved.

Results

Five frameworks for investigating community-acquired pressure ulcers were retrieved from the internet searches. One of these frameworks was a pan-London framework endorsed by NHS London for application by all organisations investigating community-acquired pressure ulcers within its boundaries; therefore, no further frameworks were sought from this geographical cluster. Ten frameworks were received from requests made under the Freedom of Information Act.

Seventy-one percent (n = 10) of frameworks were from NHS Trusts and 29% from NHS Foundation Trusts (n = 4). Twenty percent (n = 3) of organisations from which frameworks were collected provided only community healthcare services, 33% (n = 5) provided both community healthcare services and community hospitals (that is in-patient facilities providing non-emergency services, typically rehabilitation services) and 40% (n = 6) provided integrated healthcare services (that is community healthcare services, community hospital and general hospitals). The organisation types, range of services provided and cluster groups are summarised in **figure 5**.

Ninety-three percent (n = 14) of frameworks had been adapted explicitly for use in pressure ulcer investigation. One framework had not been adapted for this purpose (Provider O) and was excluded from the analysis. To determine whether frameworks were intended for either the investigation of both community-acquired and hospital-acquired pressure ulcers, or solely community-acquired pressure ulcers, or solely hospital-acquired pressure ulcers, the patient details sections of retrieved frameworks were scrutinised; where there was opportunity to provide information regarding the home nursing team or the in-patient ward where the ulcer originated together with the family doctor or hospital consultant responsible for the patient's care, frameworks were deemed to be intended for the investigation of both community-acquired and hospital-acquired pressure ulcers; where there was only opportunity to provide information about the home nursing team together with the and family doctor, frameworks were deemed to be solely for the investigation of community-acquired pressure ulcers; and where there was only opportunity to provide information about the in-patient ward together with the hospital consultant, frameworks were deemed to be solely for the investigation of hospital-acquired pressure ulcers. Fifty percent (n = 7) were intended for use in the investigation of both community-acquired and hospital-acquired pressure ulcers (Providers B, C, E, K, L and N), 36% (n = 5) were intended for use specifically in the investigation of community-acquired pressure ulcers (Providers A,

D, F, H and M) and 14% (n = 2), although apparently used in home healthcare settings, were intended for use specifically in the investigation of only hospital-acquired pressure ulcers (Provider G and Provider I) (see **figure 6**). Moreover, these two latter frameworks posed a number of very hospital focused prompt questions:

How long was the patient on a trolley before being transferred to bed (Provider G)?

Has the patient been on any other surfaces (e.g. x-ray, ambulance and/or theatre) (Provider I)?

Of the twelve frameworks that were intended either for the investigation of both community-acquired and hospital-acquired pressure ulcers or the investigation of solely community-acquired pressure ulcers, 58% (n = 7) took cognisance of the setting where the ulcer was acquired as the patient's home and different to a hospital setting. Six recognised patient autonomy and the limited role and influence of home nursing services in the delivery of personal care activities as unique dimensions of risk. None recognised the limited opportunities for face to face contact between home nursing services and formal and informal carers (see **figure 7**).

In relation to patient autonomy, there were three key themes. The first theme was patient concordance, which was included as a prompt question in five frameworks:

Non-concordance identified as a key issue (Provider B)?

Patient compliance to using [pressure relieving] equipment (Provider C)?

Did patient agree with the [home nursing service] care plan (Provider A)?

Has patient choice been documented (Provider H)?

Were there any concern relating to non-concordance (Provider M)?

If there were concerns about non-concordance, one provider prompted the investigator to explore whether risk assessments were in place and whether mental capacity had been assessed (Provider M).

The second theme was the provision of information to patients, which was included as a prompt question in two frameworks:

What [pressure ulcer] information has been given to the patient and documented (Provider D)?

Has the patient been given a [pressure ulcer] information booklet (Provider H)?

In relation to the limited role and influence of home nursing services in the provision of personal care activities and the involvement of formal and informal carers in pressure ulcer prevention and management, there were two key themes. The first theme was the

provision of information to carers, which was included as a prompt question in two frameworks:

Did the patient's relatives/carers receive [pressure ulcer] information (Provider B)?

Has the carer been given a [pressure ulcer] information booklet (Provider H)?

The second theme was the involvement of carers in the development of the home nursing care plan, which was included as a prompt question in two frameworks:

Is there evidence that the carer(s) were involved in the [home nursing service] care plan (Provider A)?

Were carers or next of kin involved in the [home nursing service] care plan (Provider M)?

One framework queried whether the personal care activities performed by formal and informal carers were within their knowledge, skills and competencies (Provider C). Another queried whether carers followed the advice given to them by home nursing services (Provider F) and another whether carers and family members had received education and training in relation to checking the patient's skin integrity (Provider M).

The frameworks that took greatest cognisance of the setting where the ulcer originated as the patient's home and different to a hospital setting were those intended for the investigation of solely community-acquired pressure ulcers (not those intended for the investigation of both community-acquired and hospital acquired pressure ulcers). For example, 80% (n = 4) of all frameworks intended for the investigation of solely community-acquired pressure ulcers recognised patient autonomy and the limited role and influence of home nursing services in personal care provision, compared to 29% (n = 2) of all frameworks intended for the investigation of both community-acquired and hospital-acquired pressure ulcers. The organisations who produced frameworks intended solely for the investigation of community-acquired pressure ulcers were those providing only community healthcare services or community healthcare and community hospital services. For example, 33% (n = 1) of organisations providing only community healthcare services and 60% (n = 3) of organisations providing both community healthcare and community hospital services produced frameworks intended solely for the investigation of community-acquired, compared to none of the organisations providing integrated healthcare services.

Discussion

We found an absence of literature, national or international, describing the content and components of root cause analysis frameworks used to investigate community-acquired pressure ulcers. This may have been a result of searching only English Language publications, however given the emphasis in English speaking countries on pressure ulcers as 'never events' it was surprising not to find English language papers investigating this at all.

Our analysis of a purposive sample of patient safety frameworks found that a proportion completely ignored the home as a context where the dimensions of risk may be different to the hospital setting. The purpose of RCA investigation is to identify the direct cause of patient safety failures and develop an action plan to prevent reoccurrence. Anecdotal evidence suggests that a pressure ulcer RCA investigation can take a front-line nurse up to 20 hours to complete (Tissue Viability Society 2012). Although whole system learning is a worthy ambition and RCA a mechanism by which such learning has been achieved in certain healthcare settings, the findings from this study suggest that despite intensive efforts by front-line nurses and their managers, many investigations are currently unlikely to uncover at least some of the factors contributing to community-acquired pressure ulcers.

Some limitations of the study are acknowledged; for example, only a relatively small number of frameworks were analysed and no frameworks were obtained from community interest groups or commercial organisations. However, the sampling target was met and there is no evidence to suppose community interest groups or commercial organisations are more or less likely to have deployed patient safety frameworks intended specifically for the investigation of community-acquired pressure ulcers than the NHS Trusts or NHS Foundation Trusts participating in this study.

Conclusion

The study reported in this paper was underpinned by the premise that the causal or contributory factors underlying community-acquired pressure ulcers will only be detected if patient safety frameworks underpinning pressure ulcer investigation recognise and include the unique dimensions of risk in home healthcare settings. We would argue that the limitations identified in this study raise questions as to the value of the learning that could emerge from current investigations into community-acquired pressure ulcers. This study provides researchers and practitioners with an opportunity to design valid and reliable RCA frameworks to investigate community-acquired pressure ulcers. Although we acknowledge that such investigations might be more time consuming in practice, it is only through greater attention to the context of home healthcare nursing that the root causes of community-acquired pressure ulcers will be uncovered.

Relevance to Clinical Practice

Pressure ulcers involving full thickness skin loss are increasingly subject to investigation, identification of key learning points and implementation of actions to prevent future occurrences. The root causes of community-acquired pressure ulcers will only be detected if patient safety frameworks underpinning pressure ulcer investigation are empirically derived from, and tailored to fit, the particular circumstances in which they are to be applied. This study provides researchers and practitioners with evidence of the need to develop appropriate home nursing root cause analysis frameworks to investigate community-acquired pressure ulcers.

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Figure 1: Factors recognised as contributing to hospital-acquired pressure ulcers

- Lack of skin inspection
- Lack of provision of suitable pressure relieving surfaces
- Absence of patient repositioning
- Poor incontinence management
- Poor nutritional support

Figure 2: Influence of patient autonomy choice on patient outcomes in home healthcare settings

Medication Management	Pressure ulcers
A patient is advised to rotate their subcutaneous injection sites every day, but the patient chooses to use the same site	A patient may benefit clinically from returning to bed every afternoon for 2 hours, but the patient may prefer to stay sitting in their wheelchair
A patient may benefit from the provision of a pharmacist filled medication compliance device, but may prefer to continue loading their weekly medication into empty egg cartoons	A patient may benefit clinically from a hospital bed with an alternating or constant low pressure mattress, but may prefer to share a divan bed with their partner
A patient is prescribed a course of antibiotics for a urine infection and is advised to complete the course, but the patient chooses to stop taking the antibiotics when symptoms cease	A patient may benefit clinically from three visits a week for pressure ulcer dressing renewal, but may only agree to one visit a week
A patient is prescribed an opioid transdermal patch and are advised to avoid direct sources of heat, but the patient chooses to continue to sleep on their electric blanket in the winter	A patient may be prescribed nutritional supplements to prevent tissue malnutrition, but the patient may choose not to consume these supplements

Figure 3: Synonyms and search terms

Types of nursing intervention	Synonyms and search terms
Root cause analysis investigation	<ul style="list-style-type: none"> • Root cause analysis • Whole incident analysis • Systems analysis • Significant event analysis • Fault tree analysis • Sentinel event analysis • Causation analysis
Type of patient condition	<ul style="list-style-type: none"> • Pressure ulcer • Decubitus ulcer • Pressure sore • Bed sore • Decubiti • Pressure necrosis
Domiciliary care	<ul style="list-style-type: none"> • Domiciliary care • Home health care • Home care • Primary care • Community care • Social care • Ambulatory care • District nursing • Home nursing • Primary nursing • Community nursing

Figure 4: Flow diagram of the literature search process

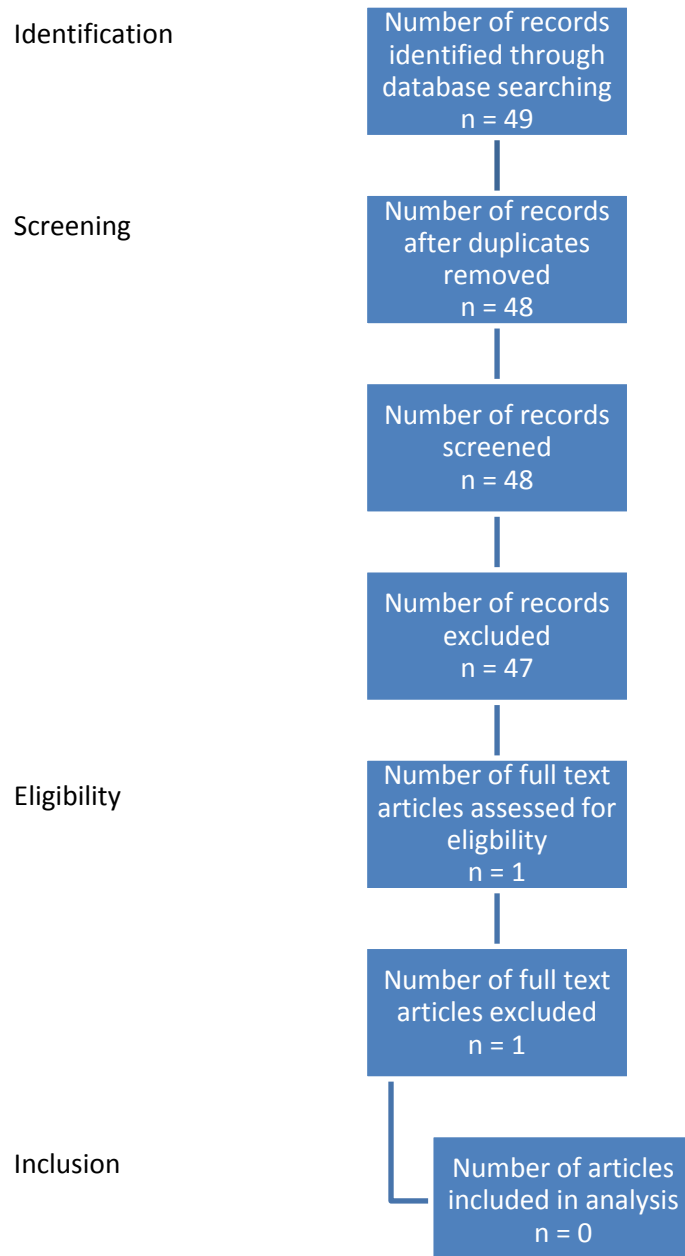


Figure 5: Provider, organisation type, services provided and geographical cluster			
Provider identity	NHS organisation type	Range of services provided	Geographical cluster
A	Not applicable	Not applicable	London
B	Foundation Trust	Integrated healthcare service	Midlands and the East
C	NHS Trust	Integrated healthcare service	
D	NHS Trust	Community healthcare services and community hospitals	
E	NHS Trust	Community healthcare services and community hospitals	
F	Foundation Trust	Community healthcare services and community hospitals	South
G	NHS Trust	Integrated healthcare service	
H	Foundation Trust	Community healthcare services and community hospitals	
I	NHS Trust	Community healthcare services and community hospitals	
J	NHS Trust	Community healthcare services	
K	Foundation Trust	Community healthcare services	North
L	NHS Trust	Integrated healthcare service	
M	NHS Trust	Community healthcare services	
N	NHS Trust	Integrated healthcare service	
O	NHS Trust	Integrated healthcare service	

Figure 6: Frameworks intended for the investigation of community-acquired pressure ulcers

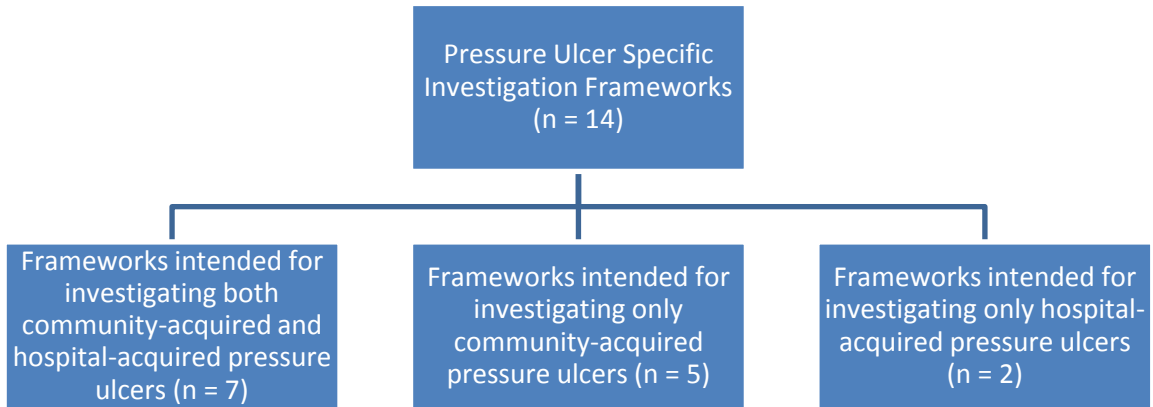


Figure 7: Cognisance of the setting where the ulcer originated

